UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ETON PHARMACEUTICALS, INC.,

Petitioner

v.

EXELA PHARMA SCIENCES, LLC,

Patent Owner

U.S. PATENT NO. 10,478,453

DECLARATION OF HARRY "WARREN" JOHNSON

1. My name is Harry "Warren" Johnson. I am over 21 years of age. I submit this declaration on behalf of Eton Pharmaceuticals, Inc. (hereinafter "Eton") in connection with the above-captioned matter. I am not being compensated for my time, although, as noted below, I have an indirect, potential financial interest in this matter.

2. In connection with this Declaration, I reviewed select business records of Allergy Laboratories, Inc. (hereinafter "Allergy Labs") and AL Pharma, Inc. (hereinafter "AL Pharma"). These records were created and maintained in the ordinary course of Allergy's and AL Pharma's business.

3. I also held discussions with several individuals who provided information that I also relied upon in preparing this Declaration.

4. Based on my personal knowledge and the results of my investigation, I am informed and understand that the facts stated in this Declaration are true.

Background

5. From January 2001 to approximately January 2017, I served as Vice President and was a 49% owner of Allergy Labs. My wife owned the remaining shares. In or around January 2017, Allergy Labs sold some of its assets and business activities, including the Allergy Laboratories name, to ALK. Allergy Labs (which changed its name to AL Pharma, Inc. ("AL Pharma") following the sale) retained the real estate, including its Oklahoma City plant, and the cysteine products, which,

as discussed below, Allergy Labs previously manufactured for Sandoz Inc. ("Sandoz"). ALK currently leases AL Pharma's Oklahoma City plant. My wife and I own all outstanding shares of AL Pharma. I have served as Vice President of AL Pharma since January 2017.

6. AL Pharma has a profit sharing arrangement with Eton in connection with Eton's proposed L-Cysteine Hydrochloride Injection drug product that is the subject of Eton's Abbreviated New Drug Application (ANDA). I understand that Eton's ANDA has prompted a suit for alleged patent infringement by Exela Pharma Sciences, LLC ("Exela"). I am advised that Exela contends the manufacture, use and/or sale of Eton's proposed ANDA product would infringe one or more claims of U.S. Patent Nos. 10,478,453 and 10,583,155.

The Sandoz L-Cysteine Product

7. In addition to serving as Vice President, my job responsibilities at Allergy Labs during the time frame of January 2001 through January 2017 included manufacturing, sales, accounting, inventory and purchasing. My wife, a chemist and pharmacist, was primarily responsible for quality assurance and quality control.

8. Prior to approximately 2008, Allergy Labs contract-manufactured an L-Cysteine Hydrochloride Injection, USP drug product for Parenta Pharmaceuticals ("Parenta"). Allergy Labs manufactured the Parenta L-Cysteine Product at Allergy's manufacturing plant in Oklahoma City, Oklahoma. In or about 2008, I

understand that Parenta products were acquired by Sandoz. From that time until 2016, Allergy Labs contract-manufactured the L-Cysteine Hydrochloride Injection Product (50 mg/mL product and available in both single dose vials and pharmacy bulk package) for Sandoz (the "Sandoz L-Cysteine Product").

9. Allergy Labs contract-manufactured the Sandoz L-Cysteine Product pursuant to Sandoz's specifications and sold the finished product to Sandoz pursuant to purchase orders.

10. Pursuant to its agreement with Sandoz, various regulatory obligations, and as part of its ordinary business practices, Allergy Labs made and kept records associated with its manufacture of the Sandoz L-Cysteine Product. These records included, but were not limited to, batch records for each lot of Sandoz L-Cysteine Product that Allergy Labs manufactured for Sandoz.

11. A true and correct copy of an exemplary batch record is attached as **Exhibit A**. This batch record is for lot #2072115 of the Sandoz L-Cysteine Product, which was manufactured on July 21, 2015. Batch records were made at or near the time of the events recorded therein by technicians who had training and knowledge and were responsible for making a record of the manufacturing process. It was Allergy Labs' regular practice to create batch records like that attached as Exhibit A, and such batch records were created and kept in the ordinary course of Allergy Labs' business. As was Allergy's practice at the time, the date on which the product

was manufactured is reflected by the lot number assigned to the product. Consistent with that practice, the numbers in the lot # that I have shown in bold represent the manufacture date (#2**072115**) of 07/21/15 and the "2" stands for manufacturing line 2 at the Oklahoma City plant.

12. The batch record for lot #2072115 includes, among other things, the following forms: a "Lot Release Approval for Customer" (*see* pp.13-16), a "Cysteine Batch Manufacturing Record" (*see* pp.19-25), a "50 mL Cysteine HCl Injection Vial Manufacturing Record" (*see* pp.26-35), a "Filled Vial Labeling Record" (*see* pp.46-50), a "Printed Container (Carton) Packaging Record" (*see* pp.51-52), a "Package Insert Record" (*see* p.56) (which includes a true and correct copy of the package insert for the Sandoz L-Cysteine Product (*see* pp.53-55)), a "Sandoz Shipping Label Record – 50 mL Cysteine" (*see* pp.57-58), a "Particulate Matter Test" (*see* p.63), and a "Certificate of Analysis" from a third-party contract laboratory KABS (*see* p.68). The Certificate of Analysis (COA) from KABS contains, among other things, the aluminum and heavy metals content of the final product. As noted on the KABS COA, the aluminum level was measured by another third-party laboratory, Metrics Inc., of Greenville, North Carolina. The KABS COA for lot #2072115 reports 17 ppb of aluminum for the sample tested by Metrics.

13. Attached as **Exhibit B** is a collection of true and correct copies of KABS COAs corresponding to lots #2012114, 2012214, 2072115, 2072215,

2081915, 2082015, 2082115, 2093015, 2100115, and 2100215. In connection with its manufacture of the Sandoz L-Cysteine Product, it was Allergy Labs' practice to have KABS analyze samples for every commercial batch of Sandoz L-Cysteine Product prior to the commercial release. As part of that practice, Allergy Labs would receive and maintain KABS COAs of the type included in Exhibit B. The KABS COAs were maintained in the ordinary course of Allergy Labs' business.

14. Pursuant to Allergy Labs' ordinary business practices, the data from the KAB COAs was included along with other data in a COA bearing the Allergy Labs letterhead. Attached as **Exhibit C** are true and correct copies of the Allergy Labs COAs that correspond to the KABS COAs of Exhibit B, namely Allergy Labs COAs for lots #2012114, 2012214, 2072115, 2072215, 2081915, 2082015, 2082115, 2093015, 2100115, and 2100215. It was Allergy Labs' practice, consistent with what I understand to be required for pharmaceuticals manufactured and distributed commercially, to generate a COA on Allergy Labs letterhead for each commercial batch of Sandoz L-Cysteine Product to assure that these products met agreed upon drug release specifications for potency and impurities. It was Allergy Labs' regular practice to create Allergy Labs COAs like those attached as Exhibit C, and such COAs were created and kept in the ordinary course of Allergy Lab's business.

15. Consistent with the aluminum levels reported in the COAs attached as Exhibits B and C, respectively, the aluminum levels initially measured in the Sandoz

L-Cysteine Products (*i.e.*, within several weeks of manufacture) were typically below about 100 ppb. Based upon stability studies of the Sandoz L-Cysteine Product, we at Allergy Labs understood that aluminum levels would increase to several hundred ppb after storage for approximately 1-24 months but remained substantially below the NMT 5,000 ppb of aluminum noted on the label of the Sandoz L-Cysteine Product. As we believed at the time, the likely source of the aluminum detected in the Sandoz L-Cysteine Product samples was aluminum leached from the glass vials in which the Sandoz L-Cysteine Product was packaged.

16. With respect to the manufacture of the Sandoz L-Cysteine Product, Allergy Labs followed materially the same manufacturing process from 2010 until 2016, which is materially the same as the process previously followed by Allergy Labs for the Parenta L-Cysteine Product since 2003. The process set forth in the "Cysteine Batch Manufacturing Record" for lot #2072115 (*see* Exhibit A) is representative of the process by which the Sandoz L-Cysteine Product was manufactured, and included the following steps, among others:

a. Stirring water for injection, USP (WFI) in a vessel at temperature not more than (NMT) about 60 C (*see* p.22 at steps 4-6 ("Allow WFI to cool between the temperature of 20C-32C" and "Insert the mixer into the WFI . . . . Turn on the mixer and set the mixer speed at 250 +/- 10 rpms"));

b. Allowing the vessel to cool to a temperature of NMT 30 C (*see* p.22 at steps 4-6);

c. Contacting the WFI with L-Cysteine Hydrochloride, Monohydrate, USP (L-Cysteine) for not longer than (NLT) 15 minutes (*see* p.23 at step 9 ("With mixing, add . . . Cysteine HCl Monohydrate (item 02) and mix for 5-10 minutes"));

d. Adjusting the pH with concentrated Hydrochloric Acid, NF and/or 5.0N Sodium Hydroxide, NF (*see* pp.23-24 at steps 11-12 (Remove sample, measure and record pH, "specification of 1.20-1.30"); the Allergy Labs process had hydrochloric acid and sodium hydroxide readily available for adjusting pH should it be needed (*see* p.20));

e. Mixing for a minimum of about 10 minutes (*see* p.25 at step 14 ("Mix for 15 +/- 5 minutes"))

f. Capping the vessel and allowing to stand (*see* p.25 at step 19 ("Close the lid on the tank");

g. Filling said mixture into container of use (*see* pp.24-25 at Vial Manufacturing Record, steps 13-16 ("Proceed with filing and stoppering of the vials");

h. Reducing the head space oxygen in said containers of use (*see* p.25 at Vial Manufacturing Record, step 17 ("Nitrogen purging Aero

50”)); and

i. Sealing said containers of use (*see* p.25 at Vial Manufacturing Record, steps 18-19 (“Perform vial capping on all filled and stoppered vials”).

17. Allergy Labs was also responsible for labeling, packaging, and shipping the finished Sandoz L-Cysteine 50 mg/mL Product. Allergy labeled the filled vials and placed a package insert in each carton. (*see* pp.34-35 at Vial Manufacturing Record, steps 28, 31-38). True and correct copies of the label and package insert are included in the batch record of Exhibit A.

18. Allergy Labs followed the above-referenced manufacturing process for the Sandoz L-Cysteine Product in the ordinary course of Allergy Labs’ business and the process was generally known by Allergy Labs personnel. Allergy Labs also did not take any overt efforts to conceal the manufacturing process for the Sandoz L-Cysteine Product.

AL Pharma NDA

19. In or about January 2018, AL Pharma filed a New Drug Application No. 209649 (the “AL Pharma NDA”) with the United States Food & Drug Administration (FDA) for 5% L-Cysteine Hydrochloride Injection, USP, via the 505(b)(2) regulatory pathway, a product which was intended for the same indications as a previously FDA-approved product, 7.25% Cysteine HCl Injection, USP (NDA

019523; Hospira).

20. The Proposed Finished Product Release Specifications ("Specifications") for the 5% L-Cysteine HCl Injection, USP, recited, among other things, an Aluminum Content of not more than (NMT) 5,000 ppb and NMT 2.0% Cystine.

21. With respect to the aluminum content of AL Pharma's proposed specifications, by e-mail dated March 9, 2018 (a true and correct copy of which is attached as **Exhibit D**) the FDA advised AL Pharma that:

> The drug product L-Cy[s]teine Hydrochloride Injection is a small volume parenteral drug product used in TPN. Based on our previous experience with small volume parenteral drug products intended for addition to the TPN, we have determined that the aluminum dose delivered by your drug product, 5% L-Cysteine Hydrochloride Injection, USP, should be limited to ≤0.6 mcg/kg/day. To comply with this limit, the aluminum content in the final drug product should be controlled to ≤350 mcg/L. This calculation is based on the clinical dose of 15 mg cysteine free base per gram of amino acid per day. Therefore, the proposed acceptance limit for the aluminum content in the finished drug product specification (3.2.P.5.1) must be revised to ≤350 mcg/L. The drug product registration batches manufactured at OKC Allergy Supplies, Oklahoma City, OK have not been shown to meet the required acceptance limit for aluminum content.

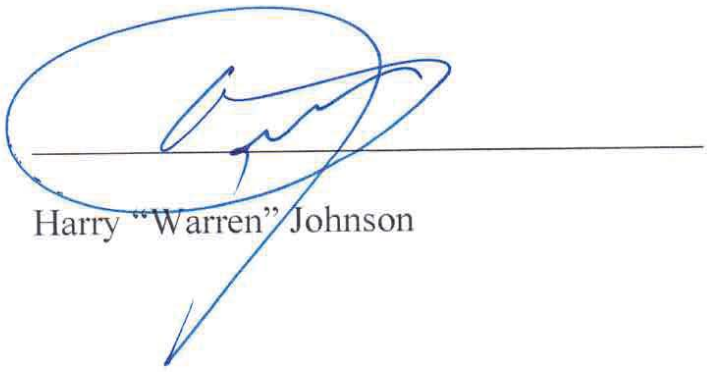
22. In response, AL Pharma amended the aluminum specification to ≤350 mcg/L (≤350 ppb) and submitted additional information demonstrating compliance

with the FDA's proposed acceptance limit for aluminum content.

23. I hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I understand that willful false statements are punishable by fine or imprisonment or both. *See* 18 U.S.C. § 1001.

Date: 05-15-2020

Respectfully submitted,



Harry "Warren" Johnson

Exhibit A

TA 07-15-15 QA 071715

	Form Title: **Lot Release Approval for Customer 714503**		Doc Number: **QA-032-01.02**
ALLERGY LABORATORIES, INC.	Lot #: **2072115**	Product: **Cysteine 50mL**	Page 1 of 4 Form Issue Date: APR 30 2015 Form Effective Date: MAY 06 2015

Manufacturing Checklist (In batch record order)

Document present? (Circle One)			Document	
(Yes)	No	N/A	Routine Intervention Log completed and approved by QA	Form #: QA-006-03
(Yes)	No	N/A	QA-006-02 "Corrective Intervention Log - Line 1 &2 Aseptic Products" completed and approved by QA	
(Yes)	No	N/A	Batch Manufacturing Record completed and approved by the Prod. Supervisor	Form #: BMR-010
(Yes)	No	N/A	Vial Manufacturing Record completed and approved by the Prod. Supervisor	Form #: VMR-014
(Yes)	No	N/A	MFG-048-01 "Filling/Stoppering and Capping Line Clearance Record	
Yes	No	(N/A)	FAE-017-01 "Volume Verification Record-Line 1"	
(Yes)	No	N/A	FAE-033-01 "Volume Verification Record-Line 2"	
(Yes)	No	N/A	MFG-036-01 "Filled Vial Inspection Record"	
(Yes)	No	N/A	QC-090-01 "AQL Vial Inspection" completed and approved by QC	
Yes	No	(N/A)	MFG-040-01 "Quarantine of Unlabeled Vials for Future Labeling Operations Form"	
(Yes)	No	N/A	PAL-002-01 "Filled Vial Labeling Record"	
(Yes)	No	N/A	PAL-002-07 "Printed Container (Carton) Packaging Record"	
(Yes)	No	N/A	PAL-002-08 "Package Insert Record"	
(Yes)	No	N/A	Sandoz Shipping Label Record	Form #: PAL-002-12
(Yes)	No	N/A	MFG-057-24 "Calculation of Percent Yields for Bulk Solution and Final Containers of Sterile Drug Products"	
Yes	No	(N/A)	FAE-016-01 "Daily Autoclave Log - Equipment ID # 0002" (Line 1) Completed and Approved by QA (On file with Document Control)	
Yes	(No)	N/A	FAE-026-01 "Daily Autoclave Log - Equipment ID # 0237 and # 0238" (Line 2) Completed and Approved by QA (On file with Document Control)	
Yes	No	(N/A)	Dry heat depyrogenating oven chart reviewed by manufacturing (Line 1) Completed and Approved by QA (On file with Document Control)	
(Yes)	No	N/A	Tunnel report reviewed by manufacturing (Line 2) Completed and Approved by QA (~~On file with Document Control~~) 08-12-15	

Comments (Reference any Deviations, OOS, or CAPA Investigations in the Investigations section [page 3]):

NONE 08-12-15

Manufacturing Checklist Completed By/Date: 08-12-15

QA Reviewed and Approved By/Date: Heidi Wilson 08-12-15

ALLERGY LABORATORIES, INC.	Form Title: **Lot Release Approval for Customer 714503**		Doc Number: **QA-032-01.02**
	Lot #: **2072115**	Product **Cysteine 50mL**	Page 2 of 4

Quality Control Checklist (In batch record order)

Document present? (Circle One)			Documentation	Results (Circle One)		Recorded By/Date
Laboratory Testing (Reference any Deviations, OOS, or CAPA Investigations in the Investigations section [page 3])						
(Yes)	No	N/A	QC-066-01 "Method: Fill Volume"	(Pass)	Fail	MA 08-12-15
(Yes)	No	N/A	QC-073-01 "Particle Matter in Injectables"	(Pass)	Fail	MA 08-12-15
(Yes)	No	N/A	QC-076-01 "Gelman Acro 50, 0.2µ Filter Integrity Testing"	(Pass)	Fail	MA 08-12-15
(Yes)	No	N/A	QC-002-02 "Extract, Diluent, Sterile Drug Product Bioburden Sample Form"	(Pass)	Fail	JW 08-12-15
(Yes)	No	N/A	QC-011-02 "Endotoxin Test Record for Product Release"	(Pass)	Fail	JW 08-12-15
(Yes)	No	N/A	QC-118-01 "Sterility Test Form"	(Pass)	Fail	JW 08-12-15
(Yes)	No	N/A	Contract Testing Certificate of Analysis	(Pass)	Fail	MA 08-12-15
Water for Injection (Reference any Deviations, OOS, or CAPA Investigations in the Investigations section [page 3])						
Data not present in batch record			QC-030-01 "WFI, Process Water and Steam Testing Sites for Buildings 1 and 2" WFI data reviewed for the manufacture date (date WFI into mixing tank)	(Pass)	Fail	MA 08-12-15
Environmental Monitoring (Reference any Deviations, OOS, or CAPA Investigations in the Investigations section [page 3])						
Data in BioTrends			Ensure the class 100 cleanroom EM data has been reviewed for the date of production of the lot	(Pass)	Fail	JW 08-12-15
Data in BioTrends			Ensure the personnel monitoring data from the date of production of the lot has been reviewed	(Pass)	Fail	JW 08-12-15
Data in Lighthouse			Ensure the non-viable particulate data from the date of production of the lot has been reviewed	(Pass)	Fail	JW 08-12-15

Comments: None

QA Reviewed and Approved By/Date:

[signature] 08-14-15

ALLERGY LABORATORIES, INC.	Form Title: **Lot Release Approval for Customer 714503**		Doc Number: **QA-032-01.02**
	Lot #: **2072115**	Product **Cysteine 50mL**	Page 3 of 4

Investigations

Investigation Type	Are there any investigations associated with the manufacture or testing of this lot? (Circle One)		Recorded By/Date
Deviation Reports	Yes (No)	If yes, DR# (s)	HW 08-12-15
CAPAs	Yes (No)	If yes, CAPA# (s)	HW 08-12-15
ENs	Yes (No)	If yes, EN# (s)	HW 08-12-15
OOS	Yes (No)	If yes, OOS# (s)	HW 08-12-15
Investigations complete and copy in batch record?	Yes No (N/A) (If investigation not complete and in batch record please provide comment)		HW 08-12-15

Comments: None

QA Reviewed and Approved By/Date:

08-14-15

ALLERGY LABORATORIES, INC.	Form Title: **Lot Release Approval for Customer 714503**		Doc Number: **QA-032-01.02**
	Lot #: **2072115**	Product: **Cysteine 50mL**	Page 4 of 4

Batch Record Review	**By/Date:** Heidi Wilson 08-12-15	
Manufacturing Lot Review and Approval	**By/Date:** 8/12/15	
Quality Assurance Batch Record Review, Release, and Approval	**Do the investigations support the release of this product? (Circle One)**	Yes No (N/A) (If No, provide comment)
	Is the product acceptable for release? (Circle One)	(Yes) No (If No, provide comment)
	Quality Assurance Management By/Date: Erin Reed 08.14.15	
	Comments: None	

Transferred to Inventory	Quantity transferred to inventory: 13200	Transferred to inventory By/Date: 8-17-15
Document	**Document present and complete?**	
Material Safety Data Sheet (MSDS) (one per pallet) revision # N/a TH 08-17-15	☐ Yes ☐ No ☑ N/A	By/Date: 08-17-15
MFG-037-01 "Retention Sample Form for Sandoz Inc. (ID# 714503) Drug Products" (last form in batch record)	☑ Yes ☐ No ☐ N/A	By/Date: 08-17-15
Allergy Laboratories, Inc. Certificate of Analysis	☑ Yes ☐ No ☐ N/A	By/Date: Elisa Hin 08-17-15

7/14 07-15-15 07-17-15

	Form Title: **Routine Intervention Log – Line 2 Aseptic Products**		Doc Number: **QA-006-03.01**
ALLERGY LABORATORIES, INC.	Lot #: **2072115**	Product Name: **Cysteine 50mL**	Page 1 of 1 ***This form shall be copied onto autoclavable paper.**
	Weight checks are documented on form FAE-033-01. Corrective interventions are recorded on form QA-006-02. **Routine interventions do not exceed one minute. If one minute is exceeded, the intervention must be documented on the corrective intervention log.** Although setup activities are routine interventions, setup time will be documented on QA-006-02.		Form Issue Date (stamp): MAY 05 2015 Form Effective Date (stamp): MAY 06 2015

		Cass Thread (Glass) 3 Doors	Full Machine (FM) 2 Doors	Stopper Bowl (SB) 6 Doors
Before Break Time: 9:47am – 9:57am. Date: 07-21-15 By: JS	Fallen Vials	1		
	Rod Jam / Stopper			(2)
	Stopper Jams			(1)
	Start/AA Device/Place Out or Pick Up Settle Plates	(1)	1	1
After Break Time: 10:49am – 12:44pm. Date: 07-21-15 By: JS	Fallen Vials	111		
	Rod Jam / Stopper			(1)
	Stopper Jams			(1)
	Start/AA Device/Place Out or Pick Up Settle Plates	(1)	(1)	(1)
Comments:	(1) N/A 07.21.15 SD	QA Review By/Date:	Leigh 08.12.15	

JK 07-15-15 QA 071715

	Form Title: **Corrective Intervention Log – Line 1 & 2 Aseptic Products**		Doc Number: **QA-006-02.02**
	Lot #: **2072115**	Product Name: **Cysteine 50mL**	Page 1 of 1 ***This form shall be copied onto autoclavable paper.**
	Setup Start Time: 6:12AM.	Setup End Time: 6:43AM.	Form Issue Date (stamp): MAY 05 2015 Form Effective Date (stamp): MAY 06 2015

Although setup is a routine activity, setup times are recorded on this form to show the full length of the intervention period during setup activities. Weight checks are documented on form FAE-017-01 or FAE-033-01. Routine interventions are recorded on form QA-006-01 or QA-006-03. Notify production management of any corrective interventions that may result in a deviation.

Corrective Interventions

Any intervention to be recorded on QA-006-01 or QA-006-03, regardless of time lapse. Open or personnel inside. Also include routine interventions that take longer than one minute.

Activity	Description (see codes from QA-006-01 or QA-006-03)	Start Time	End Time	Initial/Date

N/A 07.21.15

Comments:		QA Review/Date:	08.12.15 ~~08.22.15~~ 08.12.15

QA 07-17-15

Form Title: **Cysteine Batch Manufacturing Record (750L) -Line 2**				Doc Number: **BMR-010.00**
Formulation #	**Product**	**Company**	**Lot #**	Page 1 of 6
F1000	**Cysteine HCl Injection 50mg/mL**	**Sandoz Inc.**	**2072115**	Form Effective Date: ~~DEC 11 2013~~ TH 12-19-13 DEC 19 2013

Written by/date:	11-22-13		
Approved by Production/by/date:	11-25-13		
Approved by QA/by/date:	12.05.13		
Approved by Customer/by/date:	See attached pg. 1 for customer approval. TH 12-19-13		
Batch Size: 750L/762.0kg	**Date Issued:** 07-15-15	**Production Started:** 07-20-15	**Production Completed:** 07-20-15
Qty manufactured: 750L/762.0kg	**Qty lost:** 0	**Yield (%):** 100	**Initial:**

Item #	Part Number	Ingredients	Qty/mL	Qty required	Lot	Expiration date	Qty dispensed	Date dispensed	Dispensed by	Checked By
1.	EX-10000	Water for Injection USP	0.90mL	686.0kg	N/A	N/A	686.0kg	07-20-15		
2.	AP-10000	Cysteine HCl Monohydrate	50mg	37.5kg	6947-4 6947-5	05-11-16 05-11-16	0.056kg 37.444kg	07-20-15 07-20-15		
3.	EX-10040	Hydrochloric Acid NF	Q.S.	To adjust pH						
4.	EX-10030	~~Sodium Hydroxide NF~~	Q.S.	To adjust pH		07-20-15				
5.	EX-10000	Water for Injection USP	Q.S.	Q.S. to 762.0kg	N/A	N/A	38.5kg	07-20-15		

Form Title: **Cysteine Batch Manufacturing Record (750L) -Line 2**				Doc Number: **BMR-010.00**
Formulation #	**Product**	**Company**	**Lot #**	Page 1 of 6
F1000	**Cysteine HCl Injection 50mg/mL**	**Sandoz Inc.**		Form Effective Date:

Written by/date:	11-22-13		
Approved by Production by/date:	11-25-13		
Approved by QA by/date:	12.05.13		
Approved by Customer by/date:	McFadden Rachael Digitally signed by McFadden Rachael DN: SERIALNUMBER=1732269 + CN=McFadden Rachael, OU=GX, OU=people, DC=novartis, DC=com Reason: I am approving this document. Rachael McFadden Quality Manger for Kelly Chasis. Date: 2013.12.11 14:06:53 -5:00		
Batch Size: 750L/762.0kg	**Date Issued:**	**Production Started:**	**Production Completed:**
Qty manufactured: 750L/762.0kg	**Qty lost:**	**Yield (%):**	**Initial:**

COPY

Item #	Part Number	Ingredients	Qty/mL	Qty required	Lot	Expiration date	Qty dispensed	Date dispensed	Dispensed by	Checked by
1.	EX-10000	Water for Injection USP	0.90mL	686.0kg	N/A	N/A				
2.	AP-10000	Cysteine HCl Monohydrate	50mg	37.5kg						
3.	EX-10040	Hydrochloric Acid NF	Q.S.	To adjust pH						
4.	EX-10030	Sodium Hydroxide NF	Q.S.	To adjust pH						
5.	EX-10000	Water for Injection USP	Q.S.	Q.S. to 762.0kg	N/A	N/A				

Form Title: **Cysteine Batch Manufacturing Record (750L) -Line 2**				Doc Number: **BMR-010.00**
Formulation #	**Product**	**Company**	**Lot #**	Page 2 of 6
F1000	**Cysteine HCl Injection 50mg/mL**	**Sandoz Inc.**	**2072115**	

PRE-MANUFACTURING				
Equipment	ID#	Equipment with current calibrations (yes/no)	By	Date
Stainless Steel Tank (ID# 0331 or 0333)	0331	N/A	[signature]	07-20-15
Mixer	0188	yes	[signature]	07-20-15
Mixing shaft with blade	0266	N/A	[signature]	07-20-15
pH Meter	0205	Yes	MA	07-20-15
Floor scale (Range: 0.00–1,500.0kg) (ID# 0245 or 0244)	0245	yes	[signature]	07-20-15
Weigh Scale (Range: 0.000–15.000kg)	0263	yes	[signature]	07-20-15
Temperature Measuring Device	0267	yes	[signature]	07-20-15

Form Title: **Cysteine Batch Manufacturing Record (750L) -Line 2**			Doc Number: **BMR-010.00**
Formulation #	**Product**	**Company**	**Lot #**
F1000	**Cysteine HCl Injection 50mg/mL**	**Sandoz Inc.**	**2072115**

Step #	MANUFACTURING PROCESS	By/Date	Checked by/Date
1.	Ensure all raw materials are available for compounding and are within expiration date. Record the raw materials lot number and expiration date on page 1 of this form.		
2.	Ensure that the mixing/compounding room # 2130 and equipment in the room is clean and all cleaning forms have been signed. Verify that cleaning has been performed by referencing MFG-031-03 "Building 2 Vial Production Cleaning Checklist."		ELM 07-20-15
3.	Verify that the floor scale is within calibration and record verification on page 1 of this form. Zero floor scale and roll the tank onto the scale. Record the tank and floor scale ID#s on page 2. Record the tank weight 387.3 kg. Label the tank as QUARANTINE. Proceed to tare the scale.	07-20-15	
4.	Add 686.0 kg of USP WFI (item #1) to the tank. Record results on Page 1 of the batch record. WFI source (✓one): ○ 2130 ☒ 2130HE ○ 2131 When using WFI source 2130HE refer to the instruction in FAE-004 for operation of the heat exchanger.	07-20-15	07.20.15
5.	Allow WFI to cool between the temperatures of 20°C–32°C. Temperature of WFI: 29.0 °C Verify that the temperature measuring device ID# 0267 is within calibration.	07-20-15	07.20.15
6.	Insert the mixer into the WFI. Set-up the mixer so the shaft is in the center of the tank opening. The location of the mixing blade should be set at the middle depth of the solution in the tank. Turn on the mixer and set the mixer speed at 250 ± 10 rpms. Record mixing speed: 260 rpm.	07-20-15	07.20.15
7.	Check the raw materials for the correct name, item code and quantity. Record results on Page 1 of this form.	07-20-15	07.20.15

Form Title: **Cysteine Batch Manufacturing Record (750L) -Line 2**				Doc Number: **BMR-010.00**
Formulation #	**Product**	**Company**	**Lot #**	Page 4 of 6
F1000	**Cysteine HCl Injection 50mg/mL**	**Sandoz Inc.**	**2072115**	

Step #	MANUFACTURING PROCESS	By/Date	Checked by/Date
8.	To weigh the required amount of Cysteine. Place an empty sampling container on scale ID# 0263. Verify that the scale is displaying in "kg". Tare the scale and remove the sampling container. Add the required amount of Cysteine to the sampling container. If more than one sampling container is required, then repeat this step. Record the sampling container weights below. (* indicates Critical Process Parameter) 37.500kg* of Cysteine is required: Lot #: 6947-4 / 6947-5 Exp. date: 05-11-16 / 05-11-16 (Record lot number and expiration date on Page 1 of this form) Sampling container 1: 0.056 kg 6947-4 Sampling container 2: 13.436 kg 6947-5 Sampling container 3: 12.906 kg 6947-5 Sampling container 4: 11.102 kg 6947-5 Sampling container 5: _____ kg Sampling container 6: _____ kg Total: 37.500 kg (Record on page 1 of this form)	07-20-15	07.20.15
9.	With mixing, add 37.500kg of Cysteine HCl Monohydrate (item 02) and mix for 5–10 minutes. Start time: 3:42pm End time: 3:48pm Total mixing time: 6 min. If raw material is dissolved, proceed to Step 10. If raw material is not dissolved within 5–10 minutes notify supervisor.	07-20-15	07.20.15
10.	Using a clean container remove approximately 3L from the bottom valve of the tank and place into the top of the tank.	07-20-15	07.20.15
11.	Remove a 10mL sample and submit to QA/QC for pH testing.	07-20-15	07.20.15

Form Title: **Cysteine Batch Manufacturing Record (750L) -Line 2**			Doc Number: **BMR-010.00**
Formulation #	**Product**	**Company**	**Lot #**
F1000	**Cysteine HCl Injection 50mg/mL**	**Sandoz Inc.**	**2072115**

Step #	MANUFACTURING PROCESS	By/Date	Checked by/Date
12.	Measure pH with pH meter ID# 0205. Verify that the pH meter is in calibration. Record pH 1.28, specification of 1.20–1.30. If pH is within range, go to step 14. If pH is not within range, go to step 13.	QA/QC: MA 07-20-15	SL 07.20.15
13.	If pH is not within range, remove a 100ml sample for QC testing to determine acid/base quantity required for pH correction. The required quantity of Hydrochloric Acid (item 03) or Sodium Hydroxide (item 04) must be dissolved in WFI (item 01). Add slowly and mix 15 min before retest.	QA/QC:	QA/QC:

	1	2	3
pH Before			
pH After			
Time start			
Time finish			
Total mixing time			
Quantity of Hydrochloric Acid (item 03) required			
Quantity of Sodium Hydroxide (item 04 required			
Quantity of Hydrochloric Acid (item 03) added			
Quantity of Sodium Hydroxide (item 04) added			

Include the test results and calculation in batch production records.

Form Title: **Cysteine Batch Manufacturing Record (750L) -Line 2**				Doc Number: **BMR-010.00**
Formulation #	**Product**	**Company**	**Lot #**	Page 6 of 6
F1000	**Cysteine HCl Injection 50mg/mL**	**Sandoz Inc.**	**2072115**	

Step #	MANUFACTURING PROCESS	By/Date	Checked by/Date
14.	Q.S. WFI (item 05) to a final weight of 762kg*. (* indicates Critical Process Parameter) Total weight = 762.0 kg Mix for 15 ± 5 minutes. Start time: 4:05pm End time: 4:15pm Total mixing time: 10min.	07-20-15	07.20.15
15.	Remove a 10mL sample into a cleaned container and submit to QA/QC for pH testing.	07-20-15	07.20.15
16.	Measure pH with pH meter ID# 0205. Verify that the pH meter is in calibration. pH specification (1.20–1.30) pH actual results 1.25 * (if pH does not meet specification, notify supervisor) (* indicates Critical Process Parameter)	QA/QC: MA 07-20-15	07.20.15
17.	Remove the mixer from the tank. Clean the mixing shaft with blade according to MFG-045 "Post-Manufacturing Equipment Cleaning Procedure – Line 2". Time cleaned: 4:22pm	07-20-15	07.20.15
18.	**QA/QC RELEASE:** Prior to filling operation, identify the tank as being released and include product name, lot number, volume, initials and date.	QA/QC: MA 07-20-15	07.20.15
19.	Close the lid on the tank. Process completion time: 4:24pm (Filling must commence within 24 hours*) (* indicates Critical Process Parameter)	07-20-15	07.20.15

Document Review and Approval	
	Production Supervisor/date: 07-22-15 07.20.15
	Quality Assurance/date: MFG 08-12-15

QA 07.17.15

50mL Cysteine HCl Injection Vial Manufacturing Record - Line 2

Doc Number: **VMR-014.00**

Page 1 of 9

Form Effective Date: FEB 10 2014

Form Issue Date: JAN 30 2014

Company	Product	Product Code	Format
Sandoz Inc.	Cysteine HCl Injection 50mg/mL	CYS-002	50mL in 50mL

Lot #	Expiration Date (24 months)	Filling Date	Issue Date
2072115	07/17	07.21.15	07-15-15

Originator/date:	01-28-14
Department Approval/date:	1/28/14
QA Approval/date:	01.28.14
Customer Approval/date:	See attached page 1 for customer approval. MC 01.29.14

Item #	Part Number	Description	Lot #	Quantity per unit	Qty received	Prepared by	Qty Used	Qty returned	Checked by
1.	CYS-002	Cysteine HCl 50mg/mL	2072115	51.5mL	762.0kg	07-20-15	730.344 kg.	Quantity discarded: 27.2kg - Tank - 07-21-15 4.456 - Pathway - 07-21-15	
2.	G-16	50mL 20mm Clear Glass Vial	G-16-012115	1	13940	ADH 07-21-15	13940	0	
3.	ST-07	20mm Rubber Stopper	ST-07-041114	1	15000	EM 07-17-15	15000	0	
4.	S-023	20mm Aluminum Flip-off White Seal	S-023-062211	1	N/A				
5.	KVGLS04HH3	Opticap 4" 0.22µ Sterilizing Filter	C4MA14478	N/A	N/A				
6.	L-018-XX (current version)	Vial Label	L-018-01-062615	1	See PAL-002-01 for vial labeling operations.				
7.	L-023-XX (current version)	Vial Tray	L-023-01-121913 L-023-01-070215	5 vials per tray	See PAL-002-07 for vial carton operations.				
8.	L-028-XX (current version)	Package Insert	L-028-00-061915	1 per tray	See PAL-002-08 for package insert operations.				
9.	PC-40070	Shipping Box AL3050	N/A	5 trays per box	N/A				
10.	L-032-XX (current version)	Shipping Box Label	N/A	1 per box	See PAL-002-12 for shipping box label operations.				

50mL Cysteine HCl Injection Vial Manufacturing Record - Line 2

Doc Number: **VMR-014.00**

Company	Product	Product Code	Fill Size
Sandoz Inc.	Cysteine HCl Injection 50mg/mL	CYS-002	50mL in 50mL

Page 1 of 9

Lot #	Expiration Date (DD-MMM-YY)	Filling Date	Issue Date

Form Effective Date:

Originator/date:	01-28-14
Department Approval/date:	1/28/14 COPY
QA Approval/date:	01.28.14
Customer Approval/date:	McFadden Rachael (Digitally signed by McFadden Rachael, DN: SERIALNUMBER=17332389 + CN=McFadden Rachael, OU=GX, OU=people, DC=novartis, DC=com, Reason: I am approving this document, Date: 2014.01.28 12:02:16 -6:00)

Form Issue Date:

Item #	Part Number	Description	Lot #	Quantity Per Unit	Qty Issued	Issued By	Qty Used	Qty Returned / Quantity discarded:	Checked By
1.	CYS-002	Cysteine HCl 50mg/mL		51.5mL					
2.	G-16	50mL 20mm Clear Glass Vial	~~G16-012115~~	1	13940	ADH	13940	0 N/A CS 2.1.15	
3.	ST-07	20mm Rubber Stopper		1					
4.	S-023	20mm Aluminum Flip-off White Seal		1	N/A				
5.	KVGLS04HH3	Opticap 4" 0.22µ Sterilizing Filter		N/A	N/A				
6.	L-018-XX (current version)	Vial Label		1	See PAL-002-01 for vial labeling operations.				
7.	L-023-XX (current version)	Vial Tray		5 vials per tray	See PAL-002-07 for vial carton operations.				
8.	L-028-XX (current version)	Package Insert		1 per tray	See PAL-002-08 for package insert operations.				
9.	PC-40070	Shipping Box AL3050	N/A	5 trays per box	N/A				
10.	L-032-XX (current version)	Shipping Box Label	N/A	1 per box	See PAL-002-12 for shipping box label operations.				

50mL Cysteine HCl Injection Vial Manufacturing Record - Line 2					Doc Number: **VMR-014.00**
Company	Product	Product Code	Lot #	Expiration Date (24 months)	
Sandoz Inc.	**Cysteine HCl Injection 50mg/mL**	**CYS-002**	**2072115**	**07/17**	Page 2 of 9

Pre-Manufacturing				
Equipment	ID # (Mark applicable box)	Calibration Due Date	Checked By	Date
Vial washer	0239	N/A	[illegible]	07.20.15
Steam sterilizing autoclave(s)	0237 & 0238	12.15	[illegible]	07.20.15
Depyrogenating tunnel	0242	12.15	[illegible]	07.20.15
Vial filling and stoppering machine	0336	N/A	[illegible]	07.20.15
Vial capping machine	0250	N/A	[illegible]	07.20.15
Weigh scale (Range 0.000-310.000g) (Steps 12 & 13)	0262	8.15	[illegible]	07.20.15
Weigh scale (Range: 0.000–35.000kg) (Step 20)	0263	8.15	[illegible]	07.20.15
Floor scale (Range: 0.0–2,250.0kg) (Step 20)	0245	8.15	[illegible]	07.20.15
Floor scale (Range: 0.0–2,250.0kg) (Step 20)	0244	8.15	[illegible]	07.20.15
Vial labeling machine	☑ 0257 ☐ 0295 ☐ 0153	N/A	[illegible]	07.20.15
Carton printing machine	☐ 0120 ☐ 0289 ☑ 0391	N/A	[illegible]	07.20.15
Shrink wrap machine	☑ 0261 ☐ 0215	N/A	[illegible]	07.20.15

50mL Cysteine HCl Injection Vial Manufacturing Record - Line 2					Doc Number: VMR-014.00
Company	Product	Product Code	Lot #	Expiration Date (24 months)	
Sandoz Inc.	Cysteine HCl Injection 50mg/mL	CYS-002	2072115	07/17	Page 3 of 9

Step	Manufacturing Process		By/Date	Checked by/Date
1.	Ensure that the vial prep room (2129) and equipment in the room are clean and all cleaning checklist forms have been completed and signed. (MFG-031-03 "Building 2 Vial Production Cleaning Checklist" and MFG-005-03 "Manufacturing Daily Checklist for Line 2 Support Rooms# 2125-2131")		ECM 07-17-15	07-17-15
2.	a. Obtain depyrogenated rubber stoppers for the lot. b. Record the stopper lot number and the number of stoppers received on page 1, Item 3. c. **Sterilize the stoppers*** according to the instructions in FAE-026 "Operation of the Getinge Steam Sterilizers, ID#s 0237 and 0238." d. Include a copy of FAE-026-01 "Daily Autoclave Log/Equipment ID# 0237 and # 0238" and cycle printouts for the autoclave cycle #s with the batch record. e. At cycle completion, transfer the sterilized stoppers to the aseptic support room # 2119.	**Rubber closure (Item 3) autoclave cycle #(s)*:** 0238-71715-1	ECM 07-17-15	07-17-15
3.	Prepare equipment required for the production run according to MFG-044 "Equipment Preparation for SEV and Sterile Filled Vials, Building 2."		ECM 07-17-15	
4.	**Sterilize the equipment*** and record cycle numbers for the following equipment required for this run. Include a copy of FAE-026-01 "Daily Autoclave Log/ Equipment ID# 0237 and # 0238" and cycle printouts for the autoclave cycle #s with the batch record.	**Autoclave Cycle #*** 0238-071715-2 **Filling surge tank:** ECM 07-17-15 ~~0238-071715-2~~ **Filling machine manifold:** 0238-071715-2 **Filling needles:** 0238-071715-2 **Nitrogen manifold:** 0238-071715-2 **Stopper bowl:** 0238-071715-2 **Stopper hopper:** 0238-071715-2 **Stopper tray:** 0238-071715-2 **Stopper inhibitor:** 0238-071715-2 **Stopper wheel:** 0238-071715-2	ECM 07-17-15	07-17-15
5.	Place all prepared equipment and components in the Aseptic Support Room ID# 2119.		ADH 07-21-15	07-21-15

***Critical Process Parameter**

50mL Cysteine HCl Injection Vial Manufacturing Record - Line 2					Doc Number: **VMR-014.00**
Company	**Product**	**Product Code**	**Lot #**	**Expiration Date (24 months)**	Page 4 of 9
Sandoz Inc.	**Cysteine HCl Injection 50mg/mL**	**CYS-002**	**2072115**	**07/17**	

Step #	Manufacturing Process	By/Date	Checked by/Date
6.	Ensure that the vial prep room # 2129 and equipment in the room is clean and all cleaning checklist forms have been completed and signed. Verify that cleaning has been performed by referencing MFG-031-03 "Building 2 Vial Production Cleaning Checklist" and MFG-005-03 "Manufacturing Daily Checklist for Line 2 Support Rooms# 2125-2131."	ADH 07-21-15	ECM 07-21-15
7.	Wash the 50mL 20mm vials (Item 2) according to the instructions in FAE-025 "Operation of the PennTech Rotary Vial Washer, ID # 0239." **Depyrogenate the vials*** according to the instructions in FAE-024 "Operation of the Steriline Depyrogenating Tunnel, Model ST6, ID# 0242."	ADH 07-21-15	ECM 07-21-15

Vial Washing & Depyrogenation*	Lot #	Release date
Glass	G-16-011215	03-19-15
	N/A ADH 07-21-15	N/A ADH 07-21-15
Tunnel run #		2072115
Batch started on the tunnel computer?		☑ Yes ☐ No
Verify the run # on the tunnel batch screen matches the run # on the release label on the shrink wrap of the vials to be washed*		Verified?* ☑ Yes ☐ No
# of shrink packs at start of washing		(A) 705
# of vials per shrink wrap		(B) 68
# of shrink packs washed		(C) 705
Total # of vials washed (theoretical) [(B) x (C)] Record (D) on pg. 1, Item 2 Quantity received.		(D) 13940
# of vials discarded during washing procedure		(E) 0
Total # of vials washed and moved to the tunnel (actual) [(D) - (E)]		(F) 13940
# of shrink packs returned to inventory		0

ADH 07-21-15 (Verified?*)

ECM 07-21-15

Step #				By/Date	Checked by/Date
8.	Prior to filling operations, the release of the bulk product must be verified.	**Product :** L-Cysteine	**Lot number:** 2072115	ADH 07-21-15	ECM 07-21-15
		Release date: 07-20-15	**Weight of bulk product (kg):** 762.0 kg.		

***Critical Process Parameter**

50mL Cysteine HCl Injection Vial Manufacturing Record - Line 2					Doc Number: VMR-014.00
Company	Product	Product Code	Lot #	Expiration Date (24 months)	Page 5 of 9
Sandoz Inc.	Cysteine HCl Injection 50mg/mL	CYS-002	2072115	07/17	*This page shall be copied onto autoclavable paper.

Vial filling

Step	Manufacturing Process	By/Date	Checked by/Date
9.	Ensure that the vial filling room and equipment in the room are clean and all cleaning checklist forms have been completed and signed. (MFG-031-03 "Building 2 Vial Production Cleaning Checklist" and MFG-005-07 "Manufacturing Daily Checklist for Line 2 Filling Suite Rooms# 2114-2124")	JS 07-21-15	EM 07-21-15
10.	Set-up filling and stoppering machine according to FAE-033 "Operation of the Bosch Fill Machine, ID # 0336."	JS 07-21-15	
11.	**Record sterilizing filter pressure*** 25 psi (must be ≤ 30 psi)* **Initial Filtration Time:** 6:45AM **Final Filtration Time:** 12:38pm **Total Filtration Time*:** 5 hrs 53 min (not to exceed 6 hrs 0 min)*	JS 07-21-15	
12.	Set fill volume according to FAE-033 "Operation of the Bosch Fill Machine, ID # 0336." Use scale ID# 0262 to set the fill volume. Calculation of fill weight: Formula: Density (g) x fill volume (mL) = fill weight (g) L-Cysteine HCl 50mg/mL density=1.015g Minimum limit: 50.0mL / 50.75g; Target fill: 51.5mL / 52.27g; Maximum limit: 53.0mL / 53.80g	JS 07-21-15	EM 07-21-15
13.	Proceed with filling and stoppering of the vials. After the initial fill volume check, verify the fill volume once approximately every 10 minutes as the filling process continues. Do not exceed 15 minutes. Rotate through all eight filling needles, 4 filling needles at a time. Record the fill volumes on FAE-033-01 "Volume Verification Record-Line 2." Refer to FAE-033-01 for fill start and end time. **Filling start time:** 6:47AM **Is start time within 24 hours of completion of the batch manufacturing process?*** ☑ Yes ☐ No **Fill end time:** 12:41pm. **Total fill time:** 5HRS 54MIN.	JS 07-21-15	
14.	Transfer all filled and stoppered vials to the vial capping machine.	JS 07-21-15	EM 07-21-15
15.	Approximate # of empty vials discarded during filling and stoppering: 40 Approximate # of filled vials discarded during filling and stoppering: 20		
16.	Prior to completion of sterile filtration, pull a 3mL non-sterile sample of Cysteine HCl and place into a sterile empty vial. Label the vial with 'Bioburden', the vial contents and lot#. Submit the sample to QC and log onto QC-038-01 "Sample Log and Quality Control Analytical Results Tracking."	EM 07-22-15 07-22-15 07-22-15	SV 07.22.15

*Critical Process Parameter

50mL Cysteine HCl Injection Vial Manufacturing Record - Line 2					Doc Number: VMR-014.00
Company	Product	Product Code	Lot #	Expiration Date (24 months)	Page 6 of 9
Sandoz Inc.	Cysteine HCl Injection 50mg/mL	CYS-002	2072115	07/17	*This page shall be copied onto autoclavable paper.

Vial filling

Step #		Manufacturing Process	By/Date	Checked by/Date
17.	Record filter lot #s and perform **bubble point testing*** according to the instructions FAE-033 "Operation of the Bosch Fill Machine, ID # 0336."	**Nitrogen purging Acro 50 0.2µ filter (PN 4250) lot #:** 21856025	JS 07-21-15	EH 07-21-15
		Acro 50 0.2µ vent filter #1 (PN 4250) lot #: 21862850		
		Acro 50 0.2µ vent filter #2 (PN 4250) lot #: 21862850		
		Milipore Opticap 4" 0.22µ sterilizing filter (catalog #: KVGLS04HH3) lot #: C4MA14478		
		Sterilizing filter post-fill bubble point (nlt 50 psi)*: 59 psi	JS 08-11-15	ADH/08-11-15
		Vent filter #1 post-fill bubble point (nlt 13 psi w/methanol): Submit vent filter to QC and log onto QC-038-01 "Sample Log and Quality Control Analytical Results Tracking."	See QC-076-01 "Gelman Acro 50 0.2µ Filter Integrity Testing" for documentation	
		Vent filter #2 post-fill bubble point (nlt 13 psi w/methanol): Submit vent filter to QC and log onto QC-038-01 "Sample Log and Quality Control Analytical Results Tracking."	See QC-076-01 "Gelman Acro 50 0.2µ Filter Integrity Testing" for documentation	

***Critical Process Parameter**

50mL Cysteine HCl Injection Vial Manufacturing Record - Line 2					Doc Number: VMR-014.00
Company	Product	Product Code	Lot #	Expiration Date (24 months)	Page 7 of 9 *This page shall be copied onto autoclavable paper.
Sandoz Inc.	Cysteine HCl Injection 50mg/mL	CYS-002	2072115	07/17	

Vial capping

Step#	Manufacturing Process	By/Date	Checked by/Date
18.	Set-up capping machine according to the instructions in FAE-029 "Operation of the Westcapper Model RW600 – Line 2, ID# 0250."	JS 07-21-15	EM 07-21-15
19.	Perform vial capping on all filled and stoppered vials according to the instructions in FAE-029 "Operation of the Westcapper Model RW600 – Line 2, ID# 0250."	[illegible] 7-21-15	
20.	Approximate # of Vials with discarded during capping: 3		
21.	Using a conveyor belt, transfer vials to the inspection area.		

50mL Cysteine HCl Injection Vial Manufacturing Record - Line 2

Doc Number: **VMR-014.00**

Company	Product	Product Code	Lot #	Expiration Date (24 months)	
Sandoz Inc.	Cysteine HCl Injection 50mg/mL	CYS-002	2072115	07/17	Page 8 of 9

Step #	Manufacturing Process		By/Date	Checked by/Date
22.	Weigh any unused solution on the bench top scale or floor scale. Document the amount unused on page 1. Discard all unused solution after weighing.		07-21-15	ELM 07-21-15
23.	Upon completion of the filling operations, the filling equipment must be cleaned according to the instructions in MFG-045 "Post-Manufacturing Equipment Cleaning Procedure – Line 2."	**Time equipment cleaned:** 2:15 pm.	07.21.15	ELM 07-21-15
24.	After use of mixing tank has completed, the mixing tank must be cleaned according to the instructions in MFG-045 "Post-Manufacturing Equipment Cleaning Procedure – Line 2."	**Time mixing tank cleaned:** 12:54 pm	07-21-15	
25.	A stopper reconciliation will be performed by manufacturing personnel.		ELM 07-21-15	07.21.15
	Approximate # of stoppers at beginning of production (Item 3, page 1 Qty received)	(A) 15000		
	Approximate # of stoppers returned to equipment prep room (room # 2129)	(B) 0		
	Approximate # of stoppers used during production [(A) – (B)] = (C)	(C) 15000		
26.	All vials shall be inspected according to the instructions in MFG-036 "Manual Inspection of Filled Vials." Document the inspection process on MFG-036-01 "Filled Vial Inspection Record."		See MFG-036-01 for vial inspection signatures	See MFG-036-01 for vial inspection signatures
27.	Once vials have been inspected place vials in trays and transfer vials to the labeling area.		ELM 07-21-15	07.21.15
28.	Begin labeling vials according to the instructions in the SOP that corresponds with the equipment ID# on page 2. Record all labeling data on PAL-002-01 "Filled Vial Labeling Record." QA/QC must approve PAL-002-01 prior to labeling vials.		07-21-15	ELM 07-21-15
29.	Pull labeled sample vials from the production line for testing. Place samples into appropriate cartons (Item 7). Samples are pulled from the beginning, middle and end of lot.	Sterility = 20 vials (7 from beginning, 6 from middle, 7 from end) Particulate Matter = 4 vials (2 from beginning, 1 from middle, 2 from end) Bacterial Endotoxin = 2 vials (1 from beginning, 1 from end) Fill Volume = 1 vial (1 from beginning) Contract Testing = 7 vials (2 from beginning, 3 from middle, 2 from end) Aluminum = 1 vial (1 from middle) **Total = 35 vials**	ELM 07-21-15	07.21.15
		Other requirements (# of vials): NA TH 08-17-15		
30.	Submit 20 sample vials for sterility testing to the QC Technician responsible for Sterility Testing. Submit the remaining sample vials to QC and complete QC-038-01 "Sample Log and Quality Control Analytical Results Tracking."		ELM 07-21-15	

50mL Cysteine HCl Injection Vial Manufacturing Record - Line 2					Doc Number: **VMR-014.00**
Company	**Product**	**Product Code**	**Lot #**	**Expiration Date (24 months)**	Page 9 of 9
Sandoz Inc.	**Cysteine HCl Injection 50mg/mL**	**CYS-002**	**2072115**	**07/17**	

Step #	Manufacturing Process	By/Date	Checked by/Date
31.	Place labeled vials into the appropriate trays (Item 7).	L.M 07-21-15	ELM 07-21-15
32.	Place a package insert (Item 8) within each tray.	DDLG 07-21-15	
33.	Set-up carton printing machine according to the instructions in the SOP that corresponds with the equipment ID# on page 2. Record carton printing data on PAL-002-07 "Printed Container Packaging Record." QA/QC must approve PAL-002-07 prior to printing trays. Print lot # and exp. date on all trays.	407-1715	ELM 07-21-15
34.	Once trays have been labeled, shrink wrap the trays according to the instructions in FAE-023 "Operation of Lantech Shrink Wrappers, ID#'s 0215 and 0261."	ELM 07-21-15	SO 07.21.15
35.	Randomly pull the required amount of retention sample vials requested on MFG-037-01 "Retention Sample Form for Sandoz Inc. Drug Products" for the corresponding products. Document the data on MFG-037-01.	ELM 07-21-15	SO 07.21.15
36.	Place 5 shrink-wrapped trays in applicable shipping box (Item 9).	ELM 08-10-15	SO 08.10.15
37.	Prepare the shipping box labels. Place a label on PAL-002-12 "Sandoz Shipping Label Record – 50mL Cysteine" and submit to QA for approval.	ELM 07-21-15	SO 08.10.15
38.	Apply the approved shipping box labels (Item 10) to each shipping box.	ELM 08-10-15	
39.	Load finished product onto carts or pallets and transfer to quarantine area.	ELM 08-10-15	
40.	Document lot reconciliation on MFG-057-24 "Calculation of Percent Yields For Bulk Solution and Final Containers of Sterile Drug Products."	ELM 07-22-15	SO 07.22.15

Manufacturing Supervisor Review	**Review by/date:** 08.11.15

07-15-15 07-17-15

	Form Title: **Filling/Stoppering and Capping Line Clearance Record**			Doc Number: **MFG-048-01.01**
				Page 1 of 1
	Lot #: **2072115**	Product: **Cysteine 50mL**	* This form shall be copied onto autoclavable paper.	Form Issue Date: JAN 30 2014
				Form Effective Date: MAR 26 2014

Filling/Stoppering Area:

Pre Line Clearance Performed by/date/time:	Verified by/date/time:
JS 07-21-15 6:01AM.	Q 7-21-15 6:50AM
Post Line Clearance Performed by/date/time:	**Verified by/date/time:**
JS 07-21-15 12:41pm.	Q 7-21-15 12:50pm

Capping Area:

Pre Line Clearance Performed by/date/time:	Verified by/date/time:
JS 07-21-15 6:03AM.	Q 7-21-15 6:50 AM
Post Line Clearance Performed by/date/time:	**Verified by/date/time:**
Q 7-21-15 12:50 pm	JS 07-21-15 12:52pm.

Comments:

07-21-15

Manufacturing Supervisor Review	Performed by/date: 07-21-15

N/A 07-15-15 N/A 07-17-15

ALLERGY LABORATORIES, INC.

Form Title: **Volume Verification Record–Line 2**				Doc Number: **FAE-033-01.02** Page 1 of 3
Lot #: **2072115**	Type of Soln: **Cysteine**	Fill volume: **50mL**	Vial Size: **50mL 20mm**	***This form shall be copied onto autoclavable paper.**
Weight Range: **50.75g – 53.80g**	Target Weight: **52.27 g**	Scale ID#: 0262	Calibration due: 08-06-15	Form Issue Date: JAN 30 2014
				Form Effective Date: MAR 20 2014

Initial Check	Weight	Initial
Needle 1	51.84	JS
Needle 2	52.29	JS
Needle 3	53.06	JS
Needle 4	52.77	JS

Initial Check	Weight	Initial
Needle 5	N/A JS 07-21-15	
Needle 6		
Needle 7		
Needle 8		

	Time	Date / Initial
Filling Started	6:47AM.	07-21-15 JS
Filling Completed	12:41pm.	07-21-15 JS

Sample the volume of 4 of the filling needles at least every 10 minutes (not to exceed 15 minutes) during filling operations. Rotate through all 8 filling needles, 4 needles at a time. When 50mL and 100mL vials are being filled weight checks will only be performed on needles 5-8 due to the filling format.

	Time	Weight (g)	Volume Verified	Initial
1	6:52AM	51.78	☐ ☑	JS
2		52.27	☐ ☑	JS
3		52.98	☐ ☑	JS
4		52.71	☐ ☑	JS
5	6:58AM	52.57	☐ ☑	JS
6		52.77	☐ ☑	JS
7		53.51	☐ ☑	JS
8		53.15	☐ ☑	JS
1	7:10AM	51.92	☐ ☑	JS
2		52.00	☐ ☑	JS
3		52.69	☐ ☑	JS
4		52.59	☐ ☑	JS
5	7:20AM	52.02	☐ ☑	JS
6		52.03	☐ ☑	JS
7		52.85	☐ ☑	JS
8		52.42	☐ ☑	JS

	Time	Weight (g)	Volume Verified	Initial
1	7:30AM	51.84	☐ ☑	JS
2		51.95	☐ ☑	JS
3		52.69	☐ ☑	JS
4		52.23	☐ ☑	JS
5	7:40AM	51.84	☐ ☑	JS
6		52.10	☐ ☑	JS
7		52.63	☐ ☑	JS
8		52.30	☐ ☑	JS
1	7:50AM	51.80	☐ ☑	JS
2		51.86	☐ ☑	JS
3		52.59	☐ ☑	JS
4		52.00	☐ ☑	JS
5	8:00AM	52.73	☐ ☑	JS
6		52.90	☐ ☑	JS
7		53.34	☐ ☑	JS
8		52.72	☐ ☑	JS

	Time	Weight (g)	Volume Verified	Initial
1	8:10AM	52.64	☐ ☑	JS
2		52.73	☐ ☑	JS
3		53.14	☐ ☑	JS
4		52.78	☐ ☑	JS
5	8:20AM	51.83	☐ ☑	JS
6		52.04	☐ ☑	JS
7		52.49	☐ ☑	JS
8		51.98	☐ ☑	JS
1	8:30AM	52.42	☐ ☑	JS
2		52.62	☐ ☑	JS
3		52.86	☐ ☑	JS
4		52.48	☐ ☑	JS
5	8:40AM	51.82	☐ ☑	JS
6		51.83	☐ ☑	JS
7		52.03	☐ ☑	JS
8		52.33	☐ ☑	JS

	Form Title: **Volume Verification Record-Line 2**			Doc Number: **FAE-033-01.02**
ALLERGY LABORATORIES, INC.	Corresponding SOP(s) #: FAE-033			Page 2 of 3
	Lot #: **2072115**	Weight Range: **50.75g – 53.80g**	Target Weight: **52.27 g**	***This form shall be copied onto autoclavable paper.**

	Time	Weight (g)		Initials
1	8:50AM	51.99	☐ ☑	JS
2		52.10	☐ ☑	JS
3		52.47	☐ ☑	JS
4		52.06	☐ ☑	JS
5	9:00AM	52.88	☐ ☑	JS
6		52.96	☐ ☑	JS
7		53.19	☐ ☑	JS
8		52.71	☐ ☑	JS
1	9:10AM	52.05	☐ ☑	JS
2		52.14	☐ ☑	JS
3		52.41	☐ ☑	JS
4		51.98	☐ ☑	JS
5	9:20AM	52.08	☐ ☑	JS
6		52.07	☐ ☑	JS
7		52.46	☐ ☑	JS
8		51.76	☐ ☑	JS
1	9:30AM	52.81	☐ ☑	JS
2		52.87	☐ ☑	JS
3		53.20	☐ ☑	JS
4		52.89	☐ ☑	JS
5	9:40AM	52.68	☐ ☑	JS
6		52.66	☐ ☑	JS
7		52.82	☐ ☑	JS
8	JS 07-21-25	52.46	☐ ☑	JS

JS 07-21-25

	Time	Weight (g)		Initials
1	9:50AM	51.87	☐ ☑	JS
2		52.01	☐ ☑	JS
3		52.25	☐ ☑	JS
4		51.82	☐ ☑	JS
5	10:45AM	51.80	☐ ☑	JS
6		51.94	☐ ☑	JS
7		52.13	☐ ☑	JS
8		51.79	☐ ☑	JS
1	11:00AM	52.87	☐ ☑	JS
2		52.89	☐ ☑	JS
3		53.11	☐ ☑	JS
4		52.84	☐ ☑	JS
5	11:10AM	52.64	☐ ☑	JS
6		52.80	☐ ☑	JS
7		52.68	☐ ☑	JS
8		52.42	☐ ☑	JS
1	11:20AM	52.76	☐ ☑	JS
2		52.84	☐ ☑	JS
3		53.09	☐ ☑	JS
4		52.72	☐ ☑	JS
5	11:30AM	52.32	☐ ☑	JS
6		51.98	☐ ☑	JS
7		52.09	☐ ☑	JS
8		52.37	☐ ☑	JS

* STOPPED FOR BREAK

	Time	Weight (g)		Initials
1	11:40AM	51.74	☐ ☑	JS
2		51.88	☐ ☑	JS
3		51.96	☐ ☑	JS
4		51.82	☐ ☑	JS
5	11:50AM	52.43	☐ ☑	JS
6		52.42	☐ ☑	JS
7		52.54	☐ ☑	JS
8		52.38	☐ ☑	JS
1	12:00pm	51.94	☐ ☑	JS
2		52.17	☐ ☑	JS
3		52.27	☐ ☑	JS
4		52.08	☐ ☑	JS
5	12:10pm	51.82	☐ ☑	JS
6		52.02	☐ ☑	JS
7		52.16	☐ ☑	JS
8		51.85	☐ ☑	JS
1	12:20pm	51.70	☐ ☑	JS
2		51.85	☐ ☑	JS
3		52.13	☐ ☑	JS
4		51.80	☐ ☑	JS
5	12:30pm	52.10	☐ ☑	JS
6		52.08	☐ ☑	JS
7		52.16	☐ ☑	JS
8		52.24	☐ ☑	JS

	Form Title: **Volume Verification Record-Line 2**			Doc Number: **FAE-033-01.02**
ALLERGY LABORATORIES, INC.	Corresponding SOP(s) #: FAE-033			Page 3 of 3
	Lot #: 2072115	Weight Range: 50.75g – 53.80g	Target Weight: 52.27 g	***This form shall be copied onto autoclavable paper.**

	Time	Weight (g)	Adjustment Required Yes No	Initials
1			☐ ☐	
2			☐ ☐	
3			☐ ☐	
4			☐ ☐	
5			☐ ☐	
6			☐ ☐	
7			☐ ☐	
8			☐ ☐	
1			☐ ☐	
2			☐ ☐	
3			☐ ☐	
4			☐ ☐	
5			☐ ☐	
6			☐ ☐	
7			☐ ☐	
8			☐ ☐	
1			☐ ☐	
2			☐ ☐	
3			☐ ☐	
4			☐ ☐	
5			☐ ☐	
6			☐ ☐	
7			☐ ☐	
8			☐ ☐	

	Time	Weight (g)	Adjustment Required Yes No	Initials
1			☐ ☐	
2			☐ ☐	
3			☐ ☐	
4			☐ ☐	
5			☐ ☐	
6			☐ ☐	
7			☐ ☐	
8			☐ ☐	
1			☐ ☐	
2			☐ ☐	
3			☐ ☐	
4			☐ ☐	
5			☐ ☐	
6			☐ ☐	
7			☐ ☐	
8			☐ ☐	
1			☐ ☐	
2			☐ ☐	
3			☐ ☐	
4			☐ ☐	
5			☐ ☐	
6			☐ ☐	
7			☐ ☐	
8			☐ ☐	

N/A EM 08-21-15

	Time	Weight (g)	Adjustment Required Yes No	Initials
1			☐ ☐	
2			☐ ☐	
3			☐ ☐	
4			☐ ☐	
5			☐ ☐	
6			☐ ☐	
7			☐ ☐	
8			☐ ☐	
1			☐ ☐	
2			☐ ☐	
3			☐ ☐	
4			☐ ☐	
5			☐ ☐	
6			☐ ☐	
7			☐ ☐	
8			☐ ☐	
1			☐ ☐	
2			☐ ☐	
3			☐ ☐	
4			☐ ☐	

	Reviewed by/date:
Manufacturing Supervisor Review	08.12.15 ~~07.21.15~~ 08.12.15

TH 07-15-15 DM 07-17-15

ALLERGY LABORATORIES, INC.	Form Title: **Filled Vial Inspection Record**		Doc Number: **MFG-036-01.04**
			Page 1 of 4
	Lot #: **2072115**	Solution type: **Cysteine**	Form Issue Date: FEB 26 2015
	Fill volume: **50mL**	Vial size: **50mL 20mm**	Form Effective Date: MAR 18 2015

Pre-Inspection Line Clearance	Performed by/date/time:	Verified by/date/time:
	ELM 07-21-15 6:12AM	AR 07.21.15 6:21am

Light intensity verification: This step must be performed BEFORE vial inspection operations begin.

Inspection Station Location	○ Line 1 ○ Other _____ ✓ Line 2	Calibrated Light Meter	ID#: 0294
			Calibration Due: 03-25-2016

Inspection Station Areas	Specification: ≥2000 LUX		Acceptance	Light intensity verification performed by:		
	Reading at white background	Reading at black background		Initials	Date	Time
Area 1	6200	3600	✓ Yes ○ No, notify Supervisor	ELM	07-21-15	ELM 07-21-15 6200 6:24am
Area 2	6200	4200	✓ Yes ○ No, notify Supervisor	ELM	07-21-15	6:24am
Area 3	8400	3600	✓ Yes ○ No, notify Supervisor	ELM	07-21-15	6:24am
Area 4	9200	4400	✓ Yes ○ No, notify Supervisor	ELM	07-21-15	6:25am

According to MFG-036 "Manual Inspection of Filled Vials", each inspector MUST take a 15 minute break for every 2 hours ± 30 min. of inspection.

Vials inspected by/date: ELM 07-21-15	Vials inspected by/date: A.L 07.21.15	Vials inspected by/date: B.A 07-21-15	Vials inspected by/date: AR 07.21.15	Vials inspected by/date:	Vials inspected by/date:
Times of inspection (time – time)	Times of inspection (time – time)	Times of inspection (time – time)	Times of inspection (time – time)	Times of inspection (time – time)	Times of inspection (time – time)
9:20am 9:51am	6:50am 9:20am	7:05 am 9:35 am	6:50am 9:20am		N/A ELM 07-21-15
10:52am 12:01pm	9:36a.m 9:51a.m	10:50 am 12:31 pm	9:37am 10:00 am		
N/A ELM 07-21-15	10:49a.m 12:00p.m	N/A ELM 07-21-15	10:53am 12:15PM		
	12:25pm 12:45p.m N/A ELM 07-21-15		N/A ELM 07-21-15		

	Form Title: **Filled Vial Inspection Record**	Doc Number: **MFG-036-01.04**
ALLERGY LABORATORIES, INC.	Lot #: **2072115**	Page 2 of 4

Inspection Results:

Category	Defect	Description (not limited to the following)	# Rejected	Total # rejected from each category	Recorded by/Date	Verified by/Date
Critical	Glass defect	Broken, cracked, internal contamination, spike, bird swing	5	(A) 16	ECM 07-21-15	AR 07.21.15
	Seal integrity	Leaking vial, missing stopper	2			
	Particles	Glass	4			
		Rubber	6			
		Metal	0			
		Fibers	3			
		Other	2			
	Fill volume	Overfill (excluding diluents ≥30mL) or underfill	0			
Major	Glass defect	Bent, chipped, crizzle, flared, leaner, rocker, bulge, bump check (>2.36mm)	15	(B) 41		
	Seal Integrity	Partial crimp, missing cap	26			
	No Fill	No product in vial	0			
Minor	Cosmetic	Dented caps, blemishes, scratches (>0.2mm wide, full body length, or exceeds 360 degrees, spotting, brush marks, seams, external contamination, bump check, bubbles, stones	60	(C) 60		
	Fill volume	Overfill (diluents ≥30mL)	0			

Note – Refer to PDA tubular/molded glass lexicon for defect description if necessary

Other Defect (Description)	# Rejected (Add to A, B, or C above)	Recorded by/Date	Verified by/Date	MFG Assigned Category (Critical, Major, Minor)	QA Review	
					Initial/Date	Accepted (Yes or No)
		NLM ECM 07-21-15				

	Form Title: **Filled Vial Inspection Record**	Doc Number: **MFG-036-01.04**
ALLERGY LABORATORIES, INC.	Lot #: **2072115**	Page 3 of 4

Calculations:

	Total # of vials inspected	Recorded by/date:
Total # of rejects A+B+C=D	(D) 117	ELM 07-22-15
# of labeled vials discarded [(E) from PAL-002-01]	(E) 5	
# of labeled and packaged vials [(D) from PAL-002-01]	(F) 13301	
# of non-labeled vials discarded during labeling [(F) from PAL-002-01]	(G) 0	
# of inspected unlabeled vials submitted for QC testing (when applicable)	(H) 315	
D+E+F+G+H=J, the total # of vials inspected	(J) 13738	

Defect Rate	Meets Specification?	Performed by/Date	Verified by/Date
Critical Defects: # rejected (A) 16 / # inspected (J) 13738 x 100 = 0.12 % (Alert > 1.2% Action > 1.7%)	☑ Yes (≤ 1.2%) Acceptable ☐ Alert (> 1.2 and ≤ 1.7%)* Acceptable ☐ Action (> 1.7%)** Not Acceptable	ELM 07-22-15	AR 07-22-15
Major Defects: # rejected (B) 41 / # inspected (J) 13738 x 100 = 0.30 % (Alert > 2.4% Action > 3.4%)	☑ Yes (≤ 2.4%) Acceptable ☐ Alert (> 2.4 and ≤ 3.4%)* Acceptable ☐ Action (> 3.4%)** Not Acceptable		
Minor Defects: # rejected (C) 60 / # inspected (J) 13738 x 100 = 0.44 % (Alert > 3.6% Action > 5.1%)	☑ Yes (≤ 3.6%) Acceptable ☐ Alert (> 3.6 and ≤ 5.1%)*** Acceptable ☐ Action (> 5.1%)*** Acceptable		

* Check and document trending in comment section. CAPA required if alert level is exceeded for 3 consecutive days or 3 consecutive lots of same product.
** 100% re-inspection and CAPA required.
*** Check and document trending in comment section. Minor defects do not impact product quality or process capability.

	Performed by/date/time:	Verified by/date/time:
Post-Inspection Line Clearance	ELM 07-21-15 3:00pm	A.L 07.21.15 3:00 p.m

	Form Title: **Filled Vial Inspection Record**	Doc Number: **MFG-036-01.04**
ALLERGY LABORATORIES, INC.	Lot #: **2072115**	Page 4 of 4

Comments	8.11.15
Manufacturing Supervisor Review	**Review by/date:** 8.11.15

7/6 07-15-15 QA 071715

	Form Title: **AQL Vial Inspection**		Doc Number: **QC-090-01.01**
ALLERGY LABORATORIES, INC.	Product: **Cysteine**	Lot #: **2072115**	Page 1 of 2
	Vial Size: **50mL 20mm**	Fill Volume: **50mL**	Form Issue Date: JAN 15 2015
			Form Effective Date: JUL 02 2015

Total # Vials in Lot:	13940	# Vials Submitted to QC:	315

Light Intensity Verification

Inspection Station ID#:	0412	Calibrated Light Meter ID#:	0294	Cal Due:	03-25-2016
Reading at White Background (Spec: ≥ 2000 LUX)	6400	Performed By:	NT	Date: 07-22-15	Time: 11:55am
Reading at Black Background (Spec: ≥ 2000 LUX)	4000	Performed By:	NT	Date: 07-22-15	Time: 11:55 am

Check one: ☑ **Normal Inspection** ☐ **Tightened Re-Inspection**

Normal Inspection

Lot/Batch Size	Sample Size	Acceptance/Rejection Number: 0.65% Critical	1.0% Major	4.0% Minor
9-15	2	0 / 1	0 / 1	0 / 1
16-25	3	0 / 1	0 / 1	0 / 1
26-50	8	0 / 1	0 / 1	1 / 2
51-90	13	0 / 1	0 / 1	1 / 2
91-150	20	0 / 1	0 / 1	2 / 3
151-280	32	0 / 1	0 / 1	3 / 4
281-500	50	0 / 1	1 / 2	5 / 6
501-1,200	80	1 / 2	2 / 3	7 / 8
1,201-3,200	125	2 / 3	3 / 4	10 / 11
3,201-10,000	200	3 / 4	5 / 6	14 / 15
10,001-35,000	315	5 / 6	7 / 8	21 / 22
35,001-150,000	500	7 / 8	10 / 11	21 / 22
# Rejected*		0	0	0

Tightened Re-Inspection (if necessary)

Lot/Batch Size	Sample Size	Acceptance/Rejection Number: 0.65% Critical	1.0% Major	4.0% Minor
9-15	2	0 / 1	0 / 1	0 / 1
16-25	3	0 / 1	0 / 1	0 / 1
26-50	8	0 / 1	0 / 1	1 / 2
51-90	13	0 / 1	0 / 1	1 / 2
91-150	20	0 / 1	0 / 1	1 / 2
151-280	32	0 / 1	1 / 2	2 / 3
281-500	50	1 / 2	1 / 2	3 / 4
501-1,200	80	1 / 2	1 / 2	5 / 6
1,201-3,200	125	1 / 2	2 / 3	8 / 9
3,201-10,000	200	2 / 3	3 / 4	12 / 13
10,001-35,000	315	3 / 4	5 / 6	18 / 19
35,001-150,000	500	5 / 6	8 / 9	18 / 19
# Rejected*		N/A	NT 07-22-15	

***Describe all defects in comments section. Refer to SOP QC-090 and/or PDA TR43 Lexicon which contains defect descriptions and pictures.**

Comments/ Describe deficiency(s)	N/A NT 07-22-15
Results	**Check one:** ☑ **PASS** **or** ☐ **FAIL** **If fail, notify the Manufacturing Supervisor.**
Inspection Performed By	Initials/Date NT 07-22-15
QA/QC Review By	Initials/Date MA 07-23-15

Form Title: **Filled Vial Labeling Record**		Doc Number: **PAL-002-01.03**
		Page 1 of 5
Lot # 2072115	Form Issue Date APR 15 2014	Form Effective Date APR 25 2014

Label Information		Label Information Check (verify with production schedule)	QA recorded by/date	Pre-Line Clearance
Lot #	2072115	☑ Lot #	07-15-15	Performed by/date/time: 07-21-15 7:33 AM
Fill volume	50 mL	☑ Fill volume	Manufacturing Supervisor verified by/date: ELM 07-21-15	Checked by/date/time: 07-21-15 7:33am
Expiration date	07/17	☑ Expiration date		
Type of diluent/drug solution	Cysteine	☑ Type of diluent/drug solution		
Company	Sandoz	☑ Company		

Labeling machine used for labeling the vials (✓ one): O ID# 0153 (Building 1) O ID# 0295 (Building 1) O ID# 0257 (Building 2)

Label Issuance (PAL-004)		QA recorded by/date (using PAL-004) / Verified by/date (using PAL-004)
Label part # to be issued	L-018-01	07-15-15 / ELM 07-21-15
# of labels forecasted	13,940	
Total # of labels issued	16,000	
Label lot #	L-018-01-062615	
Labels issued by/date	07-21-15	

Place label sample here (roll #1) (affix all additional roll label samples to pages 4 and 5 of this form)

Label Sample

SANDOZ
Rx only NDC 66758-005-01
L-Cysteine
Hydrochloride Injection, USP
PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION
50 mg/mL
For IV Use Only After Dilution
Do Not Dispense As A Unit
50 mL
L-018-01
PHARMACY BULK PACKAGE

Each mL contains: 50 mg L-Cysteine Hydrochloride Monohydrate, USP; Water for Injection, USP, q.s.; Air replaced with Nitrogen. pH 1.0-2.5
Directions for Use: See package insert.
Warning: For IV use only. Must be diluted before use. Contents should be dispensed promptly after initial closure puncture. Discard unused contents after 4 hours.
Store at controlled room temperature 15°-30°C (59°-86°F). Do not freeze.
Contains no more than 5,000 mcg/L of aluminum.
Manufactured for: Sandoz Inc. Princeton, NJ 08540
Rev. 06-2012
Date/Time Entered: _____
L-CYSTEINE HYDROCHLORIDE INJECTION

(01)00364078000019
L 2072115 E 07/17.

Label Information Approval

QA check the appropriate check boxes after verifying label contents

- ☑ **Correct label part #** (refer to Label Request and Issuance above)
- ☑ **Lot #**
- ☑ **Fill volume**
- ☑ **Exp. date**
- ☑ **Type of diluent/drug solution**
- ☑ **Company**
- ☑ **Overprint**
  - Diluent labels (3 lines)
  - Drug 2mL - 5mL labels (2 lines)
  - Drug 10mL - 50mL labels (1 line)

QA label approval by/date: HW 07-21-15

	Form Title: **Filled Vial Labeling Record**	Doc Number: **PAL-002-01.03**
	Lot #: **2072115**	Page 2 of 5

Vial label challenge performed by/date/time	Vial label challenge checked by/date/time
A 07-21-15 8:03 AM	L.M 07-21-15 8:03 AM

	Cap Color	Target #	Quantity Labeled
Label Accounting	Silver		N/A
	Blue		
	Green		
	Red		
	Gold		A 07-21-15
	Orange		
	Purple		
	Pink		
	Flip-Off	13,940	13,205 N/A + 60 + 36
	Other		A 07-21-15

		Inspected by/date/time	# of labels checked	Labels correspond with sample
Label Inspection	1st inspection	L.M 07-21-15 8:15AM	10	☑ yes ☐ no
	2nd inspection	ODLG 07-21-15 12:26 PM	10	☑ yes ☐ no
	3rd inspection	A.L 07.21.15 1:21 p.m	10	☑ yes ☐ no
	Additional inspection		N/A	☐ yes ☐ no
	Additional inspection	A 07-21-15		☐ yes ☐ no
	Additional inspection			☐ yes ☐ no

	Form Title: **Filled Vial Labeling Record**	Doc Number: **PAL-002-01.03**
ALLERGAN LABORATORIES, INC.	Lot #: **2072115**	Page 3 of 5

Label Reconciliation	# of sample labels on forms	(A)	5	Label reconciliation performed by/date: A 07-22-15
	# vial labels (only) discarded	(B)	80	
	# of labeled vials discarded	(C)	5	
	# of labeled and packaged vials	(D)	13,301	
	Total # of labels used A+B+C+D=E	(E)	13,391	
	# of non-labeled vials discarded during labeling	(F)	0	Calculations verified by/date: ELM 07-22-15
	# of labels to return to inventory	(G)	2,590	
	E – C = Total # accounted for	(H)	15,981	
	H / # labels issued x (100) = I	(I) Must be within 98-102%	99.8 %	Reconciliation ☑ Pass ☐ Fail (1) If fail, request a CAPA for investigation

Vial label challenge performed by/date/time	Vial label challenge checked by/date/time
A 07-21-15 1:34 PM	A.L 07.21.15 1:34 p.m

	Performed by/date/time	Checked by/date/time	Labels returned to inventory by/date/time
Pouch Inc Clearance	A 07-21-15 1:35pm	G.R 07-21-15 1:35pm	A 07-22-15 7:40AM

Vials labeled by/date	A 07-21-15
Comments	N/A A 07-21-15

(1) Documented on 08.19.15. 08.19.15

	Form Title: **Filled Vial Labeling Record**	Doc Number: **PAL-002-01.03**
ALLERGAN LABORATORIES, INC.	Lot #: **2072115**	Page 4 of 5

Additional label samples

Roll # 2 Approval by/date

SANDOZ
Rx only NDC 66758-005-01
L-Cysteine
Hydrochloride Injection, USP
PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION
50 mg/mL
For IV Use Only After Dilution
Do Not Dispense As A Unit
50 mL

Each mL contains: 50 mg L-Cysteine Hydrochloride Monohydrate, USP; Water for Injection, USP, q.s.; Air replaced with Nitrogen. pH 1.0-2.5
Directions for Use: See package insert.
Warning: For IV use only. Must be diluted before use. Contents should be dispensed promptly after initial closure puncture. Discard unused contents after 4 hours.
Store at controlled room temperature 15°-30°C (59°-86°F). Do not freeze.
Contains no more than 5,000 mcg/L of aluminum.
Manufactured for: Sandoz Inc.
Princeton, NJ 08540
Rev. 06-2012
Date/Time Entered: _____

(01)00364758005019
L 2072115 E 07/17

Roll # 6 Approval by/date
12 07 21 15

Roll # 3 Approval by/date

SANDOZ
Rx only NDC 66758-005-01
L-Cysteine
Hydrochloride Injection, USP
PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION
50 mg/mL
For IV Use Only After Dilution
Do Not Dispense As A Unit
50 mL
L-018-01

Each mL contains: 50 mg L-Cysteine Hydrochloride Monohydrate, USP; Water for Injection, USP, q.s.; Air replaced with Nitrogen. pH 1.0-2.5
Directions for Use: See package insert.
Warning: For IV use only. Must be diluted before use. Contents should be dispensed promptly after initial closure puncture. Discard unused contents after 4 hours.
Store at controlled room temperature 15°-30°C (59°-86°F). Do not freeze.
Contains no more than 5,000 mcg/L of aluminum.
Manufactured for: Sandoz Inc.
Princeton, NJ 08540
Rev. 06-2012
Date/Time Entered: _____

(01)00364758005019
L 2072115 E 07/17

VDL6 07-21-15

Roll # 7 Approval by/date
N/A
07-21-15

Roll # 4 Approval by/date

SANDOZ
Rx only NDC 66758-005-01
L-Cysteine
Hydrochloride Injection, USP
PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION
50 mg/mL
For IV Use Only After Dilution
Do Not Dispense As A Unit
50 mL
L-018-01
PHARMACY BULK PACKAGE

Each mL contains: 50 mg L-Cysteine Hydrochloride Monohydrate, USP; Water for Injection, USP, q.s.; Air replaced with Nitrogen. pH 1.0-2.5
Directions for Use: See package insert.
Warning: For IV use only. Must be diluted before use. Contents should be dispensed promptly after initial closure puncture. Discard unused contents after 4 hours.
Store at controlled room temperature 15°-30°C (59°-86°F). Do not freeze.
Contains no more than 5,000 mcg/L of aluminum.
Manufactured for: Sandoz Inc.
Princeton, NJ 08540
Rev. 06-2012
Date/Time Entered: _____
L-CYSTEINE HYDROCHLORIDE INJECTION

(01)00364758005019
L 2072115 E 07/17

L.M07-21-15

Roll # 8 Approval by/date
07-21-15

Roll # 5 Approval by/date

SANDOZ
Rx only NDC 66758-005-01
L-Cysteine
Hydrochloride Injection, USP
PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION
50 mg/mL
For IV Use Only After Dilution
Do Not Dispense As A Unit
50 mL
L-018-01
PHARMACY BULK PACKAGE

Each mL contains: 50 mg L-Cysteine Hydrochloride Monohydrate, USP; Water for Injection, USP, q.s.; Air replaced with Nitrogen. pH 1.0-2.5
Directions for Use: See package insert.
Warning: For IV use only. Must be diluted before use. Contents should be dispensed promptly after initial closure puncture. Discard unused contents after 4 hours.
Store at controlled room temperature 15°-30°C (59°-86°F). Do not freeze.
Contains no more than 5,000 mcg/L of aluminum.
Manufactured for: Sandoz Inc.
Princeton, NJ 08540
Rev. 06-2012
Date/Time Entered: _____
L-CYSTEINE HYDROCHLORIDE INJECTION

(01)00364758005019
L 2072115 E 07/17

A 07-21-15

Roll # 9 Approval by/date

Form Title: **Filled Vial Labeling Record**

Doc Number: **PAL-002-01.03**

Page 5 of 5

Lot #: **2072115**

Additional label samples

Roll # 10 Approval by/date	Roll # 11 Approval by/date	Roll # 12 Approval by/date	Roll # 13 Approval by/date
Roll # 14 Approval by/date	Roll # 15 Approval by/date	Roll # 16 Approval by/date	Roll # 17 Approval by/date

N/A

07-21-15

Manufacturing Supervisor
Review / Date

08.11.15

Not 07-15-15 07-17-15

	Form Title: **Printed Container (Carton) Packaging Record**		Doc Number: **PAL-002-07.03**
ALLERGY LABORATORIES, INC.			Page 1 of 2
	Lot # **2072115**	Product **Cysteine 50mL**	Form Issue Date APR 15 2014
	Vial size **50mL 20mm**	Printed container name/part # (see Vial Manufacturing Record page 1) **Cysteine / L-023-01**	Form Effective Date APR 25 2014

Printed Container Request and Check-Out	# of printed containers requested	2788	Requested by/date	07-17-15	Attach a sample of the printed container to the back of this form
	Total # of printed containers issued	3055	Issued by/date	07-17-15	
	Printed container part #	L-023-01	Printed container lot #	L-023-01-121913 (1105) L-023-01-070215 (1950)	

Print Contents	Lot or L **2072115** Exp or E **07** / **17** (format: mm/yy)	**Sample container printed by**	By/date	07-17-15
		QA approval (inspect printed sample container)	By/date	at 07-17-15
Carton Coder Used	**AL ID #** 0391		By/date	07-17-15

Pre-Packaging Line Clearance	**Performed by/date/time** ELM 07-21-15 7:22am	**Checked by/date/time** AR 07-21-15 7:22am

Printed Container Reconciliation	# used	# of sample printed containers attached to form	# of printed containers discarded	# of printed containers to return to inventory	Printed containers returned to inventory by/date
	(A) 2655	(B) 1	(C) 119	(D) 279	07-21-15
	# used & returned (A+B+C+D) = Total # accounted for		(E) 3054		
	E / # cartons issued (100) = F	(F) Must be within 98-102% 99.97	Reconciliation ☑ Pass ☐ Fail If fail, request a CAPA for investigation		
	Reconciliation performed by/date	ELM 07-22-15	Calculations checked by/date	08.11.15	

	Form Title: **Printed Container (Carton) Packaging Record**	Doc Number: **PAL-002-07.03**
	Lot # **2072115**	Page 2 of 2

		Inspected by/date/time	# of packages checked	Packaging corresponds with approved sample?	Packaging contains correct pkg. insert?
Packaging inspection	1st inspection	ECM 07-21-15 3:00pm	10	☑ Yes ☐ No	☑ Yes ☐ No
	2nd inspection	L.M 07-21-15 5:00pm	10	☑ Yes ☐ No	☐ Yes ☐ No
	3rd inspection	AR 07.22.15 7:06am	10	~~☐ Yes~~ ☐ No	~~☐ Yes~~ ☐ No
	Additional inspection		N/A ECM 07-22-15	☐ Yes ☐ No	☐ Yes ☐ No
	Additional inspection			☐ Yes ☐ No	☐ Yes ☐ No
	Additional inspection			☐ Yes ☐ No	☐ Yes ☐ No

Post Packaging Line Clearance	Performed by/date/time	Checked by/date/time
	ECM 07-21-15 5:12pm	L.M 07-21-15 5:12 PM

Comments	N/A ECM 07-22-15

Manufacturing Supervisor review by/date	08.11.15

L-Cysteine Hydrochloride Injection, USP 0.5 g/10 mL (50 mg/mL)

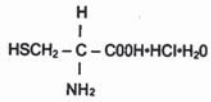
PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION

DESCRIPTION

L-Cysteine Hydrochloride Injection, USP, 50 mg/mL, is a sterile, nonpyrogenic solution. Each mL contains: 50 mg of L-Cysteine Hydrochloride Monohydrate USP; Water for Injection, USP q.s.; Air replaced with Nitrogen. pH 1.0-2.5

L-Cysteine is a sulfur-containing amino acid. In premixed solutions of crystalline amino acids, cysteine is relatively unstable over time, eventually converting to insoluble cystine. To avoid such precipitation, L-Cysteine Hydrochloride Injection USP is intended to be used as an additive with Crystalline Amino Acid Injections immediately prior to administration to the patient.

The structural formula of Cysteine Hydrochloride Monohydrate USP is:



Molecular Weight
175.63

Molecular Formula
$C_3H_7NO_2S \cdot HCl \cdot H_2O$

CLINICAL PHARMACOLOGY

L-Cysteine is synthesized from methionine via the trans-sulfuration pathway in the adult, but newborn infants lack the enzyme necessary to effect this conversion. Therefore, L-Cysteine is generally considered to be an essential amino acid in infants.

INDICATIONS AND USAGE

L-Cysteine Hydrochloride Injection, USP is intended for use only after dilution as an additive to Crystalline Amino Acid Injections to meet the intravenous amino acid nutritional requirements of infants receiving total parenteral nutrition.

CONTRAINDICATIONS

This preparation should not be used in patients with hepatic coma or metabolic disorders involving impaired nitrogen utilization.

WARNINGS

Peripheral intravenous infusion of amino acids may induce a rise in blood urea nitrogen (BUN) especially in patients with impaired hepatic or renal function. Appropriate laboratory tests should be performed periodically and infusion discontinued if BUN levels exceed normal postprandial limits and continue to rise. It should be noted that a modest rise in BUN normally occurs as a result of increased protein intake.

Administration of amino acid solutions to a patient with hepatic insufficiency may result in serum amino acid imbalances, metabolic alkalosis, prerenal azotemia, hyperammonemia, stupor and coma.

Administration of amino acid solutions in the presence of impaired renal function may augment an increasing BUN, as does any protein dietary component.

Solutions containing sodium ion should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Solutions which contain potassium ion should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

Solutions containing acetate ion should be used with great care in patients with metabolic or respiratory alkalosis. Acetate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion such as severe hepatic insufficiency.

Hyperammonemia is of special significance in infants, as it can result in mental retardation. Therefore it is essential that blood ammonia levels be measured frequently in infants.

Instances of asymptomatic hyperammonemia have been reported in patients without overt liver dysfunction. The mechanisms of this reaction are not clearly defined but may involve genetic defects and immature or subclinically impaired liver function.

Frequent Clinical Evaluation and Laboratory Determinations are Necessary for Proper Monitoring During Administration. Blood studies should include glucose, urea nitrogen, serum electrolytes, ammonia, cholesterol, acid-base balance, serum proteins, kidney and liver function tests, osmolarity and hemogram. White blood count and blood cultures are to be determined if indicated. Urinary osmolarity and glucose should be determined frequently.

Safe use during pregnancy has not been established, therefore, infusion of amino acids should be undertaken during pregnancy only when this is deemed essential to the patients' welfare, as judged by the physician.

WARNING: *This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.*

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS

Special care must be taken when administering hypertonic glucose to provide calories in diabetic or prediabetic patients.

Because of its antianabolic activity, concurrent administration of tetracycline may reduce the nitrogen sparing effects of infused amino acids.

Do not withdraw venous blood for blood chemistries through the peripheral infusion site, as interference with estimations of nitrogen containing substances may occur.

Intravenous feeding regimens which include amino acids should be used with caution in patients with a history of renal disease, pulmonary disease, or with cardiac insufficiency so as to avoid excessive fluid accumulation.

The effect of infusion of amino acids, without dextrose, upon carbohydrate metabolism of children is not known at this time.

Nitrogen intake should be carefully monitored in patients with impaired renal function. For long-term total nutrition, or if a patient has inadequate fat stores, it is essential to provide adequate exogenous calories concurrently with the amino acids. Concentrated dextrose solutions are an effective source of such calories. Such strongly hypertonic nutrient solutions should be administered through an indwelling intravenous catheter with the tip located in the superior vena cava.

ADVERSE REACTIONS

Local reactions consisting of a warm sensation, erythema, phlebitis and thrombosis at the infusion site have occurred with peripheral intravenous infusion of amino acids, particularly if the other substances, such as antibiotics, are also administered through the same site. In such cases the infusion site should be changed promptly to another vein. Use of large peripheral veins, inline filters, and slowing the rate of infusion may reduce the incidence of local venous irritation. Electrolyte additives should be spread throughout the day. Irritating additive medications may need to be injected at another venous site.

Generalized flushing, fever and nausea also have been reported during peripheral infusions of amino acid solutions.

Drug Abuse and Dependence: None known.

DOSAGE AND ADMINISTRATION

L-Cysteine Hydrochloride Injection USP is intended for use only after dilution in Crystalline Amino Acid Injection. Each 0.5 gram of L-Cysteine Hydrochloride Monohydrate should be combined aseptically with 12.5 grams of Crystalline Amino Acid Injection, such as that present in 250 mL of 5% Crystalline Amino Acid Injection. The admixture is then diluted with 250 mL of dextrose 50% or such lesser volume as indicated. Equal volumes of 5% Crystalline Amino Acid Injection and dextrose 50% produce a final solution which contains Crystalline Amino Acid Injection 2.5% in dextrose 25%, which is suitable for administration by central venous infusion. Administration of the final admixture should begin within one hour of mixing. Otherwise, the admixture should be refrigerated immediately and used within 24 hours of the time of mixing. For the recommended rate of administration, see the Crystalline Amino Acid Injection package insert.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

DIRECTIONS FOR PROPER USE OF PHARMACY BULK PACKAGE:

The pharmacy bulk package is for use in a Pharmacy Admixture Service only.

Use of this product is restricted to a suitable work area, such as a laminar flow hood. Prior to entering the vial, remove the flip-off seal and cleanse the rubber closure with a suitable antiseptic agent.

The container closure may be penetrated only one time, utilizing a suitable sterile transfer device or dispensing set which allows measured distribution of the contents. The date and time the vial was initially opened should be recorded in the space provided on the label. Transfer individual doses(s) to appropriate intravenous infusion solutions. Use of a syringe with needle is not recommended. Multiple entries increase the potential of microbial and particulate contamination.

The withdrawal of container contents should be accomplished without delay using aseptic technique. However, should this not be possible, a maximum time of 4 hours from initial closure entry is permitted to complete fluid transfer operations.

RECOMMENDED STORAGE CONDITIONS AFTER OPENING:

Keep under laminar flow hood at room temperature. Any unused portion of the vial must be discarded within 4 hours after initial entry.

HOW SUPPLIED

L-Cysteine Hydrochloride Injection, USP (50 mg/mL) is supplied as follows:

PHARMACY BULK PACKAGE

NDC Number	Volume
66758-005-01	50 mL
66758-005-02	5 x 50 mL

Also available as:

SINGLE DOSE VIAL

NDC Number	Volume
66758-004-01	10 mL
66758-004-02	10 x 10 mL

Store at controlled room temperature 15°-30°C (59°-86°F) Do not freeze.

For Sandoz Inc. Customer Service, call 1-800-525-8747

Rx only
Manufactured for:

SANDOZ
Princeton, NJ 08540

Revised: November 2009
L-028-00

Each mL contains: 50 mg L-Cysteine Hydrochloride Monohydrate, USP;
Water for Injection, USP, q.s.; Air replaced with Nitrogen. pH 1.0-2.5.
Storage: Store at controlled room temperature 15°-30°C (59°-86°F). Do not freeze.
Contents should be dispensed promptly after initial closure puncture.
Discard unused contents after 4 hours.
Warning: For IV use only. Must be diluted before use.
Directions for use: See package insert.
Contains no more than 5,000 mcg/L of aluminum.
Manufactured for: Sandoz Inc.
Princeton, NJ 08540
Rev. 06-2012

L 2072115
E 07/17

3 66758 00502 6

Rx only

For IV Use Only After Dilution
Not For Direct Infusion
Pharmacy Bulk Package

5 x 50 mL Vials NDC 66758-005-02

SANDOZ

07-15-15 07-17-15

ALLERGY LABORATORIES, INC.	Form Title: **Package Insert Record**		Doc Number: **PAL-002-08.03**
			Page 1 of 1
	Lot # **2072115**	Product **Cysteine 50mL**	Form Issue Date APR 15 2014
	Vial Size **50mL 20mm**	PI name / part # (see Vial Manufacturing Record page 1) **Cysteine 50mL/L-028-00**	Form Effective Date APR 25 2014

Package Insert Request and Check-out

# of package inserts forecasted	package inserts forecasted by/date	package insert sample
2788	ELM 07-21-15	Attach a sample of the package insert here
Total # of package inserts issued	**package inserts issued by/date**	
2796	ELM 07-21-15	
package insert lot #	**package insert part #**	
L-028-00-061915	L-028-00	

Package insert attached by/date	QA package insert approval by/date
ELM 07-21-15	MG 07.21.15

Package Insert Reconciliation

# placed in cartons	# of sample package inserts attached to form	# of package inserts discarded	# of package inserts to return to inventory	package inserts returned to inventory by/date
(A) 2653	(B) 1	(C) 2	(D) 122	ELM 07-22-15

used & returned (A+B+C+D) = Total # accounted for: (E) 2778

# inserts issued	(F) Must be within 98-102%	
E ÷ # inserts issued x (100) = F	99.36	Reconciliation ☑ Pass ☐ Fail If fail, request a CAPA for investigation
Reconciliation performed by/date	ELM 07-22-15	Calculations checked by/date: 08.11.15

Manufacturing Supervisor review by/date: 08.11.15

	Form Title: **Sandoz Shipping Label Record – 50mL Cysteine**	Doc Number: **PAL-002-12.01**
ALLERGY LABORATORIES, INC.	Lot #	Page 1 of 2
	2072115	Form Issue Date APR 15 2014
		Form Effective Date APR 25 2014

Label Requirements	**Label Type**	**White 4" x 1 ½" label**	**QA completed by/date**
	Lot #	**2072115**	07-15-15
	Exp. Date (mm/yy)	**07 / 17**	**Manufacturing Supervisor verified by/date**
	AL Part #	**L-032-00**	ELM 07-21-15 ELM 07-21-15

Label Sample

Label template

NDC 66758-005-02 LOT : XXXXXXX EXP : XX/XX

L-CYSTEINE HCl Injection, USP (50 mg/mL)

5 boxes of 5 x 50 mL Vials, Total Quantity 25 Vials

Store at Controlled Room Temperature: 15° - 30°C (59° - 86°F).

Manufactured for:
Sandoz Inc.
Princeton, NJ 08540

L-032-00

3 66758 00502 6

Affix sample label here for QA approval

NDC 66758-005-02 LOT: 2072115 EXP: 07/17

L-CYSTEINE HCl Injection, USP (50 mg/mL)

5 boxes of 5 x 50 mL Vials, Total Quantity 25 Vials

Store at Controlled Room Temperature: 15° - 30°C (59° - 86°F).

Manufactured for:
Sandoz Inc.
Princeton, NJ 08540

L-032-00

3 66758 00502 6

QA check the appropriate check boxes when verifying label content	**QA label approval by/date**
☑ White 4" x 1 ½" label	
☑ Lot #	
☑ Expiration date	
☑ Part #	KDG 07.21.15

Labels printed by/date: ELM 07-21-15

	Form Title: **Sandoz Shipping Label Record – 50mL Cysteine**	Doc Number: **PAL-002-12.01**
	Lot # **2072115**	Page 2 of 2

Label Reconciliation	# of labels printed	# of labels used (including label sample)	# of labels discarded	Reconciliation by/date
	560	532	28	EM 08-10-15

		Inspected by/date/time	# of shipping packages checked	Labels correspond with approved sample?
Packaging Inspection	1st inspection	EM 08-10-15 3:31pm	10	☑ Yes ☐ No
	2nd inspection	08.10.15 4:00 pm.	10	☐ Yes ☐ No
	3rd inspection	08.10.15 4:15 pm.	10	☐ Yes ☐ No
	Additional inspection		08.10.15	☐ Yes ☐ No
	Additional inspection			☐ Yes ☐ No
	Additional inspection			☐ Yes ☐ No

Comments	08.10.15

Manufacturing Supervisor review by/date	08.10.15

7/16 07-15-15 BA 07-17-15

ALLERGY LABORATORIES, INC.	Form Title: **Calculation of Percent Yields for Bulk Solution and Final Containers of Sterile Drug Products**	Doc Number: **MFG-057-24.02**
	Lot #: **2072115** / Product: **Cysteine 50mL**	Page 1 of 2
		Form Issue Date: MAR 27 2014
		Form Effective Date: APR 02 2014

Calculation 1	Actual amount of bulk solution used	# of weight check vials from FAE-017-01 or FAE-033-01 (include the initial weight check vials)	(A)	124
		Total # filled vials discarded from filling operations (from vial manufacturing record)	(B)	20
		Total # filled vials discarded from capping operations (from vial manufacturing record)	(C)	3
		Total # inspected (C12 from MFG-036-01)	(D) ①	~~13301~~ 13738
		# vials filled (A) + (B) + (C) + (D) = (E)	(E) ①	~~13448~~ 13885
		Target fill weight from FAE-017-01 or FAE-033-01	(F)	52.27 g
		Actual amount of bulk solution used (E) x (F) = (G)	(G) ①	~~702926.96~~ 725768.95g
Calculation 2	Theoretical amount of bulk solution used	Initial batch size (from pg 1 of BMR)	(H)	7620kg g
		Amount unused (from pg 1 of VMR) Amount unused = amount left in the mixing tank plus leftover solution from the fill pathway	(I)	31.656 g
		Theoretical amount of bulk solution used (H) - (I) = (J)	(J)	730.344 g
Calculation 3	Percent yield of bulk solution	Answer to calculation 1 (G)	(K) ①	~~702926.96~~ 725768.95
		Answer to calculation 2 (J)	(L)	~~730.344~~
		Percent yield of bulk solution (K) ÷ (L) x 100 = (M)	(M) ①	~~96.25~~ 99.37 %

① Entry error at D leading to calculation errors. Corrections made 08-12-15 ECM

ALLERGY LABORATORIES, INC.	Form Title: **Calculation of Percent Yields for Bulk Solution and Final Containers of Sterile Drug Products**	Doc Number: **MFG-057-24.02**
	Lot #: **2072115**	Page 2 of 2

		# of vials labeled and packaged (including labeled testing vials) ("D" from PAL-002-01)		(N) 13301		
		# of unlabeled vials submitted for testing (do not include AQL vials) (from vial manufacturing record)		(O) 0		
		Total # vials produced (N) + (O) = (P)		(P) 13301		
Calculation 4:	Percent yield for the number of vials prepared and # of vials labeled and packaged (including test samples)	# of vials processed (# of vials received from pg 1 of VMR)		(Q) 13940		
		Change in the number of vials prepared	# of vials unprocessed (# of vials returned from pg 1 of VMR)	0 (Ra)	Subtract from (Q) for (S) calculation	
			# of vials added to the lot	0 (Rb)	Add to (Q) for (S) calculation	
		# of vials used in manufacture of lot (Q) – (Ra) = (S) *or* (Q) + (Rb) = (S)		(S) 13940		
		Percent yield for the number of vials prepared and # of vials labeled and packaged (including test samples) (P) ÷ (S) = (T)		(T) 95.42 %		
Are the percent yields for calculations 3 or 4 below 90% or above 100%?				☑ No ☐ Yes If yes, explain in comments.		

Number of vials placed into quarantine. [(N) – (# of testing vials labeled and unlabeled) = # of vials placed into quarantine]	13265

Comments	N/A ECM 07-22-15

Calculations Performed By	By/Date: ECM 07-22-15	Manufacturing Supervisor Review	Review by/Date: 08.11.15

	Form Title: **Gelman Acro 50, 0.2µ Filter Integrity Testing**		Doc Number: **QC-076-01.00**
	QC Test#: QC- C-3004	QA/QC assigned by/date: MA 07-23-15	
	Product	L-Lysteine	Page 1 of 1
	Lot #	2072115	Form Issue Date (stamp): NOV 15 2013
			Form Effective Date (stamp): NOV 15 2013

Equipment and Materials	**Pressure Gauge**	**ID#:** 0337	**Calibration Due:** 04-09-16
	Methanol Lot #	7056	**Expiration Date:** 02-16

Vent Filter Lot #	Type of filter to test (check one)	Type of integrity test (check one)	PSI Bubble Point Limit: NLT 13psi w/methanol	Integrity test passed? (If bubble point fails notify QA)
(E) MA 07-23-15 ~~207~~ 21862850	~~O~~ Filling Vessel O L-1 In-Line (monthly) O L-1 Purging (monthly) O L-2 Purging (monthly)	O Pre-bubble point ~~O~~ Post bubble point	19	~~O~~ Yes O No
21862850 ☐ N/A	~~O~~ Filling Vessel O L-1 In-Line (monthly) O L-1 Purging (monthly) O L-2 Purging (monthly)	O Pre-bubble point ~~O~~ Post bubble point	18	~~O~~ Yes O No

QC Analyst	**Testing performed by/date:** MA 07-23-15
Quality Assurance/ Quality Control Review	**Review by/date:** JW 07-24-15

	Form Title: **Method: Fill Volume**		Doc Number: **QC-066-01.01**
ALLERGY LABORATORIES, INC.			Page 1 of 1
	QC Test #: QC- ~~C-8~~ C-3001 (E) MA 07-23-15	QA assigned by/date: MA 07-23-15	Form Effective Date: MAR 14 2013 DMC 03-14-13
	Lot number: 2072115		
	Product: L-Cysteine		

Fill Volume Results					
Fill volume	50mL				
Serial # of Graduated Cylinder	NA MA 07-24-15				
Balance Equipment ID#	0393				
Number of Vials Tested	1	☐ Pooled ☑ Tested Individually*			
Individual Results (mL)	Vial 1: 50.88mL	Vial 2: NA	Vial 3:	Vial 4:	Vial 5: MA 07-24-15
Total of vial 1 – 5 (mL)	50.88mL				
Average of vial 1 – 5 (mL)	50.88mL				
Specification	≥ 50mL				
Final Result (check one)	☑ Pass ☐ Fail				

Calculation if determining by weight:

$$\text{Volume of Injection, mL} = \frac{\text{Injection weight, g}}{\text{Injection density, (g/mL)}}$$

Specification:

Avg of Vials ≥ Labeled Vol.

*
- If the volume of each container is 10mL or more, select one (1) or more containers.
- Unless otherwise specified, one (1) vial is used.
- If the volume of each container is more than 3mL and less than 10mL, select three (3) containers.
- If the volume of each container is 3mL or less, select five (5) containers.

Comments	Vol = mass / density weight = 51.648g MA 07-24-15 L-Cysteine density = 1.015g/mL Vol = 51.648 g / 1.015g/mL = 50.88mL
Performed By/Date	MA 07-24-15
QA/QC Reviewed By/Date	MW 07-24-15

	Form Title: **Particulate Matter Test**		Doc Number: **QC-073-01.02**
ALLERGY LABORATORIES, INC.			Page 1 of 1
	QC Test #: QC-C-3003	QA assigned by/date: MA 07-23-15	Form Issue Date: DEC 11 2014
	Product	L-Cysteine	
	Lot #	2072115	Form Effective Date: DEC 12 2014
	Fill volume	50mL	

Lighthouse particulate counter ID# 0276 Cal. due	07-27-15

Test Results					
Number of vials tested	5	**Particle Count**	**Count * Fill Vol.**	☑ Pooled ☐ Tested Individually*	
Results (Four samples taken – the first discarded) Data attached.	**≥10µm** Specification: ≤6,000	1) 3.8	190	**Average:** 190	☑ Pass ☐ Fail
		2) 4.2	210		
		3) 3.4	170		
		4) ☑ N/A			
	≥25µm Specification: ≤600	1) 0.2	10	**Average:** 10	☑ Pass ☐ Fail
		2) 0.4	20		
		3) 0.0	0		
		4) ☑ N/A			

*For vials with a volume <25mL, the contents of at least 10 units are combined in a 100mL sterile empty vial to obtain a volume of not less than 25 mL.
Vials with a volume of 25-100mL may be tested individually. A total of four vials must be tested individually in this case.

Calculation:
(Fill Volume * Particle Count) = Particle Count per Vial Volume

Comments	NA MA 07-27-15
QC Analyst	**Testing performed by/date:** MA 07-27-15
QA/QC Review	**Reviewed by/date:** JLW 07-28-15

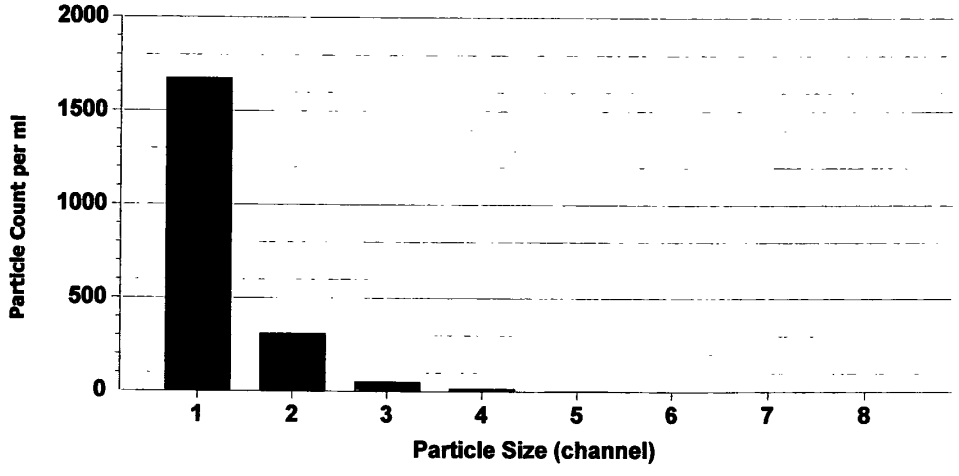
Particle Counter: LIGHTHOUSE LS-20
Serial Number: 100548001
Channel Sizes: 1.0/2.0/5.0/7.0/10.0/15.0/25.0/50.0
User Name: Anton
Lot ID: 2072115
Batch ID: L-Cysteine
Samples: 4
Recipe Name: Sample.rcp
User Entry: QC-C-3003
Discard First Sample

Sample Size: 5 ml
Location: 01
Syringe: 25 ml
Tare: 0.2 ml
Flow Rate: 20 ml/min
Dilution: 1
View Volume: 100%
LS-20 Software: V 1.5.2
Last Calibrated: 14-Jul-2015

SAMPLE DATA TABLE(CUML PER ML)

DATE	TIME	1.0	2.0	5.0	7.0	10.0	15.0	25.0	50.0
2015/07/27	13:57:54	1693.0	322.4	55.2	17.2	3.8	1.0	0.2	0.0
2015/07/27	13:58:10	1662.6	308.0	52.8	19.6	4.2	1.0	0.4	0.0
2015/07/27	13:58:31	1671.2	304.0	51.8	18.8	3.4	0.6	0.0	0.0
Total:		5026.8	934.4	159.8	55.6	11.4	2.6	0.6	0.0
Average:		1675.6	311.5	53.3	18.5	3.8	0.9	0.2	0.0

CUMULATIVE AVERAGES HISTOGRAM



Reviewed by: MA Date: 07-27-15

Reviewed by: [illegible] Date: 07-28-15

	Form Title: **Extract, Diluent, Sterile Drug Product Bioburden Sample Form**		Doc Number: **QC-002-02.01**
ALLERGY LABORATORIES, INC.	Corresponding SOP(s): QC-002		Page 1 of 1
	QC test #: QC-M-5644	Issued by/date: CH 07-23-15	Form Effective Date: TM 06-25-13 ~~JUN 26 13~~ TM 06-25-13 ~~JUN 26 13~~ JUN 26 2013
	Product: L-Cysteine 50 mL		
	Lot #: 2072115		

Media plate lot: 7197 (15148)	Media plate expiration: 08-26-15	Inc. ID #: 0395	Calibration due: 11-15
Date placed in incubator: 07-24-15	Time placed in incubator: 11:12 am	Plates read by/date:	
Date removed from incubator: 07-27-15	Time removed from incubator 10:25 am	TT 07-27-15	

Table 1

Product category	# of CFU/mL	Alert level	Action limit
Allergenic Extracts	N/A TT 07-27-15	222 CFU/mL	333 CFU/mL
Diluting Solutions		1 CFU/mL	3 CFU/mL
50 % Glycerin Extraction Soln.		1 CFU/mL	3 CFU/mL
Sterile Drug Product	0	3 CFU/mL	5 CFU/mL
Media Fill	N/A TT 07-27-15	144 CFU/mL	216 CFU/mL

Table 2 (dilution series for TNTC plates from Table 1)

Dilution level of original sample	Vol. of sample or prior dilution	Vol. of PBS or SCD (mL)	Vol. plated (mL)	Date/time placed in incubator / Date/time removed from incubator	CFU/mL
$1:10^1$				07-27-15	
$1:10^2$					
$1:10^3$					
$1:10^4$					
$1:10^5$			TT		
$1:10^6$					
Dilution performed by/date: N/A				Plates read by/date:	

Table 3

Dilution formula:

Plate count X Dilution factor = # CFU/mL in stock solution

_____ X _____ = _____ Record in Table 1

Dilution Factor:
$1:10^1$ = 10
$1:10^2$ = 100
$1:10^3$ = 1000
$1:10^4$ = 10000
$1:10^5$ = 100000
$1:10^6$ = 1000000

Alert level reached: ☐Yes ☒ No If Yes, notify QA.
Action limit reached: ☐Yes ☒ No If Yes, notify QA to issue a PACAR.

Analyst	By/date: TT 07-27-15
Quality Assurance/Quality Control Review	Review by/date: JW 07-27-15

ALLERGY LABORATORIES, INC.	Form Title: **Sterility Test Form**		Doc Number: **QC-118-01.00**
	QC Test # QC-M-5642	Issued By/Date: CH 07-23-15	Page 1 of 1
	Product Name/Potency: L-Cysteine	Lot #: 2072115	Form Issue Date: JUN 27 2014
	Fill Volume: □ NA 50mL	Vial Size: 50/20	Form Effective Date: JUL 01 2014

Membrane Filtration Testing

Number of vials tested:	20			Total pre-wet volume:	100mL		
Amount of rinse fluid added to SEV:	☒NA □ Up to vial neck □ Half the vial			Number of rinses:	2	Total rinse volume:	200mL
Filter Vendor:	Sartorius	Catalog #:	16466 GBD	Lot #:	7010	Exp. Date:	03-17
Rinse Fluid:	A	Lot #:	C) 07-28-15 T 7141	Exp. Date:	09-27-15	Release Date:	04-20-15
TSB Lot #:	7176		Exp. Date:	05-06-18	Release Date:	06-17-15	
TH Lot #:	7148		Exp. Date:	10-11-15	Release Date:	05-22-15	
RODAC Lot #:	7172		Exp. Date:	08-27-15	Release Date:	05-25-15	
20-25°C Incubator #:	0021	Calibration Date:	11-15	30-35°C Incubator #:	0025	Calibration Date:	11-15
Tested By / Date:	TT 07-28-15						

Sample Description	TH Incubated at 30-35°C			TSB Incubated at 20-25°C		
	Results			Results		
	Day 3, 4, or 5	Day 7 or 8	NLT 14 days	Day 3, 4, or 5	Day 7 or 8	NLT 14 days
Product	—	—	—	—	—	—
Negative Rinse Fluid	—	—	—	—	—	—
Read By / Date:	CH 07-31-15	CH 08-04-15	TT 08-11-15	CH 07-31-15	CH 08-04-15	TT 08-11-15

Environmental Monitoring Incubated at 20-25°C for 72-120 hours and then 30-35°C for 48-96 hours					
Isolator Surface Left	0	Isolator Surface Right	0	Isolator Surface Center	0
Glove Fingers Left	0	Glove Fingers Right	0	Read By / Date:	CH 08-04-15

Comments:	N/A TT 08-11-15

Test Results: (PASS) FAIL

QA/QC Review:	Reviewed by/date: JW 08-11-15

ALLERGY LABORATORIES, INC.	Form Title: **Endotoxin Test Record for Product Release**	Doc Number: **QC-011-02.02**
		Page 1 of 1
	QC issued by/date: CH 07-23-15	Form Issue Date: JAN 22 2014
		Form Effective Date: JAN 23 2014

Results of Controls and Samples (+) =pyrogenic (gel formed) (–) =non-pyrogenic (no gel formed)

QC Test# (if applicable)	Sample	Lot #	Lysate Sensitivity (λ)	Dilution	Sample tube #1 Un-spiked	Sample Tube #2 Un-spiked	Sample Tube #3 Spiked to 2λ	Sample tube #4 Spiked to 2λ
N/A	Control Water (positive and negative controls)	7100	0.063	1:1	–	–	+	+
M-5643	L-Cysteine	2072115	0.031	1:1	–	–	+	+

Equipment/Reagents Used

Pipettor	Equipment ID#: 0065	Calibration due: 02-16-16	
Oven/Water Bath	Equipment ID#: 0363	Calibration due: N/A CH 07-24-15	
Thermometer	Equipment ID#: 0443	Calibration due: 03-10-16	
Timer	Equipment ID#: 0368	Calibration due: 02-26-16	
Pipette Tips	Lot #: N/A CH 07-24-15	Expiration date: N/A	
Pyrogen-free Tubes	Lot #: AL0071-14	Expiration date: N/A	
Pyrogen-free Water	Lot #: 7100	Expiration date: 11-17	
LAL Reagent	Lot #: 6657	Expiration date: 11-16	Release Date: 02-19-14
Control Standard Endotoxin (CSE)	Lot #: 6870	Expiration date: 12-17	Release Date: 08-08-14

Test Time and Water Bath Temperature

Incubation start time:		Initial Incubation Temp:	Incubation end time:		Final Incubation Temp:
1:52	☐ A.M. ☒ P.M.	36.3 °C	2:53	☐ A.M. ☒ P.M.	37.7 °C

Test Performed	Test performed by/date: CH 07-24-15
Quality Assurance/ Quality Control Review	Review by/date: JW 07-24-15

KABS

CERTIFICATE OF ANALYSIS

For: **ALLERGY LABORATORIES INC.**

Certificate No: 125353

Purchase Order No:	20150727	Sample Code:	N. App.
Issuing Date:	2015/Aug/10	Sample Lot No.:	**2072115**

Product: **50 mL L-Cysteine HCl Injection, USP (50 mg/mL)**

Test	Methods	Specifications	Results
Appearance of Product	Visual	Clear colorless solution free from visible particulate matter	Clear colorless solution free from visible particulate matter
Appearance of Container/Closure	Visual	No apparent leakage or physical alteration	No apparent leakage or physical alteration
Identification A	USP 38	A bluish-gray precipitate is formed	A bluish-gray precipitate is formed
Identification B	USP 38	A red-purple color is produced, and it rapidly changes to yellow	A red-purple color is produced, and it rapidly changes to yellow
pH	USP 38 <791>	1.0 – 2.5	1.3
Heavy Metals	USP 38 <231> *Method II*	NMT 2 ppm	< 2 ppm
Assay	KABS-1348-LC-V03	Alert limit: 95.0 – 105.0 % (47.5 – 52.5 mg/mL) Action limit: 85.0 – 115.0 % (42.5 – 57.5 mg/mL)	98.7 % LC[1] (49.3 mg/mL)
Aluminum Content[2]	USP 38 <206>	NMT 5000 ppb	17 ppb

KM 08-11-15
Reviewed By
KM 08-11-15

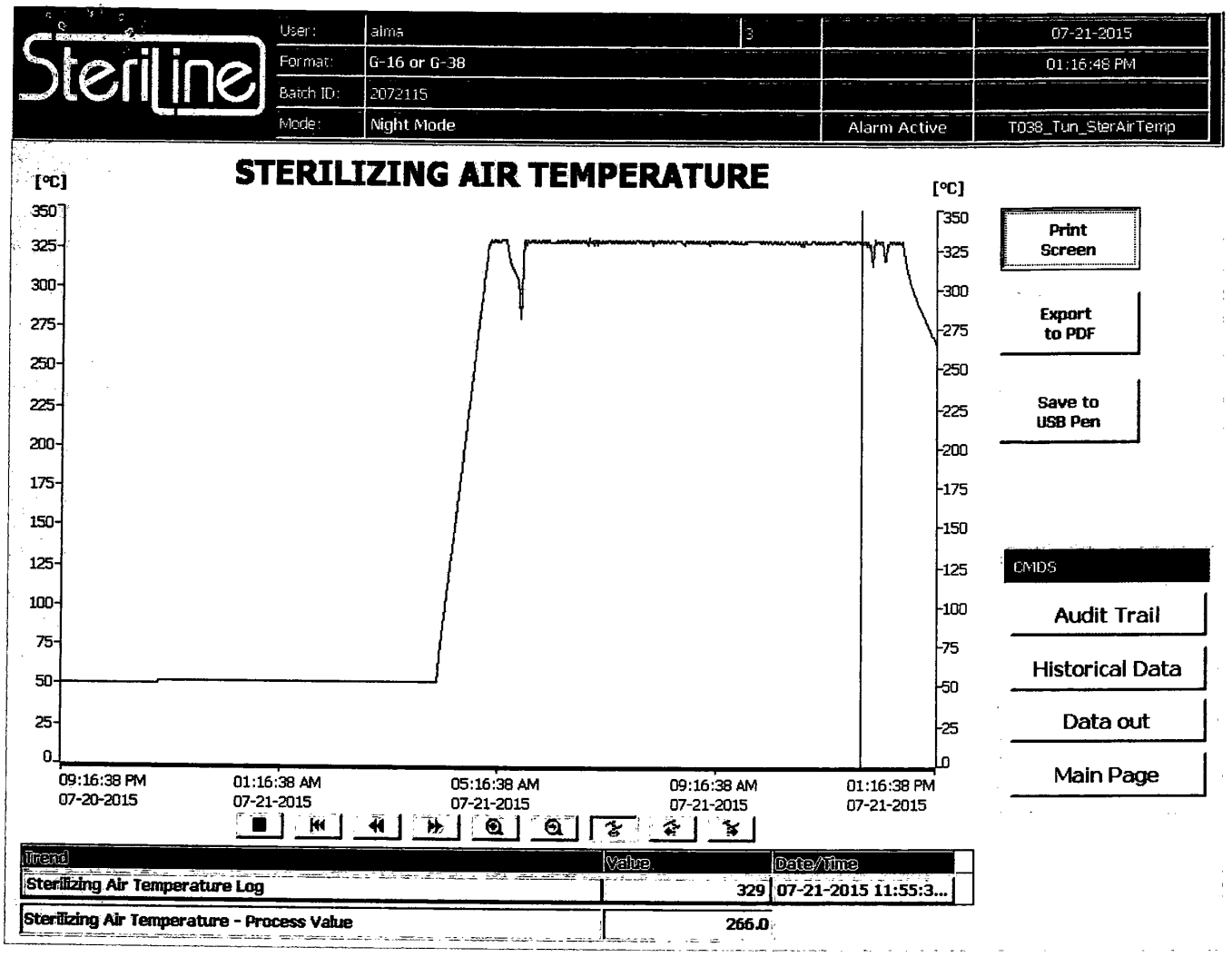
[1] *Label Claim: 50 mg/mL*
[2] *Analyses outsourced to Metrics Inc., Greenville, NC, USA*

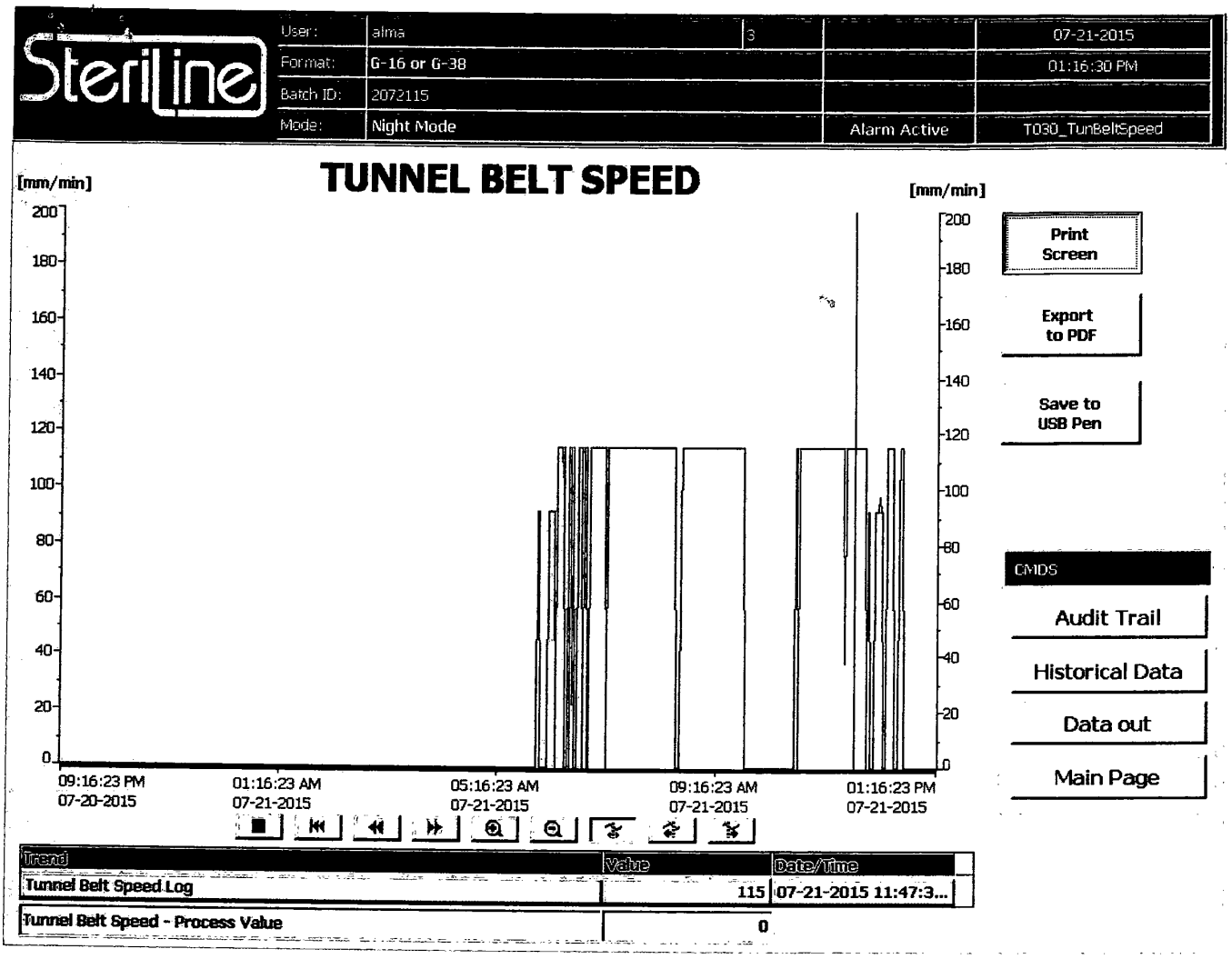
2015/Aug/10

Verified by: Ning-Min Zhang, B.Sc.
Analyst, Quality Assurance

2015/Aug/10

Approved by: Karim Mtalsi, Ph.D., Chemist
Director, R & D Department


SteriLine
User: alms
3
07-21-2015
Format: G-16 or G-38
01:16:48 PM
Batch ID: 2072115
Mode: Night Mode
Alarm Active
T038_Tun_SterAirTemp
STERILIZING AIR TEMPERATURE
[°C]
[°C]
350
325
300
275
250
225
200
175
150
125
100
75
50
25
0
09:16:38 PM
07-20-2015
01:16:38 AM
07-21-2015
05:16:38 AM
07-21-2015
09:16:38 AM
07-21-2015
01:16:38 PM
07-21-2015
Print Screen
Export to PDF
Save to USB Pen
CMDS
Audit Trail
Historical Data
Data out
Main Page
Trend
Value
Date/Time
Sterilizing Air Temperature Log
329
07-21-2015 11:55:3...
Sterilizing Air Temperature - Process Value
266.0


SteriLine
User: alma
3
07-21-2015
Format: G-16 or G-38
01:16:30 PM
Batch ID: 2072115
Mode: Night Mode
Alarm Active
T030_TunBeltSpeed
TUNNEL BELT SPEED
[mm/min]
[mm/min]
200
180
160
140
120
100
80
60
40
20
0
09:16:23 PM 07-20-2015
01:16:23 AM 07-21-2015
05:16:23 AM 07-21-2015
09:16:23 AM 07-21-2015
01:16:23 PM 07-21-2015
Print Screen
Export to PDF
Save to USB Pen
CMDS
Audit Trail
Historical Data
Data out
Main Page
Trend
Value
Date/Time
Tunnel Belt Speed Log
115
07-21-2015 11:47:3...
Tunnel Belt Speed - Process Value
0

BATCH REPORT
Line: ST6 - DEPYROGENATION TUNNEL

Batch Name: 2072115
Batch Number: 2072115
Product Name: 50ml-20mm
Product Number: G-16 or G-38
Format Name: G-16 or G-38
Date: 07-21-2015

Batch start time: 07-21-2015 05:47:54 AM

Logged user at batch start: alma

PROCESS PARAMETERS

Tunnel - Conveyor Belt Speed [mm/min]:	115
Tunnel - Steril Air Temperature [°C]:	330.0
Tunnel - Cooling Air Temperature [°C]:	20.0
Tunnel - Inlet Air Speed [m/s]:	0.60
Tunnel - Sterilizing Air Speed [m/s]:	0.72
Tunnel - Cooling Air Speed [m/s]:	0.75
Tunnel - Inlet chamber/Env. DP [Pa]:	20.0
Tunnel - Cooling chamber/Env. DP [Pa]:	22.0
Tunnel - Doors Positions [mm]:	76

Author: 9
Version: 09-27-2011 03:27:22 PM

ALLARM PARAMETERS

Conveyor Speed Range [mm/min]:	10
Inlet Air Speed Range [m/s]:	0.02
Sterilizing Air Speed Range [m/s]:	0.02
Cooling Air Speed Range [m/s]:	0.02
Inlet Chamber/Env. dP Range [Pa]:	5.0
Cooling Chamber/Env. dP Range [Pa]:	5.0
Doors Position Range [mm]:	2
Steriliz. Air Min Temp. Range [°C]:	5.0
Steriliz. Air Max Temp. Range [°C]:	10.0
Cooling Air Min. Temp. Range [°C]:	5.0
Cooling Air Max. Temp. Range [°C]:	10.0
Exhaust Air Max. Temperature Range [°C]:	60.0

OPERATOR NOTE AT BATCH START
"2072115 50ml-20mm"

EVENTS

TIME STAMP	EV.ID.	EVENT DESCRIPTION
07-21-2015 05:48:12 AM	Ev_id: 1001	Signed: Batch file - 2072115 - recording started
07-21-2015 05:52:10 AM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 05:53:13 AM	Ev_id: 1013	User Logout
07-21-2015 05:58:45 AM	Ev_id: 1050	USER 7 has logged on local HMI
07-21-2015 06:04:14 AM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 06:09:48 AM	Ev_id: 1050	USER 7 has logged on local HMI
07-21-2015 06:20:56 AM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 06:35:21 AM	Ev_id: 1050	USER 7 has logged on local HMI
07-21-2015 06:47:29 AM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 07:16:16 AM	Ev_id: 1050	USER 7 has logged on local HMI
07-21-2015 07:21:23 AM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 07:55:53 AM	Ev_id: 1050	USER 7 has logged on local HMI
07-21-2015 08:00:58 AM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 11:54:55 AM	Ev_id: 1050	USER 7 has logged on local HMI
07-21-2015 11:59:04 AM	Ev_id: 9560	TUN - RESET CYCLE PRESSED by 7
07-21-2015 11:59:49 AM	Ev_id: 9564	START CYCLE PRESSED by 7
07-21-2015 12:02:51 PM	Ev_id: 9560	TUN - RESET CYCLE PRESSED by 7
07-21-2015 12:06:10 PM	Ev_id: 9564	START CYCLE PRESSED by 7
07-21-2015 12:07:08 PM	Mode: Selection	Night mode selected by 7
07-21-2015 12:12:48 PM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 12:16:57 PM	Ev_id: 1050	USER 7 has logged on local HMI
07-21-2015 12:17:07 PM	Ev_id: 9560	TUN - RESET CYCLE PRESSED by 7
07-21-2015 12:19:46 PM	Ev_id: 9560	TUN - RESET CYCLE PRESSED by 7
07-21-2015 12:19:59 PM	Ev_id: 9564	START CYCLE PRESSED by 7
07-21-2015 12:25:35 PM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 12:34:11 PM	Ev_id: 1050	USER 7 has logged on local HMI
07-21-2015 12:38:47 PM	Ev_id: 9560	TUN - RESET CYCLE PRESSED by 7
07-21-2015 12:44:47 PM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 12:51:58 PM	Ev_id: 1013	User '7' logged on with group 'Administrator'.
07-21-2015 12:52:35 PM	Ev_id: 1013	User Logout
07-21-2015 01:02:31 PM	Ev_id: 1050	USER 7 has logged on local HMI
07-21-2015 01:06:14 PM	Ev_id: 9560	TUN - RESET CYCLE PRESSED by 7
07-21-2015 01:07:22 PM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 01:07:50 PM	Ev_id: 1050	USER 7 has logged on local HMI
07-21-2015 01:08:15 PM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 01:08:28 PM	Ev_id: 1050	USER 9 has logged on local HMI

07-21-2015 01:08:52 PM	Ev_id: 1051	USER Logoff on local HMI
07-21-2015 01:09:05 PM	Ev_id: 1050	USER alma has logged on local HMI
07-21-2015 01:15:50 PM	Ev_id: 1013	User 'alma' logged on with group 'Operator'.
07-21-2015 01:15:54 PM	Ev_id: 1003	Batch file - 2072115 - recording stopped

ALARMS MESSAGES

TIME STAMP	EV.ID.	DESCRIPTION
07-21-2015 06:15:51 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:15:55 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:15:56 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:22:07 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:22:28 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:23:18 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:23:23 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:23:31 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:23:37 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:23:44 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:23:45 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:23:47 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:23:48 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:23:54 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:24:00 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:24:10 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:24:13 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:25:39 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:26:03 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:27:07 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 06:27:22 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 06:27:24 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:27:31 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:27:42 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:27:56 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:28:57 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 06:30:42 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 06:30:54 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 06:31:17 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 06:31:46 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 06:32:28 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 06:33:07 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:33:08 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:33:14 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:33:17 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:33:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:33:28 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:33:32 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:33:36 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:34:34 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 06:35:34 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 06:36:15 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:36:16 AM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 06:36:47 AM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 06:36:57 AM	Alarm_027	4.th DOOR JAMMED - In
07-21-2015 06:36:58 AM	Alarm_022	3.rd DOOR IN WRONG POSITION - In
07-21-2015 06:37:06 AM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 06:37:16 AM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 06:37:20 AM	Alarm_022	3.rd DOOR IN WRONG POSITION - Out
07-21-2015 06:37:20 AM	Alarm_027	4.th DOOR JAMMED - Out
07-21-2015 06:37:20 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:37:20 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:37:25 AM	Alarm_027	4.th DOOR JAMMED - In
07-21-2015 06:37:25 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:37:30 AM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 06:37:43 AM	Alarm_027	4.th DOOR JAMMED - Out
07-21-2015 06:37:51 AM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 06:37:57 AM	Alarm_027	4.th DOOR JAMMED - In
07-21-2015 06:38:17 AM	Alarm_027	4.th DOOR JAMMED - Out
07-21-2015 06:38:20 AM	Alarm_022	3.rd DOOR IN WRONG POSITION - In
07-21-2015 06:38:27 AM	Alarm_022	3.rd DOOR IN WRONG POSITION - Out
07-21-2015 06:38:47 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:38:53 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:38:59 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:39:03 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:39:06 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:39:07 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:39:11 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:39:15 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:39:32 AM	Alarm_085	TUNNEL BELT MANUAL STOP - In
07-21-2015 06:40:21 AM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 06:40:35 AM	Alarm_085	TUNNEL BELT MANUAL STOP - Out
07-21-2015 06:40:35 AM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 06:40:36 AM	Alarm_085	TUNNEL BELT MANUAL STOP - In
07-21-2015 06:40:36 AM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 06:40:52 AM	Alarm_023	4.th DOOR IN WRONG POSITION - In

07-21-2015 06:40:52 AM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 06:41:10 AM	Alarm_023	4.th DOOR IN WRONG POSITION - Out
07-21-2015 06:41:19 AM	Alarm_085	TUNNEL BELT MANUAL STOP - Out
07-21-2015 06:42:09 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 06:42:36 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 06:43:04 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:43:25 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:45:38 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 06:46:00 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 06:46:08 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 06:46:15 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 06:46:22 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:46:23 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:46:25 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:46:28 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:46:33 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:46:38 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:48:08 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 06:49:06 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 06:50:11 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 06:50:24 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 06:50:31 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:50:51 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:51:43 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:52:05 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:52:36 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:52:50 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:53:42 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 06:55:22 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:55:23 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 06:55:25 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:55:26 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:55:27 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:55:32 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:55:33 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:55:35 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:55:37 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:55:45 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:55:49 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:55:54 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:55:59 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:56:33 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:56:39 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:56:55 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:57:16 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:57:50 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:58:10 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 06:59:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 06:59:40 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:00:39 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:00:43 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:01:22 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:01:40 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:03:09 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:03:19 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:03:53 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:04:11 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:04:41 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:04:47 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:05:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:05:33 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:10:15 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:10:35 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:10:59 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:11:05 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:15:02 AM	Alarm_021	2.nd DOOR IN WRONG POSITION - In
07-21-2015 07:16:17 AM	Alarm_021	2.nd DOOR IN WRONG POSITION - Out
07-21-2015 07:20:24 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:20:33 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:20:49 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:21:07 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:21:35 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:21:46 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:22:20 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:22:28 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:23:03 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:23:11 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:23:46 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:23:55 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:24:30 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:24:31 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:24:57 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:25:04 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out

07-21-2015 07:25:30 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:25:37 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:26:11 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:26:14 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:26:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:26:33 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:28:11 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:28:14 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:29:38 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:29:46 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:30:17 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:30:27 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:30:57 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:30:59 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:31:34 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:31:50 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:32:36 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:32:51 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:33:04 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:33:20 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:34:00 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:34:15 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:39:05 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:39:26 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:40:35 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:40:40 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:40:41 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:40:42 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:40:46 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:40:48 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:41:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:41:32 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:45:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:45:46 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:46:50 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 07:47:23 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 07:47:53 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:47:55 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:48:09 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:48:23 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:48:55 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:49:10 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:49:35 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 07:49:38 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 07:55:26 AM	Alarm_021	2.nd DOOR IN WRONG POSITION - In
07-21-2015 07:55:55 AM	Alarm_021	2.nd DOOR IN WRONG POSITION - Out
07-21-2015 08:00:15 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:00:22 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:00:56 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:01:05 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:02:01 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:02:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:03:15 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:03:18 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:03:45 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:03:57 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:04:37 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:04:58 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:05:39 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:05:46 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:11:51 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:11:53 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:12:17 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:12:43 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:13:24 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:13:34 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:14:00 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:14:14 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:14:43 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:15:05 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:15:31 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:15:57 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:16:22 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:16:32 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:16:59 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:17:09 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:17:41 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:18:04 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:19:00 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:19:16 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:19:34 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:19:46 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:19:58 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In

07-21-2015 08:20:05 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:20:45 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:20:46 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:24:30 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:24:48 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:25:16 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:25:36 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:26:13 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:26:31 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:27:35 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:27:50 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:28:20 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:28:31 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:29:02 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:29:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:30:46 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 08:36:47 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 08:37:41 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:38:02 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:38:35 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:38:37 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:40:37 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:41:00 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:42:11 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 08:42:30 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 08:42:57 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:43:00 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:43:29 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:43:33 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:44:02 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:44:12 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:44:49 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:44:56 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:46:42 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:46:52 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:47:23 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:47:26 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:51:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:51:27 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:52:03 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:52:27 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:53:28 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:53:44 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:54:40 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:54:51 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:55:16 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:55:26 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:55:46 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:55:50 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:56:17 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:56:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 08:57:27 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 08:57:58 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:01:55 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:02:07 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:02:34 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:02:43 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:03:15 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:03:29 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:03:56 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:04:07 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:04:08 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:04:10 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:04:39 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:04:59 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:06:25 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:06:34 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:11:00 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:11:06 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:11:53 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:12:06 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:16:52 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:17:15 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:18:19 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:18:22 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:18:56 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:19:03 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:19:48 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:19:57 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:20:29 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:20:34 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:20:52 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:21:12 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out

07-21-2015 09:23:51 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:24:11 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:35:01 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:35:17 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:35:43 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:35:54 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:36:01 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:36:14 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:38:47 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:39:03 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:39:58 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:40:19 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:40:36 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:40:43 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:41:14 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:41:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:43:59 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:44:18 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:44:55 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:45:02 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:45:25 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:45:33 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:45:59 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 09:46:11 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 09:46:44 AM	Alarm_096	TUNNEL OUTLET MAXIMUM LOAD - In
07-21-2015 10:42:45 AM	Alarm_096	TUNNEL OUTLET MAXIMUM LOAD - Out
07-21-2015 10:43:18 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 10:43:39 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 10:45:08 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 10:45:28 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 10:45:33 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 10:45:49 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 10:46:03 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 10:46:16 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 10:47:04 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 10:47:08 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 10:47:38 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 10:47:50 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 10:48:22 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 10:48:43 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 10:49:03 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 10:49:09 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 10:49:14 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 10:49:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 10:49:27 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 10:49:37 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 10:50:44 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 10:50:54 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 10:51:42 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 10:51:56 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:05:00 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:05:14 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:05:46 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:05:59 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:06:33 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:06:41 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:14:32 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:14:52 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:15:20 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:15:25 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:15:29 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:15:32 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:15:36 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:15:41 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:19:56 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:20:23 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:28:27 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:28:34 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:33:52 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:34:11 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:35:31 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - In
07-21-2015 11:35:46 AM	Alarm_094	TUNNEL INLET MINIMUM LOAD - Out
07-21-2015 11:36:14 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:36:35 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:36:57 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:37:01 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:37:03 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:37:06 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:37:09 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:37:13 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:37:18 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:37:20 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:38:04 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In

07-21-2015 11:38:16 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:39:57 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:40:18 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:41:05 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:41:18 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:41:51 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:41:53 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:42:48 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:43:12 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:49:03 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:49:23 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:50:15 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:50:16 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:52:43 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:53:00 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:53:32 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:53:34 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:54:21 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:54:35 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:54:48 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - In
07-21-2015 11:55:13 AM	Alarm_095	TUNNEL INLET MAXIMUM LOAD - Out
07-21-2015 11:59:16 AM	Alarm_026	3.rd DOOR JAMMED - In
07-21-2015 11:59:16 AM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 11:59:26 AM	Alarm_026	3.rd DOOR JAMMED - Out
07-21-2015 12:02:27 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 12:02:32 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 12:03:24 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 12:03:28 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 12:04:53 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - In
07-21-2015 12:04:58 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - Out
07-21-2015 12:04:58 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 12:04:59 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - In
07-21-2015 12:04:59 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 12:05:06 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - Out
07-21-2015 12:05:06 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 12:05:07 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - In
07-21-2015 12:05:07 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 12:05:11 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 12:05:16 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 12:05:42 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 12:05:50 PM	Alarm_026	3.rd DOOR JAMMED - In
07-21-2015 12:05:53 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 12:06:00 PM	Alarm_026	3.rd DOOR JAMMED - Out
07-21-2015 12:06:00 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - Out
07-21-2015 12:06:00 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 12:06:01 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - In
07-21-2015 12:06:01 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 12:06:22 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - Out
07-21-2015 12:07:17 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 12:07:23 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 12:16:59 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 12:19:09 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - In
07-21-2015 12:20:00 PM	Alarm_027	4.th DOOR JAMMED - In
07-21-2015 12:20:14 PM	Alarm_027	4.th DOOR JAMMED - Out
07-21-2015 12:20:14 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - Out
07-21-2015 12:28:43 PM	Alarm_021	2.nd DOOR IN WRONG POSITION - In
07-21-2015 12:34:13 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 12:34:18 PM	Alarm_021	2.nd DOOR IN WRONG POSITION - Out
07-21-2015 12:38:54 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 12:39:04 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 12:39:31 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 12:39:37 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 12:40:49 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - In
07-21-2015 01:02:32 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 01:02:46 PM	Alarm_027	4.th DOOR JAMMED - In
07-21-2015 01:02:53 PM	Alarm_027	4.th DOOR JAMMED - Out
07-21-2015 01:02:53 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - Out
07-21-2015 01:02:57 PM	Alarm_027	4.th DOOR JAMMED - In
07-21-2015 01:03:13 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 01:05:38 PM	Alarm_027	4.th DOOR JAMMED - Out
07-21-2015 01:05:38 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 01:05:39 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 01:06:02 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 01:06:08 PM	Alarm_086	DOORS IN MANUAL MODE - In
07-21-2015 01:06:27 PM	Alarm_086	DOORS IN MANUAL MODE - Out
07-21-2015 01:08:57 PM	Alarm_083	COOLING CHAMBER TEMPERATURE LOW - In

Batch stop time: 07-21-2015 01:15:54 PM

Logged user at batch stop: alma

Batch total time: 7 [h]- 28 [min]- 0 [s]

SIGNATURES

A) Operator: Alma Delia Hernandez 07-21-15

B) Supervisor: 07.22.15

C) Quality Assurance: 07/27/15

Results : 20 Samplings

Point	Type	Personnel	Method	Area	Alert	Action	Bacteria	Fungi and Yeast	Count	Result Type	Exceeding	Date	Deviations	Batch	Sampling plan	Department	Microorganisms	LAL Alert	LAL Action	LAL Test	Types of Control
Chest	Personnel	Salas Junior			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 10:00:00		L-Cysteine L-Cysteine	P-JS-1 JS Personnel 1	Line 2					During Production
Left Finger	Personnel	Salas Junior			>= 1 cfu/glove	>= 2 cfu/glove	0		0	Acceptable		7/21/2015 10:00:00		L-Cysteine L-Cysteine	P-JS-1 JS Personnel 1	Line 2					During Production
Left Forearm	Personnel	Salas Junior			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 10:00:00		L-Cysteine L-Cysteine	P-JS-1 JS Personnel 1	Line 2					During Production
Right Finger	Personnel	Salas Junior			>= 1 cfu/glove	>= 2 cfu/glove	0		0	Acceptable		7/21/2015 10:00:00		L-Cysteine L-Cysteine	P-JS-1 JS Personnel 1	Line 2					During Production
Right Forearm	Personnel	Salas Junior			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 10:00:00		L-Cysteine L-Cysteine	P-JS-1 JS Personnel 1	Line 2					During Production
Chest	Personnel	Quintero Juan Carlos			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 10:00:00		L-Cysteine L-Cysteine	P-JCQ-1 JCQ Personnel 1	Line 2					During Production
Left Finger	Personnel	Quintero Juan Carlos			>= 1 cfu/glove	>= 2 cfu/glove	0		0	Acceptable		7/21/2015 10:00:00		L-Cysteine L-Cysteine	P-JCQ-1 JCQ Personnel 1	Line 2					During Production
Left Forearm	Personnel	Quintero Juan Carlos			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 10:00:00		L-Cysteine L-Cysteine	P-JCQ-1 JCQ Personnel 1	Line 2					During Production
Right Finger	Personnel	Quintero Juan Carlos			>= 1 cfu/glove	>= 2 cfu/glove	0		0	Acceptable		7/21/2015 10:00:00		L-Cysteine L-Cysteine	P-JCQ-1 JCQ Personnel 1	Line 2					During Production
Right Forearm	Personnel	Quintero Juan Carlos			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 10:00:00		L-Cysteine L-Cysteine	P-JCQ-1 JCQ Personnel 1	Line 2					During Production
Chest	Personnel	Salas Junior			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 12:42:00		L-Cysteine L-Cysteine	P-JS-2 JS Personnel 2	Line 2					End of Production
Left Finger	Personnel	Salas Junior			>= 1 cfu/glove	>= 2 cfu/glove	0		0	Acceptable		7/21/2015 12:42:00		L-Cysteine L-Cysteine	P-JS-2 JS Personnel 2	Line 2					End of Production
Left Forearm	Personnel	Salas Junior			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 12:42:00		L-Cysteine L-Cysteine	P-JS-2 JS Personnel 2	Line 2					End of Production
Right Finger	Personnel	Salas Junior			>= 1 cfu/glove	>= 2 cfu/glove	0		0	Acceptable		7/21/2015 12:42:00		L-Cysteine	P-JS-2 JS	Line 2					End of Production

														L-Cysteine	Personnel 2							
Right Forearm	Personnel	Salas Junior			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 12:42:00		L-Cysteine L-Cysteine	P-JS-2 JS Personnel 2	Line 2						End of Production
Chest	Personnel	Quintero Juan Carlos			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	P-JCQ-2 JCQ Personnel 2	Line 2						End of Production
Left Finger	Personnel	Quintero Juan Carlos			>= 1 cfu/glove	>= 2 cfu/glove	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	P-JCQ-2 JCQ Personnel 2	Line 2						End of Production
Left Forearm	Personnel	Quintero Juan Carlos			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	P-JCQ-2 JCQ Personnel 2	Line 2						End of Production
Right Finger	Personnel	Quintero Juan Carlos			>= 1 cfu/glove	>= 2 cfu/glove	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	P-JCQ-2 JCQ Personnel 2	Line 2						End of Production
Right Forearm	Personnel	Quintero Juan Carlos			>= 2 cfu/site	>= 3 cfu/site	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	P-JCQ-2 JCQ Personnel 2	Line 2						End of Production

Results : 26 Samplings

Point	Description	Type	Class	Method	Area	Alert	Action	Bacteria	Fungi and Yeast	Count	Result Type	Exceeding	Date	Deviations	Batch	Sampling plan	Department	Microorganisms	LAL Alert	LAL Action	LAL Test
Production Set-up	Fill machine base	Air	100	Active Air Sampling	Filling and Capping Line 2	>= 1 cfu/290L	>= 1 cfu/290L	0		0	Acceptable		7/21/2015 06:30:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
During Filling AA-B2-1	AA during filling	Air	100	Active Air Sampling	Filling and Capping Line 2	>= 1 cfu/290L	>= 1 cfu/290L	0		0	Acceptable		7/21/2015 06:55:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
Filling Turntable	AA on filling turntable	Air	100	Active Air Sampling	Filling and Capping Line 2	>= 1 cfu/290L	>= 1 cfu/290L	0		0	Acceptable		7/21/2015 07:04:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
Stopper Unit	AA Stopper Bowl/Chute	Air	100	Active Air Sampling	Filling and Capping Line 2	>= 1 cfu/290L	>= 1 cfu/290L	0		0	Acceptable		7/21/2015 07:09:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
During Filling AA-B2-2	AA during filling	Air	100	Active Air Sampling	Filling and Capping Line 2	>= 1 cfu/290L	>= 1 cfu/290L	0		0	Acceptable		7/21/2015 07:55:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
Filling Turntable B2	On the floor, beneath the intervention area	Air	100	Settle Plate	Filling and Capping Line 2	>= 1 cfu/plate/4hours	>= 2 cfu/plate/4hours	0		0	Acceptable		7/21/2015 08:36:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
Filling Machine B2	On the floor by the filling machine	Air	100	Settle Plate	Filling and Capping Line 2	>= 1 cfu/plate/4hours	>= 2 cfu/plate/4hours	0		0	Acceptable		7/21/2015 08:36:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
Stopper Bowl B2	On the floor, beneath stopper bowl	Air	100	Settle Plate	Filling and Capping Line 2	>= 1 cfu/plate/4hours	>= 2 cfu/plate/4hours	0		0	Acceptable		7/21/2015 08:36:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
During Filling AA-B2-3	AA during filling	Air	100	Active Air Sampling	Filling and Capping Line 2	>= 1 cfu/290L	>= 1 cfu/290L	0		0	Acceptable		7/21/2015 08:55:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
During Filling AA-B2-4	AA during filling	Air	100	Active Air Sampling	Filling and Capping Line 2	>= 1 cfu/290L	>= 1 cfu/290L	0		0	Acceptable		7/21/2015 09:55:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
During Filling AA-B2-5	AA during filling	Air	100	Active Air Sampling	Filling and Capping Line 2	>= 1 cfu/290L	>= 1 cfu/290L	0		0	Acceptable		7/21/2015 10:55:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
During Filling AA-B2-6	AA during filling	Air	100	Active Air Sampling	Filling and Capping Line 2	>= 1 cfu/290L	>= 1 cfu/290L	0		0	Acceptable		7/21/2015 11:55:00		L-Cysteine L-Cysteine	Air-L2-Daily L2-Viable Air Monitoring	Line 2		N.A.	N.A.	N.A.
7 (1B)	Fill Turntable	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 4 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
8 (1C)	SW corner	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 4 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
9 (2B)	In front of	Surfaces	100	Contact	Filling	>= 2 cfu/plate	>= 4 cfu/plate	0		0	Acceptable		7/21/2015		L-	S-L2-	Line 2		N.A.	N.A.	N.A.

	filler			Plate	and Capping Line 2								12:50:00		Cysteine L-Cysteine	Tuesday L2 Tuesday						
10 (2C)	Behind filler	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 4 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
11 (3B)	In front of conveyor	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 4 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
12 (3C)	Behind conveyor	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 4 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
6 (Filling Turntable 2A)	Filling Turntable	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 3 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
1 (Filling Machine S)	Base of top surface, S side	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 3 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
3 (Inside Stopper Bowl)	Inside Stopper Bowl	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 1 cfu/plate	>= 1 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
13 (Turntable #2)	Turntable #2	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 3 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
2 (Filling Machine N)	Base of top surface, N side	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 3 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
5 (Conveyor)	Conveyor leading onto filler	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 3 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
4 (Stopper Chute)	Surface of stopper chute where stoppers pass.	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 3 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.
16 (Filling Turntable 2B)	On filling turntable, opposite of 2A	Surfaces	100	Contact Plate	Filling and Capping Line 2	>= 2 cfu/plate	>= 3 cfu/plate	0		0	Acceptable		7/21/2015 12:50:00		L-Cysteine L-Cysteine	S-L2-Tuesday L2 Tuesday	Line 2		N.A.	N.A.	N.A.

QA Review JW 08-12-15

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 06:40:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:41:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:42:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:43:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:44:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:45:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:46:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:47:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:48:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:49:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:50:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:51:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:52:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:53:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:54:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:55:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:56:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:57:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:58:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:59:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:00:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:01:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:02:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:03:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:04:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:05:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:06:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:07:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:08:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:09:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:10:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:11:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:12:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:13:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:14:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:15:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:16:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:17:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:18:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:19:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:20:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:21:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:22:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:23:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:24:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:25:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:26:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:27:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:28:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:29:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:30:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:31:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:32:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:33:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:34:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:35:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:36:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:37:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:38:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:39:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:40:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:41:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:42:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:43:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:44:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:45:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:46:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 07:47:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:48:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:49:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:50:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:51:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:52:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:53:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:54:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:55:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:56:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:57:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:58:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:59:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:00:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:01:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:02:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:03:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:04:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:05:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:06:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:07:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:08:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:09:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:10:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:11:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:12:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:13:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:14:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:15:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:16:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:17:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:18:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:19:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:20:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:21:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:22:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:23:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:24:49	RPC-2120-01 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 08:25:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:26:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:27:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:28:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:29:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:30:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:31:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:32:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:33:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:34:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:35:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:36:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:37:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:38:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:39:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:40:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:41:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:42:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:43:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:44:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:45:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:46:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:47:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:48:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:49:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:50:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:51:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:52:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:53:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 08:54:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:55:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:56:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:57:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:58:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:59:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:00:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:01:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:02:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:03:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:04:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:05:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:06:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:07:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:08:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:09:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:10:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:11:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:12:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:13:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:14:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:15:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:16:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:17:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:18:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:19:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:20:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:21:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:22:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:23:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:24:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:25:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:26:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:27:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:28:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:29:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:30:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:31:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:32:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:33:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:34:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:35:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:36:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:37:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:38:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:39:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:40:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:41:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:42:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:43:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:44:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:45:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:46:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:47:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:48:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:49:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:50:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:51:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:52:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:53:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:54:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:55:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:56:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:57:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:58:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:59:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:00:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 10:01:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:02:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:03:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:04:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:05:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:06:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:07:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:08:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:09:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:10:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:11:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:12:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:13:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:14:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:15:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:16:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:17:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:18:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:19:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:20:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:21:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:22:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:23:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:24:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:25:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:26:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:27:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:28:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:29:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:30:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:31:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:32:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:33:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:34:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:35:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:36:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:37:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:38:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:39:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:40:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:41:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:42:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:43:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:44:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:45:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:46:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:47:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:48:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:49:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:50:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:51:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:52:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:53:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:54:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:55:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:56:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:57:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:58:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:59:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:00:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:01:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:02:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:03:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:04:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:05:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:06:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:07:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 11:08:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:09:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:10:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:11:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:12:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:13:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:14:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:15:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:16:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:17:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:18:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:19:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:20:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:21:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:22:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:23:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:24:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:25:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:26:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:27:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:28:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:29:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:30:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:31:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:32:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:33:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:34:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:35:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:36:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:37:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:38:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:39:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:40:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:41:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:42:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:43:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:44:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:45:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:46:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:47:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:48:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:49:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:50:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:51:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:52:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:53:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:54:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:55:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:56:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:57:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:58:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:59:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:00:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:01:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:02:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:03:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:04:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:05:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:06:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:07:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:08:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:09:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:10:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:11:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:12:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:13:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:14:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 12:15:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:16:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:17:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:18:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:19:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:20:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:21:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:22:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:23:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:24:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:25:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:26:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:27:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:28:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:29:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:30:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:31:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:32:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:33:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:34:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:35:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:36:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:37:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:38:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:39:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:40:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:41:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:42:49	RPC-2120-01 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 06:40:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:41:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:42:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:43:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:44:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:45:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:46:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:47:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:48:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:49:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:50:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:51:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:52:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:53:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:54:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:55:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:56:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:57:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:58:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:59:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:00:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:01:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:02:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:03:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:04:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:05:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:06:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:07:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:08:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:09:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:10:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:11:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:12:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:13:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:14:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:15:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:16:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:17:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:18:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:19:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:20:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:21:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:22:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:23:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:24:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:25:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:26:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:27:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:28:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:29:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:30:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:31:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:32:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:33:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:34:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:35:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:36:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:37:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:38:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:39:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:40:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:41:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:42:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:43:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:44:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:45:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:46:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 07:47:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:48:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:49:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:50:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:51:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:52:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:53:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:54:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:55:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:56:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:57:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:58:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:59:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:00:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:01:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:02:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:03:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:04:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:05:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:06:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:07:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:08:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:09:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:10:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:11:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:12:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:13:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:14:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:15:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:16:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:17:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:18:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:19:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:20:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:21:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:22:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:23:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:24:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:25:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:26:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:27:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:28:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:29:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:30:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:31:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:32:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:33:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:34:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:35:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:36:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:37:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:38:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:39:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:40:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:41:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:42:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:43:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:44:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:45:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:46:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:47:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:48:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:49:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:50:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:51:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:52:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:53:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 08:54:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:55:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:56:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:57:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:58:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:59:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:00:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:01:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:02:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:03:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:04:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:05:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:06:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:07:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:08:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:09:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:10:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:11:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:12:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:13:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:14:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:15:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:16:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:17:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:18:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:19:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:20:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:21:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:22:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:23:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:24:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:25:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:26:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:27:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:28:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:29:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:30:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:31:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:32:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:33:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:34:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:35:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:36:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:37:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:38:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:39:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:40:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:41:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:42:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:43:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:44:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:45:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:46:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:47:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:48:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:49:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:50:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:51:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:52:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:53:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:54:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:55:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:56:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:57:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:58:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:59:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:00:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 10:01:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:02:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:03:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:04:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:05:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:06:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:07:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:08:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:09:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:10:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:11:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:12:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:13:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:14:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:15:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:16:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:17:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:18:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:19:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:20:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:21:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:22:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:23:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:24:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:25:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:26:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:27:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:28:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:29:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:30:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:31:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:32:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:33:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:34:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:35:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:36:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:37:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:38:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:39:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:40:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:41:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:42:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:43:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:44:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:45:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:46:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:47:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:48:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:49:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:50:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:51:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:52:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:53:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:54:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:55:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:56:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:57:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:58:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:59:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:00:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:01:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:02:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:03:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:04:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:05:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:06:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:07:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 11:08:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:09:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:10:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:11:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:12:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:13:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:14:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:15:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:16:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:17:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:18:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:19:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:20:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:21:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:22:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:23:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:24:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:25:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:26:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:27:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:28:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:29:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:30:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:31:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:32:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:33:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:34:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:35:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:36:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:37:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:38:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:39:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:40:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:41:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:42:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:43:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:44:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:45:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:46:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:47:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:48:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:49:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:50:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:51:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:52:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:53:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:54:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:55:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:56:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:57:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:58:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:59:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:00:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:01:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:02:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:03:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:04:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:05:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:06:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:07:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:08:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:09:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:10:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:11:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:12:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:13:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:14:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 12:15:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:16:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:17:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:18:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:19:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:20:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:21:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:22:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:23:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:24:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:25:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:26:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:27:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:28:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:29:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:30:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:31:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:32:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:33:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:34:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:35:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:36:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:37:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:38:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:39:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:40:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:41:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:42:48	RPC-2120-02 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 06:40:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:41:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:42:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:43:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:44:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:45:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:46:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 06:47:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:48:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:49:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:50:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:51:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:52:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:53:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:54:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:55:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:56:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:57:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:58:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 06:59:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:00:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 07:01:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:02:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:03:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:04:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:05:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:06:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:07:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 07:08:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 07:09:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:10:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:11:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:12:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:13:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 07:14:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:15:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 07:16:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:17:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:18:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:19:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:20:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:21:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:22:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:23:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:24:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:25:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:26:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:27:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:28:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:29:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:30:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:31:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 07:32:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:33:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:34:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:35:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:36:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:37:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 07:38:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:39:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 07:40:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:41:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:42:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 07:43:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:44:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:45:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:46:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 07:47:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:48:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:49:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 07:50:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 07:51:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:52:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:53:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 07:54:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 07:55:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 07:56:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 07:57:08	RPC-2120-03 0.5	13 p/ft³	Normal	Valid	I/O
07/21/15 07:58:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 07:59:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:00:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:01:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 08:02:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 08:03:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:04:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:05:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:06:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 08:07:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 08:08:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 08:09:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:10:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:11:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:12:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:13:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:14:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:15:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:16:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:17:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:18:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:19:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:20:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:21:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:22:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:23:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:24:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:25:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:26:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:27:08	RPC-2120-03 0.5	5 p/ft³	Normal	Valid	I/O
07/21/15 08:28:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:29:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:30:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:31:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:32:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:33:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:34:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:35:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:36:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:37:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:38:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:39:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:40:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:41:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 08:42:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:43:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:44:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:45:08	RPC-2120-03 0.5	8 p/ft³	Normal	Valid	I/O
07/21/15 08:46:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:47:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 08:48:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:49:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:50:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 08:51:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:52:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:53:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 08:54:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 08:55:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:56:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 08:57:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:58:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 08:59:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:00:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:01:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:02:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:03:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:04:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 09:05:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:06:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 09:07:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 09:08:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:09:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:10:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 09:11:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:12:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:13:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:14:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:15:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:16:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:17:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:18:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 09:19:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 09:20:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:21:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 09:22:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:23:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 09:24:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:25:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 09:26:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:27:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:28:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:29:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:30:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:31:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:32:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 09:33:08	RPC-2120-03 0.5	5 p/ft³	Normal	Valid	I/O
07/21/15 09:34:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:35:08	RPC-2120-03 0.5	6 p/ft³	Normal	Valid	I/O
07/21/15 09:36:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:37:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:38:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:39:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:40:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 09:41:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:42:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:43:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:44:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 09:45:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:46:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 09:47:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:48:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:49:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:50:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:51:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:52:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:53:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:54:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:55:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:56:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:57:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:58:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 09:59:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:00:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 10:01:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:02:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:03:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:04:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:05:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:06:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:07:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:08:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:09:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:10:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:11:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:12:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:13:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:14:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:15:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:16:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:17:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:18:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:19:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:20:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:21:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:22:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:23:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:24:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:25:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:26:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:27:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:28:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:29:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:30:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:31:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:32:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:33:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:34:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:35:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:36:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:37:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:38:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:39:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:40:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:41:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:42:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:43:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:44:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 10:45:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 10:46:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:47:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:48:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:49:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:50:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:51:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:52:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:53:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:54:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 10:55:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:56:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:57:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:58:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 10:59:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 11:00:08	RPC-2120-03 0.5	23 p/ft³	Normal	Valid	I/O
07/21/15 11:01:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 11:02:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:03:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 11:04:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:05:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:06:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:07:08	RPC-2120-03 0.5	5 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 11:08:08	RPC-2120-03 0.5	6 p/ft³	Normal	Valid	I/O
07/21/15 11:09:08	RPC-2120-03 0.5	11 p/ft³	Normal	Valid	I/O
07/21/15 11:10:08	RPC-2120-03 0.5	8 p/ft³	Normal	Valid	I/O
07/21/15 11:11:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:12:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 11:13:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 11:14:08	RPC-2120-03 0.5	5 p/ft³	Normal	Valid	I/O
07/21/15 11:15:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:16:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:17:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:18:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:19:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:20:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:21:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:22:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:23:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:24:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:25:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:26:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:27:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:28:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:29:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:30:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 11:31:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:32:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:33:08	RPC-2120-03 0.5	6 p/ft³	Normal	Valid	I/O
07/21/15 11:34:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:35:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 11:36:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:37:08	RPC-2120-03 0.5	6 p/ft³	Normal	Valid	I/O
07/21/15 11:38:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 11:39:08	RPC-2120-03 0.5	6 p/ft³	Normal	Valid	I/O
07/21/15 11:40:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 11:41:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:42:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:43:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 11:44:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 11:45:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:46:08	RPC-2120-03 0.5	5 p/ft³	Normal	Valid	I/O
07/21/15 11:47:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:48:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 11:49:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:50:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 11:51:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:52:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 11:53:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:54:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 11:55:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 11:56:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 11:57:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 11:58:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 11:59:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 12:00:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:01:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:02:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:03:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:04:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:05:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:06:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:07:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:08:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:09:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:10:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:11:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 12:12:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:13:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:14:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O

Time	Data	Value	Alarm Status	Quality	Origin
07/21/15 12:15:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:16:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:17:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:18:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:19:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:20:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:21:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:22:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:23:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 12:24:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 12:25:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:26:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:27:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:28:08	RPC-2120-03 0.5	2 p/ft³	Normal	Valid	I/O
07/21/15 12:29:08	RPC-2120-03 0.5	3 p/ft³	Normal	Valid	I/O
07/21/15 12:30:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:31:08	RPC-2120-03 0.5	5 p/ft³	Normal	Valid	I/O
07/21/15 12:32:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:33:08	RPC-2120-03 0.5	5 p/ft³	Normal	Valid	I/O
07/21/15 12:34:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:35:08	RPC-2120-03 0.5	5 p/ft³	Normal	Valid	I/O
07/21/15 12:36:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:37:08	RPC-2120-03 0.5	1 p/ft³	Normal	Valid	I/O
07/21/15 12:38:08	RPC-2120-03 0.5	20 p/ft³	Normal	Valid	I/O
07/21/15 12:39:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:40:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:41:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O
07/21/15 12:42:08	RPC-2120-03 0.5	0 p/ft³	Normal	Valid	I/O

TKT 07-15-15 QM 071715

	Form Title: **Retention Sample Form for Sandoz Inc. (ID# 714503) Drug Products**	Doc Number: **MFG-037-01.02**
ALLERGY LABORATORIES, INC.	Lot #: **2072115**	Form Issue Date: JUN 27 2014
		Form Effective Date: AUG 26 2014

Product (check one)	☐	L-Cysteine HCl Injection, USP, 10 mL in a 10mL 22mm 13mm vial	minimum # of vials to retain = 64
	☑	L-Cysteine HCl Injection, USP, 50 mL in a 50mL 20mm vial	minimum # of vials to retain = 58
	☐	Ephedrine Sulfate Injection, USP, 1 mL in a 2mL 13mm vial	minimum # of vials to retain = 158
	☐	Phenylephrine HCl Injection, USP, 5 mL in a 5mL 22mm 13mm vial	minimum # of vials to retain = 68
	☐	Phenylephrine HCl Injection, USP, 10 mL 10mL 22mm 13mm vial	minimum # of vials to retain = 56

Retention sample preparation and storage	**Actual number of vials retained**	**Beginning:** 25	**Middle:** 25	**End:** 10	**Total:** 60
	Label Retention Samples with the items listed below.	**Prepared By/Date:** EM 07-21-15			
	Retention samples labeled with:	**Sample Label Check**			
	• Retention sample	☑ Yes ☐ No			
	• Product	☑ Yes ☐ No			
	• Product lot number	☑ Yes ☐ No			
	• Expiration date	☑ Yes ☐ No			
	• Quantity	☑ Yes ☐ No			
	Retention samples stored properly?	☑ Yes ☐ No	**Stored by/date:** 8-17-15		

Exhibit B

KABS
SERVICES PHARMACEUTIQUES

CERTIFICATE OF ANALYSIS

For: **ALLERGY LABORATORIES INC.**

Certificate No: 113622

Purchase Order No:	20140127	Sample Code:	N. App.
Issuing Date:	2014/Feb/12	Sample Lot No.:	**2012114**

Product: **10 mL L-Cysteine HCl Injection, USP (50 mg/mL)**

Test	Methods	Specifications	Results
Appearance of Product	Visual	Clear colorless solution free from visible particulate matter	Clear colorless solution free from visible particulate matter
Appearance of Container/Closure	Visual	No apparent leakage or physical alteration	No apparent leakage or physical alteration
Identification A	USP 36	A bluish-gray precipitate is formed	A bluish-gray precipitate is formed
Identification B	USP 36	A red-purple color is produced, and it rapidly changes to yellow	A red-purple color is produced, and it rapidly changes to yellow
pH	USP 36 <791>	1.0 – 2.5	1.3
Heavy Metals	USP 36 <231> *Method II*	NMT 2 ppm	< 2 ppm
Assay	KABS-1348-LC	Alert limit: 95.0 – 105.0 % (47.5 – 52.5 mg/mL) Action limit: 85.0 – 115.0 % (42.5 – 57.5 mg/mL)	102.3 % LC[1] (51.2 mg/mL)
Aluminum Content[2]	USP 36	NMT 5000 ppb	61 ppb

[1] *Label Claim: 50 mg/mL*
[2] *Analyses outsourced to Metrics Inc., Greenville, NC, USA.*

2014/Feb/12

Verified by: Ning-Min Zhang, B.Sc.
Analyst, Quality Assurance

2014/02/12

Approved by: Karim Mtalsi, Ph.D.
Director, R&D Department

KABS

SERVICES PHARMACEUTIQUES

CERTIFICATE OF ANALYSIS

For: **ALLERGY LABORATORIES INC.**

Certificate No: **113621**

Purchase Order No:	20140127	Sample Code:	N. App.
Issuing Date:	2014/Feb/12	Sample Lot No.:	**2012214**

Product: **10 mL L-Cysteine HCl Injection, USP (50 mg/mL)**

Test	Methods	Specifications	Results
Appearance of Product	Visual	Clear colorless solution free from visible particulate matter	Clear colorless solution free from visible particulate matter
Appearance of Container/Closure	Visual	No apparent leakage or physical alteration	No apparent leakage or physical alteration
Identification A	USP 36	A bluish-gray precipitate is formed	A bluish-gray precipitate is formed
Identification B	USP 36	A red-purple color is produced, and it rapidly changes to yellow	A red-purple color is produced, and it rapidly changes to yellow
pH	USP 36 <791>	1.0 – 2.5	1.3
Heavy Metals	USP 36 <231> *Method II*	NMT 2 ppm	< 2 ppm
Assay	KABS-1348-LC	Alert limit: 95.0 – 105.0 % (47.5 – 52.5 mg/mL) Action limit: 85.0 – 115.0 % (42.5 – 57.5 mg/mL)	98.8 % LC[1] (49.4 mg/mL)
Aluminum Content[2]	USP 36	NMT 5000 ppb	37 ppb

[1] *Label Claim: 50 mg/mL*
[2] *Analyses outsourced to Metrics Inc., Greenville, NC, USA.*

2014/Feb/12

Verified by: Ning-Min Zhang, B.Sc.
Analyst, Quality Assurance

2014/12/12

Approved by: Karim Mtalsi, Ph.D.
Director, R&D Department

KABS

CERTIFICATE OF ANALYSIS

For: **ALLERGY LABORATORIES INC.**

Certificate No: 125353

Purchase Order No:	20150727	Sample Code:	N. App.
Issuing Date:	2015/Aug/10	Sample Lot No.:	**2072115**

Product: **50 mL L-Cysteine HCl Injection, USP (50 mg/mL)**

Test	Methods	Specifications	Results
Appearance of Product	Visual	Clear colorless solution free from visible particulate matter	Clear colorless solution free from visible particulate matter
Appearance of Container/Closure	Visual	No apparent leakage or physical alteration	No apparent leakage or physical alteration
Identification A	USP 38	A bluish-gray precipitate is formed	A bluish-gray precipitate is formed
Identification B	USP 38	A red-purple color is produced, and it rapidly changes to yellow	A red-purple color is produced, and it rapidly changes to yellow
pH	USP 38 <791>	1.0 – 2.5	1.3
Heavy Metals	USP 38 <231> *Method II*	NMT 2 ppm	< 2 ppm
Assay	KABS-1348-LC-V03	Alert limit: 95.0 – 105.0 % (47.5 – 52.5 mg/mL) Action limit: 85.0 – 115.0 % (42.5 – 57.5 mg/mL)	98.7 % LC[1] (49.3 mg/mL)
Aluminum Content[2]	USP 38 <206>	NMT 5000 ppb	17 ppb

MA 08-11-15
Reviewed By
MA 08-11-15

[1] *Label Claim: 50 mg/mL*
[2] *Analyses outsourced to Metrics Inc., Greenville, NC, USA*

Verified by: Ning-Min Zhang, B.Sc.
Analyst, Quality Assurance
2015/Aug/10

Approved by: Karim Mtalsi, Ph.D., Chemist
Director, R & D Department
2015/Aug/10

KABS

CERTIFICATE OF ANALYSIS

For: **ALLERGY LABORATORIES INC.**

Certificate No: **125354**

Purchase Order No:	20150727	Sample Code:	N. App.
Issuing Date:	2015/Aug/10	Sample Lot No.:	**2072215**

Product: **50 mL L-Cysteine HCl Injection, USP (50 mg/mL)**

Test	Methods	Specifications	Results
Appearance of Product	Visual	Clear colorless solution free from visible particulate matter	Clear colorless solution free from visible particulate matter
Appearance of Container/Closure	Visual	No apparent leakage or physical alteration	No apparent leakage or physical alteration
Identification A	USP 38	A bluish-gray precipitate is formed	A bluish-gray precipitate is formed
Identification B	USP 38	A red-purple color is produced, and it rapidly changes to yellow	A red-purple color is produced, and it rapidly changes to yellow
pH	USP 38 <791>	1.0 – 2.5	1.3
Heavy Metals	USP 38 <231> *Method II*	NMT 2 ppm	< 2 ppm
Assay	KABS-1348-LC-V03	Alert limit: 95.0 – 105.0 % (47.5 – 52.5 mg/mL) Action limit: 85.0 – 115.0 % (42.5 – 57.5 mg/mL)	98.5 % LC[1] (49.3 mg/mL)
Aluminum Content[2]	USP 38 <206>	NMT 5000 ppb	18 ppb

Reviewed By mt08-11-15

[1] *Label Claim: 50 mg/mL*
[2] *Analyses outsourced to Metrics Inc., Greenville, NC, USA*

Verified by: Ning-Min Zhang, B.Sc.
Analyst, Quality Assurance

Approved by: Karim Mtalsi, Ph.D., Chemist
Director, R & D Department

F-0014-0022-Rev-E01
CONFIDENTIAL

KABS
PHARMACEUTICAL SERVICES

CERTIFICATE OF ANALYSIS

For: **ALLERGY LABORATORIES INC.**

Certificate No: 125929

Purchase Order No:	20150827	Sample Code:	N. App.
Issuing Date:	2015/Sep/10	Sample Lot No.:	2081915

Product: **10 mL L-Cysteine HCl Injection, USP (50 mg/mL)**

Test	Methods	Specifications	Results
Appearance of Product	Visual	Clear colorless solution free from visible particulate matter	Clear colorless solution free from visible particulate matter
Appearance of Container/Closure	Visual	No apparent leakage or physical alteration	No apparent leakage or physical alteration
Identification A	USP 38	A bluish-gray precipitate is formed	A bluish-gray precipitate is formed
Identification B	USP 38	A red-purple color is produced, and it rapidly changes to yellow	A red-purple color is produced, and it rapidly changes to yellow
pH	USP 38 <791>	1.0 - 2.5	1.3
Heavy Metals	USP 38 <231> *Method II*	NMT 2 ppm	< 2 ppm
Assay	KABS-1348-LC-V03	Alert limit: 95.0 – 105.0 % (47.5 – 52.5 mg/mL) Action limit: 85.0 – 115.0 % (42.5 – 57.5 mg/mL)	96.4 % LC[1] (48.2 mg/mL)
Aluminum Content[2]	USP 38 <206>	NMT 5000 ppb	50 ppb

Reviewed By MAO 9-15-15

[1] *Label Claim: 50 mg/mL*
[2] *Analyses outsourced to Metrics Inc., Greenville, NC, USA*

2015/Sep/10

Verified by: Ning-Min Zhang, B.Sc.
Analyst, Quality Assurance

2015/9/10

Approved by: Karim Mtalsi, Ph.D., Chemist
Director, R & D Department

(450) 656-4404 / kabs@kabs.com
4500, de Tonnancour, St-Hubert (Québec) Canada J3Y 9G2
www.kabs.com

KABS
PHARMACEUTICAL SERVICES

CERTIFICATE OF ANALYSIS

For: **ALLERGY LABORATORIES INC.**

Certificate No: 125930

Purchase Order No:	20150827	Sample Code:	N. App.
Issuing Date:	2015/Sep/10	Sample Lot No.:	2082015

Product: **10 mL L-Cysteine HCl Injection, USP (50 mg/mL)**

Test	Methods	Specifications	Results
Appearance of Product	Visual	Clear colorless solution free from visible particulate matter	Clear colorless solution free from visible particulate matter
Appearance of Container/Closure	Visual	No apparent leakage or physical alteration	No apparent leakage or physical alteration
Identification A	USP 38	A bluish-gray precipitate is formed	A bluish-gray precipitate is formed
Identification B	USP 38	A red-purple color is produced, and it rapidly changes to yellow	A red-purple color is produced, and it rapidly changes to yellow
pH	USP 38 <791>	1.0 – 2.5	1.3
Heavy Metals	USP 38 <231> *Method II*	NMT 2 ppm	< 2 ppm
Assay	KABS-1348-LC-V03	Alert limit: 95.0 – 105.0 % (47.5 – 52.5 mg/mL) Action limit: 85.0 – 115.0 % (42.5 – 57.5 mg/mL)	96.4 % LC[1] (48.2 mg/mL)
Aluminum Content[2]	USP 38 <206>	NMT 5000 ppb	54 ppb

Reviewed By
MA 09-15-15

[1] *Label Claim: 50 mg/mL*
[2] *Analyses outsourced to Metrics Inc., Greenville, NC, USA*

2015/Sep/10

Verified by: Ning-Min Zhang, B.Sc.
Analyst, Quality Assurance

2015/09/10

Approved by: Karim Mtalsi, Ph.D., Chemist
Director, R & D Department

(450) 656-4404 / kabs@kabs.com
4500, de Tonnancour, St-Hubert (Québec) Canada J3Y 9G2
www.kabs.com

KABS
PHARMACEUTICAL SERVICES

CERTIFICATE OF ANALYSIS

For: **ALLERGY LABORATORIES INC.**

Certificate No: 125931

Purchase Order No:	20150827	Sample Code:	N. App.
Issuing Date:	2015/Sep/10	Sample Lot No.:	2082115

Product: **10 mL L-Cysteine HCl Injection, USP (50 mg/mL)**

Test	Methods	Specifications	Results
Appearance of Product	Visual	Clear colorless solution free from visible particulate matter	Clear colorless solution free from visible particulate matter
Appearance of Container/Closure	Visual	No apparent leakage or physical alteration	No apparent leakage or physical alteration
Identification A	USP 38	A bluish-gray precipitate is formed	A bluish-gray precipitate is formed
Identification B	USP 38	A red-purple color is produced, and it rapidly changes to yellow	A red-purple color is produced, and it rapidly changes to yellow
pH	USP 38 <791>	1.0 – 2.5	1.3
Heavy Metals	USP 38 <231> *Method II*	NMT 2 ppm	< 2 ppm
Assay	KABS-1348-LC-V03	Alert limit: 95.0 – 105.0 % (47.5 – 52.5 mg/mL) Action limit: 85.0 – 115.0 % (42.5 – 57.5 mg/mL)	96.2 % LC[1] (48.1 mg/mL)
Aluminum Content[2]	USP 38 <206>	NMT 5000 ppb	46 ppb

Reviewed By MA 09-15-15

[1] *Label Claim: 50 mg/mL*
[2] *Analyses outsourced to Metrics Inc., Greenville, NC, USA*

2015/sep/10

Verified by: Ning-Min Zhang, B.Sc.
Analyst, Quality Assurance

2015/09/10

Approved by: Karim Mtalsi, Ph.D., Chemist
Director, R & D Department

(450) 656-4404 / kabs@kabs.com
4600, de Tonnancour, St-Hubert (Québec) Canada J3Y 9G2
www.kabs.com

KABS
PHARMACEUTICAL SERVICES

CERTIFICATE OF ANALYSIS

For: **ALLERGY LABORATORIES INC.**

Certificate No: 126842

Purchase Order No:	20151013	Sample Code:	N. App.
Issuing Date:	2015/Oct/27	Sample Lot No.:	**2093015**

Product: **50 mL L-Cysteine HCl Injection, USP (50 mg/mL)**

Test	Methods	Specifications	Results
Appearance of Product	Visual	Clear colorless solution free from visible particulate matter	Clear colorless solution free from visible particulate matter
Appearance of Container/Closure	Visual	No apparent leakage or physical alteration	No apparent leakage or physical alteration
Identification A	USP 38	A bluish-gray precipitate is formed	A bluish-gray precipitate is formed
Identification B	USP 38	A red-purple color is produced, and it rapidly changes to yellow	A red-purple color is produced, and it rapidly changes to yellow
pH	USP 38 <791>	1.0 – 2.5	1.3
Heavy Metals	USP 38 <231> *Method II*	NMT 2 ppm	< 2 ppm
Assay	KABS-1348-LC-V03	Alert limit: 95.0 – 105.0 % (47.5 – 52.5 mg/mL) Action limit: 85.0 – 115.0 % (42.5 – 57.5 mg/mL)	97.1 % LC[1] (48.5 mg/mL)
Aluminum Content[2]	USP 38 <206>	NMT 5000 ppb	47 ppb

Reviewed By
MA 10-28-15

[1] *Label Claim: 50 mg/mL*
[2] *Analyses outsourced to Metrics Inc., Greenville, NC, USA*

2015/Oct/27

Verified by: Ning-Min Zhang, B.Sc.
Analyst, Quality Assurance

2015/10/27

Approved by: Karim Mtalsi, Ph.D., Chemist
Director, R & D Department

(450) 656-4404 / kabs@kabs.com
4500, de Tonnancour, St-Hubert (Québec) Canada J3Y 9G2
www.kabs.com

KABS
PHARMACEUTICAL SERVICES

CERTIFICATE OF ANALYSIS

For: **ALLERGY LABORATORIES INC.**

Certificate No: 126843

Purchase Order No:	20151013	Sample Code:	N. App.
Issuing Date:	2015/Oct/27	Sample Lot No.:	**2100115**

Product: **50 mL L-Cysteine HCl Injection, USP (50 mg/mL)**

Test	Methods	Specifications	Results
Appearance of Product	Visual	Clear colorless solution free from visible particulate matter	Clear colorless solution free from visible particulate matter
Appearance of Container/Closure	Visual	No apparent leakage or physical alteration	No apparent leakage or physical alteration
Identification A	USP 38	A bluish-gray precipitate is formed	A bluish-gray precipitate is formed
Identification B	USP 38	A red-purple color is produced, and it rapidly changes to yellow	A red-purple color is produced, and it rapidly changes to yellow
pH	USP 38 <791>	1.0 – 2.5	1.3
Heavy Metals	USP 38 <231> *Method II*	NMT 2 ppm	< 2 ppm
Assay	KABS-1348-LC-V03	Alert limit: 95.0 – 105.0 % (47.5 – 52.5 mg/mL) Action limit: 85.0 – 115.0 % (42.5 – 57.5 mg/mL)	97.9 % LC[1] (49.0 mg/mL)
Aluminum Content[2]	USP 38 <206>	NMT 5000 ppb	48 ppb

Reviewed By
MA 10-28-15

[1] *Label Claim: 50 mg/mL*
[2] *Analyses outsourced to Metrics Inc., Greenville, NC, USA*

2015/Oct/27
Verified by: Ning-Min Zhang, B.Sc.
Analyst, Quality Assurance

2015/10/27
Approved by: Karim Mtalsi, Ph.D., Chemist
Director, R & D Department

(450) 656-4404 / kabs@kabs.com
4500, de Tonnancour, St-Hubert (Québec) Canada J3Y 9G2
www.kabs.com

KABS
PHARMACEUTICAL SERVICES

CERTIFICATE OF ANALYSIS

For: **ALLERGY LABORATORIES INC.**

Certificate No: 126844

Purchase Order No:	20151013	Sample Code:	N. App.
Issuing Date:	2015/Oct/27	Sample Lot No.:	**2100215**

Product: **50 mL L-Cysteine HCl Injection, USP (50 mg/mL)**

Test	Methods	Specifications	Results
Appearance of Product	Visual	Clear colorless solution free from visible particulate matter	Clear colorless solution free from visible particulate matter
Appearance of Container/Closure	Visual	No apparent leakage or physical alteration	No apparent leakage or physical alteration
Identification A	USP 38	A bluish-gray precipitate is formed	A bluish-gray precipitate is formed
Identification B	USP 38	A red-purple color is produced, and it rapidly changes to yellow	A red-purple color is produced, and it rapidly changes to yellow
pH	USP 38 <791>	1.0 – 2.5	1.3
Heavy Metals	USP 38 <231> *Method II*	NMT 2 ppm	< 2 ppm
Assay	KABS-1348-LC-V03	Alert limit: 95.0 – 105.0 % (47.5 – 52.5 mg/mL) Action limit: 85.0 – 115.0 % (42.5 – 57.5 mg/mL)	97.3 % LC[1] (48.6 mg/mL)
Aluminum Content[2]	USP 38 <206>	NMT 5000 ppb	< 43 ppb

Reviewed By
MA 10-28-15

[1] *Label Claim: 50 mg/mL*
[2] *Analyses outsourced to Metrics Inc., Greenville, NC, USA*

Verified by: Ning-Min Zhang, B.Sc.
Analyst, Quality Assurance

Approved by: Karim Mtalsi, Ph.D., Chemist
Director, R & D Department

(450) 656-4404 / kabs@kabs.com
4500, de Tonnancour, St-Hubert (Québec) Canada J3Y 9G2
www.kabs.com

Exhibit C

Allergy Laboratories, Inc.

Certificate of Analysis

Product: **L-Cysteine HCl Injection, USP (50mg/mL)** Manufactured for Sandoz

Volume: **10 mL**

Lot number: 2012114

Vial size: 10ml-22-13mm Manufacture date: 01/21/2014 Expiration Date: 01 - 2016

Quality Release Testing			
Test / Parameter	**Method**	**Specifications**	**Results**
Sterility	USP<71> or TEM-3003	Sterile (no microbial growth)	Meets Specification
Bacterial Endotoxins	USP<85> or TEM-3001	NMT 0.7 EU/mg L-Cysteine HCl	Meets Specification
Appearance of Product	Visual or TEM-2005	Clear, colorless solution free from particulate matter	Meets Specification
Appearance of Container / Closure	Visual or TEM-2005	No apparent leakage or physical alteration	Meets Specification
Identification A	USP or TEM-2005	A bluish-gray precipitate is formed	Meets Specification
Identification B	USP or TEM-2005	A red-purple color is produced and it rapidly changes to yellow	Meets Specification
pH	USP<791> or TEM-1000	1.0 - 2.5	1.3
Heavy Metals	USP<231>Method II or TEM-2003	NMT 2 ppm	Meets Specification
Fill Volume	USP<1> or TEM-2000	To deliver NLT 10.0 mL	Meets Specification
Particulate Matter	USP<788> or TEM-2035	NMT 6000 particles (≥10µm)/vial NMT 600 particles (≥25µm)/vial	60.0 particles ≥10µm/vial 2.0 particles ≥25µm/vial
Assay	USP, KABS-1348-LC, ARL-AM121 or TEM-2011	Alert limit: 95.0 - 105.0% (47.5 – 52.5mg/mL) Action limit: 85.0 - 115.0% (42.5 – 57.5mg/mL)	102.3 %
Aluminum Content	USP	NMT 5000 ppb	61 ppb

This product has been manufactured in accordance with the principles and guidelines of CFR Parts 210 and 211 Current Good Manufacturing Practices and in accordance with the Finished Product Specifications of Allergy Laboratories, Inc. All deviations and out of specifications, if any, have been investigated and closed. This lot is acceptable for release.

Release Date	02/13/2014	**Release Quantity**	36,800

Quality Assurance Approval

By / Date MCoto 02-14-14

Original Certificate

1005 S.W. Second Street
Oklahoma City, OK 73109

Tel: (800)654-3971
Fax: (800)811-3389

www.AllergyLabs.com
TLM021314TLM

Allergy Laboratories, Inc.

Certificate of Analysis

Product: **L-Cysteine HCl Injection, USP (50mg/mL)** Manufactured for Sandoz

Volume: **10 mL**

Lot number: 2012214

Vial size: 10ml-22-13mm Manufacture date: 01/22/2014 Expiration Date: 01 - 2016

Quality Release Testing			
Test / Parameter	**Method**	**Specifications**	**Results**
Sterility	USP<71> or TEM-3003	Sterile (no microbial growth)	Meets Specification
Bacterial Endotoxins	USP<85> or TEM-3001	NMT 0.7 EU/mg L-Cysteine HCl	Meets Specification
Appearance of Product	Visual or TEM-2005	Clear, colorless solution free from particulate matter	Meets Specification
Appearance of Container / Closure	Visual or TEM-2005	No apparent leakage or physical alteration	Meets Specification
Identification A	USP or TEM-2005	A bluish-gray precipitate is formed	Meets Specification
Identification B	USP or TEM-2005	A red-purple color is produced and it rapidly changes to yellow	Meets Specification
pH	USP<791> or TEM-1000	1.0 - 2.5	1.3
Heavy Metals	USP<231>Method II or TEM-2003	NMT 2 ppm	Meets Specification
Fill Volume	USP<1> or TEM-2000	To deliver NLT 10.0 mL	Meets Specification
Particulate Matter	USP<788> or TEM-2035	NMT 6000 particles (≥10µm)/vial NMT 600 particles (≥25µm)/vial	48.0 particles ≥10µm/vial 1.3 particles ≥25µm/vial
Assay	USP, KABS-1348-LC, ARL-AM121 or TEM-2011	Alert limit: 95.0 - 105.0% (47.5 – 52.5mg/mL) Action limit: 85.0 - 115.0% (42.5 – 57.5mg/mL)	98.8 %
Aluminum Content	USP	NMT 5000 ppb	37 ppb

This product has been manufactured in accordance with the principles and guidelines of CFR Parts 210 and 211 Current Good Manufacturing Practices and in accordance with the Finished Product Specifications of Allergy Laboratories, Inc. All deviations and out of specifications, if any, have been investigated and closed. This lot is acceptable for release.

Release Date	02/13/2014	**Release Quantity**	37,300

Quality Assurance Approval

By / Date MC 02-14-14

Original Certificate

1005 S.W. Second Street
Oklahoma City, OK 73109

Tel: (800)654-3971
Fax: (800)811-3389

www.AllergyLabs.com
TLM021314TLM

Allergy Laboratories, Inc.

Certificate of Analysis

Product: **L-Cysteine HCl Injection, USP (50mg/mL)** Manufactured for Sandoz

Volume: **50 mL**

Lot number: 2072115

Vial size: 50ml-20mm Manufacture date: 07/21/2015 Expiration Date: 07 - 2017

Quality Release Testing			
Test / Parameter	**Method**	**Specifications**	**Results**
Sterility	USP<71> or TEM-3003	Sterile (no microbial growth)	Meets Specification
Bacterial Endotoxins	USP<85> or TEM-3001	NMT 0.7 EU/mg L-Cysteine HCl	Meets Specification
Appearance of Product	Visual or TEM-2005	Clear, colorless solution free from particulate matter	Meets Specification
Appearance of Container / Closure	Visual or TEM-2005	No apparent leakage or physical alteration	Meets Specification
Identification A	USP or TEM-2005	A bluish-gray precipitate is formed	Meets Specification
Identification B	USP or TEM-2005	A red-purple color is produced and it rapidly changes to yellow	Meets Specification
pH	USP<791> or TEM-1000	1.0 - 2.5	1.3
Heavy Metals	USP<231>Method II or TEM-2003	NMT 2 ppm	Meets Specification
Fill Volume	USP<1> or TEM-2000	To deliver NLT 50.0 mL	Meets Specification
Particulate Matter	USP<788> or TEM-2035	NMT 6000 particles (≥10µm)/vial NMT 600 particles (≥25µm)/vial	190.0 particles ≥10µm/vial 10.0 particles ≥25µm/vial
Assay	USP, KABS-1348-LC, ARL-AM121 or TEM-2011	Alert limit: 95.0 - 105.0% (47.5 – 52.5mg/mL) Action limit: 85.0 - 115.0% (42.5 – 57.5mg/mL)	98.7 %
Aluminum Content	USP	NMT 5000 ppb	17 ppb

This product has been manufactured in accordance with the principles and guidelines of CFR Parts 210 and 211 Current Good Manufacturing Practices and in accordance with the Finished Product Specifications of Allergy Laboratories, Inc. All deviations and out of specifications, if any, have been investigated and closed. This lot is acceptable for release.

Release Date	08/17/2015	**Release Quantity**	13,200

Quality Assurance Approval

By / Date Heidi Wilson 08-17-15

Original Certificate

1005 S.W. Second Street
Oklahoma City, OK 73109

Tel: (800)654-3971
Fax: (800)811-3389

www.AllergyLabs.com
TLM081715TLM

Allergy Laboratories, Inc.

Certificate of Analysis

Product: **L-Cysteine HCl Injection, USP (50mg/mL)** Manufactured for Sandoz

Volume: **50 mL**

Lot number: 2072215

Vial size: 50ml-20mm Manufacture date: 07/22/2015 Expiration Date: 07 - 2017

Quality Release Testing			
Test / Parameter	**Method**	**Specifications**	**Results**
Sterility	USP<71> or TEM-3003	Sterile (no microbial growth)	Meets Specification
Bacterial Endotoxins	USP<85> or TEM-3001	NMT 0.7 EU/mg L-Cysteine HCl	Meets Specification
Appearance of Product	Visual or TEM-2005	Clear, colorless solution free from particulate matter	Meets Specification
Appearance of Container / Closure	Visual or TEM-2005	No apparent leakage or physical alteration	Meets Specification
Identification A	USP or TEM-2005	A bluish-gray precipitate is formed	Meets Specification
Identification B	USP or TEM-2005	A red-purple color is produced and it rapidly changes to yellow	Meets Specification
pH	USP<791> or TEM-1000	1.0 - 2.5	1.3
Heavy Metals	USP<231>Method II or TEM-2003	NMT 2 ppm	Meets Specification
Fill Volume	USP<1> or TEM-2000	To deliver NLT 50.0 mL	Meets Specification
Particulate Matter	USP<788> or TEM-2035	NMT 6000 particles (≥10µm)/vial NMT 600 particles (≥25µm)/vial	173.3 particles ≥10µm/vial 16.7 particles ≥25µm/vial
Assay	USP, KABS-1348-LC, ARL-AM121 or TEM-2011	Alert limit: 95.0 - 105.0% (47.5 – 52.5mg/mL) Action limit: 85.0 - 115.0% (42.5 – 57.5mg/mL)	98.5 %
Aluminum Content	USP	NMT 5000 ppb	18 ppb

This product has been manufactured in accordance with the principles and guidelines of CFR Parts 210 and 211 Current Good Manufacturing Practices and in accordance with the Finished Product Specifications of Allergy Laboratories, Inc. All deviations and out of specifications, if any, have been investigated and closed. This lot is acceptable for release.

Release Date	08/17/2015	**Release Quantity**	13,225

Quality Assurance Approval
By / Date Heidi Wilson 08-27-15

Original Certificate

1005 S.W. Second Street
Oklahoma City, OK 73109

Tel: (800)654-3971
Fax: (800)811-3389

www.AllergyLabs.com
TLM081715TLM

Allergy Laboratories, Inc.

Certificate of Analysis

Product: **L-Cysteine HCl Injection, USP (50mg/mL)** Manufactured for Sandoz

Volume: **10 mL**

Lot number: 2081915

Vial size: 10ml-22-13mm Manufacture date: 08/19/2015 Expiration Date: 08 - 2017

Quality Release Testing			
Test / Parameter	**Method**	**Specifications**	**Results**
Sterility	USP<71> or TEM-3003	Sterile (no microbial growth)	Meets Specification
Bacterial Endotoxins	USP<85> or TEM-3001	NMT 0.7 EU/mg L-Cysteine HCl	Meets Specification
Appearance of Product	Visual or TEM-2005	Clear, colorless solution free from particulate matter	Meets Specification
Appearance of Container / Closure	Visual or TEM-2005	No apparent leakage or physical alteration	Meets Specification
Identification A	USP or TEM-2005	A bluish-gray precipitate is formed	Meets Specification
Identification B	USP or TEM-2005	A red-purple color is produced and it rapidly changes to yellow	Meets Specification
pH	USP<791> or TEM-1000	1.0 - 2.5	1.3
Heavy Metals	USP<231>Method II or TEM-2003	NMT 2 ppm	Meets Specification
Fill Volume	USP<1> or TEM-2000	To deliver NLT 10.0 mL	Meets Specification
Particulate Matter	USP<788> or TEM-2035	NMT 6000 particles (≥10µm)/vial NMT 600 particles (≥25µm)/vial	148.0 particles ≥10µm/vial 2.7 particles ≥25µm/vial
Assay	USP, KABS-1348-LC, ARL-AM121 or TEM-2011	Alert limit: 95.0 - 105.0% (47.5 – 52.5mg/mL) Action limit: 85.0 - 115.0% (42.5 – 57.5mg/mL)	96.4 %
Aluminum Content	USP	NMT 5000 ppb	50 ppb

This product has been manufactured in accordance with the principles and guidelines of CFR Parts 210 and 211 Current Good Manufacturing Practices and in accordance with the Finished Product Specifications of Allergy Laboratories, Inc. All deviations and out of specifications, if any, have been investigated and closed. This lot is acceptable for release.

Release Date	09/22/2015	**Release Quantity**	36,760

Quality Assurance Approval
By / Date Heidi Wilson 09-23-15

Original Certificate

1005 S.W. Second Street
Oklahoma City, OK 73109

Tel: (800)654-3971
Fax: (800)811-3389

www.AllergyLabs.com
TLM092315TLM

Allergy Laboratories, Inc.

Certificate of Analysis

Product: **L-Cysteine HCl Injection, USP (50mg/mL)** Manufactured for Sandoz

Volume: **10 mL**

Lot number: 2082015

Vial size: 10ml-22-13mm Manufacture date: 08/20/2015 Expiration Date: 08 - 2017

Quality Release Testing			
Test / Parameter	**Method**	**Specifications**	**Results**
Sterility	USP<71> or TEM-3003	Sterile (no microbial growth)	Meets Specification
Bacterial Endotoxins	USP<85> or TEM-3001	NMT 0.7 EU/mg L-Cysteine HCl	Meets Specification
Appearance of Product	Visual or TEM-2005	Clear, colorless solution free from particulate matter	Meets Specification
Appearance of Container / Closure	Visual or TEM-2005	No apparent leakage or physical alteration	Meets Specification
Identification A	USP or TEM-2005	A bluish-gray precipitate is formed	Meets Specification
Identification B	USP or TEM-2005	A red-purple color is produced and it rapidly changes to yellow	Meets Specification
pH	USP<791> or TEM-1000	1.0 - 2.5	1.3
Heavy Metals	USP<231>Method II or TEM-2003	NMT 2 ppm	Meets Specification
Fill Volume	USP<1> or TEM-2000	To deliver NLT 10.0 mL	Meets Specification
Particulate Matter	USP<788> or TEM-2035	NMT 6000 particles (≥10µm)/vial NMT 600 particles (≥25µm)/vial	68.0 particles ≥10µm/vial 0.7 particles ≥25µm/vial
Assay	USP, KABS-1348-LC, ARL-AM121 or TEM-2011	Alert limit: 95.0 - 105.0% (47.5 – 52.5mg/mL) Action limit: 85.0 - 115.0% (42.5 – 57.5mg/mL)	96.4 %
Aluminum Content	USP	NMT 5000 ppb	54 ppb

This product has been manufactured in accordance with the principles and guidelines of CFR Parts 210 and 211 Current Good Manufacturing Practices and in accordance with the Finished Product Specifications of Allergy Laboratories, Inc. All deviations and out of specifications, if any, have been investigated and closed. This lot is acceptable for release.

Release Date	09/22/2015	**Release Quantity**	36,790

Quality Assurance Approval
By / Date Heidi Wilson 09-23-15

Original Certificate

1005 S.W. Second Street
Oklahoma City, OK 73109

Tel: (800)654-3971
Fax: (800)811-3389

www.AllergyLabs.com
TLM092315TLM

Allergy Laboratories, Inc.

Certificate of Analysis

Product: **L-Cysteine HCl Injection, USP (50mg/mL)** Manufactured for Sandoz

Volume: **10 mL**

Lot number: 2082115

Vial size: 10ml-22-13mm Manufacture date: 08/21/2015 Expiration Date: 08 - 2017

Quality Release Testing			
Test / Parameter	**Method**	**Specifications**	**Results**
Sterility	USP<71> or TEM-3003	Sterile (no microbial growth)	Meets Specification
Bacterial Endotoxins	USP<85> or TEM-3001	NMT 0.7 EU/mg L-Cysteine HCl	Meets Specification
Appearance of Product	Visual or TEM-2005	Clear, colorless solution free from particulate matter	Meets Specification
Appearance of Container / Closure	Visual or TEM-2005	No apparent leakage or physical alteration	Meets Specification
Identification A	USP or TEM-2005	A bluish-gray precipitate is formed	Meets Specification
Identification B	USP or TEM-2005	A red-purple color is produced and it rapidly changes to yellow	Meets Specification
pH	USP<791> or TEM-1000	1.0 - 2.5	1.3
Heavy Metals	USP<231>Method II or TEM-2003	NMT 2 ppm	Meets Specification
Fill Volume	USP<1> or TEM-2000	To deliver NLT 10.0 mL	Meets Specification
Particulate Matter	USP<788> or TEM-2035	NMT 6000 particles (≥10µm)/vial NMT 600 particles (≥25µm)/vial	69.0 particles ≥10µm/vial 2.0 particles ≥25µm/vial
Assay	USP, KABS-1348-LC, ARL-AM121 or TEM-2011	Alert limit: 95.0 - 105.0% (47.5 – 52.5mg/mL) Action limit: 85.0 - 115.0% (42.5 – 57.5mg/mL)	96.2 %
Aluminum Content	USP	NMT 5000 ppb	46 ppb

This product has been manufactured in accordance with the principles and guidelines of CFR Parts 210 and 211 Current Good Manufacturing Practices and in accordance with the Finished Product Specifications of Allergy Laboratories, Inc. All deviations and out of specifications, if any, have been investigated and closed. This lot is acceptable for release.

Release Date	09/22/2015	**Release Quantity**	36,520

Quality Assurance Approval

By / Date Heidi Wilson 09-23-15

Original Certificate

1005 S.W. Second Street
Oklahoma City, OK 73109

Tel: (800)654-3971
Fax: (800)811-3389

www.AllergyLabs.com
TLM092315TLM

Allergy Laboratories, Inc.

Certificate of Analysis

Product: **L-Cysteine HCl Injection, USP (50mg/mL)** Manufactured for Sandoz

Volume: **50 mL**

Lot number: 2093015

Vial size: 50ml-20mm Manufacture date: 09/30/2015 Expiration Date: 09 - 2017

Quality Release Testing			
Test / Parameter	**Method**	**Specifications**	**Results**
Sterility	USP<71> or TEM-3003	Sterile (no microbial growth)	Meets Specification
Bacterial Endotoxins	USP<85> or TEM-3001	NMT 0.7 EU/mg L-Cysteine HCl	Meets Specification
Appearance of Product	Visual or TEM-2005	Clear, colorless solution free from particulate matter	Meets Specification
Appearance of Container / Closure	Visual or TEM-2005	No apparent leakage or physical alteration	Meets Specification
Identification A	USP or TEM-2005	A bluish-gray precipitate is formed	Meets Specification
Identification B	USP or TEM-2005	A red-purple color is produced and it rapidly changes to yellow	Meets Specification
pH	USP<791> or TEM-1000	1.0 - 2.5	1.3
Heavy Metals	USP<231>Method II or TEM-2003	NMT 2 ppm	Meets Specification
Fill Volume	USP<1> or TEM-2000	To deliver NLT 50.0 mL	Meets Specification
Particulate Matter	USP<788> or TEM-2035	NMT 6000 particles (≥10µm)/vial NMT 600 particles (≥25µm)/vial	103.3 particles ≥10µm/vial 3.3 particles ≥25µm/vial
Assay	USP, KABS-1348-LC, ARL-AM121 or TEM-2011	Alert limit: 95.0 - 105.0% (47.5 – 52.5mg/mL) Action limit: 85.0 - 115.0% (42.5 – 57.5mg/mL)	97.1 %
Aluminum Content	USP	NMT 5000 ppb	47 ppb

This product has been manufactured in accordance with the principles and guidelines of CFR Parts 210 and 211 Current Good Manufacturing Practices and in accordance with the Finished Product Specifications of Allergy Laboratories, Inc. All deviations and out of specifications, if any, have been investigated and closed. This lot is acceptable for release.

Release Date	11/12/2015	**Release Quantity**	13,097

Quality Assurance Approval
By / Date Wendy Trumbull 11-16-15

Original Certificate

1005 S.W. Second Street
Oklahoma City, OK 73109

Tel: (800)654-3971
Fax: (800)811-3389

www.AllergyLabs.com
TLM111615TLM

Allergy Laboratories, Inc.

Certificate of Analysis

Product: **L-Cysteine HCl Injection, USP (50mg/mL)** Manufactured for Sandoz

Volume: **50 mL**

Lot number: 2100115

Vial size: 50ml-20mm Manufacture date: 10/01/2015 Expiration Date: 10 - 2017

Quality Release Testing			
Test / Parameter	**Method**	**Specifications**	**Results**
Sterility	USP<71> or TEM-3003	Sterile (no microbial growth)	Meets Specification
Bacterial Endotoxins	USP<85> or TEM-3001	NMT 0.7 EU/mg L-Cysteine HCl	Meets Specification
Appearance of Product	Visual or TEM-2005	Clear, colorless solution free from particulate matter	Meets Specification
Appearance of Container / Closure	Visual or TEM-2005	No apparent leakage or physical alteration	Meets Specification
Identification A	USP or TEM-2005	A bluish-gray precipitate is formed	Meets Specification
Identification B	USP or TEM-2005	A red-purple color is produced and it rapidly changes to yellow	Meets Specification
pH	USP<791> or TEM-1000	1.0 - 2.5	1.3
Heavy Metals	USP<231>Method II or TEM-2003	NMT 2 ppm	Meets Specification
Fill Volume	USP<1> or TEM-2000	To deliver NLT 50.0 mL	Meets Specification
Particulate Matter	USP<788> or TEM-2035	NMT 6000 particles (≥10µm)/vial NMT 600 particles (≥25µm)/vial	200.0 particles ≥10µm/vial 3.3 particles ≥25µm/vial
Assay	USP, KABS-1348-LC, ARL-AM121 or TEM-2011	Alert limit: 95.0 - 105.0% (47.5 – 52.5mg/mL) Action limit: 85.0 - 115.0% (42.5 – 57.5mg/mL)	97.9 %
Aluminum Content	USP	NMT 5000 ppb	48 ppb

This product has been manufactured in accordance with the principles and guidelines of CFR Parts 210 and 211 Current Good Manufacturing Practices and in accordance with the Finished Product Specifications of Allergy Laboratories, Inc. All deviations and out of specifications, if any, have been investigated and closed. This lot is acceptable for release.

Release Date	02/08/2016	**Release Quantity**	13,000

Quality Assurance Approval
By / Date Heidi Wilson 02-08-16

Original Certificate

1005 S.W. Second Street
Oklahoma City, OK 73109

Tel: (800)654-3971
Fax: (800)811-3389

www.AllergyLabs.com
TLM020816TLM

Allergy Laboratories, Inc.

Certificate of Analysis

Product: **L-Cysteine HCl Injection, USP (50mg/mL)** Manufactured for Sandoz

Volume: **50 mL**

Lot number: 2100215

Vial size: 50ml-20mm Manufacture date: 10/02/2015 Expiration Date: 10 - 2017

Quality Release Testing			
Test / Parameter	**Method**	**Specifications**	**Results**
Sterility	USP<71> or TEM-3003	Sterile (no microbial growth)	Meets Specification
Bacterial Endotoxins	USP<85> or TEM-3001	NMT 0.7 EU/mg L-Cysteine HCl	Meets Specification
Appearance of Product	Visual or TEM-2005	Clear, colorless solution free from particulate matter	Meets Specification
Appearance of Container / Closure	Visual or TEM-2005	No apparent leakage or physical alteration	Meets Specification
Identification A	USP or TEM-2005	A bluish-gray precipitate is formed	Meets Specification
Identification B	USP or TEM-2005	A red-purple color is produced and it rapidly changes to yellow	Meets Specification
pH	USP<791> or TEM-1000	1.0 - 2.5	1.3
Heavy Metals	USP<231>Method II or TEM-2003	NMT 2 ppm	Meets Specification
Fill Volume	USP<1> or TEM-2000	To deliver NLT 50.0 mL	Meets Specification
Particulate Matter	USP<788> or TEM-2035	NMT 6000 particles (≥10µm)/vial NMT 600 particles (≥25µm)/vial	126.7 particles ≥10µm/vial 0.0 particles ≥25µm/vial
Assay	USP, KABS-1348-LC, ARL-AM121 or TEM-2011	Alert limit: 95.0 - 105.0% (47.5 – 52.5mg/mL) Action limit: 85.0 - 115.0% (42.5 – 57.5mg/mL)	97.3 %
Aluminum Content	USP	NMT 5000 ppb	43 ppb

This product has been manufactured in accordance with the principles and guidelines of CFR Parts 210 and 211 Current Good Manufacturing Practices and in accordance with the Finished Product Specifications of Allergy Laboratories, Inc. All deviations and out of specifications, if any, have been investigated and closed. This lot is acceptable for release.

Release Date	11/12/2015	**Release Quantity**	13,000

Quality Assurance Approval
By / Date (W) Wendy Arendt 11-16-15

Original Certificate

1005 S.W. Second Street
Oklahoma City, OK 73109

Tel: (800)654-3971
Fax: (800)811-3389

www.AllergyLabs.com
TLM111615TLM

Exhibit D

From: Covert, Evangela [mailto:Evangela.Covert@fda.hhs.gov]
Sent: Friday, March 9, 2018 3:35 PM
To: Gold, Lynn <LGold@camargopharma.com>
Subject: NDA 209649: 5% L-Cysteine Hydrochloride Injection, USP: Information Request

Hello Dr. Gold: Information Request

Please see the FDA comments below:

CMC

Based on our preliminary review of your NDA submission, we have identified several deficiencies. The deficiencies outlined below should be addressed in order for the application to be considered complete.

1. You have not submitted the release and stability data for the primary/registration batches of the drug product manufactured at the proposed commercial manufacturing facility, Grand River Aseptic manufacturing (GRAM), Grand Rapids, MI. If this NDA is given a priority review status, a minimum of 9 months long-term and 6 months accelerated stability data from three primary stability batches of drug product manufactured at the proposed commercial manufacturing facility must be provided at time of submission of the NDA with additional 3 months of long-term stability (total 12 months of long-term) to be submitted within 60 days from the filing of the application.
2. You have not provided data for elemental impurities of the drug product as per ICH guidance Q3D for parenteral products.
3. The drug product L-Cycteine Hydrochloride Injection is a small volume parenteral drug product used in TPN. Based on our previous experience with small volume parenteral drug products intended for addition to the TPN, we have determined that the aluminum dose delivered by your drug product, 5% L-Cysteine Hydrochloride Injection, USP, should be limited to $\leq$ 0.6 mcg/kg/day. To comply with this limit, the aluminum content in the final drug product should be controlled to $\leq$ 350 mcg/L. This is calculated based on the clinical dose of 15 mg cysteine free base per gram of amino acid per day. Therefore, the proposed acceptance limit for the aluminum content in the finished drug product specification (3.2.P.5.1) must be revised to $\leq$ 350mcg/L. The drug product registration batches manufactured at OKC Allergy Supplies, Oklahoma City, OK have not been shown to meet the required acceptance limit for aluminum content.
4. We remind you that due to low pH of the drug product, full assessment of the proposed container closure leachables/extractables (E&L) must be performed. The data should be accompanied with appropriate toxicological evaluations of the detected leachable compounds. Container closure integrity must also be established during accelerated and long-term stability to ensure that it is capable of protecting the drug product from its

external environment and maintaining the drug product sterility throughout the proposed product shelf-life.

5. We acknowledge that you have conducted the stability study of the admixture solution (CPS 2016-0001). We remind you that testing for Particulate Matter must be performed as per USP <788> in the final mixture of Cysteine Hydrochloride Injection and Amino Acid Solutions. Additionally, provide in-use stability data that supports the 24-hour duration of the administration at room temperature.
6. The established name of the drug product is Cysteine Hydrochloride Injection based upon the USP monograph; therefore, the strength in the labelling (Package Insert, Carton and Container Labels) should be expressed as Cysteine Hydrochloride Salt with an equivalency statement to indicate the amount of the free base Cysteine per USP salt policy. See the guidance on Naming of Drug Products Containing Salt Drug Substances: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM379753.pdf

7. In future communications, please refer to the product as cysteine hydrochloride and any discussion of the strength or dosing should be in terms of the hydrochloride salt. However, we acknowledge that the label for the approved Hospira product (NDA 19523), the dosing information appears to be based upon cysteine, not cysteine hydrochloride. Also, the published literature predominately discusses dosing based upon cysteine. Therefore, in your communications and submission you may wish to include equivalency statements to ensure there is no misunderstanding of the dose.
8. It is noted that the registration batches were manufactured at the OKC site but the proposed commercial manufacturing facility is the GRAM site. We recommend that you provide the side-by-side comparison of the registration batches of the proposed drug product (5% L-Cysteine Hydrochloride Injection, USP) manufactured at both the OKC and GRAM sites (e.g., description, composition, formulation, pH, osmolality, drug concentration, etc.). Provide justification/assurance that when comparing to the LD product, your proposed final drug product would demonstrate comparable pH, osmolality, and final cysteine concentration in admixtures with amino acids prior to IV administration towards similar *in vivo* pharmacokinetic performance and clinical outcomes.

Clinical

Our thinking on the approach to this type of NDA submission, which is primarily based on literature, has evolved and additional feedback is provided below on the recommended content of the submission. The data presented in your submission should allow the reviewer(s) to understand all the relevant aspects of the publications, sufficient to permit an understanding of the study results/conclusions without rereading the entire publication.

9. Based on our preliminary review of the published clinical information provided in the submission, we are concerned that the information, as presented, does not provide persuasive evidence to support safety and efficacy in the intended patient population. We are not convinced the plasma levels of cysteine reflect a clinically meaningful outcome. Therefore, you should provide rationale to support that cysteine supplementation is necessary to add into TPN for each of the intended patient populations. You should provide evidence to support that the proposed dose of cysteine is necessary to meet age-appropriate requirements/recommendations for protein intake. Additionally, consider including the following:
    a. Studies that included short and long-term efficacy analysis such as assessments of growth, and prevention of complications associated with reduction of glutathione (i.e., risk of death, bronchopulmonary dysplasia (BPD), retinopathy of pre-maturity (ROP), necrotizing enterocolitis (NEC), periventricular leukomalacia, and intraventricular hemorrhage).

    b. Nitrogen balance and or turn over studies.

    c. Studies that evaluated the integration steps in assimilation of cysteine in to the final product (i.e. AA/protein).

    d. Provide summary of supportive evidence from literature/clinical studies for the normal/optimal blood amino acid (AA) levels that should be achieved in all age groups.

10. Briefly (in a few paragraphs) summarize the prevailing rationale for adding cysteine to standard parenteral nutrition formulations.
    a. Include the best available evidence to support that cysteine is essential using information based on animals and humans, the mechanism of action, etc. A claim stating that cysteine is essential in premature infants and other specific patient populations must be supported by studies which substantiate this claim. The literature submitted to date does not clearly support all patient populations represented in the proposed indication.
    b. It is anticipated that some of this information may come from textbooks (and constitute general medical knowledge); therefore, it does not need to be extensively written/supported.
    c. This information can be used to write Section 12.1 Mechanism of Action of the label.

11. Summarize the evidence to support the proposed <u>dosing</u> for cysteine in parenteral nutrition. As part of the summary, describe the quality of the efficacy data, strengths and

weaknesses, how persuasive, what are the limitations? What are the uncertainties in the available evidence to support the proposed dosing regimen?

a. Provide separate tables for each age group.
b. Include details on the specific ages studied for each cited publication.
c. Include mention of whether patients were receiving TPN only, TPN plus oral feeds, or TPN with other types of supplementation.
d. Summarize the current clinical practice guidelines, including but not limited to ASPEN/ESPGHAN, dosing recommendations in adults/pediatrics for cysteine relation to the proposed dosing.
    i. In a paragraph or two summarize the rationale and basis for the current ASPEN (2015) and ESPGHAN recommendations supported by primary literature references.

    ii. Discuss any changes to the ASPEN and ESPGHAN recommendations over time and include the primary literature references to support the more recent changes in the recommendations.

    iii. If societal guidelines are available, other than ASPEN and ESPGHAN, provide a discussion on any points of uncertainty or controversy between the guidelines with regards to best practices.

12. Identify clinical conditions, medical settings, or population subgroups that may require higher or lower doses of cysteine for parenteral nutrition.
    a. Briefly summarize what is known about the cysteine in Renal Impairment, Hepatic Impairment, Geriatric Use, and Pregnancy.

13. Provide a summary of publications related to the <u>efficacy</u> of cysteine. Each table should be based on the efficacy outcome studied [i.e., prevention of deficiency (prophylaxis/maintenance), development of deficiency with suboptimal supplementation, or deficiency that responded to supplementation (treatment)]. The tables should include information on the following:
    a. Study design.
    b. Patient population.
    c. Specify whether cysteine administration was for prevention of deficiency, maintenance, development of deficiency with suboptimal supplementation, or deficiency that responded to supplementation.
    d. Duration of the study.
    e. Daily and total cysteine dose received.
    f. Primary and secondary efficacy criteria: include clinical, laboratory and/or radiological outcomes.
    g. Short and long-term assessment and benefit(s).

h. Whether efficacy criteria were met to support the cysteine dose.

A shell table, as shown below, may be considered as a template to create tables. Additional columns may be added to convey the complete information.

Example: Summary of Publications of Cysteine – According to Efficacy Outcome Reported

Author/Year of Pub/reference #	*Study design*[1]	*Study population*[2]	*Dose(s)* *Duration of treatment* *Other co-administered amino acids, electrolytes and trace elements*	*Reason for cysteine supplementation*	*Efficacy Outcome* *Include descriptive and/or quantitative information for any of the outcomes provided* *Specify clinical, laboratory*[3] *and/or radiological outcomes*	*Comments*[4]

[1]Study design to include design (RCT or other), number of patients on treatment, number on placebo (if applicable), primary disease.

[2]Study population to include demographics (age [mean ± SD], race, gender, country) and baseline characteristics (other comorbidities, pregnancy/lactation, renal impairment, hepatic impairment, elderly, etc). Number of patients who discontinued.

[3]Laboratory includes both standard chemistries measured during and at the end of study.

[4]The Comments column is a free text column to capture any other relevant information included in the publication.

14. Provide a summary of efficacy (maximum 3-5 pages). Integrate the data in the efficacy tables with the other available evidence to summarize the efficacy, considering the totality of the evidence. Describe the quality of the efficacy data, strengths and weaknesses, persuasiveness of the findings, and limitations of the studies.

15. Provide a summary of publications related to the safety of cysteine, using a similar format to the shell efficacy table.
    a. Provide separate tables for each age group.
    b. Describe toxicities or adverse events associated with cysteine when used for parenteral nutrition.
    c. Include any available evidence from the literature.

Example: Summary of Publications of Cysteine – According to Safety or Toxicity Outcome Reported

Author/Year of Pub/reference #	*Study design*[1]	*Study population*[2]	*Dose(s)* *Duration of treatment* *Reason for cysteine supplementation* *Other co-administered amino acids, electrolytes and trace elements*	*Safety Outcome* *Include descriptive and/or quantitative information for any of the outcomes provided* *Specify clinical, laboratory*[3] *and/or radiological outcomes*	*Comments*[4]

[1] Study design to include design (RCT or other), number of patients on treatment, number on placebo (if applicable), primary disease.
[2] Study population to include demographics (age [mean ± SD], race, gender, country) and baseline characteristics (other comorbidities, pregnancy/lactation, renal impairment, hepatic impairment, elderly, etc). Number of patients who discontinued.
[3] Laboratory includes both standard chemistries measured during and at the end of study.
[4] The Comments column is a free text column to capture any other relevant information included in the publication.

16. Provide the summary of safety (maximum 3-5 pages). Integrate the data in the safety tables to describe the quality of the safety data, strengths and weaknesses, persuasiveness of the data, and any limitations. Discuss the uncertainties in the available evidence to support the proposed indication and dosing.
17. Provide a summary of the overall risk/benefit assessment using the available evidence and any uncertainties about the quality/strength of the evidence presented in the efficacy and safety tables and summaries. Provide rationale to support the addition of cysteine to TPN for each of the intended populations in the proposed label. You should also consider the risk of deficiency vs. toxicity for cysteine, and which one drives the overall assessment.

Kind Regards,

Evangela Covert, BS
Regulatory Health Project Manager
Division of Gastroenterology and Inborn Errors Products

Office of Drug Evaluation III
Office of New Drugs
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993 - *Use zip code **20903** if shipping via United States Postal Service (USPS)*
Bldg. 22, Room 5245
office: 301-796-4075
fax: 301-796-9904
Evangela.Covert@fda.hhs.gov

*****Secure Email*****

Secure email between CDER and sponsors is useful for informal communications when confidential information may be included in the message (for example, trade secrets or patient information). It is the only way FDA can communicate confidential information to you via email. If you have not already established secure email with the FDA and would like to set it up, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications (except for 7-day safety reports for INDs not in eCTD format).