CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204485Orig1s000

CHEMISTRY REVIEW(S)

Memorandum

NDA #	204-485 (Division of Cardiovascular and Renal Products)
Date:	18-Oct-2013, Resubmission
Product Name:	Vasostrict™ (vasopressin injection, USP)
Company Name:	Par Sterile Products, LLC
Subject:	Overall OC Recommendation Updated Drug Product Specification (Amendment 28-Mar-2014) Updated Labeling (Amendment 28-Mar-2014)

Overall Recommendation

Pursuant the overall **Acceptable OC Recommendation** issued on 04-Apr-2014 (refer to attachment to this Memo), the overall quality recommendation is for "approval".

Updated Drug Product Specification

The applicant has provided the following updated drug product specification.

Revised Release and Shelf Life Drug Product Specification

Test	Methods	Release Limits	Shelf Life Limits
Description	00215	A 3 mL vial containing a clear, colorless to practically colorless solution, essentially free of visible particulates	A 3 mL vial containing a clear, colorless to practically colorless solution, essentially free of visible particulates
pH	31636	2.5 – 4.5	2.5 – 4.5
Volume in Container	95204	NLT (b) (4)	Not Applicable
Identification (HPLC)	20545	Positive The UV spectrum of the peak in the sample matches the vasopressin peak in standard	Not Applicable
Chlorobutanol	20451	(b) (4)	
Assay (HPLC)	20545		
Degradation products (b) (4)	20545	NMT (b) (4) % NMT % NMT % NMT % NMT % NMT % NMT %	NMT (b) (4) % NMT % NMT % NMT % NMT % NMT % NMT %
Total Degradation Products		NMT (b) (4) %	NMT (b) (4) %
Particulate Matter (USP <788> Method 1)	07020	NMT (b) (4) µm NMT (b) (4) µm	NMT (b) (4) µm NMT (b) (4) µm
Bacterial Endotoxin	60570	NMT (b) (4)	NMT (b) (4)
Sterility	80200	Passes Test	Passes Test

Evaluation: Adequate. The firm has revised the limits for several test parameters in the shelf-life and release specifications to make both specifications identical except for the levels of Total Degradation Products that are different. In the release specification, revision of the pH and Assay acceptance criteria was made, and in the shelf-life specifications the revision of the acceptance criteria for Assay and for chlorobutanol was made. The limits for Assay comply with the USP requirements in both sets of the specifications. All revisions in the shelf-life and release specifications are acceptable.

Structured Product Labeling (SPL)

The applicant has provided the updated Product Data Elements (PDE) in the Structured Product Labeling (SPL) text.

Evaluation: Adequate.

Carton/Container Labels

The applicant has removed the word “synthetic” from the drug product container and carton labels, as requested. Acceptable.

Recommendation and Conclusion on Approvability

NDA 204-485 for Vasostrict™ (vasopressin injection, USP), 20 units /ml, is recommended for APPROVAL from a Chemistry, Manufacturing and Controls standpoint. The drug substance DMF (b) (4) remains adequate. Based on the drug product stability data, the 12-month expiration dating period is recommended for drug product stored in the proposed container/closure system at the recommended storage condition, between 15°C and 25°C (59°F and 77°F)”. The overall Acceptable OC recommendation for drug substance and drug product facilities is issued on 04-Apr-2014.

Attachment

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application:	NDA 204485/000	**Sponsor:**	PAR STERILE PRODUCTS
Org. Code:	110		1 UPPER POND RD BLDG D 3RD FL
Priority:	7		PARSIPPANY, NJ 07054
Stamp Date:	26-SEP-2012	**Brand Name:**	VASOSTRICT
PDUFA Date:	18-APR-2014	**Estab. Name:**	
Action Goal:		**Generic Name:**	VASOPRESSIN INJECTION
District Goal:	27-MAY-2013	**Product Number; Dosage Form; Ingredient; Strengths**	001; INJECTION; VASOPRESSIN; 20UNT/1ML

FDA Contacts:	L. SOLDATOVA	Prod Qual Reviewer		3017961758
	E. PFEILER	Micro Reviewer	(HF-22)	3017960642
	T. BOUIE	Product Quality PM		3017961649
	Q. NGUYEN	Regulatory Project Mgr	(HFD-110)	3017960510
	K. SRINIVASACHAR	Team Leader		3017961760

Overall Recommendation:	ACCEPTABLE	on 04-APR-2014	by R. SAFAAI-JAZI	()	3017964463
	PENDING	on 23-JAN-2014	by EES_PROD		
	PENDING	on 16-NOV-2013	by EES_PROD		
	PENDING	on 15-NOV-2013	by EES_PROD		
	ACCEPTABLE	on 08-JAN-2013	by EES_PROD		
	PENDING	on 26-DEC-2012	by EES_PROD		
	PENDING	on 26-DEC-2012	by EES_PROD		
	PENDING	on 23-OCT-2012	by EES_PROD		
	PENDING	on 23-OCT-2012	by EES_PROD		

Establishment: **CFN:** (b) (4) **FEI:** (b) (4)
(b) (4)
(b) (4)

DMF No: **AADA:**
Responsibilities: FINISHED DOSAGE RELEASE TESTER
Profile: CONTROL TESTING LABORATORY **OAI Status:** NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 24-OCT-2012
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

Establishment: **CFN:** **FEI:** (b) (4)
(b) (4)

DMF No: **AADA:**
Responsibilities: DRUG SUBSTANCE MANUFACTURER
Profile: NON-STERILE API BY CHEMICAL SYNTHESIS **OAI Status:** NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 27-DEC-2012
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

Attachment (Cont'd)

Establishment:	**CFN:** (b) (4)	**FEI:** (b) (4)	
	(b) (4)		
DMF No:		**AADA:**	
Responsibilities:	DRUG SUBSTANCE OTHER TESTER		
Profile:	CONTROL TESTING LABORATORY	**OAI Status:**	NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	29-OCT-2012		
Decision:	ACCEPTABLE		
Reason:	BASED ON PROFILE		

Establishment:	**CFN:** 1818977	**FEI:** 1818977	
	JHP PHARMACEUTICALS, LLC		
	ROCHESTER, , UNITED STATES 483071740		
DMF No:		**AADA:**	
Responsibilities:	DRUG SUBSTANCE RELEASE TESTER		
	FINISHED DOSAGE MANUFACTURER		
Profile:	CONTROL TESTING LABORATORY	**OAI Status:**	NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	24-OCT-2012		
Decision:	ACCEPTABLE		
Reason:	BASED ON PROFILE		
Profile:	(b) (4)	**OAI Status:**	NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	01-DEC-2013		
Decision:	ACCEPTABLE		
Reason:	DISTRICT RECOMMENDATION		

Establishment:	**CFN:**	**FEI:** (b) (4)	
	(D) (4)		
DMF No:		**AADA:**	
Responsibilities:	DRUG SUBSTANCE RELEASE TESTER		
Profile:	CONTROL TESTING LABORATORY	**OAI Status:**	NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	04-APR-2014		
Decision:	ACCEPTABLE		
Reason:	DISTRICT RECOMMENDATION		

Establishment:	**CFN:** (b) (4)	**FEI:** (b) (4)	
	(b) (4)		
DMF No:		**AADA:**	
Responsibilities:	DRUG SUBSTANCE OTHER TESTER		
Profile:	CONTROL TESTING LABORATORY	**OAI Status:**	NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	16-NOV-2013		
Decision:	ACCEPTABLE		
Reason:	BASED ON PROFILE		

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.