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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-372

Chemistry Review(s)

NDA 21-372

Aloxi (palonosetron HCl) Injection 25 mg/5 mL

CHEMISTRY DIVISION DIRECTOR REVIEW

Applicant: Helsinn Healthcare S.A.

Indication: Prevention of acute and delayed nausea and vomiting associated with initial and repeated courses of emetogenic cancer therapy

Presentation: 25 mg/5mL —

EER Status: Acceptable 14-JUL-2003

Consults: ODS – Tradename: Aloxi- acceptable 9-JAN-2003
Statistics – none
EA – no consult - waiver requested – granted

CMC Phase IV Commitments: none

The original NDA was received 26-SEP-2002

The **drug substance** is manufactured by:

Helsinn Advanced Synthesis
Biasca, SZ

DMF 16,063

The synthetic process is — from well characterized commercially available starting materials. The manufacturing process is well defined and in-process controls are adequate.

Structural characterization of the drug substance was satisfactory. Specifications were found acceptable. Impurities and degradation products were well studied and are adequately controlled. A re-test period of 12 months is supported by submitted stability data – the applicant had requested a — re-test period. The stability testing protocol is considered adequate.

Conclusion

Drug substance is acceptable.

The **drug product** is formulated as an aqueous solution with mannitol, buffering agents with pH adjustment _____ 25 mg/5 mL.

Manufacturer:

SP Pharmaceutical
Albuquerque, NM

The manufacturing method is a standard process for a parenteral product with _____ sterilization. The proposed regulatory specifications are acceptable including impurities. The proposed _____ expiry is not supported with sufficient data – the 18 months of data provided support a 24 month expiry. The stability testing protocol is considered adequate.

The overall Compliance recommendation is acceptable as of 14-JUL-20003

All associated DMFs are acceptable.

Conclusion

Drug product is acceptable

Overall Conclusion

From a CMC perspective the application should be approved.

Eric P Duffy, PhD
Director, DNDC II/ONDC

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