

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**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

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Eric Duffy  
7/18/03 11:43:39 AM  
CHEMIST

Redacted 6

pages of trade

secret and/or

confidential

commercial

information

# 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.