

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-228

CHEMISTRY REVIEW(S)

NDA 22-288

Bepotastine Besilate 1.5% Ophthalmic Solution

ISTA Pharmaceuticals, Inc.

**Shrikant Pagay
ONDQA/OPS/DAIOP**

Table of Contents

Table of Contents	2
Chemistry Review Data Sheet.....	3
The Executive Summary	8
I. Recommendations	8
A. Recommendation and Conclusion on Approvability	8
B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable - NA.....	8
II. Summary of Chemistry Assessments	8
A. Description of the Drug Product(s) and Drug Substance(s)	8
B. Description of How the Drug Product is Intended to be Used.....	9
C. Basis for Approvability or Not-Approval Recommendation.....	9
III. Administrative.....	9
A. Reviewer's Signature.....	9
B. Endorsement Block.....	10
C. CC Block.....	10
Chemistry Assessment	11
Draft Comment:.....	12
Attachment A	13

Chemistry Review Data Sheet

1. NDA #22-288
2. REVIEW #: 3 (Methods validation only)
3. REVIEW DATE: 2-September-2009
4. REVIEWER: Shrikant Pagay

5. PREVIOUS DOCUMENTS:

Previous Documents

IND 66,864/ Original
Amendment

Document Date

12/20/06/
9/10/08

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Original NDA
Amendment
Amendment
Amendment
Amendment

Document Date

11/12/08
12/10/08
7/2/09
7/8/09
7/31/09

7. NAME & ADDRESS OF APPLICANT:

Name:

ISTA Pharmaceuticals Inc



CHEMISTRY REVIEW



Chemistry Review Data Sheet

Address: 15295 Alton Parkway, Irvine, CA 92618
Representative: Paul Nowacki, Director, Regulatory Affairs
Telephone: 949-789-3109

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Bepreve
- b) Non-Proprietary Name (USAN): Bepotastine Besilate
- c) Code Name/# (ONDC only): TAU-284; SNJ-1773
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: 1
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505(b) (1)

10. PHARMACOL. CATEGORY: Allergic Conjunctivitis

11. DOSAGE FORM: Solution

12. STRENGTH/POTENCY: 1.5% by weight

13. ROUTE OF ADMINISTRATION: Ophthalmic

14. Rx/OTC DISPENSED: Rx OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

SPOTS product – Form Completed

Not a SPOTS product

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.