

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-193

CHEMISTRY REVIEW(S)



NDA 22-193

**Next Generation Ophthalmic Irrigating Solution
(intraocular irrigating solution)**

Alcon, Inc.

Christopher Hough

Review Chemist

**Office of New Drug Quality Assessment
Division of Office of New Drug Quality Assessment
Pre-Marketing Division II, Branch III**

CMC REVIEW OF NDA 22 193

**For the Division of Anti-Infective and Ophthalmology Products
(HFD-520)**



Table of Contents

Table of Contents2

CMC Review Data Sheet4

The Executive Summary8

I. Recommendations8

 A. Recommendation and Conclusion on Approvability 8

 B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable 8

II. Summary of CMC 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..... 8

 C. Basis for Approvability or Not-Approval Recommendation 8

III. Administrative.....9

CMC Assessment..... 10

I. Review Of Common Technical Document-Quality (Ctd-Q) Module 3.2: Body Of Data..... 10

S DRUG SUBSTANCE..... 10

 S.1 General Information..... 10

P DRUG PRODUCT 10

 P.1 Description and Composition of the Drug Product 10

 P.2 Pharmaceutical Development..... 11

 P.3 Manufacture 18

 P.4 Control of Excipients 22

 P.5 Control of Drug Product 25

 P.6 Reference Standards or Materials 38

 P.7 Container Closure System..... 38

 P.8 Stability..... 39

A APPENDICES 43

 A.1 Facilities and Equipment (biotech only) 43

 A.2 Adventitious Agents Safety Evaluation 43

 A.3 Novel Excipients 43

R REGIONAL INFORMATION 43

 R1 Executed Batch Records 43

 R2 Comparability Protocols 44

 R3 Methods Validation Package 44

II. Review Of Common Technical Document-Quality (Ctd-Q) Module 1 44



A. Labeling & Package Insert..... 44

B. Environmental Assessment Or Claim Of Categorical Exclusion 48

III. List Of Deficiencies to be Communicated.....49

CMC Review Data Sheet

CMC Review Data Sheet

- 1. NDA 22-193
- 2. REVIEW #: 1
- 3. REVIEW DATE: 31 Jan 2008
- 4. REVIEWER: Christopher Hough
- 5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
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6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Original Submission	24 Sept. 2007
Correspondence (C)	
Amendment (BC)	
Amendment (BC)	

7. NAME & ADDRESS OF APPLICANT:

Name: Alcon, Inc.
 Address: P.O. Box 62, Bosch 69, CH-6331 Hunenburg, Switzerland
 Representative: Sarah Cantrell
 Telephone: (817) 551-4517

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Sterile Intraocular Irrigating Solution b(4)
- b) Non-Proprietary Name: Balanced Salt Intraocular Irrigating Solution with , glutathione, hypromellose and sodium bicarbonate.
- c) Code Name/# (ONDQA only): Next Generation Ophthalmic Irrigating Solution (NGOIS)
- d) Chem. Type/Submission Priority (ONDQA only):
 - Chem. Type: Balanced Salts
 - Submission Priority: Normal

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



CMC Review Data Sheet

10. PHARMACOL. CATEGORY: Ophthalmic Sterile Intraocular Irrigating Solution (balanced salts)

11. DOSAGE FORM: Irrigating Solution

12. STRENGTH/POTENCY: N/A

13. ROUTE OF ADMINISTRATION: Irrigating Solution

14. Rx/OTC DISPENSED: Rx OTC

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

SPOTS product – Form Completed

Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT: There is no active moiety.

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17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
	III			4	Adequate	03/10/2007	
	III			3	Adequate	10/04/2007	

b(4)

- ¹ Action codes for DMF Table:
 1 – DMF Reviewed.
 Other codes indicate why the DMF was not reviewed, as follows:
 2 –Type 1 DMF
 3 – Reviewed previously and no revision since last review
 4 – Sufficient information in application
 5 – Authority to reference not granted
 6 – DMF not available
 7 – Other (explain under "Comments")

² Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND		
NDA	18-469	Balance salt solution Plus

CMC Review Data Sheet

18. STATUS:

ONDQA:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A	N/A	
EES	Pending	10/19,25/07	
Pharm/Tox			
Biopharm			
LNC			
Methods Validation	N/A		
DMETS	Pending		
EA	Categorical exclusion (see review)		
Microbiology	Pending		



Executive Summary Section

The CMC Review for NDA 22-193

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

Reviewer recommends approval.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

II. Summary of CMC Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

(1) Drug Substance

There is no drug substance in this product.

(2) Drug Product

The drug product is a set of two sterile solutions, Part I and Part II, to be mixed together immediately before use to make the sterile, "reconstituted" product. The drug product comes as a set for making either 250 mL or 500 mL of irrigating solution.

B. Description of How the Drug Product is Intended to be Used

The "reconstituted" product is intended to be used as a sterile irrigating solution for intraocular surgery for a single patient. The solution is to be discarded 6 hours after reconstitution.

C. Basis for Approvability or Not-Approval Recommendation

The drug product is identical to that of the same sponsor in NDA 18-469 with one key difference. The present NDA includes enough hypromellose ' _____

_____. Other than the one component, the composition, processes, analytical methods, container/closure systems, etc. are identical to the earlier product (Balanced Salt Solution Plus Parts I and II). The sponsor has been diligent in showing the validity of the manufacturing process, the material and critical step controls,

b(4)

Executive Summary Section

the sterility and stability of the product. From the prospective of chemistry and manufacturing controls, the product is safe.

III. Administrative**A. Reviewer's Signature:**

(See appended electronic signature page)

Christopher J. Hough, Ph.D.

B. Endorsement Block:

(See appended electronic signature page)

Norman Schmuff, Ph.D., Branch Chief, Branch IV, ONDQA

C. CC Block: entered electronically in DFS

40 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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

/s/

Christopher Hough
2/28/2008 09:33:49 AM
CHEMIST

Norman Schmuff
2/28/2008 09:39:41 AM
CHEMIST