

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**205388Orig1s000**

**CHEMISTRY REVIEW(S)**

**NDA 205388**

**Omidria<sup>™</sup>**

**(phenylephrine and ketorolac  
ophthalmic injection) 1% / 0.3%  
4 mL/Vial**

**Omeros Corporation**

**Mark R. Seggel  
ONDQA  
Division of New Drug Quality Assessment II  
Branch V**

**for the Division of Transplant and Ophthalmic Products**

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# Chemistry Review Data Sheet

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2. REVIEW #: 1 Addendum
3. REVIEW DATE: 30-MAY-2014
4. REVIEWER: Mark R. Seggel
5. PREVIOUS DOCUMENTS:

<u>Previous Documents</u>	<u>Document Date</u>
Not Applicable	

6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed (eCTD)</u>	<u>Document Date</u>
Original (0000)	30-JUL-2013
Amendment (0003); product stability update	23-AUG-2013
Amendment (0004); quality micro - reconst. sol'n storage	26-OCT-2013
Amendment (0009); updates to MV package	16-OCT-2013
Amendment (0010); package insert	18-OCT-2013
Amendment (0011); quality micro - stopper endotoxins	24-OCT-2013
Amendment (0013); quality micro - in-use hold time	22-NOV-2013
Amendment (0015); stability update	27-DEC-2013
Amendment (0016); identification of RLDs	08-JAN-2014
Amendment (0018); compatibility with BSS	14-MAR-2014
Amendment (0019); revised package insert	24-MAR-2014
Amendment (0021); CMC response	17-APR-2014
Amendment (0023); final labeling	21-MAY-2014

7. NAME & ADDRESS OF APPLICANT:

Name:	Omeros Corporation
Address:	201 Elliott Avenue West Seattle, WA 98119
Representative(s):	Catherine A. Melfi
Telephone:	206-676-5000

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Omidria™
- b) Non-Proprietary Name (USAN): Phenylephrine HCl and Ketorolac tromethamine
- c) Code Name/#: OMS302

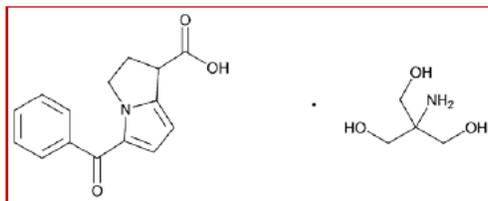


## Chemistry Review Data Sheet

IUPAC Chemical Name: (±)-5-Benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)

USAN: Ketorolac Tromethamine

Structural Formula:



Molecular Formula:  $C_{15}H_{13}NO_3 \cdot C_4H_{11}NO_3$ .

Molecular Weight: 376.40.

## 17. RELATED/SUPPORTING DOCUMENTS

### A. DMFs:

DMF # (b) (4)	TYPE	HOLDER (b) (4)	ITEM REFERENCED (b) (4)	CODE <sup>1</sup>	STATUS <sup>2</sup>	DATE REVIEW COMPLETED	COMMENTS
(b) (4)	V	(b) (4)	(b) (4)	-	-	See S. Donald's Product Quality Micro. Review	LoA 12/03/2012
(b) (4)	II	(b) (4)	(b) (4)	3	Adequate	06/13/2011 (K. Tiwari)	LoA 06/01/2012
(b) (4)	II	(b) (4)	(b) (4)	3	Adequate	05/28/13 (Y. Amin)	LoA 12/18/2012
(b) (4)	III	(b) (4)	(b) (4)	3	Adequate	04/25/13 (J. Tang)	LoA 03/08/2013
(b) (4)	III	(b) (4)	(b) (4)	3	Adequate	06/06/11 (J. Jee)	LoA 03/11/2013
(b) (4)	III	(b) (4)	(b) (4)	-	-	See S. Donald's Product Quality Micro. Review	LoA 03/11/2013

<sup>1</sup> 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")

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

### B. Other Documents:

APPLICATION NUMBER	DESCRIPTION	DOCUMENT
IND 78227	OMS302 (phenylephrine/ketorolac)	Omeros IND
NDA 203510	Phenylephrine HCl Ophthalmic Solution, USP, 2.5% and 10%	Paragon Biotech NDA
NDA 19700	Acular (Ketorolac tromethamine ophthalmic solution) 0.5%	Allergan Inc. NDA

**18. STATUS**

<b>CONSULTS/ CMC RELATED REVIEWS</b>	<b>RECOMMENDATION</b>	<b>DATE</b>	<b>REVIEWER</b>
Biometrics	N/A		
EES	Overall Acceptable	5/30/14	Office of Compliance
Pharm/Tox	Concurs with revised acceptance criteria for impurities	4/18/14	Maria Rivera
ONDQA Biopharmaceutics	Recommended for Approval	12/09/13	Houda Mahayni
LNC	N/A		
Methods Validation	Methods are acceptable with modifications (as stated in accompanying report).	3/28/14	DPA St. Louis Laboratory
DMEPA	Proprietary name acceptable. Recommendations to prevent medication errors.	11/08/13 04/07/14	A. Winiarski R. Kapoor
EA	Acceptable	CMC Review #1, 04/22/14	M. Seggel
Quality Microbiology	Recommended for Approval	12/16/13	Steve Donald

**19. GOAL DATES**

<b>GRMP Goal</b>	25-APR-2014
<b>PDUFA Goal</b>	30-MAY-2014

# The Chemistry Review for NDA 205388

## The Executive Summary

### I. Recommendations

#### A. Recommendation and Conclusion on Approvability

This NDA, as amended, has provided sufficient information to assure the identity, strength, quality, purity, potency and bioavailability of Omidria, a new combination product containing phenylephrine and ketorolac. The proposed regulatory analytical HPLC procedure has been verified at CDER's St. Louis Laboratory (DPA). Based on their review of product quality microbiology, the New Drug Microbiology Staff recommends Approval. ONDQA Biopharmaceutics also recommends Approval. Labeling negotiations have been completed. The revised labeling is acceptable from the CMC perspective. On May 30, 2014, the Office of Compliance issued an overall recommendation of Acceptable for the drug substance and drug product manufacturing, packaging and test facilities (see attached EES Detail Report).

Therefore, from the CMC perspective, this NDA is recommended for Approval.

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

Not applicable.

### II. Summary of Chemistry Assessments

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

Omidria™ is a sterile solution of phenylephrine HCl, a mydriatic agent, and ketorolac tromethamine, a nonsteroidal anti-inflammatory agent. Each vial contains the equivalent of 40.64 mg phenylephrine (1% w/v) and 11.51 mg ketorolac (0.3% w/v) in 4.0 mL of (b) (4) pH 6.3 sodium citrate buffer. (b) (4)

The proposed commercial container closure system consists of a 5-mL Type 1 clear (b) (4) glass tubing vial and an elastomeric closure (b) (4)

A risk assessment of the container closure system was conducted by the applicant along with limited leachables/extractables testing. The applicant will continue leachables testing on product throughout its shelf life.

## Executive Summary Section

The product is manufactured at a contract manufacturing facility (b) (4) via a relatively straightforward process of (b) (4). The latter two operations have been reviewed by the New Drug Microbiology Staff. Sterility assurance has been evaluated from the Product Quality Microbiology perspective and found adequate.

The drug product specification provides additional assurance that Omidria has the purported identity, strength, quality, purity and potency. The specification includes tests for identity, pH, osmolality, assay, degradation products, sterility, endotoxins and particulate matter. Based on discussions with the Pharm/Tox review team, and a comparison to related products, and on the available, albeit limited, release and stability data, it was determined that tighter acceptance criteria for individual specified and unspecified degradants, and total degradants were warranted. The applicant has tightened the acceptance criteria accordingly.

The stability of the drug product at 25°C is subject to ongoing characterization. However, the initial data suggest that the product has satisfactory stability when stored at 25°C and protected from light. The primary stability batch data from three registration batches through 12 months at 25°C/60% RH suggests an expiration dating period of 24 months may be reasonable. However, batch failure (b) (4) at 40°C months, currently precludes extrapolation of a shelf life beyond 18 months. Until additional stability data become available to support a longer shelf-life, an 18-month expiration dating period has been assigned to the drug product stored at 25°C.

It should be noted that throughout the application, Omeros' assessment of patient risk from exposure to leachables and impurities is based on the observation that approximately 1% of the dose (equivalent to 0.04 mL Omidria) is systemically absorbed following intraocular irrigation. Local, ocular exposure seems to be dismissed. However, the manner in which the drug product is used (i.e., one time use per eye, dilution in 500 mL BSS, and administration as an irrigant) may alleviate some concern. See Pharm/Tox review for additional assessment.

The physical and chemical compatibility of Omidria with balanced salt solutions (specifically, BSS and BSS Plus) has been demonstrated (no loss of potency, increase in impurities, or formation of subvisible particulate matter contamination). However, compatibility with other irrigation solutions has not been demonstrated. It was therefore recommended that the labeling specify dilution in balanced salt solutions. However, the clinical review team prefers use of "ophthalmic irrigating solution," which they indicate is understood by practitioner's to be BSS (and BSS Plus) and generic equivalents.

Phenylephrine HCl is manufactured by (b) (4). The chemistry, manufacturing and controls of the drug substance are documented in Type II DMF (b) (4).

## Executive Summary Section

Ketorolac tromethamine is manufactured by (b) (4). The chemistry, manufacture and controls of the drug substance are documented in Type II DMF (b) (4).

Each active ingredient is present in numerous approved formulations including ophthalmic solutions and intravenous injections. Potential risks associated with the actives seem to be limited to the inherent properties of the drugs, potential process impurities and potential degradation products. The phenylephrine and ketorolac salts are subjects of USP and Ph.Eur. monographs, and must meet DMF and NDA application requirements that assure identity, quality, purity and strength. Potential degradation of the actives in the drug product by, for example, oxidation and photodegradation, is mitigated by product manufacturing process controls and storage conditions.

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

Omidria (phenylephrine-ketorolac ophthalmic injection) 1% / 0.3%, 4.0 mL per vial, is indicated for the (b) (4) prevention of intraoperative miosis, and reduction of pain in the early postoperative period in lens replacement surgery. An admixture of 4 mL Omidria in 500 mL Balanced Salt Solution is used to irrigate the surgical site during the procedure.

The proposed product labeling states: Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]; excursions permitted to (b) (4). Protect from light. An expiration dating period of 18 months has been assigned. The storage period for the diluted product is not more than 4 hours at room temperature or 24 hours under refrigerated conditions.

**C. Basis for Approvability or Not-Approval Recommendation**

The sponsor has provided sufficient information on raw material controls, manufacturing processes and process controls. As revised, the specifications for assuring consistent product quality of the drug substance and drug product have been established. The NDA, as amended, also has provided sufficient stability information on three registration lots of the drug product to assure strength, purity, and quality of the drug product during the assigned expiration dating period of 18 months.

The proposed trademark, Omidria, has been found acceptable by DMEPA. Review and negotiation of the package insert, vial label, individual vial carton, and boxes (of four and ten individual cartons) have been completed. The revised labeling (0023, 05/21/2014) is acceptable from the CMC perspective, and meets the preferences and requirements of the ophthalmic drug review team.

Based on file review and recent inspections of the drug substance and drug product manufacturing, packaging and test facilities, the Office of Compliance issued an overall recommendation of Acceptable for this application (see attached EES Detailed Report).

**A. Reviewer's Signature**

*{see electronic signature page}*  
Mark R. Seggel, Chemistry Reviewer

**B. Endorsement Block**

*{see electronic signature page}*  
Rapti Madurawe, Ph.D., Branch Chief

**C. CC Block**

*{see DARRTS}*

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MARK R SEGCEL  
05/30/2014

RAPTI D MADURAWA  
05/30/2014

**NDA 205388**

**Omidria<sup>™</sup>**

**(phenylephrine and ketorolac  
ophthalmic injection) 1% / 0.3%  
4 mL/Vial**

**Omeros Corporation**

**Mark R. Seggel  
ONDQA  
Division of New Drug Quality Assessment II  
Branch V**

**for the Division of Transplant and Ophthalmic Products**

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# Chemistry Review Data Sheet

1. NDA 205388
2. REVIEW #: 1
3. REVIEW DATE: 20-APR-2014
4. REVIEWER: Mark R. Seggel
5. PREVIOUS DOCUMENTS:

<u>Previous Documents</u>	<u>Document Date</u>
Not Applicable	

6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed (eCTD)</u>	<u>Document Date</u>
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Amendment (0003); product stability update	23-AUG-2013
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Amendment (0015); stability update	27-DEC-2013
Amendment (0016); identification of RLDs	08-JAN-2014
Amendment (0018); compatibility with BSS	14-MAR-2014
Amendment (0019); revised package insert	24-MAR-2014
Amendment (0021); CMC response	17-APR-2014

7. NAME & ADDRESS OF APPLICANT:

Name:	Omeros Corporation
Address:	201 Elliott Avenue West Seattle, WA 98119
Representative(s):	Catherine A. Melfi
Telephone:	206-676-5000

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Omidria™
- b) Non-Proprietary Name (USAN): Phenylephrine HCl and Ketorolac tromethamine
- c) Code Name/#: OMS302
- d) CAS Registry Number: Phenylephrine HCl      CAS-61-76-7

## Chemistry Review Data Sheet

Ketorolac tromethamine CAS-74103-07-4

e) Chem. Type/Submission Priority:

- i. Chem. Type: 4, New Combination
- ii. Submission Priority: Standard

9. LEGAL BASIS FOR SUBMISSION: 505(b)(2)

10. PHARMACOL. CATEGORY:

Phenylephrine HCl	Ophthalmic-Mydriatic (4041170)
Ketorolac tromethamine	Ophthalmic-NSAID (4041430)

11. DOSAGE FORM: Injection, ophthalmic

12. STRENGTH/POTENCY: 12.4 mg/mL PE and 4.24 mg/mL KE; 4 mL/vial

13. ROUTE OF ADMINISTRATION: Intraocular injection / Intracameral irrigation

14. Rx/OTC DISPENSED:  Rx  OTC

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

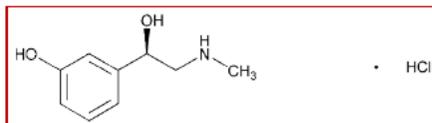
 SPOTS product – Form Completed Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT

Phenylephrine HydrochlorideCAS Chemical Name: Benzenemethanol, 3-hydroxy- $\alpha$ -[(methylamino)methyl]-, hydrochloride (R)-;IUPAC Chemical Name: (-)-m-Hydroxy- $\alpha$ -[(methylamino)methyl]benzyl alcohol hydrochloride

USAN: Phenylephrine Hydrochloride

Structural Formula:

Molecular Formula: C<sub>9</sub>H<sub>13</sub>NO<sub>2</sub>·HCl.

Molecular Weight: 203.67.

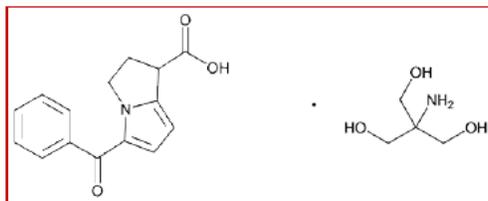
Ketorolac TromethamineCAS Chemical Name: 1*H*-Pyrrolizine-1-carboxylic acid, 5-benzoyl-2,3-dihydro, ( $\pm$ )-, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)

## Chemistry Review Data Sheet

IUPAC Chemical Name: (±)-5-Benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)

USAN: Ketorolac Tromethamine

Structural Formula:



Molecular Formula:  $C_{15}H_{13}NO_3 \cdot C_4H_{11}NO_3$ .

Molecular Weight: 376.40.

## 17. RELATED/SUPPORTING DOCUMENTS

### A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE <sup>1</sup>	STATUS <sup>2</sup>	DATE REVIEW COMPLETED	COMMENTS
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	III	(b) (4)	(b) (4)	3	Adequate	06/06/11 (J. Jee)	LoA 03/11/2013
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<sup>2</sup> Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

### B. Other Documents:

APPLICATION NUMBER	DESCRIPTION	DOCUMENT
IND 78227	OMS302 (phenylephrine/ketorolac)	Omeros IND
NDA 203510	Phenylephrine HCl Ophthalmic Solution, USP, 2.5% and 10%	Paragon Biotech NDA
NDA 19700	Acular (Ketorolac tromethamine ophthalmic solution) 0.5%	Allergan Inc. NDA

**18. STATUS**

<b>CONSULTS/ CMC RELATED REVIEWS</b>	<b>RECOMMENDATION</b>	<b>DATE</b>	<b>REVIEWER</b>
Biometrics	N/A		
EES	<i>pending</i>	<i>pending</i>	Office of Compliance
Pharm/Tox	Concurs with revised acceptance criteria for impurities	4/18/14	Maria Rivera
ONDQA Biopharmaceutics	Recommended for Approval	12/09/13	Houda Mahayni
LNC	N/A		
Methods Validation	Methods are acceptable with modifications (as stated in accompanying report).	3/28/14	DPA St. Louis Laboratory
DMEPA	Proprietary name acceptable. Recommendations to prevent medication errors.	11/08/13 04/07/14	A. Winiarski R. Kapoor
EA	Acceptable	this review	M. Seggel
Quality Microbiology	Recommended for Approval	12/16/13	Steve Donald

**19. GOAL DATES**

<b>GRMP Goal</b>	25-APR-2014
<b>PDUFA Goal</b>	30-MAY-2014

# The Chemistry Review for NDA 205388

## The Executive Summary

### I. Recommendations

#### A. Recommendation and Conclusion on Approvability

This NDA, as amended, has provided sufficient information to assure the identity, strength, quality, purity, potency and bioavailability of Omidria, a new combination product containing phenylephrine and ketorolac. The proposed regulatory analytical HPLC procedure has been verified at CDER's St. Louis Laboratory (DPA). Based on their review of product quality microbiology, the New Drug Microbiology Staff recommends Approval. ONDQA Biopharmaceutics also recommends Approval.

Office of Compliance evaluations of the phenylephrine drug substance manufacturing facility and of the drug product facility are pending. Therefore, from the CMC perspective, this NDA is recommended for Approval pending issuance of an overall acceptable recommendation from the Office of Compliance, and finalization of labeling.

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

Not applicable.

### II. Summary of Chemistry Assessments

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

Omidria™ is a sterile solution of phenylephrine HCl, a mydriatic agent, and ketorolac tromethamine, a nonsteroidal anti-inflammatory agent. Each vial contains the equivalent of 40.64 mg phenylephrine (1% w/v) and 11.51 mg ketorolac (0.3% w/v) in 4.0 mL of (b) (4), pH 6.3 sodium citrate buffer. (b) (4)

The proposed commercial container closure system consists of a 5-mL Type 1 clear (b) (4) glass tubing vial and an elastomeric closure (b) (4)

A risk assessment of the container closure system was conducted by the applicant along with limited leachables/extractables testing. The applicant will continue leachables testing on product throughout its shelf life.

## Executive Summary Section

The product is manufactured at a contract manufacturing facility (b) (4) via a relatively straightforward process of (b) (4). The latter two operations have been reviewed by the New Drug Microbiology Staff. Sterility assurance has been evaluated from the Product Quality Microbiology perspective and found adequate.

The drug product specification provides additional assurance that Omidria has the purported identity, strength, quality, purity and potency. The specification includes tests for identity, pH, osmolality, assay, degradation products, sterility, endotoxins and particulate matter. Based on discussions with the Pharm/Tox review team, and a comparison to related products, and on the available, albeit limited, release and stability data, it was determined that tighter acceptance criteria for individual specified and unspecified degradants, and total degradants were warranted. The applicant has tightened the acceptance criteria accordingly.

The stability of the drug product at 25°C is subject to ongoing characterization. However, the initial data suggest that the product has satisfactory stability when stored at 25°C and protected from light. The primary stability batch data from three registration batches through 12 months at 25°C/60% RH suggests an expiration dating period of 24 months may be reasonable. However, batch failure (b) (4) at 40°C months, currently precludes extrapolation of a shelf life beyond 18 months. Until additional stability data become available to support a longer shelf-life, an 18-month expiration dating period has been assigned to the drug product stored at 25°C.

It should be noted that throughout the application, Omeros' assessment of patient risk from exposure to leachables and impurities is based on the observation that approximately 1% of the dose (equivalent to 0.04 mL Omidria) is systemically absorbed following intraocular irrigation. Local, ocular exposure seems to be dismissed. However, the manner in which the drug product is used (i.e., one time use per eye, dilution in 500 mL BSS, and administration as an irrigant) may alleviate some concern. See Pharm/Tox review for additional assessment.

The physical and chemical compatibility of Omidria with Balanced Salt Solution has been demonstrated (no loss of potency, increase in impurities, or formation of subvisible particulate matter contamination). However, compatibility with other irrigation solutions has not been demonstrated. The product will be labeled accordingly.

Phenylephrine HCl is manufactured by (b) (4). The chemistry, manufacturing and controls of the drug substance are documented in Type II DMF (b) (4).

Ketorolac tromethamine is manufactured by (b) (4). The chemistry, manufacture and controls of the drug substance are documented in Type II DMF (b) (4).

Each active ingredient is present in numerous approved formulations including ophthalmic solutions and intravenous injections. Potential risks associated with the actives seem to be limited to the inherent properties of the drugs, potential process impurities and potential degradation products. The phenylephrine and ketorolac salts are subjects of USP and Ph.Eur. monographs, and must meet DMF and NDA application requirements that assure identity, quality, purity and strength. Potential degradation of the actives in the drug product by, for example, oxidation and photodegradation, is mitigated by product manufacturing process controls and storage conditions.

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

Omidria (phenylephrine-ketorolac ophthalmic injection) 1% / 0.3%, 4.0 mL per vial, is indicated for (b) (4) prevention of intraoperative miosis, and reduction of pain in the early postoperative period in lens replacement surgery. An admixture of 4 mL Omidria in 500 mL Balanced Salt Solution is used to irrigate the surgical site during the procedure.

The proposed product labeling states: Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]; (b) (4) Protect from light. An expiration dating period of 18 months has been assigned. The storage period for the diluted product is not more than 4 hours at room temperature or 24 hours under refrigerated conditions.

## C. Basis for Approvability or Not-Approval Recommendation

The sponsor has provided sufficient information on raw material controls, manufacturing processes and process controls. As revised, the specifications for assuring consistent product quality of the drug substance and drug product have been established. The NDA, as amended, also has provided sufficient stability information on three registration lots of the drug product to assure strength, purity, and quality of the drug product during the assigned expiration dating period of 18 months.

An overall recommendation from the Office of Compliance is pending completion of inspections and review of inspection reports.

The proposed trademark, Omidria, has been found acceptable by DMEPA. Review and negotiation of the package insert, vial label, individual vial carton, and box (ten individual cartons) is ongoing.

An addendum to this review will be filed upon receipt of a final recommendation from the Office of Compliance, and agreement on the final labeling.

**A. Reviewer's Signature**

*{see electronic signature page}*  
Mark R. Seggel, Chemistry Reviewer

**B. Endorsement Block**

*{see electronic signature page}*  
Rapti Madurawe, Ph.D., Branch Chief

**C. CC Block**

*{see DARRTS}*

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MARK R SEGCEL  
04/20/2014

RAPTI D MADURAWA  
04/22/2014