CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214679Orig1s000

PRODUCT QUALITY REVIEW(S)

U.S. FOOD & DRUG ADMINISTRATION

RECOMMENDATION: Approval

NDA 214679
Review 1

Drug Product Name	Topiramate
Dosage Form	Oral solution
Strength	25 mg/mL
Route of Administration	Oral
Rx/OTC Dispensed	Rx
Applicant	Azurity Pharmaceuticals
US agent, if applicable	N/A

QUALITY TEAM

Discipline	Primary Assessment	Secondary Assessment
Drug Substance	Friedrich Burnett	Donna Christner
Drug Product	Renishkumar Delvadia	Julia Pinto
Manufacturing	David Bateman	Joanne Wang
Microbiology	David Bateman	Christine Craig
Biopharmaceutics	N/A	
Regulatory Business Process Manager	Erica Keafer	
Application Technical Lead	Martha Heimann	
Laboratory (OTR)	N/A	
Environmental	N/A	

Submission(s)	Document Date	Discipline(s) Affected
SD-01: Original NDA	10/6/2020	All
SD-02: Response to IR	10/28/2020	Manufacturing
SD-09: Response to IR	3/18/2021	Manufacturing
SD-10, Response to IR	3/26/2021	Drug product
SD-13, Labeling, container	5/21/2021	Drug product
SD-14, Response to IR	5/18/2021	Drug product
SD-16, Response to IR	9/29/2021	Drug product

QUALITY ASSESSMENT DATA SHEET

1. RELATED/SUPPORTING DOCUMENTS

A. DMFs:

DMF #	Type	Holder	Item Referenced	Status	Date Assessed	Comments
(b) (4)	II		(b) (4)	Adequate	1/24/2021	Review by Q. Shi
	III			N/A [1]		
	III			N/A [1]		
	III			N/A [1]		
	III			N/A [1]		
	III			N/A [1]		
	III			N/A [1]		
	IV				09/29/2021	Reviewed by R. Delvadia

[1] The applicant provided adequate information in NDA; therefore, the DMF was not reviewed.

B. Other Documents: *IND, RLD, or sister applications*

Document	Application Number	Description
NDA	20844	Approved application for Topamax (topiramate) sprinkle capsules, referenced to support safety and efficacy of topiramate under 505(b)(2)
NDA	20505	Approved application for Topamax (topiramate) tablets
Pre-IND	139533	Pre-IND written responses provided to Eton Pharmaceuticals and development of pediatric study plan. No studies were performed under the IND.

2. CONSULTS

Justification for (b) (4) limits discussed with nonclinical reviewer and division director and deemed acceptable. No formal consult.

EXECUTIVE SUMMARY

I. RECOMMENDATIONS AND CONCLUSION ON APPROVABILITY

The OPQ review team recommends **APPROVAL** of NDA 214679 for Topiramate Oral Solution. The application, as amended, provides adequate assurance of product quality to ensure the product is suitable for use in the intended patient population.

II. SUMMARY OF QUALITY ASSESSMENTS

A. Product Overview

Topiramate was originally developed by Ortho McNeil/Janssen Pharmaceuticals (Ortho) for treatment of epilepsy. The innovator product, Topamax® (topiramate) tablets, was approved for treatment of epilepsy under NDA 20-505 in 1996. Topamax was later approved for preventive treatment of migraine. In addition to Topamax tablets, currently approved dosage forms include sprinkle capsules (Topamax Sprinkles/Ortho), extended-release capsules (Trokendi XR/Supernus Pharmaceuticals and Qudexy XR/Upsher Smith Laboratories), and corresponding generic products.

In the current 505(b)(2) NDA Azurity Pharmaceuticals (applicant) proposes marketing topiramate as a nonaqueous solution containing 25 mg topiramate per mL. The applicant is seeking the same indications as approved for Topamax.

Proposed indication(s) including intended patient population	Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older. Adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older. Preventative treatment of migraine in patients 12 years and older.
Duration of treatment	Chronic
Maximum daily dose	400 mg
Alternative methods of administration	None

B. Quality Assessment Overview

Note: NDA 214679 was submitted by Eton Pharmaceuticals and transferred to Azurity Pharmaceuticals during the review cycle. Therefore, some reviews refer to Eton Pharmaceuticals as the applicant.

Drug Substance: Adequate

Topiramate USP is a well-characterized small molecule that is approved under multiple NDAs and ANDAs. Information regarding manufacture and control of the bulk drug substance is incorporated by cross-reference to DMF (b) (4) ((b) (4) (b) (4)). The DMF has been reviewed in support of this NDA and is deemed adequate to support approval. The information submitted directly to the NDA includes general properties of topiramate, manufacturing facilities, the (b) (4) release specification (summary table) and certificates of analysis. The (b) (4) (b) (4) (drug product manufacturer) acceptance specification is provided. The applicant has provided a detailed description of the analytical methods employed for acceptance testing and provided a validation or verification report for each of the analytical methods. Based on the validation data, the analytical methods have been demonstrated to be adequate for their intended purpose. The drug substance meets USP monograph requirements, and the specification includes appropriate controls for process impurities, and residual solvents. and an elemental impurities risk assessment was performed consistent with ICH Q3D requirements. The drug substance specifications are adequate to ensure the quality of topiramate as it relates to the safety and efficacy of the eventual drug product.

Drug Product: Adequate

Topiramate oral solution (25 mg/mL), is a colorless to slightly yellow colored clear viscous solution filled into a 16 fl. oz (473 mL) white HDPE bottle. The commercial formulation contains compendial excipients that are typically used in an oral solution product, plus a proprietary mixed-berry flavor. The Applicant has performed adequate product development studies to justify selection of the excipients, the chemical compatibility of topiramate with the excipients and suitability of the proposed container closure.

A key issue during the review was adequacy of the proposed product specification and analytical procedures to ensure product quality. The applicant based the specification and methods proposed in the original NDA on the USP monographs for topiramate tablets and capsules. However, on review of the provided data, deficiencies related to absence of a mass balance between topiramate and related impurities on storage were identified. Specifically, the product failed assay (b) (4)% decrease) within 6 months under accelerated storage conditions and significant degradation (b) (4)) within 12 months under intermediate storage conditions. A corresponding increase in impurities was not observed and the initial root-cause analysis performed by the applicant failed to identify the cause of the observed low mass balance. Per the response to an information request,

further investigation by the manufacturer identified a previously undetected impurity, (b) (4) and (b) (4) as degradation products. The applicant has developed and validated analytical methods for (b) (4) and (b) (4). The proposed limit for (b) (4) was deemed acceptable by the nonclinical team and the limit for (b) (4) is with ICH limits for (b) (4) as a (b) (4) The applicant also revised and validated analytical methods for other known impurities.

The applicant has provided 18-month stability data using the updated degradation products methods and initially requested a (b) (4)-month shelf life for the product. However, due to the lack of information on (b) (4) and (b) (4) levels for the earlier stability timepoints, statistical analysis of the data to justify the requested shelf life is not possible. Therefore, a 21-month shelf-life has been granted for product stored at 20°C – 25°C. The applicant has agreed to the granted expiry. Based on the available "in-use" stability data, an in-use period of 30 days after opening the bottle is granted and will be included in labeling.

Labeling: Adequate

Due to limited "in-use" stability data provided by the applicant during the review cycle, the product labeling was revised to include instructions to discard the remaining contents of the bottle 30 days after opening. No other labeling deficiencies were identified during the review.

Manufacturing: Adequate

The drug product is a solution consisting of the active pharmaceutical ingredient (API) (b) (4) (b) (4). The manufacturing process involves (b) (4) (b) (4). The process is medium risk, and the exhibit batches were conducted at the maximum proposed manufacturing scale, (b) (4) L ((b) (4) gallon). The applicant has established appropriate controls for (b) (4) to ensure consistent and demonstrated compatibility of the formulation with manufacturing and filling equipment.

All facilities involved in the manufacture and testing of Topiramate USP and Topiramate oral solution are currently acceptable. Facility status should be verified prior to final action.

Microbiology: Adequate

(b) (4) hold times (b) (4) are supported by hold studies that support absence of microbial growth. The applicant provided acceptable antimicrobial effectiveness testing results which support the release and shelf-life specifications. All test procedures have been adequately validated. In response to an Agency information request, the applicant revises the drug product release specification to include testing for *Burkholderia cepacia complex* (BCC) following USP <60>.

Environmental: Adequate

The applicant claims a categorical exclusion under 21 CFR 25.31(a). The applicant indicates that approval of the NDA will not increase use of the active moiety as the oral solution will be used for the same indication(s), at the same dosage levels, and for the same duration of use as previously approved by the Agency for listed drug. No extraordinary circumstances are known to exist.

C. Risk Assessment

From Initial Risk Identification			Review Assessment		
Attribute/ CQA	**Factors that can impact the CQA**	**Initial Risk Ranking**	**Risk Mitigation Approach**	**Final Risk Evaluation**	**Comments**
Assay, stability	Formulation, container closure, process parameters	**L**	(b) (4)	**Adequate**	
Dosing accuracy	Dosing device, raw materials, formulation	**L**		**Adequate**	
Palatability	Formulation, raw materials, container closure, process parameters	**M**		**Adequate**	
Leachables	Formulation, raw materials, container closure, equipment	**M**		**Adequate**	
Microbial limits	Formulation, raw materials, container closure, process parameters, scale, equipment	**L**		**Adequate**	

D. List of Deficiencies for Complete Response

Not applicable

Application Technical Lead Name and Date:

Martha R. Heimann, Ph.D.
Senior Product Quality Assessor for Neurology Products
Office of New Drug Products

10/6/2021

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CHAPTER IV: LABELING

IQA NDA Assessment Guide Reference

1.0 PRESCRIBING INFORMATION

Assessment of Product Quality Related Aspects of the Prescribing Information: PI comments/edits added to the draft label in SharePoint for the Applicant.

1.1 HIGHLIGHTS OF PRESCRIBING INFORMATION

Item	Information Provided in the NDA	Assessor's Comments
Product Title in Highlights		
Proprietary name	N/A	
Established name(s)	TOPIRAMATE Oral Solution, (b) (4)	Change to "TOPIRAMATE oral solution"
Route(s) of administration		
Dosage Forms and Strengths Heading in Highlights		
Summary of the dosage form(s) and strength(s) in metric system.	Topiramate Oral Solution: 25 mg/mL (b) (4) (b) (4)	Change to "Oral solution: 25 mg/mL (b) (4)"
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored"	N/A	
For injectable drug products for parental administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package terms include pharmacy bulk package and imaging bulk package.	N/A	

1.2 FULL PRESCRIBING INFORMATION

1.2.1 Section 2 (DOSAGE AND ADMINISTRATION)

Item	Information Provided in the NDA	Assessor's Comments
DOSAGE AND ADMINISTRATION section		
Special instructions for product preparation (e.g., reconstitution and resulting concentration, dilution, compatible diluents, storage conditions needed to maintain the stability of the reconstituted or diluted product)	N/A	

1.2.2 Section 3 (DOSAGE FORMS AND STRENGTHS)

Item	Information Provided in the NDA	Assessor's Comments
DOSAGE FORMS AND STRENGTHS section		
Available dosage form(s)	(b) (4) Oral Solution 25 mg/mL (b) (4) (473 mL) in white HDPE bottles.	Change to "(b) (4) oral solution 25 mg/mL is supplied as a colorless to slightly yellow colored clear viscous liquid in (b) (4) (b) (4) white HDPE bottles."
Strength(s) in metric system	Yes	
If the active ingredient is a salt, apply the USP Salt Policy per FDA Guidance	Yes	
A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, and imprinting	Yes	
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored"	N/A	
For injectable drug products for parental administration, use appropriate labeling term (e.g., single-dose, multiple-dose, single-patient-use). Other package type terms include pharmacy bulk package and imaging bulk package.	N/A	

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Item	Information Provided in the NDA	Assessor's Comments
DESCRIPTION section		
Proprietary and established name(s)	Yes	
Dosage form(s) and route(s) of administration	Yes	
If the active ingredient is a salt, apply the USP Salt Policy and include the equivalency statement per FDA Guidance.	Yes	
List names of all inactive ingredients. Use USP/NF names. Avoid Brand names.	Yes	
For parenteral injectable dosage forms, include the name and quantities of all inactive ingredients. For ingredients added to adjust the pH or make isotonic, include the name and statement of effect.	N/A	
If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol	N/A	
Statement of being sterile (if applicable)	N/A	
Pharmacological/ therapeutic class	Not included	The Applicant will be asked to include pharmacological class
Chemical name, structural formula, molecular weight	Yes	
If radioactive, statement of important nuclear characteristics.	N/A	
Other important chemical or physical properties (such as pKa or pH)	Yes	

Section 11 (DESCRIPTION) Continued

Item	Information Provided in the NDA	Assessor's Comments
For oral prescription drug products, include gluten statement if applicable	N/A	
Remove statements that may be misleading or promotional (e.g., "synthesized and developed by Drug Company X," "structurally unique molecular entity"	N/A	

1.2.4 Section 16 (HOW SUPPLIED/STORAGE AND HANDLING)

Original:

16.1 How Supplied

(b) (4) Oral Solution 25 mg/mL (b) (4)
(b) (4)(473 mL) in white HDPE bottles (NDC 52652-9001-1).

16.2 Storage and Handling

(b) (4) is stored at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Proposed changes:

Item	Information Provided in the NDA	Assessor's Comments
HOW SUPPLIED/STORAGE AND HANDLING section		
Available dosage form(s)	Yes	
Strength(s) in metric system	Yes	
Available units (e.g., bottles of 100 tablets)	Yes	
Identification of dosage forms, e.g., shape, color, coating, scoring, imprinting, NDC number	Yes	
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored"	N/A	
For injectable drug products for parental administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package terms include pharmacy bulk package and imaging bulk package.		

Section 16 (HOW SUPPLIED/STORAGE AND HANDLING) (Continued)

Item	Information Provided in the NDA	Assessor's Comments
Special handling about the supplied product (e.g., protect from light, refrigerate). If there is a statement to "Dispense in original container," provide reason why (e.g. to protect from light or moisture, to maintain stability, etc.)	Not included	"Discard unused portion 30 days after first opening."
If the product contains a desiccant, ensure the size and shape differ from the	N/A	

dosage form and desiccant has a warning such as “Do not eat.”		
Storage conditions. Where applicable, use USP storage range rather than storage at a single temperature.	Yes	
Latex: If product does not contain latex and manufacturing of product and container did not include use of natural rubber latex or synthetic derivatives of natural rubber latex, state: “Not made with natural rubber latex. Avoid statements such as “latex-free.”	N/A	
Include information about child-resistant packaging	N/A (not claimed in the label)	

1.2.5 Other Sections of Labeling

N/A

1.2.6 Manufacturing Information After Section 17 (for drug products)

Item	Information Provided in the NDA	Assessor’s Comments
Manufacturing Information After Section 17		
Name and location of business (street address, city, state and zip code) of the manufacturer, distributor, and/or packer	Manufactured by: Tulex Pharmaceuticals 5 Cedarbrook Dr Cranbury Township, NJ 08512 USA Manufactured for: Azurity Pharmaceuticals Inc. Wilmington, MA 01887 USA	Acceptable

2.0 PATIENT LABELING

The Applicant will be asked to include statement in PI “Discard unused portion 30 days after first opening”

3.0 CARTON AND CONTAINER LABELING

3.1 Container Label

(Copy/paste or refer to a representative example of a proposed container)

3.2 Carton Labeling

(Copy/paste or refer to a representative example of a proposed carton labeling)

Item	Information Provided in the NDA	Assessor's Comments about Carton Labeling
Proprietary name, established name, and dosage form (font size and prominence	Yes	
Dosage strength	Yes	
Route of administration	Yes	
If the active ingredient is a salt, include the equivalency statement per FDA Guidance	N/A	
Net contents (e.g. tablet count)	Yes	
"Rx only" displayed on the principal display	Yes	
NDC number	Yes	
Lot number and expiration date	Yes	
Storage conditions. If applicable, include a space on the carton labeling for the user to write the new BUD.	Yes;	Should be same as PI label "Stored at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59° to 86°F) [see USP Controlled Room Temperature]." Comment conveyed to DMEPA reviewer.
For injectable drug products for parental administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use)	N/A	
Other package terms include pharmacy bulk package and imaging bulk package which require "Not for direct infusion" statement.	N/A	

If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol	N/A	
Bar code		

Item	Information Provided in the NDA	Assessor's Comments about Carton Labeling
Name of manufacturer/distributor	Yes	
Medication Guide (if applicable)	Yes	
No text on Ferrule and Cap overseal	N/A	
When a drug product differs from the relevant USP standard of strength, quality, or purity, as determined by the application of the tests, procedures, and acceptance criteria set forth in the relevant compendium, its difference shall be plainly stated on its label.	N/A	
And others, if space is available	N/A	

Assessment of Carton and Container Labeling: *Adequate*

ITEMS FOR ADDITIONAL ASSESSMENT

Overall Assessment and Recommendation:

Adequate; outstanding PI comments/edits added to the draft label in SharePoint for the Applicant.

Primary Labeling Assessor Name and Date: Renishkumar Delvadia, 09/29/2021

Secondary Assessor Name and Date (and Secondary Summary, as needed): Julia Pinto, 09/29/2021

Renishkumar Delvadia

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Julia Pinto

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CHAPTER VII: MICROBIOLOGY

Product Information	
NDA Number	214679
Assessment Cycle Number	MR01
Drug Product Name/ Strength	Topiramate Oral Solution, 25 mg/mL, 473 mL fill multi-dose bottle
Route of Administration	Oral solution
Applicant Name	Azurity Pharmaceuticals, Inc.
Therapeutic Classification/ OND Division	Division of Neurology Products
Manufacturing Site	Tulex Pharmaceuticals Inc. 5 Cedar Brook Drive Cranbury, NJ, 08512
Method of Sterilization	None.

Assessment Recommendation: **Adequate**

Assessment Summary:
The drug product is [redacted] (b) (4) into 16 oz HDPE bottles.

List Submissions being assessed (table):

Document(s) Assessed	Date Received
eCTD Seq #0001 Original	October 6, 2020
eCTD seq #0006 Response to Microbiology Information request	February 22, 2021
eCTD seq#0010 Response to Microbiology Information request	March 26, 2021

Highlight Key Issues from Last Cycle and Their Resolution: N/A

Remarks: The drug product is a non-sterile viscose [redacted] (b) (4) solution supplied in 16 oz HDPE bottles [redacted] (b) (4).

Concise Description of Outstanding Issues
None.

Supporting Documents: None

P.1 Description of the Composition of the Drug Product

- **Description of drug product:** This is a non-sterile, colorless to yellow viscous solution filled to 473 mL in 16 oz white HDPE round bottles fitted with 28 mm white (b) (4) cap.

- **Drug product composition:**

Ingredient	Function	Content per mL
Topiramate, USP	Active Ingredient	25 mg
Polyethylene glycol (b) (4), NF	(b) (4)	
Methylparaben		
Propylparaben		
Sucralose		
Berry, Mixed flavor (b) (4) (b) (4)		
Glycerin, USP		

- **Description of container closure system:**

Component	Description	Manufacturer
Bottle	16 oz white HDPE (b) (4) round bottle with 28 mm wide mouth	(b) (4)
Cap	28 mm white (b) (4) (b) (4) cap	

Adequate

Reviewer's Assessment:
The applicant provided an adequate description of the drug product composition and the container closure system designed to maintain product sterility.

P.2 Pharmaceutical Development

(b) (4)

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P.8 Stability

P. 8.1 Stability Summary and Conclusion

(0001, 3.2.P.8.1 Stab Summary Conclusion, page 6)

The applicant is requesting a (b) (4) month expiry when stored at 20-25 °C. The shelf life specification is the same as outline for the drug product release.

Adequate

Reviewer's Assessment:
The applicant's proposed (b) (4) month expiry is acceptable based on current microbial testing data.

P. 8.2 Post-Approval Stability Protocol and Stability Commitment

(0001, 3.2.P.8.2 Post Approval Stability Commitment)

The applicant commits to placing the first three commercial production batches on stability at 25 °C ± 2 °C at 60 ± 5 % RH, with testing conducted up to 36 months. Yearly thereafter, at least one production batch will be placed on the stability program. The applicant may submit a revised protocol to the Agency to extend the expiration date to (b) (4) months at a later date. Microbial tests (USP <60>, <61> and <62> with acceptance criteria per USP <1111>) will be conducted at time point zero (release), 6 months, 12 months, 24 months and 36 months following the same release specification.

The following informational request was forwarded to the applicant on March 22, 2021:

We acknowledge the antimicrobial effectiveness study conducted on lot RB0042-0560 provided as attachment 2 in document "produc-development-report.pdf". However a commitment to conduct antimicrobial effectiveness testing on one batch at the end of shelf life or the results from such study was not found within the application. Provide a commitment that at least one batch will be tested for antimicrobial effectiveness testing at the end of the proposed maximum shelf life per ICH Q1a or provide the data if the results from this study are available.

Applicant's Response (March 26, 2021):
The applicant provided a commitment to conduct antimicrobial effectiveness testing on one batch at the end of shelf life for the samples stored at long term test conditions. The stability protocol was revised to perform antimicrobial effectiveness testing as per USP<51>.

Adequate

Reviewer's Assessment:
The applicant provided an acceptable stability program for microbial testing.

P.8.3 Stability Data

(0001, 12-moth long term stability data)
The applicant provided microbial testing data for three lots up to 12 months under long term storage conditions with TAMC less than (b) (4) CFU/g, TYMC less than (b) (4) CFU/g and *E. coli* and *Burkholderia cepacia* complex being absent.

Adequate

Reviewer's Assessment:
The applicant provided acceptable microbiology stability data.

A Appendices

A.2 Adventitious Agents Safety Evaluation

Not Applicable

Reviewer's Assessment:

A.2.1 Materials of Biological Origin

Not Applicable

Reviewer's Assessment:

A.2.2 Testing at Appropriate Stages of Production

Not Applicable

Reviewer's Assessment:

A.2.3. Viral Testing of Unprocessed Bulk

Not Applicable

Reviewer's Assessment:

A. 2.4 Viral Clearance Studies

Not Applicable

Reviewer's Assessment:

R Regional Information

Executed Batch Records

The batch records were provided for batches TB0891 and TB089 which followed the proposed manufacturing process.

Adequate

Reviewer's Assessment:
The applicant provided detailed batch records for batches TB089 and TB0891. Batch TB090 included only the 6 month stability assessment.

Comparability Protocols
(3.2.R Regional Information, 0001, 3.2.R.2.P Comparability Protocols)
The applicant manufactured the exhibit batches at the proposed maximum commercial batch scale and thus did not provide any comparability protocols nor anticipates any post-approval changes to the manufacturing process.

Adequate

Reviewer's Assessment:
The applicant did not provide any comparability protocols.

2. REVIEW OF COMMON TECHNICAL DOCUMENT – QUALITY (CTD-Q) MODULE 1

2.A. Package Insert
(0001, SBS-Comparison of Prop PI with Topamax-PDF)

Storage 20-25 °C, excursions permitted between 15 to 30 °C.
Route of administration: Oral multiple dose solution.

Adequate

Reviewer's Assessment:

Antimicrobial effectiveness testing was performed per USP<51> demonstrating the effectiveness of the [redacted] (b) (4) for the room temperature storage.

MICROBIOLOGY LIST OF DEFICIENCIES

None

Primary Microbiology Assessor Name and Date:
David Bateman, Ph.D. (April 2, 2021)

Secondary Assessor Name and Date:
Christine Craig, Ph.D. (April 5, 2021)

Christine Craig

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David Bateman

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MARTHA R HEIMANN
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