CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219847Orig1s000

PRODUCT QUALITY REVIEW(S)

Title:	NDA IQA Template Title Page- EXEC SUMMARY
Document ID:	OPQ-ALL-TEM-0040
Effective Date:	18 Sep 2023 Revision: 00
Total Pages:	4

Template Revision: 03

Office of Pharmaceutical Quality

New Drug Application (NDA)
Integrated Quality Assessment

NDA Executive Summary

1. Application/Product Information

NDA Number	#219847		
Applicant Name	Azurity Pharmaceuticals, Inc.		
Drug Product Name	Arynta (Lisdexamfetamine Dimesylate) oral solution		
Dosage Form	Solution		
Proposed Strength(s)	10 mg/mL		
NDA Classification	Type 5 – New Formulation or New Manufacturer		
Route of Administration	Oral		
Maximum Daily Dose	70 mg		
Rx/OTC Dispensed	Rx		
Proposed Indication	For the treatment of: • Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older. • Moderate to severe binge eating disorder (BED) in adults		
Drug Product Description	A clear colorless solution, contains 10 mg/mL of lisdexamfetamine dimesylate (equivalent to 5.8 mg of lisdexamfetamine)		
Co-packaged product information	One press-in bottle adapter and one (b) (4) oral dispenser assembly (i.e., dosing syringe)		
Device information	N/A		
Storage Temperature/ Conditions	Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP controlled room temperature]. Keep the container tightly closed. Discard unused product (b) (4) after first opening the bottle.		
Review Team	**Discipline**	**Primary**	**Secondary**
	Drug Substance	Zhixing Shan	Donna Christner

	Drug Product/ Labeling	Renish Delvadia	Andrei Ponta / Julia Pinto
	Manufacturing	Khalid Khan	Tim Zhou
	Biopharmaceutics	NA	NA
	Microbiology	Lauren Walling	Erin Wall
	Other (specify)	NA	NA
	RBPM	Teshara Bouie	
	ATL	Andrei Ponta	
Consults	Not Applicable		

2. Final Overall Recommendation - *Approval*

3. Action Letter Information

a. Expiration Dating

18 months for product stored at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP controlled room temperature].

b. Additional Comments for Action

There are no additional comments for the action letter.

4. Basis for Recommendation:

a. Summary of Rationale for Recommendation:

OPQ recommends **Approval** for NDA 219847. Based on our evaluation of the available information, the applicant provided sufficient information to support an approval recommendation from the product quality perspective. The Applicant provided adequate information to ensure the identity, strength, purity, and strength of the proposed drug product. The overall manufacturing inspection recommendation is approval for all the facilities associated with this application. The proposed labeling is adequate to meet the regulatory requirements. Refer to the individual discipline primary reviews for additional information.

b. Is the overall recommendation in agreement with the individual discipline recommendations? Yes

Recommendation by Subdiscipline:

Drug Substance	**-**	**Adequate**
Drug Product	**-**	**Adequate**
Quality Labeling	**-**	**Adequate**
Manufacturing	**-**	**Adequate**
Biopharmaceutics	**-**	**N/A**
Microbiology	**-**	**Adequate**

Environmental Assessment: Categorical Exclusion - Adequate
QPA for EA(s): No

5. **Life-Cycle Considerations**
   Established Conditions per ICH Q12: No

   Comparability Protocols (PACMP): No

   Additional Lifecycle Comments: Not Applicable

Application Technical Lead Name and Date: Andrei Ponta 30 – Apr - 2025

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CHAPTER IV: LABELING

NDA 219847 (lisdexamfetamine dimesylate) Oral Solution

1.0 PRESCRIBING INFORMATION

Assessment of Product Quality Related Aspects of the Prescribing Information: Adequate

1.1 HIGHLIGHTS OF PRESCRIBING INFORMATION

Item	Information Provided in the NDA	Assessor's Comments
Product Title in Highlights **TRADENAME (lisdexamfetamine dimesylate) Oral Solution**		
Proprietary name	Not included	Under review
Established name(s)	(lisdexamfetamine dimesylate)	Adequate
Route(s) of administration	**Oral Solution**	Adequate
Dosage Forms and Strengths Heading in Highlights Oral solution: 10 mg/mL.		
Summary of the dosage form(s) and strength(s) in metric system.	10 mg/mL	Adequate
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)	None	

1.2.2 Section 3 (DOSAGE FORMS AND STRENGTHS)

Item	Information Provided in the NDA	Assessor's Comments
DOSAGE FORMS AND STRENGTHS section TRADENAME oral solution 10 mg/mL is supplied as a clear colorless solution.		
Available dosage form(s)	10 mg/mL	Adequate
Strength(s) in metric system	Yes	Adequate
If the active ingredient is a salt, apply the USP Salt Policy per FDA Guidance	Strength based on amount of salt	USP salt policy exceptions applied, because all current oral product strengths are based on the salt amount
A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, and imprinting	clear colorless solution	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	See the Edit above
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.	Strength based on amount of salt. Equivalency statement included for base amount	USP salt policy exceptions applied, because all current oral product strengths are based on the salt amount.
List names of all inactive ingredients. Use USP/NF names. Avoid Brand names.	Yes	Adequate
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	Yes	Adequate
Chemical name, structural formula, molecular weight	Yes	Adequate
If radioactive, statement of important nuclear characteristics.	N/A	
Other important chemical or physical properties (such as pKa or pH)		The Applicant will be asked to include information for pKa and pH for the solution.

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)

(b) (4)

Item	Information Provided in the NDA	Assessor's Comments
HOW SUPPLIED/STORAGE AND HANDLING section		
Available dosage form(s)	Oral solution	Adequate
Strength(s) in metric system	10 mg/mL	Adequate
Available units (e.g., bottles of 100 tablets)	100 mL PET bottle; Each sealed bottle is co-packaged with one press-in bottle adapter and one (b) (4) oral dispenser assembly (i.e., dosing syringe).	Adequate
Identification of dosage forms, e.g., shape, color, coating, scoring, imprinting, NDC number	a clear colorless solution	Adequate
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	

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.)	Keep the container tightly closed. Discard unused portion(b) (4) days after first opening.	Adequate
If the product contains a desiccant, ensure the size and shape differ from the dosage form and desiccant has a warning such as “Do not eat.”	N/A	
Storage conditions. Where applicable, use USP storage range rather than storage at a single temperature.	TRADENAME is stored at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].	Adequate
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	child resistant cap	The Applicant will be asked to include information about child resistant cap.

1.2.5 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 for: Azurity Pharmaceuticals, Inc. Woburn, MA 01801	Adequate

2.0 PATIENT LABELING

Assessment of Product Quality Related Aspects of Patient Labeling (e.g., Medication Guide, Patient Information, Instructions for Use):

(b) (4)

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Item	Information Provided in the NDA	Assessor's Comments about Carton Labeling
Proprietary name, established name, and dosage form (font size and prominence	(b) (4) (Lisdexamfetamine Dimesylate) oral solution	Adequate
Dosage strength	10 mg/mL	Adequate
Route of administration	Oral Use Only	Adequate
If the active ingredient is a salt, include the equivalency statement per FDA Guidance	Strength based on amount of salt. Equivalency statement included for base amount	USP salt policy exceptions applied, because all current oral product strengths are based on the salt amount
Net contents (e.g. tablet count)	100 mL	Adequate
"Rx only" displayed on the principal display	Yes	Adequate
NDC number	Yes	Adequate
Lot number and expiration date	Yes	Adequate
Storage conditions. If applicable, include a space on the carton labeling for the user to write the new BUD.	(b) (4)	Adequate
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	Yes	Adequate

Item	Information Provided in the NDA	Assessor’s Comments about Carton Labeling
Name of manufacturer/distributor	(b) (4)	Adequate
Medication Guide (if applicable)		Adequate
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 (b) (4)	Adequate

Assessment of Carton and Container Labeling: *Adequate*

ITEMS FOR ADDITIONAL ASSESSMENT

None

Overall Assessment and Recommendation:

Adequate

Primary Labeling Assessor Name and Date: Renishkumar Delvadia

Secondary Assessor Name and Date (and Secondary Summary, as needed): Julia Pinto

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CHAPTER VII: MICROBIOLOGY

IQA NDA Assessment Guide Reference

Product Information	
NDA Number	219847
Assessment Cycle Number	1
Drug Product Name/ Strength	Lisdexamfetamine Dimesylate Oral Solution, 10 mg/mL
Route of Administration	Oral Solution
Applicant Name	Azurity Pharmaceuticals, Inc.
Therapeutic Classification/ OND Division	ON/DP
Manufacturing Site	(b) (4)
Method of Sterilization	N/A, non-sterile

Assessment Recommendation: **Adequate**

Assessment Summary:

List Submissions being assessed (table):

Document(s) Assessed	Date Received
ORIG-1 (SD# 1)	08/16/2024
IR Response (SD# 5)*	11/12/2024

*Note that SD# 5 was provided in response to filing IRs, including micro IRs pertaining to AET and BCC testing method suitability.

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

Remarks: The drug product is a non-sterile, clear, colorless solution for oral administration packaged in a 100 mL PET bottle with a child-resistant cap. Each bottle is co-packaged with one press-in bottle adapter and one (b) (4) dosing syringe. The drug product is indicated in the treatment of ADHD in adults and pediatric patients 6 years and older, as well as in the treatment of moderate to severe binge eating disorder in adults.

Concise Description of Outstanding Issues: N/A

Supporting Documents: N/A

S DRUG SUBSTANCE

The drug substance is not provided sterile. Therefore, a product quality microbiology review of the drug substance is not reviewed.

P.1 DESCRIPTION OF THE COMPOSITION OF THE DRUG PRODUCT

- **Description of drug product –** Section 3.2.P.1., p. 1 of 4
  Lisdexamfetamine Dimesylate Oral Solution is a non-sterile, clear, colorless solution packaged in a multi-dose 100 mL PET bottle.
- **Drug product composition –** Section 3.2.P.1, p. 1 of 4

Ingredient	Quantity per mL	Function
Lisdexamfetamine Dimesylate	10.0 mg	API
Methylparaben Sodium	(b) (4)	
Propylparaben Sodium		
Monobasic Sodium Phosphate Dihydrate		
Dibasic Sodium Phosphate Dihydrate		
Propylene Glycol		
Saccharin Sodium		
Hydrochloric Acid		
Sodium Hydroxide		
Purified Water		

- **Description of container closure system –** Section 3.2.P.7, *Container Closure System* pdf, p. 4-5 of 6

Component	Description	Manufacturer
100 mL PET Bottle	Bottle 100 mL (b) (4) PET 28 mm	(b) (4)
28 mm Child Resistant (CR) Closure	Closure, (b) (4)	
28 mm Bottle Adapter*	Closure – Push in Bottle Adapter, 28 mm (b) (4) (b) (4)	
(b) (4) Oral Dispenser Assembly (Dosing Syringe)*	Oral Dispenser (b) (4)	

*The bottle adapter and dosing syringe are co-packaged with the drug product and are not primary packaging components.

Assessment: *Adequate*
The applicant has provided sufficient description of the drug product composition and container closure system.

P.2 PHARMACEUTICAL DEVELOPMENT

P.2.5 MICROBIOLOGICAL ATTRIBUTES

(b) (4)

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

2.A. Prescribing Information
Section 1.14.1.3, *Prescribing Information Label* pdf

Storage temperature: 20-25°C
Maximum storage time: (b) (4) after opening
Route of administration: Oral

The oral solution is ready to use and is not reconstituted or diluted.

Assessment: *Adequate*
There is no reconstitution or dilution prior to use and stability data (including AET) was provided in support of the storage conditions described in the product labeling.

MICROBIOLOGY LIST OF DEFICIENCIES
N/A

Primary Microbiology Assessor Name and Date: Lauren Walling, PhD, 11/22/2024
Secondary Assessor Name and Date (and Secondary Summary, as needed): Erin A. Wall, PhD, 11/25/2024

Lauren Walling

Digitally signed by Lauren Walling
Date: 3/25/2025 08:52:54AM
GUID: 62abd28d007b1e5fb079688cfa702925

Erin Wall

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Date: 3/25/2025 08:56:33AM
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