CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

090533Orig1s014

Trade Name:	Zenzedi
Generic or Proper Name:	Dextroamphetamine Sulfate
Sponsor:	Azurity Pharmaceuticals, Inc.
Approval Date:	July 16, 2025
Indication:	For treatment of attention-deficit hyperactivity disorder and narcolepsy.

ANDA 090533/S-014

CHANGES BEING EFFECTED IN 30 DAYS
APPROVAL

Azurity Pharmaceuticals, Inc.
8 Cabot Road
Suite 2000
Woburn, MA 01801
Attention: Mr. Nagarjuna Brahmanapalle
Senior Manager, Regulatory Affairs

Dear Mr. Nagarjuna Brahmanapalle:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on April 22, 2025, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Dextroamphetamine Sulfate Tablets, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 30 mg.

The sANDA, submitted as "Changes Being Effected in 30 Days," provides for:

> The periodic/skip testing (one lot per year) of specified tests (Specific Rotation, pH, Residue on Ignition, [redacted] Related Compounds, Residual Solvents, and Particle Size) in drug substance specifications during routine release testing at drug product manufacturing site [redacted]

We have completed the review of this sANDA and it is **approved**.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements

regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

If you have any questions, contact Thaoly Nguyen, Regulatory Business Process Manager, at (301) 796 - 2469 or Thaoly.Nguyen@fda.hhs.gov.

Sincerely yours,

{See appended electronic signature page}

For:
Thomas Oliver, Ph.D.
Director
Division of Product Quality Assessment I
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
Silver Spring, MD 20993
www.fda.gov

Disciplines Involved	Outcome		Disciplines Involved	Outcome
Chemistry	AQ		Biopharmaceutics	NA
Microbiology	NA		Bioequivalence	NA
Facilities	NA		DMF (Chemistry)	NA
Labeling	NA		DMF (Microbiology)	NA
Submissions Assessed				
Received Date:	4/22/2025			
Amendment(s) Date:				

OFFICE OF PHARMACEUTICAL QUALITY
ASSESSMENT OF SUPPLEMENT TO ABBREVIATED NEW DRUG APPLICATION

Chemistry Assessment Number : 01

ANDA/Supplement Number : ANDA 090533/S-14

Drug Product Name, Strength : Dextroamphetamine Sulfate Tablets, 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg, 30mg

Pharmacological Category/ Indication(s) : For treatment of attention-deficit hyperactivity disorder, and narcolepsy

Applicant Name (or US Agent if Applicable) : Azurity Pharmaceuticals, Inc.

Supplement Provides For : The periodic / skip testing (one lot per year) of specified tests (Specific Rotation, pH, Residue on Ignition, (b)(4) Related Compounds, Residual Solvents, and Particle Size) in drug substance specifications during routine release testing at drug product manufacturing site (b)(4)

Filing Category with basis for decision/comments (based on guidance for industry/CFR quotes) : CBE-30: the Guidance for Industry *Changes to an Approved NDA or ANDA*, Section VIII.C.1.a

Relevant Supporting DMF(s) Cited (If Applicable)

DMF No.	DMF	Result of Assessment	Date Assessment Completed
	Comment (if any) on DMF Assessment, Assessor		

ASSESSMENT NOTES

Azurity Pharmaceuticals, Inc. (Azurity) proposes to implement the periodic / skip testing of specified tests in drug substance specifications (Dextroamphetamine Sulfate) during routine release testing at drug product manufacturing site (b)(4) by relying on the results (CoAs) from the drug substance supplier (b)(4)

The test parameters (Description, Identification A, Identification B, Loss on Drying, and Assay) listed in the drug substance specifications will be tested on every drug substance lot at drug product manufacturer (b)(4)

The other test parameters (Specific Rotation, pH, Residue on Ignition, (b)(4) Related Compounds, Residual Solvents, and Particle Size) listed in the drug substance specifications will be tested on one lot per year.

The applicant's proposed drug substance specification in Section 3.2.S.4.1 comply with current Dextroamphetamine Sulfate USP monograph.

Table 1: Proposed drug substance specifications for Dextroamphetamine Sulfate

TEST IN ACCORDANCE WITH [redacted] PROCEDURE RMP0918

TEST	SPECIFICATIONS	RESULTS	DATE/CHEMIST
*DESCRIPTION	(b)(4)		
*IDENTIFICATION A			
IDENTIFICATION B			
*LOSS ON DRYING			
*ASSAY			
ANNUAL SUPPLIER VALIDATION TESTING			
SPECIFIC ROTATION	(b)(4)		
pH			
RESIDUE ON IGNITION			
(b)(4)			
*RELATED COMPOUNDS Cathinone Benzaldehyde Dextroamphetamine Related Compound A Dextroamphetamine Related Compound B Individual Unspecified Impurity Total			
RESIDUAL SOLVENTS (MFR) (b)(4)			
PARTICLE SIZE** (b)(4)			
(b)(4)			

The comparative test data between drug substance supplier (b)(4) and drug product manufacturing facility (b)(4) for three most recently tested drug substance lots are provided in Section 1.11.1, and listed in Table 2 below:

Table 2: The comparative test data for three most recently tested drug substance lots

Test	Specification	Drug Substance testing results					
		(b)(4)					
		0000168663	25R0038	0000157033	24R0133	0000148345	24R0017
Description							
Identification A							
Identification B							
Specific Rotation							
pH							
Loss on Drying							
Residue on Ignition							
(b)(4)							
Related Compounds							
Cathinone							
Benzaldehyde							
Dextroamphetamine RC A							
Dextroamphetamine RC B							
Individual Unspecified Impurity							
Total							
Assay							
Residual Solvents							
(b)(4)							
Particle Size*							
(b)(4)							
(b)(4)							

(b)(4)

The above tabulated data indicates that the batch results of all test parameters listed in the drug substance specifications have no significant trends, and well meet the proposed limits. In addition, the batch results of tested lots at drug product manufacturing facility (b)(4) are comparable with that of drug substance supplier (b)(4) No other change is made on the drug substance specifications and analytical procedures except the proposed change.

The applicant also states that the proposed periodic / skip testing of drug substance is based on following inferences from the satisfactory vendor qualification study performed by drug product manufacturer.

1. Sufficient information regarding the raw material and the manufacturer has been furnished.
2. The overall assessment of the manufacturing site was satisfactory.
3. Passing results on full testing performed on three lots of Dextroamphetamine Sulfate USP indicates that the raw material was consistently able to meet [redacted] specification.
4. Supplier trend data on multiple lots showed no complaint investigations or discrepancy investigations on confirmed OOS results for Dextroamphetamine Sulfate USP.

The drug product manufacturer also commits that if any batch fails to meet the criteria for full testing, an investigation will be conducted in accordance with internal SOP.

The Applicant contact details for this ANDA are also updated in the Cover Letter, Form 356h, and Section 1.3.1.2.

In conclusion, the proposed drug substance reduced testing during routine release at drug product manufacturing site [redacted] does not have adverse effect on the quality of drug substance and drug products. The proposed CBE-30 change is acceptable from CMC perspective.

RECOMMENDATION

☒ Supplement is CMC Approvable

☐ Supplement is NOT CMC Approvable (with brief explanation:)

(Choose ☐ IR, ☐ CR-Minor, ☐ CR-Major); Deficiencies noted below:

Deficiencies to be communicated:
None.

Primary Assessor : Xinming Liu **Date : 07/14/2025**