

Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-Dec-2014
 Document Type: USP Monographs
 DocId: GUID-95BFFF17-0809-4238-A1AB-04444214332F_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M24060_02_01
 DOI Ref: e9um4

© 2025 USPC
 Do not distribute

Dextroamphetamine Sulfate Tablets

DEFINITION

Dextroamphetamine Sulfate Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of dextroamphetamine sulfate $[(C_9H_{13}N)_2 \cdot H_2SO_4]$.

IDENTIFICATION

• A.

Sample: Nominally 50 mg of dextroamphetamine sulfate from a portion of finely ground Tablets

Analysis: Transfer the *Sample* to a suitable centrifuge tube. Add 25 mL of water, shake vigorously, and centrifuge until clear. Decant the clear solution into a 250-mL separator, add 5 mL of 2.5 N sodium hydroxide, and extract with 60 mL of ether. Wash the ether extract with two 5-mL portions of 0.25 N sodium hydroxide, and discard the washings. Filter the ether extract through a pledget of cotton, previously saturated with ether, into a 100-mL beaker, and evaporate on a steam bath in a current of air to 1 mL. Dissolve the residue in 3 mL of alcohol, and transfer to a glass-stoppered, 125-mL conical flask containing 25 mL of water. Rinse the beaker with 3 mL of alcohol, and transfer to the flask. Cool to 15°, add 3 mL of 1 N sodium hydroxide, then add 1 mL of a mixture of 1 volume of benzoyl chloride and 2 volumes of anhydrous ethyl ether, and shake for 2 min. Filter the precipitate, wash with 15 mL of cold water, and recrystallize twice from diluted alcohol to obtain the benzoyl derivative of dextroamphetamine. Dry the crystals at 105° for 1 h.

Acceptance criteria: The crystals melt between 154° and 160°.

• B. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Solution A: Glacial acetic acid in water (14 in 100)

Mobile phase: Dissolve 1.1 g of sodium 1-heptanesulfonate in 525 mL of water. Add 25 mL of *Solution A* and 450 mL of methanol. Adjust dropwise, if necessary, with glacial acetic acid to a pH of 3.3 ± 0.1 . Pass through a membrane filter of 0.5-μm pore size.

Diluent: 0.12 N phosphoric acid

Standard solution: 0.3 mg/mL of [USP Dextroamphetamine Sulfate RS](#) in *Diluent*

Sample solution: Nominally 0.3 mg/mL of dextroamphetamine sulfate from NLT 20 Tablets prepared as follows. Finely powder NLT 20 Tablets, and transfer a portion of the powder, equivalent to 15 mg of dextroamphetamine sulfate, to a 50-mL volumetric flask. Add 40 mL of *Diluent*, and sonicate for 15 min. Dilute with *Diluent* to volume. Pass through a membrane filter of 0.5-μm pore size, discarding the first 20 mL of the filtrate.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 50 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 3

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dextroamphetamine sulfate $[(C_9H_{13}N)_2 \cdot H_2SO_4]$ in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Dextroamphetamine Sulfate RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of dextroamphetamine sulfate in the *Sample solution* (mg/mL)

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Procedure for a pooled sample

Medium: Water; 500 mL

Apparatus 1: 100 rpm

Time: 45 min

Mobile phase: Dissolve 1.1 g of sodium 1-heptanesulfonate in 575 mL of water. Add 25 mL of dilute glacial acetic acid (14 in 100) and 400 mL of methanol. Adjust by the dropwise addition of glacial acetic acid to a pH of 3.3 ± 0.1 , if necessary.

Standard solution: [USP Dextroamphetamine Sulfate RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Column: 3.9-mm \times 30-cm; packing L1

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 100 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dextroamphetamine sulfate $[(C_9H_{13}N)_2 \cdot H_2SO_4]$ dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times V \times (1/L) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Dextroamphetamine Sulfate RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of dextroamphetamine sulfate in the *Sample solution* (mg/mL)

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of dextroamphetamine sulfate $[(C_9H_{13}N)_2 \cdot H_2SO_4]$ is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at controlled room temperature.

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Dextroamphetamine Sulfate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
DEXTROAMPHETAMINE SULFATE TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 39(5)

Current DocID: GUID-95BFFF17-0809-4238-A1AB-04444214332F_2_en-US

Previous DocID: GUID-95BFFF17-0809-4238-A1AB-04444214332F_1_en-US

DOI: https://doi.org/10.31003/USPNF_M24060_02_01

DOI ref: [e9um4](#)

OFFICIAL