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Dobutamine for Injection

DEFINITION

Dobutamine for Injection is a sterile mixture of Dobutamine Hydrochloride with suitable diluents. It contains an amount of dobutamine hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of dobutamine ($C_{18}H_{23}NO_3$).

[**Caution**—Great care should be taken to prevent inhaling particles of Dobutamine for Injection and exposing the skin to it. Protect the eyes.]

IDENTIFICATION

• **A.**

Standard solution: Freshly prepare 10 mg/mL of USP Dobutamine Hydrochloride RS in methanol.

Sample solution: 10 mg/mL of dobutamine hydrochloride in methanol, clarified by centrifugation

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 10 µL

Developing solvent system: Ethyl acetate, *n*-propyl alcohol, glacial acetic acid, and water (100:40:5:15)

Analysis

Samples: *Standard solution* and *Sample solution*

Allow the spots to dry, and develop the chromatogram in the *Developing solvent system*, until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate at room temperature. Observe the plate under short-wavelength UV light.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• **Procedure**

Ion-pair solution: Dissolve 3.38 g of sodium 1-octanesulfonate in 1000 mL of water, and pipet 3 mL of triethylamine into the solution. Adjust the solution with phosphoric acid to a pH of 2.5.

Mobile phase: Acetonitrile, methanol, and *Ion-pair solution* (28:14:58)

[Note—The ratio of acetonitrile to methanol is critical to the elution order of the *System suitability solution* components.]

System suitability solution: 0.3 mg/mL of 4-(4-hydroxyphenyl)-2-butanone and 0.56 mg/mL of USP Dobutamine Hydrochloride RS in *Mobile phase*

Standard solution: 0.56 mg/mL (equivalent to 0.5 mg/mL of dobutamine) of USP Dobutamine Hydrochloride RS in *Mobile phase*

Sample solution: 0.5 mg/mL of dobutamine in *Mobile phase* prepared as follows. Inject 10 mL of *Mobile phase* into 1 vial of Dobutamine for Injection, taking care not to let pressure build up in the vial. Shake to dissolve the sample completely. Transfer the solution to a suitable volumetric flask, and dilute with *Mobile phase*.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-µm, base-deactivated packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for 4-(4-hydroxyphenyl)-2-butanone and dobutamine are about 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between 4-(4-hydroxyphenyl)-2-butanone and dobutamine

Tailing factor: NMT 1.5 for dobutamine

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dobutamine ($C_{18}H_{23}NO_3$) in each container of Dobutamine for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Dobutamine Hydrochloride RS in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of dobutamine, 301.38

M_{r2} = molecular weight of dobutamine hydrochloride, 337.84

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample solution: Dissolve contents of 1 vial in 10 mL of water.

Acceptance criteria: 2.5–5.5

• **Injections and Implanted Drug Products ⟨1⟩:** Meets the requirements

• **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 5.56 USP Endotoxin Units/mg of dobutamine

• **Constituted Solution:** At the time of use, it meets the requirements in *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*. Do not use the constituted solution if it is brown or contains a precipitate.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*, at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Dobutamine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DOBUTAMINE FOR INJECTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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