Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Apr-2017
Document Type: USP Monographs
DocId: GUID-15C22623-F61D-46A9-B045-8E8E3CA708B3_3_en-US
DOI: https://doi.org/10.31003/USPNF_M27775_03_01
DOI Ref: flv2l

Dobutamine Injection

DEFINITION

Dobutamine Injection is a sterile solution of Dobutamine Hydrochloride in Water for Injection. It contains an amount of Dobutamine Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of dobutamine ($C_{18}H_{23}NO_3$). It may contain one or more suitable antioxidants, chelating agents, or preservatives.

IDENTIFICATION

• **A.**

Standard solution: 10 mg/mL of USP Dobutamine Hydrochloride RS in methanol (freshly prepared)

Sample solution: Use the neat Injection.

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. Mark the solvent front, and allow it 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 1 L 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: Equivalent to a suitable volume of 0.5 mg/mL of dobutamine in *Mobile phase*, from Injection

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 the portion of 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, 301.39

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 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⟩:** It contains NMT 2.08 USP Endotoxin Units/mg of dobutamine.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass.
- **Labeling:** Label it to indicate that it is to be diluted with a suitable parenteral vehicle to appropriate strength before administration.
- **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 INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 47(1)

Current DocID: GUID-15C22623-F61D-46A9-B045-8E8E3CA708B3_3_en-US
Previous DocID: GUID-15C22623-F61D-46A9-B045-8E8E3CA708B3_1_en-US
DOI: https://doi.org/10.31003/USPNF_M27775_03_01
DOI ref: flv2l