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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 μ L

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 $\times$ 25-cm; 5- μ m, base-deactivated packing L1

Flow rate: 1 mL/min

Injection volume: 20 μ L

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:

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