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# Dobutamine in Dextrose Injection

**DEFINITION**

Dobutamine in Dextrose Injection is a sterile solution of Dobutamine Hydrochloride and Dextrose 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 ($C_{18}H_{23}NO_3$) and NLT 90.0% and NMT 110.0% of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$). It may contain one or more suitable antioxidants or chelating agents.

**IDENTIFICATION**

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay, Procedure 2: Dobutamine*.

• **B.**

**Sample solution:** Nominally 50 mg/mL of dextrose from Injection

**Analysis:** Add a few drops of the *Sample solution* to 5 mL of hot alkaline cupric tartrate TS.

**Acceptance criteria:** A copious red precipitate of cuprous oxide is formed.

**ASSAY**

***Change to read:***

• **Procedure 1: Dextrose**

**Sample solution:** Injection

**Analysis**

**Sample:** *Sample solution*

Determine the angular rotation of the *Sample solution* in a suitable polarimeter tube (see *Optical Rotation* ⟨781⟩).

Calculate the percentage of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$) in the portion of Injection taken:

$$\text{Result} = [(100 \times a)^{\blacktriangle}/_{\blacktriangle\ (\text{ERR 1-Jan-2021})}\ (l^{\blacktriangle} \times_{\blacktriangle\ (\text{ERR 1-Jan-2021})}\ \alpha)] \times (1/C_U) \times (M_{r1}/M_{r2}) \times 100$$

$a$ = observed rotation (°)

$l$ = length of the polarimeter tube (dm)

$\alpha$ = midpoint of the specific rotation range for anhydrous dextrose, 52.9°

$C_U$ = nominal concentration of dextrose in the *Sample solution* (g/100 mL)

$M_{r1}$ = molecular weight of dextrose monohydrate, 198.17

$M_{r2}$ = molecular weight of anhydrous dextrose, 180.16

**Acceptance criteria:** 90.0%–110.0%

• **Procedure 2: Dobutamine**

**Buffer:** Transfer about 23 g of monobasic ammonium phosphate to a 2-L volumetric flask. Add 1900 mL of water. Adjust with phosphoric acid to a pH of 2.2, and dilute with water to volume.

**Mobile phase:** Acetonitrile and *Buffer* (20:80). Filter and degas.

**System suitability solution:** 0.5 mg/mL of USP Dobutamine Hydrochloride RS and 0.01 mg/mL of 5-hydroxymethylfurfural in water

**Standard solution:** 0.5 mg/mL of USP Dobutamine Hydrochloride RS in water. [Note—Prepare fresh daily, and refrigerate until injected.]

**Sample solution:** Nominally 0.446 mg/mL of dobutamine from Injection in water. [Note—Refrigerate until injected, and use within 8 h.]

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 280 nm

**Column:** 3.9-mm × 30-cm; packing L1

**Flow rate:** 1.5 mL/min

**Injection volume:** 20 µL

**System suitability**

**Samples:** *System suitability solution* and *Standard solution*

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**Suitability requirements**

**Relative retention time:** 1.0 for dobutamine and NMT 0.62 for 5-hydroxymethylfurfural, *System suitability solution*

**Retention time:** NMT 5.3 min for dobutamine, *System suitability solution*

**Tailing factor:** NMT 2.0, *Standard solution*

**Relative standard deviation:** NMT 2.0%, *Standard solution*

**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 of dobutamine from the *Sample solution*

$r_S$ = peak response of dobutamine 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%

## IMPURITIES

• **Organic Impurities**

**Buffer, Mobile phase, System suitability solution, Standard solution,** and **Chromatographic system:** Proceed as directed in the *Assay, Procedure 2: Dobutamine*.

**Sample solution:** Nominally 0.446 mg/mL of dobutamine from Injection in water

**Analysis**

**Sample:** *Sample solution*

Calculate the percentage of each impurity, excluding 5-hydroxymethylfurfural from all calculations, in the portion of Injection taken:

$$\text{Result} = (r_U/r_T) \times 100$$

$r_U$ = peak response for each impurity

$r_T$ = sum of all the peak responses

**Acceptance criteria**

**Any individual impurity:** NMT 1.0%

**Total impurities:** NMT 2.0%

• **Limit of 5-Hydroxymethylfurfural**

**Ion-exchange column:** Fill an 8-mm chromatographic tube to a height of 40 mm with a 100- to 200-mesh, strongly acidic, styrene-divinylbenzene cation-exchange resin. Wash the column with 30 mL of water, and discard the eluate.

[Note—Prepare a new column for each *Sample solution* and *Blank*, and use each column only once.]

**Sample solution:** Transfer 2 mL of Injection to the *Ion-exchange column*, and collect the eluate in a 50-mL volumetric flask. Pass 25 mL of water through the column, and collect the eluate in the same volumetric flask. Dilute the eluate with water to volume. Remove the stopper from the flask, and allow the solution to stand for about 30 min in order to oxidize any bisulfite ions present.

**Blank:** Prepare as directed in the *Sample solution* by passing 27 mL of water through an *Ion-exchange column* and collecting the eluate in a 50-mL volumetric flask. Dilute with water to volume.

**Instrumental conditions**

**Mode:** UV

**Analytical wavelength:** 284 nm

**Cell:** 1 cm

**Analysis**

**Samples:** *Sample solution* and *Blank*

Determine the absorbance of the *Sample solution* after correcting for the *Blank*.

**Acceptance criteria:** NMT 0.25

## SPECIFIC TESTS

• **pH ⟨791⟩:** 2.5–5.5

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

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

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

**ADDITIONAL REQUIREMENTS**

• **Packaging and Storage:** Preserve in single-dose containers, preferably of Type II glass, or of a suitable plastic material. Store at room temperature, avoid excessive heat, and protect from freezing.

• **Labeling:** The label states the total osmolar concentration in mOsmol/L.

• **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 IN DEXTROSE INJECTION | Documentary Standards Support | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

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