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Dopamine Hydrochloride and Dextrose Injection

» Dopamine Hydrochloride and Dextrose Injection is a sterile solution of Dopamine Hydrochloride and Dextrose in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of dopamine hydrochloride ($C_8H_{11}NO_2 \cdot HCl$) and of dextrose ($C_6H_{12}O_6 \cdot H_2O$).

[NOTE—Do not use the Injection if it is darker than slightly yellow or discolored in any other way.]

Packaging and storage—Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass.

Labeling—The label states the total osmolar concentration in mOsmol per L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol per mL.

USP Reference standards ⟨11⟩—
USP Dopamine Hydrochloride RS

Identification—

A: Add a few drops of a solution (1 in 20) to 5 mL of hot alkaline cupric tartrate TS. A copious red precipitate of cuprous oxide is formed.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay for dopamine hydrochloride*.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 16.67 USP Endotoxin Units per mg of dopamine hydrochloride.

pH ⟨791⟩**:** between 2.5 and 4.5.

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

Change to read:

Limit of 5-hydroxymethylfurfural and related substances—

Diluting solution—Prepare a solution containing approximately 0.022 N sodium hydroxide in water.

Cation-exchange column—Proceed as directed under ▲*Chromatography* ⟨621⟩*, General Procedures, Column Chromatography,*▲ (ERR 1-Jan-2021) using a chromatographic tube capable of providing a 0.8-cm × 4-cm bed volume (or about 2 mL) of 100- to 200-mesh, strongly acidic, styrene-divinylbenzene cation-exchange resin. Condition the column by washing with about 30 mL of water, discarding the eluate.

Procedure—Pass a volume of Injection containing about 100 mg of hydrous dextrose through the resin bed in the *Cation-exchange column*, allowing the specimen to flow down the wall of the column so as not to disturb the resin bed, and collect the eluate in a 50-mL volumetric flask. Wash the column with 25 mL of water, and collect the eluate in the same 50-mL volumetric flask. Dilute the eluate with *Diluting solution* to volume, and mix to obtain the test solution. In a similar manner, prepare a blank by passing 27 mL of water through a freshly conditioned *Cation-exchange column,* collecting the eluate in a 50-mL volumetric flask, diluting with *Diluting solution* to volume, and mixing. Determine the absorbance of the test solution against the blank in a 1-cm cell at 284 nm, with a suitable spectrophotometer: the absorbance is not more than 0.25.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay for dopamine hydrochloride—Proceed with Injection as directed in the *Assay* under *Dopamine Hydrochloride Injection*.

Assay for dextrose—Transfer an accurately measured volume of Injection, containing 2 to 5 g of dextrose, to a 100-mL volumetric flask. Add 0.2 mL of 6 N ammonium hydroxide, dilute with water to volume, and mix. Determine the angular rotation in a suitable polarimeter tube (see *Optical Rotation* ⟨781⟩). Calculate the percentage (g per 100 mL) of dextrose ($C_6H_{12}O_6 \cdot H_2O$) in the portion of Injection taken by the formula:

$$(100/52.9)(198.17/180.16)AR$$

in which 100 is the percentage; 52.9 is the midpoint of the specific rotation range for anhydrous dextrose, in degrees; 198.17 and 180.16 are the molecular weights for dextrose monohydrate and anhydrous dextrose, respectively; *A* is 100 mm divided by the length of the polarimeter tube, in mm; and *R* is the observed rotation, in degrees.

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

Topic/Question	Contact	Expert Committee
DOPAMINE HYDROCHLORIDE AND DEXTROSE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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