Dopamine Hydrochloride Injection

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Posting Date	28–Aug–2020
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Expert Committee	Chemical Medicines Monographs 2
Reason for Revision	Compliance

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Chemical Medicines Monographs 2 Expert Committee has revised the Dopamine Hydrochloride Injection monograph. The purpose for the revision is to update the *Packaging and Storage* requirements from "Preserve in single-dose containers of Type I glass" to "Preserve in single-dose containers, preferably of Type I glass", in order to allow flexibility and accommodate FDA-approved drug product applications.

Additionally, minor editorial changes have been made to update the monograph to current *USP* style.

The Dopamine Hydrochloride Injection Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Tsion Bililign, Scientific Liaison (301-816-8286 or tb@usp.org).

Revision Bulletin
Official: September 1, 2020

Dopamine Hydrochloride Injection

DEFINITION

Dopamine Hydrochloride Injection is a sterile solution of Dopamine Hydrochloride in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of dopamine hydrochloride ($C_8H_{11}NO_2 \cdot HCl$). It may contain a suitable antioxidant.

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

IDENTIFICATION

- **A. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST ⟨201⟩**

Standard solution: 1.6 mg/mL of USP Dopamine Hydrochloride RS in dilute methanol (1:5)

Sample solution: Nominally 1.6 mg/mL of dopamine hydrochloride prepared as follows. Transfer a volume of Injection to a suitable container, and dilute if necessary, with dilute methanol (1:5).

Chromatographic system

Application volume: 5 µL

Developing solvent system: *n*-Butyl alcohol, glacial acetic acid, and water (4:1:1)

Analysis

Samples: *Standard solution* and *Sample solution*

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

ASSAY

- **PROCEDURE**

Solution A: 0.005 M sodium 1-octanesulfonate in 1% glacial acetic acid

Mobile phase: Acetonitrile and *Solution A*, (13:87). Filtered and degassed.

System suitability stock solution A: About 20 mg/mL of benzoic acid in methanol

System suitability stock solution B: About 5 mg/mL of benzoic acid from *System suitability stock solution A* prepared as follows. Dilute the *System suitability stock solution A* with *Mobile phase* (1:3, v/v).

Standard stock solution: About 1.6 mg/mL of USP Dopamine Hydrochloride RS in *Mobile phase*

System suitability solution: 0.16 mg/mL of USP Dopamine Hydrochloride RS and 0.5 mg/mL of benzoic acid prepared as follows. Transfer 10.0 mL of *System suitability stock solution B* and 10.0 mL of *Standard stock solution* to a 100-mL volumetric flask, dilute with *Mobile phase* to volume.

Standard solution: About 0.16 mg/mL of USP Dopamine Hydrochloride RS from the *Standard stock solution* in *Mobile phase*

Sample solution: Nominally 0.16 mg/mL of dopamine hydrochloride prepared as follows. Transfer an accurately measured volume of Injection, equivalent to about 16 mg of dopamine hydrochloride, to a 100-mL volumetric flask, dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 40 µL

System suitability

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

Suitability requirements

Resolution: NLT 4.0 between benzoic acid and dopamine hydrochloride, *System suitability solution*

Relative standard deviation: NMT 3.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dopamine hydrochloride ($C_8H_{11}NO_2 \cdot HCl$) in the portion of Injection taken:

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

r_U = peak response of dopamine from the *Sample solution*

r_S = peak response of dopamine from the *Standard solution*

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

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

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** NMT 16.67 USP Endotoxin Units/mg of dopamine hydrochloride
- **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections
- **pH ⟨791⟩:** 2.5–5.0
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

Change to read:

- **Packaging and Storage:** Preserve in single-dose containers, ▲preferably▲ (RB 1-Sep-2020) of Type I glass.
- **Labeling:** Label it to indicate that the Injection is to be diluted with a suitable parenteral vehicle prior to intravenous infusion.
- **USP Reference standards ⟨11⟩**
  USP Dopamine Hydrochloride RS

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