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Dopamine Hydrochloride Injection

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click

<https://www.uspnf.com/rb/dopamine-hcl-inj-20200828>.

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 μ L

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 $\times$ 30-cm; packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 40 μ L

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](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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