Dopamine Hydrochloride Injection

Type of Posting  Revision Bulletin
Posting Date  28–Aug–2020
Official Date  01–Sep–2020
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).
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 (C₈H₁₁NO₂·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<sub>F</sub> 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 System suitability 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:

\[
\text{Result} = \left( \frac{r_U}{r_S} \right) \times \left( \frac{C_S}{C_U} \right) \times 100
\]

- $r_U$ = 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 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*

---

**Page Information:**

Not Applicable

**DocID:**

© 2020 The United States Pharmacopeial Convention *All Rights Reserved.*