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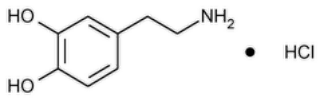
Dopamine Hydrochloride



$C_8H_{11}NO_2 \cdot HCl$ 189.64

1,2-Benzenediol, 4-(2-aminoethyl)-, hydrochloride;

4-(2-Aminoethyl)pyrocatechol hydrochloride CAS RN®: 62-31-7; UNII: 7L3E358N9L.

DEFINITION

Dopamine Hydrochloride contains NLT 98.0% and NMT 102.0% of dopamine hydrochloride ($C_8H_{11}NO_2 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** ▲197A or▲ (USP 1-Aug-2022) 197K

Delete the following:

▲• **B. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*:** 197U

Sample solution: 40 µg/mL in *Medium*

Medium: Sodium bisulfite in water (1 in 1000)▲ (USP 1-Aug-2022)

Add the following:

▲• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2022)

• **C. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Chloride*:** Meets the requirements

ASSAY

Change to read:

• **Procedure**

▲**Buffer:** Dissolve 21 g of citric acid in 200 mL of 1 N sodium hydroxide in a 1-L flask. Dilute with water to volume. To 600 mL of this solution add 400 mL of 0.1 N hydrochloric acid.

Solution A: Dissolve 1.08 g of 1-octanesulfonic acid sodium salt in 880 mL of *Buffer* in a 1-L flask. Add 50 mL of methanol and 70 mL of acetonitrile.

Solution B: Dissolve 1.08 g of 1-octanesulfonic acid sodium salt in 700 mL of *Buffer* in a 1-L flask. Add 100 mL of methanol and 200 mL of acetonitrile.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	90	10
5.0	90	10
20.0	40	60
25.0	40	60
25.1	90	10
35.0	90	10

Standard solution: 0.5 mg/mL of USP Dopamine Hydrochloride RS in *Solution A*

Sample solution: 0.5 mg/mL of Dopamine Hydrochloride in *Solution A*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 15-cm; 4.0-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dopamine hydrochloride ($C_8H_{11}NO_2 \cdot HCl$) in the portion of Dopamine Hydrochloride 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 = concentration of Dopamine Hydrochloride in the *Sample solution* (mg/mL)▲ (USP 1-Aug-2022)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Chloride and Sulfate ⟨221⟩, *Sulfate***

Standard solution: 0.10 mL of 0.020 N sulfuric acid

Sample solution: 500 mg of Dopamine Hydrochloride in 40 mL of water

Acceptance criteria: Any turbidity produced in the *Sample solution* is NMT that produced in the *Standard solution*.

Change to read:

• **Organic Impurities**

▲**Buffer, Solution A, Solution B, Mobile phase,** and **Chromatographic system:** Proceed as directed in the *Assay*.

System suitability solution: 0.024 mg/mL each of USP Dopamine Related Compound A RS and USP Dopamine Related Compound B RS in *Solution A*

Sensitivity solution: 0.001 mg/mL of USP Dopamine Hydrochloride RS in *Solution A*

Standard solution: 0.002 mg/mL each of USP Dopamine Hydrochloride RS, USP Dopamine Related Compound A RS, USP Dopamine Related Compound B RS, and USP Dopamine Related Compound C RS in *Solution A*

Sample solution: 2.0 mg/mL of Dopamine Hydrochloride in *Solution A*

System suitability

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

[Note—See *Table 2* for the relative retention times.]

Suitability requirements

Resolution: NLT 5.0 between dopamine related compound B and dopamine related compound A, *System suitability solution*

Relative standard deviation: NMT 5.0% for dopamine related compound A, dopamine related compound B, and dopamine related compound C, *Standard solution*

Signal-to-noise ratio: NLT 20, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dopamine related compound A, dopamine related compound B, and dopamine related compound C in the portion of Dopamine Hydrochloride taken:

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

r_U = peak response of dopamine related compound A, dopamine related compound B, or dopamine related compound C from the *Sample solution*

r_S = peak response of dopamine related compound A, dopamine related compound B, or dopamine related compound C from the *Standard solution*

C_S = concentration of the USP Dopamine Related Compound A RS, USP Dopamine Related Compound B RS, or USP Dopamine Related Compound C RS in the *Standard solution* (mg/mL)

C_U = concentration of Dopamine Hydrochloride in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified impurity in the portion of Dopamine Hydrochloride taken:

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

r_U = peak response of any unspecified impurity from the *Sample solution*

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

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

C_U = concentration of Dopamine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 2*. The reporting threshold is 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Dopamine	1.0	—
Dopamine related compound B	2.1	0.1
Dopamine related compound A	2.8	0.1
Dopamine related compound C	4.2	0.1
Any unspecified impurity	—	0.10
Total impurities	—	0.2▲ (USP 1-Aug-2022)

SPECIFIC TESTS

Delete the following:

▲• **Readily Carbonizable Substances Test** ⟨271⟩

Sample solution: 100 mg of Dopamine Hydrochloride in 5 mL of sulfuric acid

Acceptance criteria: The solution has no more color than *Matching Fluid A* (see *Color and Achromicity* ⟨631⟩, *Color Determination and Standards*).▲ (USP 1-Aug-2022)

• **pH** ⟨791⟩

Sample solution: 1 in 25

Acceptance criteria: 3.0–5.5

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 0.5%

Delete the following:

▲• **Clarity and Color of Solution**

Sample solution: 400 mg of Dopamine Hydrochloride in 10 mL of sodium bisulfite solution (1 in 1000)

Acceptance criteria: This solution is clear and colorless, or practically colorless.▲ (USP 1-Aug-2022)

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight containers. Store at ▲controlled▲ (USP 1-Aug-2022) room temperature.

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Dopamine Hydrochloride RS

▲ USP Dopamine Related Compound A RS

5-(2-Aminoethyl)-2-methoxyphenol.

$C_9H_{13}NO_2$ 167.21

USP Dopamine Related Compound B RS

4-(2-Aminoethyl)-2-methoxyphenol.

$C_9H_{13}NO_2$ 167.21

USP Dopamine Related Compound C RS

2-(3,4-Dimethoxyphenyl)ethan-1-amine.

$C_{10}H_{15}NO_2$ 181.23▲ (USP 1-Aug-2022)

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

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

Chromatographic Database Information: Chromatographic Database

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