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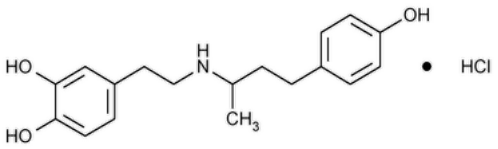
Dobutamine Hydrochloride

Change to read:



$C_{18}H_{23}NO_3 \cdot HCl$ 337.84

1,2-Benzenediol, 4-[2-[[3-(4-hydroxyphenyl)-1-methylpropyl]amino]ethyl]-, hydrochloride, (±)-;

(±)-4-[2-[[3-(*p*-Hydroxyphenyl)-1-methylpropyl]amino]ethyl]-pyrocatechol hydrochloride CAS RN®: 49745-95-1; ▲UNII: 0WR771DJXV.▲ (USP 1-Aug-2023)

DEFINITION

Dobutamine Hydrochloride contains NLT 98.0% and NMT 102.0% of dobutamine hydrochloride ($C_{18}H_{23}NO_3 \cdot HCl$), calculated on the anhydrous basis.

[**Caution—**Great care should be taken to prevent inhaling particles of dobutamine hydrochloride and exposing the skin to it. Protect the eyes.]

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A or 197K

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

Delete the following:

▲• **C. Chloride**▲ (USP 1-Aug-2023)

Add the following:

▲• **C. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Chloride***

Sample solution: 50 mg/mL of Dobutamine Hydrochloride in a mixture of water and methanol (50:50)

Analysis: Proceed as directed in the chapter using the procedure for amine hydrochlorides, except wash the precipitate with three 1-mL portions of water.

Acceptance criteria: Meets the requirements of the test for amine hydrochlorides▲ (USP 1-Aug-2023)

ASSAY

Change to read:

• **Procedure**

Solutions containing dobutamine hydrochloride must be prepared fresh at the time of use and refrigerated until injected.

Solution A: Transfer 23 g of monobasic ammonium phosphate to a 2-L volumetric flask, and add 1900 mL of water. Adjust with phosphoric acid to a pH of 2.2, and dilute with water to volume.

Mobile phase: Acetonitrile and *Solution A* (20:80)

Standard solution: 0.5 mg/mL of USP Dobutamine Hydrochloride RS in water

Sample solution: 0.5 mg/mL of Dobutamine Hydrochloride in water

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; 15–20-µm packing L1. ▲[Note—Alternatively, a column with 10-µm particle size may be used.]▲ (USP 1-Aug-2023)

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dobutamine hydrochloride ($C_{18}H_{23}NO_3 \cdot HCl$) in the portion of Dobutamine Hydrochloride taken:

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

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

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

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

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

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

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.2%

Change to read:

• **Organic Impurities**

Solution A: 2.6 g/L of sodium 1-octanesulfonate in water. Pipet 3 mL of triethylamine into 1 L of this solution. Adjust the solution with phosphoric acid to a pH of 2.5.

Solution B: Methanol and acetonitrile (82:18)

Diluent: *Solution A* and *Solution B* (50:50)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	65	35
5	65	35
20	20	80
25	20	80
26	65	35
30	65	35

Sensitivity solution: 1.25 µg/mL of USP Dobutamine Hydrochloride RS in *Diluent*

Standard solution: 0.025 mg/mL each of USP Dobutamine Related Compound C RS, USP Dopamine Hydrochloride RS, and USP Raspberry Ketone RS; and 0.005 mg/mL of USP Dobutamine Hydrochloride RS in *Diluent*

Sample solution: 5 mg/mL of Dobutamine Hydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *Sensitivity solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between dopamine and raspberry ketone, *Standard solution*

Tailing factor: NMT 2.0 for dobutamine, *Standard solution*

Relative standard deviation: NMT 2.0% for dobutamine, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ▲dopamine, raspberry ketone, and dobutamine related compound C▲ (USP 1-Aug-2023) in the portion of Dobutamine Hydrochloride taken:

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

r_U = peak response of ▲dobutamine related compound C, dopamine, and raspberry ketone▲ (USP 1-Aug-2023) from the *Sample solution*

r_S = peak response of ▲dobutamine related compound C, dopamine, and raspberry ketone▲ (USP 1-Aug-2023) from the *Standard solution*

C_S = concentration of the corresponding Reference Standard in the *Standard solution* (mg/mL)

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

Calculate the percentage of ▲any▲ (USP 1-Aug-2023) unspecified impurities in the portion of Dobutamine Hydrochloride taken:

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

r_U = peak response of ▲any▲ (USP 1-Aug-2023) unspecified impurity from the *Sample solution*

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

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

C_U = concentration of Dobutamine 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	0.33	0.5
Raspberry ketone	0.45	0.5
Dobutamine	1.00	—
Dobutamine related compound C	1.38	0.5
Any unspecified impurity	—	0.10
Total impurities	—	1.0

SPECIFIC TESTS

• **Water Determination ⟨921⟩, *Method I*:** NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature.

Change to read:

• **USP Reference Standards ⟨11⟩**

USP Dobutamine Hydrochloride RS

USP Dobutamine Related Compound C RS

▲*N*-(3,4-Dimethoxyphenethyl)-4-(4-methoxyphenyl)butan-2-amine hydrochloride.

$C_{21}H_{29}NO_3 \cdot HCl$ 379.93▲ (USP 1-Aug-2023)

USP Dopamine Hydrochloride RS

USP Raspberry Ketone RS

4-(4-Hydroxyphenyl)butan-2-one.

$C_{10}H_{12}O_2$ 164.20

Topic/Question	Contact	Expert Committee
DOBUTAMINE HYDROCHLORIDE	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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