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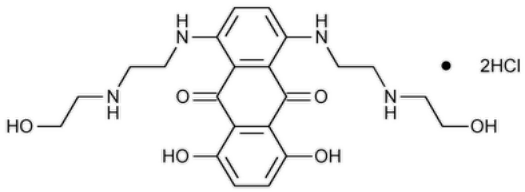
Mitoxantrone Hydrochloride



$C_{22}H_{28}N_4O_6 \cdot 2HCl$ 517.40

9,10-Anthracenedione, 1,4-dihydroxy-5,8-bis[[2-[(2-hydroxyethyl)amino]ethyl]amino]-, dihydrochloride;

1,4-Dihydroxy-5,8-bis[[2-[(2-hydroxyethyl)amino]ethyl]amino]anthraquinone dihydrochloride CAS RN®: 70476-82-3.

DEFINITION

Mitoxantrone Hydrochloride contains NLT 97.0% and NMT 102.0% of mitoxantrone hydrochloride ($C_{22}H_{28}N_4O_6 \cdot 2HCl$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩**, *Infrared Spectroscopy*, 197A or 197K▲ (CN 1-May-2020): Meets the requirements

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

ASSAY

• **Procedure**

Solution A: 0.09 g/mL of sodium 1-heptanesulfonate prepared as follows. Dissolve 22.0 g of sodium 1-heptanesulfonate in 150 mL of water. Pass through a filter of NMT 0.5-µm pore size and transfer the filtrate to a 250-mL volumetric flask. Wash the filter with 50 mL of water and add the washings to the flask. Add 32.0 mL of glacial acetic acid to the flask, and dilute with water to volume.

Mobile phase: Acetonitrile, *Solution A*, and water (10:1:30)

System suitability solution: 0.2 mg/mL of monoalkyl mitoxantrone hydrochloride and 0.1 mg/mL of mitoxantrone hydrochloride from USP Mitoxantrone System Suitability Mixture RS in *Mobile phase*

Standard solution: 0.4 mg/mL of USP Mitoxantrone Hydrochloride RS prepared as follows. Transfer a suitable amount of USP Mitoxantrone Hydrochloride RS to an appropriate volumetric flask. Add 80% of the flask volume of *Mobile phase*. Sonicate for about 5 min to dissolve. Cool to room temperature and dilute with *Mobile phase* to volume.

Sample solution: 0.4 mg/mL of Mitoxantrone Hydrochloride prepared as follows. Transfer a suitable amount of Mitoxantrone Hydrochloride to an appropriate volumetric flask. Add 80% of the flask volume of *Mobile phase*. Sonicate for about 5 min to dissolve. Cool to room temperature and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; 10-µm packing L11

[Note—After use, wash the column with a mixture of acetonitrile and water (50:50), and store in this mixture.]

Flow rate: 3 mL/min

Injection volume: 50 µL

System suitability

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

[Note—The relative retention times for mitoxantrone and monoalkyl mitoxantrone hydrochloride are about 1.0 and 1.4, respectively.]

Suitability requirements

Resolution: NLT 3.0 between mitoxantrone and monoalkyl mitoxantrone hydrochloride, *System suitability solution*

Tailing factor: NMT 2.0 for mitoxantrone, *System suitability solution*

Capacity factor, *k'*: NLT 3.5 for mitoxantrone, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

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 https://trungtamthuoc.com/

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of mitoxantrone dihydrochloride ($C_{22}H_{28}N_4O_6 \cdot 2HCl$) in the portion of Mitoxantrone Hydrochloride taken:

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

r_U = peak area of mitoxantrone from the *Sample solution*

r_S = peak area of mitoxantrone from the *Standard solution*

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

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

Acceptance criteria: 97.0%–102.0% on the anhydrous basis

IMPURITIES

• **Organic Impurities**

Analysis: Using the chromatogram of the *Sample solution* obtained as directed in the *Assay*, calculate the percentage of each impurity in the portion of Mitoxantrone Hydrochloride taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each impurity

r_T = sum of all peak responses

Acceptance criteria

Individual impurities: NMT 1.0%

Total impurities: NMT 2.0%

• **Limit of Alcohol**

Proceed as directed in *Residual Solvents* ⟨467⟩.

Acceptance criteria: NMT 1.5%

SPECIFIC TESTS

• **Water Determination** ⟨921⟩, *Method I*: NMT 6.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards** ⟨11⟩

USP Mitoxantrone Hydrochloride RS

USP Mitoxantrone System Suitability Mixture RS

0.2 mg of 1-Amino-5,8-dihydroxy-4-({2-[(2-hydroxyethyl)amino]ethyl}amino)anthracene-9,10-dione hydrochloride [monoalkyl mitoxantrone hydrochloride ($C_{18}H_{19}N_3O_5 \cdot HCl$, 393.82)] and 0.1 mg of USP Mitoxantrone Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
MITOXANTRONE HYDROCHLORIDE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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