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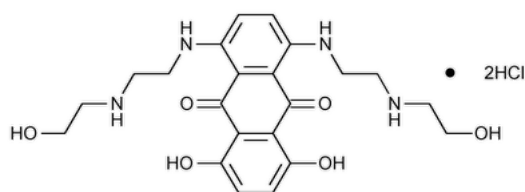
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Mitoxantrone Hydrochloride


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

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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