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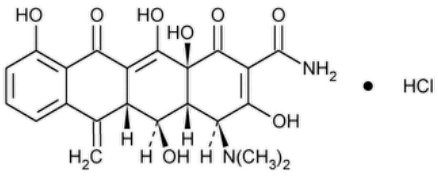
Methacycline Hydrochloride



$C_{22}H_{22}N_2O_8 \cdot HCl$ 478.88

2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,lum12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methylene-1,11-dioxo-, monohydrochloride, [4*S*-(4α,4aα,5α,5aα,12aα)]-.

4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methylene-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride CAS RN®: 3963-95-9; UNII: 9GJ0N7ZAP0.

» Methacycline Hydrochloride has a potency equivalent to not less than 832 µg and not more than 970 µg of methacycline ($C_{22}H_{22}N_2O_8$) per mg.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—
USP Doxycycline Hyclate RS
USP Methacycline Hydrochloride RS

Change to read:

Identification, ▲**Spectroscopic Identification Tests** ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: **197U**▲ (CN 1-May-2020) —

Solution: 20 µg per mL.

Medium: hydrochloric acid in methanol (1 in 1200).

Absorptivity at 345 nm, calculated on the dried basis, is between 88.4% and 96.4% of the USP Methacycline Hydrochloride RS, the potency of the Reference Standard being taken into account.

Crystallinity ⟨695⟩**:** meets the requirements.

pH ⟨791⟩**:** between 2.0 and 3.0, in a solution containing 10 mg of methacycline per mL.

Water Determination, *Method I* ⟨921⟩ **:** not more than 2.0%.

Assay—

Mobile phase—Prepare a mixture of 0.2 M ammonium oxalate, dimethylformamide, and 0.1 M edetate disodium (11:5:4), adjust with tetrabutylammonium hydroxide, 40 percent in water, to a pH of 7.0, and filter. Make adjustments, if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

System suitability preparation—Prepare a solution of USP Methacycline Hydrochloride RS and USP Doxycycline Hyclate RS in *Mobile phase* containing about 0.5 mg of each per mL.

Standard preparation—Quantitatively dissolve an accurately weighed quantity of USP Methacycline Hydrochloride RS in *Mobile phase* to obtain a solution having a known concentration of about 0.5 mg per mL.

Assay preparation—Transfer about 50 mg of Methacycline Hydrochloride, accurately weighed, to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 354-nm detector and a 4.6-mm × 15-cm column that contains 3.5-µm packing L1. The flow rate is about 1 mL per minute. Chromatograph the *System suitability preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.75 for methacycline and 1.0 for doxycycline; and the resolution, *R,* between methacycline and doxycycline is not less than 1.5. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 1.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in µg, of methacycline ($C_{22}H_{22}N_2O_8$) in each mg of Methacycline Hydrochloride taken by the formula:

$$100(CE/W)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Methacycline Hydrochloride RS in the *Standard preparation; E* is the methacycline content, in µg per mg, of USP Methacycline Hydrochloride RS; W is the quantity, in mg, of Methacycline Hydrochloride taken to prepare the

Assay preparation; and r_U and r_S are the methacycline peak areas obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
METHACYCLINE HYDROCHLORIDE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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