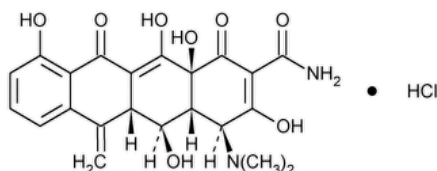


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Methacycline Hydrochloride



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

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

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 μ g and not more than 970 μ g 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 μ g 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 $\times$ 15-cm column that contains 3.5- μ m 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 μ L) 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 μ g, 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 μ g 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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