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Oxytetracycline Hydrochloride

$C_{22}H_{24}N_2O_9 \cdot HCl$ 496.89

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

4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride CAS RN®: 2058-46-0; UNII: 4U7K4N52ZM.

» Oxytetracycline Hydrochloride has a potency equivalent to not less than 835 µg of oxytetracycline ($C_{22}H_{24}N_2O_9$) per mg, calculated on the dried basis.

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

Labeling—Where it is intended for use in preparing injectable or ophthalmic dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable or ophthalmic dosage forms.

USP Reference standards ⟨11⟩—
USP Oxytetracycline RS

Identification—

Change to read:

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

Solution: 20 µg per mL.

Medium: 0.1 N hydrochloric acid.

Absorptivity, calculated on the dried basis, at 353 nm is between 88.2% and 96.8% of that of USP Oxytetracycline RS, the potency of the Reference Standard being taken into account.

B: To 1 mg add 2 mL of sulfuric acid: a light red color is produced.

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

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

Loss on drying ⟨731⟩—Dry about 100 mg, accurately weighed, in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 2.0% of its weight.

Other requirements—Where the label states that Oxytetracycline Hydrochloride is sterile, it meets the requirements for *Sterility* and *Bacterial endotoxins* under *Oxytetracycline for Injection*. Where the label states that Oxytetracycline Hydrochloride must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* under *Oxytetracycline for Injection*. Where it is intended for use in preparing ophthalmic dosage forms, it is exempt from the requirements for *Bacterial endotoxins*.

Assay—

Tetrabutylammonium hydrogen sulfate solution, Edetate disodium solution, pH 7.5 Phosphate buffer, Mobile phase, Standard preparation, System suitability solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Oxytetracycline*.

Assay preparation—Transfer about 44 mg of Oxytetracycline Hydrochloride to a 200-mL volumetric flask, add about 25 mL of 0.01 N hydrochloric acid, swirl to dissolve, dilute with 0.01 N hydrochloric acid to volume, and mix.

Procedure—Proceed as directed in the *Assay* under *Oxytetracycline*. Calculate the quantity, in µg, of oxytetracycline ($C_{22}H_{24}N_2O_9$) in each mg of Oxytetracycline Hydrochloride taken by the formula:

$$200(CP/W)(r_U/r_S)$$

in which the terms are as defined therein.

Topic/Question	Contact	Expert Committee
OXYTETRACYCLINE HYDROCHLORIDE	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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