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Oxytetracycline Hydrochloride Capsules

» Oxytetracycline Hydrochloride Capsules contain the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amount of oxytetracycline ($C_{22}H_{24}N_2O_9$).

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

USP Reference standards ⟨11⟩—
USP Oxytetracycline RS

Identification—Shake a suitable quantity of Capsule contents with methanol to obtain a solution containing 1 mg of oxytetracycline per mL, and filter. Using the filtrate as the *Test Solution*, proceed as directed for *Method II* under *Identification—Tetracyclines ⟨193⟩*.

Dissolution ⟨711⟩—
Medium: water; 900 mL.
Apparatus 2: 75 rpm.
Time: 60 minutes.
Procedure—Determine the amount of $C_{22}H_{24}N_2O_9$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 273 nm of filtered portions of the solution under test, suitably diluted with water, in comparison with a Standard solution having a known concentration of USP Oxytetracycline RS in the same medium, using 5 mL of 0.1 N hydrochloric acid to dissolve the Standard.
Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{22}H_{24}N_2O_9$ is dissolved in 60 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Loss on drying ⟨731⟩—Dry about 100 mg of Capsule contents, 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 5.0% of its weight.

Assay—
Tetrabutylammonium hydrogen sulfate solution, *Edetate disodium solution*, *pH 7.5 Phosphate buffer*, *Mobile phase*, *Standard preparation*, *Resolution solution*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Oxytetracycline*.
Assay preparation—Remove, as completely as possible, the contents of not less than 20 Capsules, and mix. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of oxytetracycline, to a 500-mL volumetric flask, add about 50 mL of 0.01 N hydrochloric acid, and swirl to dissolve. Dilute with 0.01 N hydrochloric acid to volume, mix, and filter a portion of the solution through a 0.5-µm or finer porosity filter. Use the filtrate as the *Assay preparation*.
Procedure—Proceed as directed for *Procedure* in the *Assay* under *Oxytetracycline*. Calculate the quantity, in mg, of oxytetracycline ($C_{22}H_{24}N_2O_9$) in the portion of Capsules taken by the formula:

$$0.5(CP)(r_U/r_S)$$

in which the terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
OXYTETRACYCLINE HYDROCHLORIDE CAPSULES	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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