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Oxytetracycline Tablets

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

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

USP Reference standards ⟨11⟩—

USP Oxytetracycline RS

Identification—Shake a suitable quantity of finely powdered Tablets with methanol to obtain a solution containing about 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: 0.1 N hydrochloric acid; 900 mL.

Apparatus 1: 100 rpm.

Time: 45 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 353 nm of filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Oxytetracycline RS in the same medium.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{22}H_{24}N_2O_9$ is dissolved in 45 minutes.

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

Water Determination, *Method I* ⟨921⟩: not more than 7.5%.

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—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of oxytetracycline, to a 500-mL volumetric flask, add about 25 mL of 0.01 N hydrochloric acid, and mix. Dilute with 0.01 N hydrochloric acid to volume, and mix. Filter a portion of this solution through a 0.5-µm or finer porosity filter, and use the filtrate as the *Assay preparation.*

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Oxytetracycline*. Calculate the quantity, in mg, of $C_{22}H_{24}N_2O_9$ in the portion of Tablets taken by the formula:

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

in which C is the concentration, in mg per mL, of USP Oxytetracycline RS in the *Standard preparation,* and the other terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
OXYTETRACYCLINE TABLETS	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

Most Recently Appeared In:
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