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Do not distribute

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:

$$0.5(CP)(r_f/r_s)$$

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

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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