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Oxytetracycline Injection

» Oxytetracycline Injection is a sterile solution of Oxytetracycline with or without one or more suitable anesthetics, antioxidants, buffers, complexing agents, preservatives, and solvents. It contains 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 single-dose or multiple-dose containers, protected from light.

USP REFERENCE STANDARDS (11).—
[USP Oxytetracycline RS](#)

Identification—To an accurately measured volume of Injection, equivalent to about 50 mg of oxytetracycline, add 50 mL of methanol, and shake. Using the clear solution so obtained as the *Test Solution*, proceed as directed for [Method II](#) under [Identification—Tetracyclines \(193\)](#).

BACTERIAL ENDOTOXINS TEST (85).—It contains not more than 0.4 USP Endotoxin Unit per mg of oxytetracycline.

STERILITY TESTS (71).—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH (791): between 8.0 and 9.0.

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 an accurately measured volume of Injection, equivalent to about 100 mg of oxytetracycline, to a 500-mL volumetric flask, dilute with 0.01 N hydrochloric acid to volume, and mix.

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 each mL of the Injection taken by the formula:

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

in which *C* is the concentration, in mg per mL, of [USP Oxytetracycline RS](#) in the *Standard preparation*; *V* is the volume, in mL, of Injection taken to prepare the *Assay 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 INJECTION	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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