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Oxytetracycline for Injection

» Oxytetracycline for Injection contains an amount of Oxytetracycline Hydrochloride equivalent to not less than 90.0 percent and not more than 115.0 percent of the labeled amount of oxytetracycline ($C_{22}H_{24}N_2O_9$).

Packaging and storage—Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*, protected from light.

USP Reference standards ⟨11⟩—
USP Oxytetracycline RS

Constituted solution—At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

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*, *Fluid D* being used instead of *Fluid A*.

pH ⟨791⟩: between 1.8 and 2.8, in a solution containing 25 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 3.0% of its weight.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

Other requirements—It responds to *Identification* test *B* under *Oxytetracycline Hydrochloride*. It also meets the requirements for *Uniformity of Dosage Units ⟨905⟩* and *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

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 1 (where it is represented as being in a single-dose container)—Constitute Oxytetracycline for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively with 0.01 N hydrochloric acid to obtain a solution having a concentration of about 0.2 mg of oxytetracycline per mL.

Assay preparation 2 (where the label states the quantity of oxytetracycline in a given volume of constituted solution)—Constitute Oxytetracycline for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Dilute an accurately measured volume of the constituted solution quantitatively with 0.01 N hydrochloric acid to obtain a solution having a concentration of about 0.2 mg of oxytetracycline per mL.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Oxytetracycline*. Calculate the quantity, in mg, of oxytetracycline ($C_{22}H_{24}N_2O_9$) withdrawn from the container or in the portion of constituted solution taken by the formula:

$$(L/D)(CP)(r_U/r_S)$$

in which L is the labeled quantity, in mg, of oxytetracycline ($C_{22}H_{24}N_2O_9$) in the container or in the portion of constituted solution taken; D is the concentration, in mg per mL, of oxytetracycline in *Assay preparation 1* or in *Assay preparation 2*, based on the labeled quantity in the container or in the portion of constituted solution taken, respectively, and the extent of dilution; 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 FOR INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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