Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-4EA17434-BCE1-4077-B794-6DC27F8ADAD4_2_en-US
DOI: https://doi.org/10.31003/USPNF_M60055_02_01
DOI Ref: 0mu6u

Oxytetracycline Hydrochloride Soluble Powder

» Oxytetracycline Hydrochloride Soluble Powder is a dry mixture of Oxytetracycline Hydrochloride and one or more suitable excipients. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of oxytetracycline hydrochloride ($C_{22}H_{24}N_2O_9 \cdot HCl$).

Packaging and storage—Preserve in well-closed containers.

Labeling—Label it to indicate that it is for oral veterinary use only.

USP Reference standards ⟨11⟩—

USP Oxytetracycline RS

Identification—

A: Shake a quantity of Soluble Powder with methanol to obtain a solution containing about 1 mg of oxytetracycline hydrochloride per mL. Filter if necessary to obtain a clear solution. Using the filtrate as the *Test solution*, proceed as directed for *Method II* under *Identification—Tetracyclines ⟨193⟩*.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

pH ⟨791⟩: between 1.5 and 3.0, in the solution obtained as directed in the labeling.

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.

Minimum fill ⟨755⟩: meets the requirements.

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 weighed portion of the Soluble Powder, equivalent to about 100 mg of oxytetracycline hydrochloride, to a 500-mL volumetric flask, dilute with 0.01 N hydrochloric acid to volume, and mix. Pass a portion of this solution through a filter having a 0.5-µm or finer porosity. Use the filtrate as the *Assay preparation*.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Oxytetracycline*. Calculate the quantity, in g, of oxytetracycline hydrochloride ($C_{22}H_{24}N_2O_9 \cdot HCl$) in each g of Soluble Powder taken by the formula:

$$0.5(496.90/460.44)(CP/W)(r_U/r_S)$$

in which 496.90 and 460.44 are the molecular weights of oxytetracycline hydrochloride and oxytetracycline, respectively; C is the concentration, in mg per mL, of USP Oxytetracycline RS in the *Standard preparation; P* is the assigned potency, in µg of oxytetracycline per mg, of USP Oxytetracycline RS; W is the weight, in g, of Soluble Powder taken to prepare the *Assay preparation;* and r_U and r_S are the oxytetracycline peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
OXYTETRACYCLINE HYDROCHLORIDE SOLUBLE POWDER	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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

Current DocID: GUID-4EA17434-BCE1-4077-B794-6DC27F8ADAD4_2_en-US
Previous DocID: GUID-4EA17434-BCE1-4077-B794-6DC27F8ADAD4_1_en-US
DOI: https://doi.org/10.31003/USPNF_M60055_02_01
DOI ref: 0mu6u