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Chlortetracycline Hydrochloride Soluble Powder

(This monograph has been updated to the current USP style. No revisions or changes to tests have been made.)

DEFINITION

Chlortetracycline Hydrochloride Soluble Powder contains NLT 90.0% and NMT 125.0% of the labeled amount of chlortetracycline hydrochloride $(C_{22}H_{22}CIN_2O_8 \cdot HCI)$.

ASSAY

• PROCEDURE

Standard: USP Chlortetracycline Hydrochloride RS

Sample solution 1 (where it is labeled on a weight basis): Dissolve about 3 g of Powder in an accurately measured volume of 0.01 N hydrochloric acid sufficient to obtain a solution containing NLT 1000 μ g/mL of chlortetracycline hydrochloride ($C_{22}H_{23}CIN_2O_8 \cdot HCI$).

Sample solution 2 (where the label states the amount of chlortetracycline in the immediate container): Transfer the contents of 1 container of Powder to an accurately measured volume of 0.01 N <u>hydrochloric acid</u> sufficient to obtain a solution containing NLT 1000 μ g/mL of chlortetracycline hydrochloride ($C_{22}H_{23}CIN_2O_8 \cdot HCI$).

Analysis: Proceed with Powder as directed for chlortetracycline in Antibiotics—Microbial Assays (81), using an accurately measured volume of the Sample solution diluted quantitatively and stepwise with water to yield a Test Dilution having a concentration assumed to be equal to the median dose level of the Standard.

Acceptance criteria: 90.0%-125.0%

SPECIFIC TESTS

• Loss on Drying (731)

Sample: About 100 mg, accurately weighed

Analysis: Dry the Sample in a capillary-stoppered bottle in a vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 h.

Acceptance criteria: NMT 2.0%

ADDITIONAL REQUIREMENTS

- Packaging and Storage: Preserve in tight containers, protected from light.
- Label it to indicate that it is intended for oral veterinary use only.
- <u>USP REFERENCE STANDARDS (11)</u> USP Chlortetracycline Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
CHLORTETRACYCLINE HYDROCHLORIDE SOLUBLE POWDER	Jennifer Tong Sun Senior Scientist II	BIO42020 Biologics Monographs 4 - Antibiotics

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