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Chlortetracycline Hydrochloride Tablets

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

DEFINITION

Chlortetracycline Hydrochloride Tablets contain NLT 90.0% and NMT 120.0% of the labeled amount of chlortetracycline hydrochloride ($C_{22}H_{23}ClN_2O_8 \cdot HCl$).

IDENTIFICATION

- **A. Identification—Tetracyclines ⟨193⟩, *Procedures, Method II***

  Sample solution: 0.5 mg/mL of chlortetracycline hydrochloride in methanol from a suitable quantity of finely ground Tablet powder; shake the solution, then filter.

  Resolution solution: 0.5 mg/mL each of USP Chlortetracycline Hydrochloride RS, USP Oxytetracycline RS, and USP Tetracycline Hydrochloride RS in methanol

  Analysis: Proceed as directed in the chapter.

  Acceptance criteria: Meet the requirements

ASSAY

- **Procedure**

  Standard: USP Chlortetracycline Hydrochloride RS

  Sample solution: Transfer NLT 5 Tablets to a high-speed glass blender jar containing a suitable volume of 0.01 N hydrochloric acid, so that after blending for 3–5 min, a solution of convenient concentration is obtained.

  Analysis: Proceed as directed for chlortetracycline under *Antibiotics—Microbial Assays* ⟨81⟩, using a suitable volume of the *Sample solution* diluted with water to obtain a test dilution having a concentration assumed to be equal to the median dose level of the *Standard*.

  Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

- **Disintegration ⟨701⟩**

  Medium: Simulated gastric fluid TS in place of water

  Time: 1 h

  Acceptance criteria: Meet the requirements

- **Uniformity of Dosage Units ⟨905⟩, *Weight Variation*:** Meet the requirements

SPECIFIC TESTS

- **Water Determination ⟨921⟩, *Method I***

  Sample: A quantity of finely ground Tablet powder

  Acceptance criteria: NMT 3%; or where the Tablets have a diameter of greater than 15 mm, NMT 6%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, protected from light.
- **Labeling:** Label the Tablets to indicate that they are intended for veterinary use only.
- **USP Reference Standards ⟨11⟩**

  USP Chlortetracycline Hydrochloride RS
  USP Oxytetracycline RS
  USP Tetracycline Hydrochloride RS

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

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