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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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