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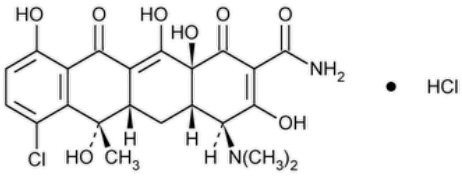
Chlortetracycline Hydrochloride

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



$C_{22}H_{23}ClN_2O_8 \cdot HCl$ 515.34

2-Naphthacenecarboxamide, 7-chloro-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, monohydrochloride [4*S*-(4α,4aα,5aα,6β,12aα)]-;
(4*S*,4a*S*,5a*S*,6*S*,12a*S*)-7-Chloro-4-(dimethylamino)-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide monohydrochloride CAS RN®: 64-72-2; UNII: O1GX33ON8R.

DEFINITION

Chlortetracycline Hydrochloride has a potency of NLT 900 µg/mg of chlortetracycline hydrochloride ($C_{22}H_{23}ClN_2O_8 \cdot HCl$).

[NOTE—Chlortetracycline Hydrochloride labeled solely for use in preparing oral veterinary dosage forms has a potency of NLT 820 µg/mg of chlortetracycline hydrochloride ($C_{22}H_{23}ClN_2O_8 \cdot HCl$).]

IDENTIFICATION

- **A. IDENTIFICATION—TETRACYCLINES ⟨193⟩, *Procedures, Method II***

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

  Test solution: 0.5 mg/mL in methanol

  Acceptance criteria: Meets the requirements

- **B. IDENTIFICATION TESTS—GENERAL ⟨191⟩, *Chemical Identification Tests, Chloride***

  Sample solution: 1 in 20 solution

  Acceptance criteria: Meets the requirements

ASSAY

- **PROCEDURE**

  Standard: USP Chlortetracycline Hydrochloride RS

  Analysis: Proceed as directed under *Antibiotics—Microbial Assays ⟨81⟩*.

  Acceptance criteria: NLT 900 µg/mg of chlortetracycline hydrochloride ($C_{22}H_{23}ClN_2O_8 \cdot HCl$); when labeled solely for use in preparing oral veterinary dosage forms: NLT 820 µg/mg

SPECIFIC TESTS

- **OPTICAL ROTATION ⟨781S⟩, *Procedures, Specific Rotation***

  Sample solution: 5 mg/mL in water that has been allowed to stand in the dark for 30 min

  Acceptance criteria: −235° to −250°

- **CRYSTALLINITY ⟨695⟩:** Meets the requirements

- **pH ⟨791⟩**

  Sample solution: 10 mg/mL solution

  Acceptance criteria: 2.3–3.3

- **LOSS ON DRYING ⟨731⟩**

  Sample: About 100 mg, accurately weighted

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

Acceptance criteria: NMT 2.0%

• **Sterility Tests** ⟨71⟩

Sample: 3.0% in *Fluid D* with membrane filtration

Acceptance criteria: Where the label states that Chlortetracycline Hydrochloride is sterile, it meets the requirements when tested as directed for *Test for Sterility of the Product to Be Examined.*

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **Labeling:** Where it is intended for use in preparing sterile dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of sterile dosage forms.

• **USP Reference Standards** ⟨11⟩

USP Chlortetracycline Hydrochloride RS
USP Oxytetracycline RS
USP Tetracycline Hydrochloride RS

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

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

Chromatographic Database Information: Chromatographic Database

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