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Chlortetracycline and Sulfamethazine Bisulfates Soluble Powder

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

DEFINITION
Chlortetracycline and Sulfamethazine Bisulfates Soluble Powder is a dry mixture of Chlortetracycline Bisulfate and Sulfamethazine Bisulfate and one or more suitable buffers and diluents. It contains the equivalent of NLT 85.0% and NMT 125.0% of the labeled amounts of chlortetracycline hydrochloride ($C_{22}H_{24}N_2O_8 \cdot HCl$) and sulfamethazine ($C_{12}H_{14}N_4O_2S$).

ASSAY

• **CHLORTETRACYCLINE HYDROCHLORIDE**

Standard: [USP Chlortetracycline Hydrochloride RS](#)

Analysis: Proceed as directed for chlortetracycline in [Antibiotics—Microbial Assays \(81\)](#), using an accurately weighed quantity of Powder, equivalent to about 100 mg of chlortetracycline hydrochloride, dissolved in an accurately measured volume of 0.01 N [hydrochloric acid](#) to obtain a stock solution having a convenient concentration. Dilute an accurately measured volume of this stock solution quantitatively and stepwise with water to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the *Standard*.

Acceptance criteria: 85.0%–125.0%

• **SULFAMETHAZINE**

Analysis: Proceed as directed in [Nitrite Titration \(451\)](#), using an accurately weighed quantity of Powder, equivalent to about 500 mg of sulfamethazine. Each mL of 0.1 M [sodium nitrite](#) is equivalent to 27.83 mg of sulfamethazine.

Acceptance criteria: 85.0%–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, light-resistant containers.
- **LABELING:** Label it to indicate that it is intended for veterinary use only.
- **USP REFERENCE STANDARDS (11)**
[USP Chlortetracycline Hydrochloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

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