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Tetracycline Hydrochloride and Novobiocin Sodium Tablets

» Tetracycline Hydrochloride and Novobiocin Sodium Tablets contain the equivalent of not less than 90.0 percent and not more than 125.0 percent of the labeled amounts of tetracycline hydrochloride ($C_{22}H_{24}N_2O_8 \cdot HCl$) and novobiocin ($C_{31}H_{36}N_2O_{11}$).

Packaging and storage—Preserve in tight containers.

Labeling—Label the Tablets to indicate that they are intended for veterinary use only.

USP Reference standards ⟨11⟩—
USP Tetracycline Hydrochloride RS
USP Novobiocin RS

Identification—Shake a suitable quantity of finely powdered Tablets with methanol to obtain a solution containing 1 mg of tetracycline hydrochloride per mL, and filter. Using the filtrate as the *Test Solution*, proceed as directed under *Identification—Tetracyclines ⟨193⟩*.

Disintegration ⟨701⟩: 60 minutes, simulated gastric fluid TS being substituted for water in the test.

Uniformity of dosage units ⟨905⟩: meet the requirements for *Weight Variation* with respect to tetracycline hydrochloride and to novobiocin sodium.

Loss on drying ⟨731⟩—Dry about 100 mg, accurately weighed, of finely powdered Tablets in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 6.0% of its weight.

Limit of 4-epianhydrotetracycline ⟨226⟩—To an accurately weighed quantity of finely powdered Tablets, equivalent to about 250 mg of tetracycline hydrochloride, add 10 mL of 0.1 N hydrochloric acid, and adjust with 6 N ammonium hydroxide to a pH of 7.8. Transfer this solution with the aid of *EDTA Buffer* to a 50-mL volumetric flask, dilute with *EDTA Buffer* to volume, and mix. Use this solution, without delay, as the *Test Solution:* not more than 2.0% is found.

Assay for tetracycline hydrochloride—Proceed as directed for tetracycline under *Antibiotics—Microbial Assays ⟨81⟩*, except to use *Escherichia coli* ATCC 10536 as the test organism instead of *Staphylococcus aureus* ATCC 29737 and an inoculum composition of about 0.2 mL of stock suspension in each 100 mL of *Medium 3*. Transfer not less than 5 Tablets to a high-speed blender jar containing an accurately measured volume of 0.1 N hydrochloric acid, so that, after blending for about 3 to 5 minutes, the solution so obtained contains not less than 150 µg of tetracycline hydrochloride per mL. Dilute an accurately measured volume of this solution quantitatively and stepwise with water to obtain a *Test Dilution* having a concentration of tetracycline hydrochloride assumed to be equal to the median dose level of the Standard.

Assay for novobiocin—Proceed as directed for novobiocin under *Antibiotics—Microbial Assays ⟨81⟩*, blending not less than 5 Tablets for 3 to 5 minutes in a high-speed glass blender jar containing 1.0 mL of polysorbate 80 and a sufficient accurately measured volume of *Buffer B.3* to provide a stock solution of convenient concentration. Dilute an accurately measured volume of this stock solution quantitatively and stepwise with *Buffer B.6* to obtain a *Test Dilution* having a concentration of novobiocin assumed to be equal to the median dose level of the Standard.

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

Topic/Question	Contact	Expert Committee
TETRACYCLINE HYDROCHLORIDE AND NOVOBIOCIN SODIUM TABLETS	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

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