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Tetracycline Hydrochloride, Novobiocin Sodium, and Prednisolone Tablets

» Tetracycline Hydrochloride, Novobiocin Sodium, and Prednisolone Tablets contain 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 ($C_{31}H_{36}N_2O_{11}$), and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of prednisolone ($C_{21}H_{28}O_5$).

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
USP Prednisolone RS

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 and for *Content Uniformity* with respect to prednisolone.

Procedure for content uniformity for prednisolone—

Mobile phase, Internal standard solution, and *Chromatographic system*— Prepare as directed in the *Assay* under *Prednisolone*.

Standard preparation—Prepare as directed in the *Assay for prednisolone*.

Test preparation—Transfer 1 Tablet to a suitable container, add 7 mL of diluted methanol (2 in 7) for each 1.5 mg of prednisolone in the Tablet, based on the labeled amount, and allow to stand for 90 minutes, occasionally agitating gently to ensure that the Tablet disintegrates. For each 1.5 mg of prednisolone, add 3.0 mL of *Internal standard solution*, 12 mL of water-saturated chloroform, and about 10 glass beads. Securely close the container, and shake by mechanical means for 30 minutes. Carefully open the container, add 0.5 mL of sodium carbonate solution (1 in 4), reclose the container, and shake by mechanical means for 5 minutes. Centrifuge, remove the upper layer by aspiration, discarding the aspirated liquid, and retain the clear chloroform layer (*Test preparation*).

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Prednisolone*. Calculate the quantity, in mg, of prednisolone ($C_{21}H_{28}O_5$) in the Tablet taken by the formula:

$$0.015C(R_U/R_S)$$

in which the terms are as defined therein.

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.

Other requirements—Tablets respond to the *Identification* test and meet the requirements of the test for *Loss on drying* under *Tetracycline Hydrochloride and Novobiocin Sodium Tablets*.

Assay for tetracycline hydrochloride and Assay for novobiocin—Using Tablets, proceed as directed in the *Assay for tetracycline hydrochloride* and the *Assay for novobiocin* under *Tetracycline Hydrochloride and Novobiocin Sodium Tablets*.

Assay for prednisolone—

Mobile phase, Internal standard solution, and *Chromatographic system*—Prepare as directed in the *Assay* under *Prednisolone*.

Standard preparation—Transfer about 10 mg of USP Prednisolone RS, accurately weighed, to a 100-mL volumetric flask, add 20.0 mL of *Internal standard solution*, and swirl to dissolve. Dilute with water-saturated chloroform to volume, and mix. Transfer 15.0 mL of this solution to a suitable container, add 7 mL of diluted methanol (2 in 7), securely close the container, and shake by mechanical means for 30 minutes. Carefully open the container, add 0.5 mL of sodium carbonate solution (1 in 4), reclose the container, and shake by mechanical means for 5

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minutes. Centrifuge, remove the upper layer by aspiration, discarding the aspirated liquid, and retain the clear chloroform layer (*Standard preparation*).

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 1.5 mg of prednisolone, to a suitable container containing about 10 glass beads. Add 3.0 mL of *Internal standard solution*, 12 mL of water-saturated chloroform, and 7 mL of diluted methanol (2 in 7), securely close the container, and shake by mechanical means for 30 minutes. Carefully open the container, add 0.5 mL of sodium carbonate solution (1 in 4), reclose the container, and shake by mechanical means for 5 minutes. Centrifuge, remove the upper layer by aspiration, discarding the aspirated liquid, and retain the clear chloroform layer (*Assay preparation*).

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Prednisolone*. Calculate the quantity, in mg, of prednisolone ($C_{21}H_{28}O_5$) in the portion of Tablets taken by the formula:

$$0.015C(R_U/R_S)$$

in which the terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
TETRACYCLINE HYDROCHLORIDE, NOVOBIOCIN SODIUM, AND PREDNISOLONE 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

Chromatographic Database Information: Chromatographic Database

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