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Neomycin Sulfate and Methylprednisolone Acetate Cream

DEFINITION

Neomycin Sulfate and Methylprednisolone Acetate Cream contains the equivalent of NLT 90.0% and NMT 135.0% of the labeled amount of neomycin, and NLT 90.0% and NMT 110.0% of the labeled amount of methylprednisolone acetate ($C_{24}H_{32}O_6$).

IDENTIFICATION

- **A. Thin-Layer Chromatographic Identification Test ⟨201BNP⟩:** Meets the requirements for neomycin
- **B.**

Solution A, Solution B, Standard solution, Sample solution, Adsorbent, Application volume, and **Developing solvent system:** Proceed as directed in the *Assay* for *Methylprednisolone Acetate*.

Analysis: Proceed with thin-layer chromatography as directed in the *Assay* for *Methylprednisolone Acetate*.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

- **Neomycin**

(See *Antibiotics—Microbial Assays ⟨81⟩*.)

Sample solution: Shake a portion of Cream containing nominally 3.5 mg of neomycin in a separator with 50 mL of ether. Extract with four 20-mL portions of *Buffer B.3*. Combine the aqueous extracts, and dilute with *Buffer B.3* to a suitable volume.

Analysis: Proceed as directed in the chapter. Dilute the *Sample solution* with *Buffer B.3* to obtain a *Test Dilution* having a neomycin concentration that is nominally equivalent to the median level of the standard.

Acceptance criteria: 90.0%–135.0%

- **Methylprednisolone Acetate**

Solution A: Alcohol and chloroform (1:1)

Solution B: Alcohol and tetramethylammonium hydroxide TS (9:1)

Standard solution: 500 µg/mL of USP Methylprednisolone Acetate RS in *Solution A*

Sample solution: Transfer a portion of Cream containing nominally 5 mg of methylprednisolone acetate to a 125-mL separator, and add 50 mL of solvent hexane. Extract with three 10-mL portions of acetonitrile, and evaporate the combined extracts on a steam bath with the aid of a current of air nearly to dryness. Transfer the residue to a 10-mL volumetric flask with the aid of one 5-mL portion and two 2-mL portions of *Solution A*. Dilute with *Solution A* to volume.

Adsorbent: 0.5-mm layer of chromatographic silica gel mixture (see *Chromatography ⟨621⟩*)

Application volume: 250 µL

Developing solvent system: Ethyl acetate and chloroform (7:5)

Analysis

Samples: *Standard solution* and *Sample solution*

Divide the plate into three equal sections, the left and right sections to be used for the *Sample solution* and *Standard solution*, respectively, and the center section for the blank. Apply the solutions as streaks 2.5 cm from the bottom of the designated section of the plate, and dry the streaks with the aid of a current of air. Develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, mark the solvent front, and allow the solvent to evaporate. Locate the principal bands from the *Standard solution* and the *Sample solution* (see also *Identification*test *B*) by viewing under short-wavelength UV light. Mark these bands and the corresponding band in the section of the plate representing the blank. Quantitatively remove the silica gel containing these bands, and transfer to separate glass-stoppered, 50-mL centrifuge tubes. Add 25.0 mL of alcohol to each tube, shake for 2 min, and centrifuge at about 1500 rpm for 5 min. Transfer 20.0 mL of each supernatant to separate glass-stoppered, 50-mL conical flasks. Add 2.0 mL of blue tetrazolium TS to each solution, and to each flask, add 2.0 mL of *Solution B*. Mix, and allow the solutions to stand in the dark for 90 min.

Instrumental conditions

Mode: Vis

Analytical wavelength: Maximum at about 525 nm

Cell: 1 cm

Calculate the percentage of the labeled amount of methylprednisolone acetate ($C_{24}H_{32}O_6$) in the portion of Cream taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Methylprednisolone Acetate RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of methylprednisolone acetate in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Minimum Fill ⟨755⟩:** Meets the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in collapsible tubes or in tight containers, protected from light.

• **USP Reference Standards ⟨11⟩**
USP Methylprednisolone Acetate RS
USP Neomycin Sulfate RS

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

Topic/Question	Contact	Expert Committee
NEOMYCIN SULFATE AND METHYLPREDNISOLONE ACETATE CREAM	Rebecca C. Potts Associate Scientific 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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