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Hydrocortisone Acetate Cream

DEFINITION

Hydrocortisone Acetate Cream is Hydrocortisone Acetate in a suitable cream base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of hydrocortisone acetate ($C_{23}H_{32}O_6$).

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Standard solution: 250 µg/mL of USP Hydrocortisone Acetate RS in methanol

Sample solution: To 1 g of Cream add 40.0 mL of a 35% solution of acetonitrile in methanol, and shake until dissolved. To 20.0 mL of this solution add 10.0 mL of isooctane, and mix. Allow the layers to separate, and use the bottom layer.

Developing solvent system: Ethyl acetate, toluene, and acetone (140:40:13)

Analysis: Heat the prepared chromatographic plate at 105° for 10 min, and cool. Develop in the *Developing solvent system* in a paper-lined chromatographic chamber equilibrated in an atmosphere of ammonia vapor.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Mobile phase: Butyl chloride, water-saturated butyl chloride, tetrahydrofuran, methanol, and glacial acetic acid (475:475:70:35:30)

Standard solution: 0.10 mg/mL of USP Hydrocortisone Acetate RS in *Mobile phase*

Sample solution: Transfer a quantity of Cream, nominally equivalent to 25 mg of hydrocortisone acetate, to a suitable container, add 100.0 mL of tetrahydrofuran, and shake until the Cream dissolves. Transfer 10.0 mL of the resulting solution to another container, and add 15.0 mL of *Mobile phase*.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; 10-µm packing L3

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of hydrocortisone acetate ($C_{23}H_{32}O_6$) in the portion of Cream taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = nominal concentration of hydrocortisone acetate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

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

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** It meets the requirements of the tests for the absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**
USP Hydrocortisone Acetate RS

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

Topic/Question	Contact	Expert Committee
HYDROCORTISONE ACETATE CREAM	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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