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Hydrocortisone Ointment

DEFINITION

Hydrocortisone Ointment is Hydrocortisone in a suitable ointment base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of hydrocortisone ($C_{21}H_{30}O_5$).

IDENTIFICATION

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

Sample solution: Transfer a portion of Ointment, equivalent to 5 mg of hydrocortisone, to a flask. Add 10 mL of methanol, and heat on a steam bath for 5 min with frequent shaking. Cool to solidify the ointment base, and filter. Use the filtrate.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Diluent: Dilute alcohol (1 in 2)

Mobile phase: Acetonitrile and water (25:75)

Standard stock solution: 500 µg/mL of USP Hydrocortisone RS in alcohol

Standard solution: 50 µg/mL of USP Hydrocortisone RS prepared by mixing *Standard stock solution* and *Diluent* (1:9). [Note—If alcohol is used in the final dilution of the *Sample solution*, similarly use alcohol instead of aqueous alcohol in the final dilution of the *Standard solution*.]

Sample solution: Transfer a quantity of Ointment, nominally equivalent to 10 mg of hydrocortisone, to a 150-mL beaker. Add 40 mL of alcohol, and heat on a steam bath while stirring to melt and disperse the Ointment. Cool to room temperature, and filter through glass wool into a 100-mL volumetric flask. Repeat the extraction with two 20-mL portions of alcohol, combining the filtrates in the 100-mL volumetric flask. Add alcohol to volume, and mix. Quantitatively dilute one volume of this solution with an equal volume of water, and pass through a membrane filter of 5-µm pore size. If precipitation occurs on dilution with water, and the solution is still cloudy after filtration, dilute the initial *Sample solution* with alcohol instead of water. Pass this solution through a membrane filter of 5-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Injection volume: 10–25 µL

System suitability

[Note—Adjust the composition of the *Mobile phase* so that the retention time of hydrocortisone is about 10 min.]

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0% for 5 replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of hydrocortisone ($C_{21}H_{30}O_5$) in the portion of Ointment 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 RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of hydrocortisone in the *Sample solution* (µg/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 Organisms ⟨62⟩:** It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

ADDITIONAL REQUIREMENTS

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

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

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

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

Chromatographic Database Information: Chromatographic Database

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