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Hydrocortisone Valerate Ointment

DEFINITION

Hydrocortisone Valerate Ointment contains NLT 90.0% and NMT 110.0% of the labeled amount of hydrocortisone valerate ($C_{26}H_{38}O_6$) in a suitable ointment base.

IDENTIFICATION

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

Samples: *Standard solution* and *Sample solution* from the *Assay*

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (45:55)

Internal standard solution: 2.0 mg/mL of ethyl benzoate in methanol

Standard stock solution: 0.5 mg/mL of USP Hydrocortisone Valerate RS in methanol. Prepare immediately before use.

Standard solution: 0.1 mg/mL of USP Hydrocortisone Valerate RS in methanol, prepared as follows. Pipet 2 mL of the *Standard stock solution* and 2 mL of the *Internal standard solution* into a 10-mL volumetric flask, and dilute with methanol to volume.

Sample solution: Nominally 0.1 mg/mL of hydrocortisone valerate, prepared as follows. Transfer a quantity of Ointment, equivalent to 1 mg of hydrocortisone valerate, to a screw-capped tube. Add 8.0 mL of a mixture of methanol and water (3:1), and swirl to disperse. Heat in a steam bath until melted (about 30 s), swirl again, and allow to cool to room temperature. Add 2.0 mL of the *Internal standard solution*. Centrifuge for 5 min, and filter the supernatant, if necessary, to obtain a clear solution.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for ethyl benzoate and hydrocortisone valerate are about 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between ethyl benzoate and hydrocortisone valerate

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of hydrocortisone valerate ($C_{26}H_{38}O_6$) in the portion of Ointment taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of hydrocortisone valerate to the internal standard from the *Sample solution*

R_S = peak response ratio of hydrocortisone valerate to the internal standard from the *Standard solution*

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

C_U = nominal concentration of hydrocortisone valerate 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⟩:** The total microbial count does not exceed 10^2 cfu/g. It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.

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

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

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

Chromatographic Database Information: Chromatographic Database

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