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Hydrocortisone Butyrate Cream

DEFINITION

Hydrocortisone Butyrate Cream is Hydrocortisone Butyrate in a suitable cream base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of hydrocortisone butyrate ($C_{25}H_{36}O_6$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, glacial acetic acid, and water (76:1:124)

Diluent A: Tetrahydrofuran and glacial acetic acid (1000:1)

Diluent B: Methanol, water, and glacial acetic acid (500:500:1)

System suitability stock solution: 0.1 mg/mL each of USP Hydrocortisone Butyrate RS and propyl 4-hydroxybenzoate in *Diluent A*

System suitability solution: 0.02 mg/mL each of USP Hydrocortisone Butyrate RS and propyl 4-hydroxybenzoate in *Diluent B*, from *System suitability stock solution*

Standard stock solution: 0.1 mg/mL of USP Hydrocortisone Butyrate RS in *Diluent A*

Standard solution: 0.02 mg/mL of USP Hydrocortisone Butyrate RS in *Diluent B*, from *Standard stock solution*

Sample solution: Nominally 0.02 mg/mL of hydrocortisone butyrate, prepared as follows. Transfer a sufficient quantity of Cream to a volumetric flask of suitable size, add 20% of the flask volume of *Diluent A*, shake by mechanical means for 30 min, and dilute with *Diluent B* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.0-mm × 10-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 5 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for propyl 4-hydroxybenzoate and hydrocortisone butyrate are 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 4.0 between propyl 4-hydroxybenzoate and hydrocortisone butyrate, *System suitability solution*

Column efficiency: NLT 4000 theoretical plates, *Standard solution*

Tailing factor: NMT 1.6, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of hydrocortisone butyrate ($C_{25}H_{36}O_6$) 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 Butyrate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of hydrocortisone butyrate 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*.

• **pH ⟨791⟩:** 3.5–4.5

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Hydrocortisone Butyrate RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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