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Hydrocortisone Lotion

DEFINITION

Hydrocortisone Lotion is Hydrocortisone in a suitable aqueous vehicle. 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)**

Standard solution: 500 µg/mL of [USP Hydrocortisone RS](#) in methanol

Sample solution: Transfer a quantity of Lotion, nominally equivalent to 5 mg of hydrocortisone, to a separator containing 10 mL of methylene chloride. Shake for 1 min, and allow the layers to separate. Filter the methylene chloride extract onto a suitable chromatographic column that has been packed with 2 g of activated magnesium silicate. Wash the column with 25 mL of methylene chloride with the aid of slight air pressure, discarding the washings, and elute the hydrocortisone with 10 mL of methanol.

Chromatographic system

Developing solvent system: Chloroform, methanol, and water (180:15:1)

Analysis: Proceed as directed in the chapter.

Acceptance criteria: Meets the requirements

ASSAY

- **PROCEDURE**

Mobile phase: Acetonitrile, methanol, and water (21:21:58)

Standard stock solution: 0.1 mg/mL of [USP Hydrocortisone RS](#) in alcohol

Standard solution: 0.05 mg/mL of [USP Hydrocortisone RS](#) from **Standard stock solution** in water

System suitability stock solution: 0.05 mg/mL of propylparaben in alcohol

System suitability solution: 5 µg/mL of propylparaben and 45 µg/mL of [USP Hydrocortisone RS](#), prepared by diluting 1 mL of the **System suitability stock solution** with **Standard solution** to 10 mL

Sample stock solution: Nominally 0.1 mg/mL of hydrocortisone, prepared as follows. Shake a 100-mL portion of Lotion to ensure homogeneity, and allow to stand until the entrapped air rises. Invert carefully, and transfer a quantity of this Lotion, freshly mixed but free from air bubbles, nominally equivalent to 10 mg of hydrocortisone, to a 40-mL beaker, and add 30 mL of alcohol. Warm gently until the Lotion is dispersed, and cool to room temperature. Filter the mixture into a 100-mL volumetric flask through a pledget of cotton previously moistened with alcohol. Rinse the beaker with two 20-mL portions of alcohol, and collect the washings in the same volumetric flask. Dilute with alcohol to volume.

Sample solution: Nominally 0.05 mg/mL of hydrocortisone from **Sample stock solution** in water

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: 20 µL

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between propylparaben and hydrocortisone, **System suitability solution**

Column efficiency: NLT 1000 theoretical plates for hydrocortisone, **System suitability solution**

Tailing factor: NMT 1.2 for hydrocortisone, **System suitability solution**

Relative standard deviation: NMT 3.0%, **Standard solution**

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 Lotion 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 (mg/mL)

C_U = nominal concentration of hydrocortisone 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 for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight 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 LOTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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