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Alclometasone Dipropionate Ointment

DEFINITION

Alclometasone Dipropionate Ointment contains NLT 90.0% and NMT 110.0% of the labeled amount of alclometasone dipropionate ($C_{28}H_{37}ClO_7$) in a suitable ointment base.

IDENTIFICATION

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

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

Standard solution: 0.25 mg/mL USP Alclometasone Dipropionate RS in methanol

Sample solution: Place a quantity of Ointment, equivalent to 1.25 mg of alclometasone dipropionate, in a 50-mL centrifuge tube, add 10 mL of 2,2,4-trimethylpentane, insert a stopper securely into the tube, and disperse the specimen using a vortex mixer. Add 5.0 mL of a solution of methanol in water (45 in 50), insert the stopper securely, shake vigorously for 2 min, and centrifuge at 2500 rpm for 3 min. Remove the lower, aqueous alcohol phase, and transfer to a stoppered vial.

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 20 µL

Developing solvent system: Chloroform and acetone (7:1)

Analysis

Samples: *Standard solution* and *Sample solution*

Dry the applications with the aid of a stream of nitrogen, and develop the chromatograms in a saturated, unlined chromatographic chamber. When the solvent front has moved three-fourths of the length of the plate, remove the plate from the chamber, mark the solvent front, and allow the solvent to evaporate. Observe the plate under short-wavelength UV light.

Acceptance criteria: The R_F value of the principal spot obtained from the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• **Procedure**

Buffer: 6.80 g/L of monobasic potassium phosphate (0.05 M)

Solution A: Dilute 450 mL of methanol with water to 500 mL.

Mobile phase: Methanol and *Buffer* (2:1)

Internal standard solution: 0.15 mg/mL of betamethasone dipropionate in *Solution A*

Standard stock solution: 0.1 mg/mL of USP Alclometasone Dipropionate RS in *Solution A*

Standard solution: 0.05 mg/mL of USP Alclometasone Dipropionate RS obtained by combining, in a small stoppered flask, 5.0 mL of *Standard stock solution* and 5.0 mL of *Internal standard solution*

Sample solution: Transfer a quantity of Ointment, equivalent to 0.5 mg of alclometasone dipropionate, to a 50-mL centrifuge tube, add 10 mL of 2,2,4-trimethylpentane, insert a stopper securely into the tube, and disperse the specimen using a vortex mixer. Add 5.0 mL of *Internal standard solution* and 5.0 mL of *Solution A*, insert the stopper securely, shake vigorously for 2 min, and centrifuge at 2500 rpm for 3 min. Remove the lower, aqueous alcohol phase, and transfer this *Sample solution* to a stoppered vial.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 1.2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for alclometasone dipropionate and betamethasone dipropionate are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the analyte and internal standard peaks

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of alclometasone dipropionate ($C_{28}H_{37}ClO_7$) in the portion of Ointment taken:

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

R_U = peak height ratio of alclometasone dipropionate to the internal standard from the *Sample solution*

R_S = peak height ratio of alclometasone dipropionate to the internal standard from the *Standard solution*

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

C_U = nominal concentration of alclometasone dipropionate 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⟩:** Meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Alclometasone Dipropionate RS

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

Topic/Question	Contact	Expert Committee
ALCLOMETASONE DIPROPIONATE OINTMENT	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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