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Clotrimazole Lotion

DEFINITION
Clotrimazole Lotion contains NLT 90.0% and NMT 110.0% of the labeled amount of clotrimazole ($C_{22}H_{17}ClN_2$).

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

ASSAY
• **Procedure**

Buffer: 4.35 g/L of dibasic potassium phosphate in water

Mobile phase: Methanol and *Buffer* (3:1). Pass through a filter of 0.5-µm or finer pore size.

Internal standard solution: 0.07 mg/mL of testosterone propionate in dehydrated alcohol

Standard stock solution A: 2 mg/mL of USP Clotrimazole RS in dehydrated alcohol

Standard stock solution B: 0.1 mg/mL of USP Clotrimazole Related Compound A RS in dehydrated alcohol

Standard solution: *Standard stock solution A*, *Standard stock solution B*, and *Internal standard solution* (5.0:5.0:10.0)

Sample solution: Nominally 1 mg/mL, prepared as follows. Transfer the equivalent of 10 mg of clotrimazole from freshly mixed Lotion to a screw-capped, 50-mL centrifuge tube. Add 10.0 mL of *Internal standard solution*, place the cap on the tube, and heat at 50° in a water bath for 5 min, with occasional shaking. Remove the tube from the bath, and shake vigorously for 5 min. Cool in a methanol–ice bath for 15 min, and promptly centrifuge. Transfer the supernatant to a test tube. Add 10.0 mL of dehydrated alcohol to the residue in the centrifuge tube, and repeat the extraction as directed above, beginning with “place the cap on the tube”. Transfer the supernatant to the test tube containing the supernatant from the first extraction.

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

Mode: LC

Detector: UV 254 nm

Columns

Guard: 2.1-mm × 6-cm, 10-µm packing L2

Analytical: 3.9-mm × 30-cm; 10-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for clotrimazole related compound A, clotrimazole, and testosterone propionate are 0.9, 1.0, and 1.5, respectively.]

Suitability requirements

Resolution: NLT 1.2 between clotrimazole related compound A and clotrimazole, and NLT 1.9 between clotrimazole and testosterone propionate

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount clotrimazole ($C_{22}H_{17}ClN_2$) in the portion of Lotion taken:

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

R_U = peak response ratio of clotrimazole to testosterone propionate from the *Sample solution*

R_S = peak response ratio of clotrimazole to testosterone propionate from the *Standard solution*

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

C_U = nominal concentration of clotrimazole in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Organic Impurities: Limit of Clotrimazole Related Compound A**

Analysis: Using the chromatograms of the *Standard solution* and *Sample solution* as obtained in the *Assay*, calculate the percentage of clotrimazole related compound A in the portion of Lotion taken:

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

R_U = peak response ratio of clotrimazole related compound A to testosterone propionate from the *Sample solution*

R_S = peak response ratio of clotrimazole related compound A to testosterone propionate from the *Standard solution*

C_S = concentration of USP Clotrimazole Related Compound A RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of clotrimazole related compound A in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 5%

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** It meets the requirements for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

• **pH ⟨791⟩:** 5.0–7.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store at a temperature between 2° and 30°.

• **USP Reference Standards ⟨11⟩**

USP Clotrimazole RS

USP Clotrimazole Related Compound A RS

(*o*-Chlorophenyl)diphenylmethanol.

$C_{19}H_{15}ClO$ 294.78

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

Topic/Question	Contact	Expert Committee
CLOTRIMAZOLE LOTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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