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Clotrimazole Cream

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

IDENTIFICATION
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**

Buffer: 4.35 mg/mL of dibasic potassium phosphate

Mobile phase: Acetonitrile and *Buffer* (3:1)

[Note—The ratio of volumes may be changed to obtain the required resolution.]

Standard solution: 0.5 mg/mL of USP Clotrimazole RS in methanol

System suitability solution: 0.1 mg/mL each of USP Clotrimazole RS and USP Clotrimazole Related Compound A RS in methanol

Sample solution: Transfer the equivalent of 25 mg of clotrimazole from the Cream to a 50-mL screw-capped centrifuge tube. Add 25.0 mL of methanol, 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 50-mL volumetric flask. Add 20.0 mL of methanol to the residue in the centrifuge tube, and repeat the extraction starting with "heat at 50° in a water bath". Transfer the supernatant to the volumetric flask containing the supernatant from the first extraction, dilute with methanol to volume, and mix.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.5 mL/min

Injection size: 25 µL

System suitability

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

[Note—The relative retention times for clotrimazole and clotrimazole related compound A are 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between clotrimazole and clotrimazole related compound A, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{22}H_{17}ClN_2$ in the portion of Cream taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of clotrimazole from the *Sample solution*

r_S = peak response of clotrimazole 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%

ADDITIONAL REQUIREMENTS

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

• **Labeling:** Cream that is packaged and labeled for use as a vaginal preparation shall be labeled Clotrimazole Vaginal Cream.

• **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 CREAM	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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