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Clobetasol Propionate Topical Solution

DEFINITION

Clobetasol Propionate Topical Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of clobetasol propionate ($C_{25}H_{32}ClFO_5$).

IDENTIFICATION

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

Standard solution: 0.75 mg/mL of USP Clobetasol Propionate RS in chloroform

Test solution: Nominally 0.75 mg/mL of clobetasol propionate. Transfer a portion of Topical Solution equivalent to 1.5 mg of clobetasol to a 50-mL separatory funnel. Add 5 mL of water, and extract with 5 mL of chloroform. Collect the lower layer through a cotton wool plug, and evaporate with the aid of a stream of nitrogen to dryness. Dissolve the residue in 2 mL of chloroform.

Developing solvent system: Chloroform, acetone, and alcohol (100:10:5)

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

ASSAY

• **Procedure**

Buffer: 0.05 M monobasic sodium phosphate. Adjust with 85% phosphoric acid to a pH of 2.5.

Mobile phase: Acetonitrile, methanol, and *Buffer* (95:20:85)

Internal standard solution: 0.2 mg/mL of beclomethasone dipropionate in methanol

System suitability solution: 0.001 mg/mL of USP Clobetasol Propionate Related Compound A RS and 0.1 mg/mL of USP Clobetasol Propionate RS in *Mobile phase*

Standard solution: 0.04 mg/mL of USP Clobetasol Propionate RS and 0.08 mg/mL of beclomethasone dipropionate prepared as follows. Transfer 1.0 mg of USP Clobetasol Propionate RS to a 25-mL volumetric flask, add 10.0 mL of the *Internal standard solution*, and dilute with methanol to volume.

Sample solution: Nominally 0.04 mg/mL of clobetasol propionate. Transfer a portion of Topical Solution equivalent to 1.0 mg of clobetasol propionate to a 25-mL volumetric flask, add 10.0 mL of the *Internal standard solution*, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 15-cm; packing L1

Flow rate: 1 mL/min

Injection size: 10 µL

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for clobetasol propionate and clobetasol propionate related compound A are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 1.5 between clobetasol propionate and clobetasol propionate related compound A

Column efficiency: NLT 5000 theoretical plates for the clobetasol propionate peak

Tailing factor: NMT 2.0 for the clobetasol propionate peak

Relative standard deviation: NMT 2.0% for the clobetasol propionate peak

Analysis

Samples: *Standard solution* and *Sample solution*

[Note—The relative retention times for clobetasol propionate and beclomethasone dipropionate are 1.0 and 1.6, respectively.]

Calculate the percentage of clobetasol propionate ($C_{25}H_{32}ClFO_5$) in the portion of Topical Solution taken:

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

R_U = ratio of the clobetasol propionate peak area to the internal standard peak area from the *Sample solution*

R_S = ratio of the clobetasol propionate peak area to the Internal standard peak area from the *Standard solution*

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

C_U = nominal concentration of clobetasol propionate 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⟩:** The total aerobic microbial count does not exceed 10^2 cfu/g. It meets the requirements of the tests for absence of *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Salmonella* species.

• **pH ⟨791⟩:** 4.5–6.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature. Do not refrigerate.

• **USP Reference Standards ⟨11⟩**

USP Clobetasol Propionate RS

USP Clobetasol Propionate Related Compound A RS

9α-Fluoro-11β-hydroxy-16β-methyl 3-oxo-androsta-1,4-diene-17(*R*)-spiro-2'-[4'-chloro-5'-ethylfuran-3'(2'*H*)-one].

$C_{25}H_{30}ClFO_4$ 448.96

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

Topic/Question	Contact	Expert Committee
CLOBETASOL PROPIONATE TOPICAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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