

Mometasone Furoate Cream

DEFINITION
Mometasone Furoate Cream is Mometasone Furoate in a suitable cream base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of mometasone furoate ($C_{27}H_{30}Cl_2O_6$).

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: 0.2 mg/mL of [USP Mometasone Furoate RS](#) in acetonitrile
Sample solution: 0.2 mg/mL of mometasone furoate from Cream in acetonitrile
Developing solvent system: Chloroform and ethyl acetate (3:1)
Acceptance criteria: The R_f value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

- PROCEDURE**
[NOTE—Protect from light.]
Diluent A: Tetrahydrofuran and glacial acetic acid (100:1)
Diluent B: Acetonitrile, water, and glacial acetic acid (50:50:1)
Solution A: Water
Solution B: Acetonitrile
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
2	70	30
45	45	55
46	70	30
50	70	30

Internal standard solution: 1.4 mg/mL of diethyl phthalate in acetonitrile
Standard stock solution: 0.2 mg/mL of [USP Mometasone Furoate RS](#) in *Diluent A*
Standard solution: 0.05 mg/mL of mometasone furoate and 0.35 mg/mL of diethyl phthalate from equal quantities of the *Standard stock solution* and the *Internal standard solution*, in *Diluent B*
Sample solution: Transfer a portion of Cream, equivalent to 1.0 mg of mometasone furoate, to a 50-mL, screw-capped centrifuge tube. Add 5.0 mL of *Diluent A* and a few glass beads, and mix on a vortex mixer. Add 5.0 mL of *Internal standard solution*, and mix. Add 10.0 mL of *Diluent B*, mix on a vortex mixer for 1 min, and centrifuge for 10 min. Pass the aqueous phase through a polypropylene filter of 0.2-µm pore size, discarding the first 1–2 mL of filtrate.
Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-μm packing L60

Flow rate: 2 mL/min

Injection size: 20 μL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for diethyl phthalate and mometasone furoate are 0.4 and 1.0, respectively.]

Suitability requirements

Tailing factor: NMT 1.5 for the mometasone furoate peak

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of mometasone furoate ($C_{27}H_{30}Cl_2O_6$) in the portion of Cream taken:

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

R_U = ratio of the mometasone furoate peak response to the diethyl phthalate peak response from the *Sample solution*

R_S = ratio of the mometasone furoate peak response to the diethyl phthalate peak response from the *Standard solution*

C_S = concentration of [USP Mometasone Furoate RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- [MINIMUM FILL \(755\)](#): Meets the requirements

IMPURITIES

• ORGANIC IMPURITIES

[NOTE—Protect from light.]

Diluent A, Solution A, Solution B, Mobile phase, and Standard stock solution: Prepare as directed in the Assay.

Diluent C: Acetonitrile, water, and glacial acetic acid (30:70:1)

System suitability solution: 0.1 μg/mL of [USP Mometasone Furoate RS](#) from *Standard stock solution* in *Diluent C*

Blank solution: *Diluent C* and *Diluent A* (3:1)

Sample solution: Transfer a portion of Cream, equivalent to 2.0 mg of mometasone furoate, to a 50-mL, screw-capped centrifuge tube. Add 5.0 mL of *Diluent A* and a few glass beads, and mix on a vortex mixer. Add 15.0 mL of *Diluent C*, and mix. Centrifuge for 10 min. Pass the aqueous phase through a 0.2-μm polypropylene filter, discarding the first 1–2 mL of filtrate.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-μm packing L60

Column temperature: 25 ± 5°

Flow rate: 2 mL/min

Injection size: 50 μL

System suitability

Sample: *System suitability solution*

Suitability requirements

Relative standard deviation: NMT 10%

Analysis

Samples: *System suitability solution*, *Blank solution*, and *Sample solution*

[NOTE—Exclude any peak areas less than those from the *System suitability solution*. Also exclude any peaks with the same retention time as that observed in the *Blank solution*. Any peaks having a relative retention time of about 1.04 or 1.13 are controlled in the Mometasone Furoate monograph and, therefore, are not included in the total specified and unspecified impurities limit.]