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

Change to read:

- **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: Use water.
  Solution B: Use 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 the *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% ▲*USP33*

PERFORMANCE TESTS

- **MINIMUM FILL ⟨755⟩:** Meets the requirements

IMPURITIES

Change to read:

▲• **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 the *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 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
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*, *Sample solution*, and *Blank 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.]
Calculate the percentage of each impurity in the portion of Cream taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each impurity from the *Sample solution*
r_T = sum of all the peak responses from the *Sample solution*

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
9α-Chloro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 17-(2-furoate)	0.56	0.1
9α,21-Dichloro-11β,17-dihydroxy-16α-methylpregna-1,4-diene-3,20-dione	0.73	0.1
21-Chloro-17-hydroxy-16α-methylpregna-1,4-diene-3,11,20-trione 17-(2-furoate)	0.88	0.1
21-Chloro-9β,11β-epoxy-17-hydroxy-16α-methylpregna-1,4-diene-3,20-dione 17-(2-furoate)	0.94	•1.0•(RB 1-Oct-2010)
Mometasone furoate	1.0	—
Unspecified individual impurity	—	0.2
Total impurities	—	•1.0•(RB 1-Oct-2010)

▲*USP33*

SPECIFIC TESTS

- **MICROBIAL ENUMERATION TESTS ⟨61⟩** and **TESTS FOR SPECIFIED MICROORGANISMS ⟨62⟩:** It meets the requirements of the tests for absence of *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Salmonella* species.

ADDITIONAL REQUIREMENTS

Change to read:

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, ▲and store at controlled room temperature.▲*USP33*
- **USP REFERENCE STANDARDS ⟨11⟩**
  USP Mometasone Furoate RS