Mometasone Furoate Topical Solution

DEFINITION

Mometasone Furoate Topical Solution is Mometasone Furoate in a suitable aqueous vehicle. 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: 1 mg/mL of USP Mometasone Furoate RS in a mixture of chloroform and methanol (4:1)
  Sample solution: Transfer the equivalent of 2 mg of mometasone furoate from Topical Solution to a 50-mL centrifuge tube. Add 10 mL of water. Extract the aqueous solution with 20 mL of chloroform. Remove the chloroform layer, dry over anhydrous sodium sulfate, and filter through a cotton pledget. Repeat the chloroform extraction, and combine the dried extracts. Evaporate the chloroform solution to dryness on a steam bath under a stream of nitrogen. Allow the sample specimen to cool to room temperature. Dissolve the residue in a mixture of chloroform and methanol (4:1) to obtain 1 mg/mL of the *Sample solution*.
  Application volume: 20 µL
  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: 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

  Standard solution: 0.1 mg/mL of USP Mometasone Furoate RS in *Solution B*
  Sample solution: Transfer a portion of Topical Solution, equivalent to about 2.5 mg of mometasone furoate, to a 25-mL flask. Dilute with *Diluent* to volume, and mix. Pass a portion of the solution 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: 50 µL
  System suitability
  Sample: *Standard solution*
  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 Topical Solution taken:

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

  r_U = peak response from the *Sample solution*
  r_S = 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*

IMPURITIES

Change to read:

▲• **ORGANIC IMPURITIES**
  [NOTE—Protect from light.]
  Diluent, Solution A, Solution B, Mobile phase, Standard solution, and **Sample solution:** Prepare as directed in the *Assay*.
  System suitability solution: 0.1 µg/mL of USP Mometasone Furoate RS from the *Standard solution* in *Diluent*
  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: *Diluent*, *Sample solution*, and *System suitability solution*
  [NOTE—Exclude any peak areas less than that of the *System suitability solution*. Also, exclude any peaks with the same retention times as those observed in the *Diluent*. Any peaks having a relative retention time of 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 Topical Solution 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	0.3
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	—	●0.5●(RB 1-Oct-2010)
Total impurities	—	●2.0●(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.
- **pH** ⟨**791**⟩**:** 4.0–5.0

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