tor and a 4.6-mm × 25-cm column that contains packing L11. The flow rate is about 1.5 mL per minute.

Procedure—Separately inject equal volumes (about 100 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the peak heights. Determine the amount of molindone hydrochloride ($C_{16}H_{24}N_2O_2 \cdot HCl$) dissolved.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{16}H_{24}N_2O_2 \cdot HCl$ is dissolved in 30 minutes.

Assay—

Mobile phase, *Solvent mixture*, *Internal standard solution*, *Standard preparation,* and *Chromatographic system*—Proceed as directed in the *Assay* under *Molindone Hydrochloride*.

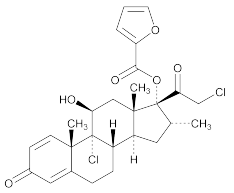
Assay preparation—Accurately weigh not less than 20 Tablets, grind the Tablets to a homogeneous mixture, and transfer an accurately weighed portion, equivalent to about 50 mg of molindone hydrochloride, to a 250-mL conical flask. Add 10.0 mL of *Internal standard solution* and 90.0 mL of *Solvent mixture*, shake for 30 minutes, and filter.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Molindone Hydrochloride*. Calculate the quantity, in mg, of molindone hydrochloride ($C_{16}H_{24}N_2O_2 \cdot HCl$) in the portion of Tablets taken by the formula:

$$100C(R_U / R_S)$$

in which C is the concentration, in mg per mL, of USP Molindone Hydrochloride RS in the *Standard preparation,* and R_U and R_S are the ratios of the peak response of molindone to that of butylparaben obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Mometasone Furoate



$C_{27}H_{30}Cl_2O_6$ 521.43

Pregna-1,4-diene-3,20-dione, 9,21-dichloro-17-[(2-furanylcarbonyl)oxy]-11-hydroxy-16-methyl-, (11β,16α)-; 9,21-Dichloro-11β,17-dihydroxy-16α-methylpregna-1,4-diene-3,20-dione 17-(2-furoate) [83919-23-7].

DEFINITION

Mometasone Furoate contains NLT 97.0% and NMT 102.0% of mometasone furoate ($C_{27}H_{30}Cl_2O_6$), calculated on the dried basis.

IDENTIFICATION

- **A. Infrared Absorption** ⟨197M⟩
- **B.** The retention time of the *Sample solution* corresponds to that of the *Standard solution*, both relative to the internal standard, as obtained in the *Assay*.

ASSAY

- **Procedure**

Mobile phase: Methanol and water (65:35)
Diluent: Methanol, acetic acid, and water (65: 0.2: 35)
Internal standard solution: 0.4 mg/mL of beclomethasone dipropionate in *Diluent*
Standard stock solution: 0.1 mg/mL of USP Mometasone Furoate RS, prepared by dissolving USP Mometasone Furoate RS in methanol and diluting quantitatively and stepwise, if necessary, with *Diluent*
Standard solution: 0.02 mg/mL of USP Mometasone Furoate RS and 0.08 mg/mL of beclomethasone dipropionate, prepared by pipetting equal volumes of *Standard stock solution* and *Internal standard solution* into a suitable volumetric flask and diluting with *Diluent* to volume, if necessary
Sample stock solution: 0.1 mg/mL of mometasone furoate, prepared by dissolving Mometasone Furoate in methanol and diluting quantitatively and stepwise, if necessary, with *Diluent*
Sample solution: 0.02 mg/mL of mometasone furoate and 0.08 mg/mL of beclomethasone dipropionate, prepared by pipetting 10 mL each of *Sample stock solution* and *Internal standard solution* into a 50-mL volumetric flask and diluting with *Diluent* to volume
Chromatographic system
(See *Chromatography* ⟨621⟩*, System Suitability*.)
Mode: LC
Detector: UV 254 nm
Column: 4.6-mm × 25-cm; packing L7
Flow rate: 1.7 mL/min
Injection size: 20 µL
System suitability
Sample: *Standard solution*
[NOTE—The relative retention times for mometasone furoate and beclomethasone dipropionate are about 1.0 and 1.6, respectively.]
Suitability requirements
Resolution: NLT 4.0 between the mometasone furoate and beclomethasone dipropionate peaks
Tailing factor: NMT 1.8 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 Mometasone Furoate taken:

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

R_U = peak response ratio of mometasone furoate to the internal standard from the *Sample solution*
R_S = peak response ratio of mometasone furoate to the internal standard from the *Standard solution*
C_S = concentration of USP Mometasone Furoate RS in the *Standard solution* (mg/mL)
C_U = concentration of Mometasone Furoate in the *Sample solution* (mg/mL)
Acceptance criteria: 97.0%–102.0% on the dried basis

IMPURITIES

- **Residue on Ignition** ⟨281⟩**:** NMT 0.1%

Delete the following:

- **Heavy Metals,** *Method II* ⟨231⟩**:** NMT 30 µg/g (Official 1-Jan-2018)

- **Organic Impurities**

Standard stock solution: 10 mg/mL of USP Mometasone Furoate RS in dichloromethane
Standard solution A (5%): 0.5 mg/mL of USP Mometasone Furoate RS in dichloromethane from the *Standard stock solution*
Standard solution B (2%): 0.2 mg/mL of USP Mometasone Furoate RS in dichloromethane, from the *Standard stock solution*
Standard solution C (1%): 0.1 mg/mL of USP Mometasone Furoate RS in dichloromethane, from the *Standard stock solution*

Standard solution D (0.2%): 0.02 mg/mL of USP Mometasone Furoate RS in dichloromethane, from the *Standard stock solution*
Standard solution E (0.1%) 0.01 mg/mL of USP Mometasone Furoate RS in dichloromethane, from the *Standard stock solution*
Sample solution: 10 mg/mL of Mometasone Furoate in dichloromethane
Chromatographic system
(See *Chromatography* ⟨621⟩*, Thin-Layer Chromatography*.)
Mode: TLC
Adsorbent: 0.25-mm layer of chromatographic silica gel
Application volume: 40 µL
Developing solvent system: Chloroform and ethyl acetate (3:1)
Analysis
Samples: *Standard solutions* and *Sample solution*
Proceed as directed in the chapter. Examine the plate under short-wavelength UV light. Compare the intensities of any secondary spots from the *Sample solution* with those of the principal spots from the *Standard solutions*.
Acceptance criteria: No secondary spot from the *Sample solution* is larger or more intense than the principal spot from *Standard solution C*; and the sum of the intensities of the secondary spots from the *Sample solution* is NMT 2.0%.

SPECIFIC TESTS
- **OPTICAL ROTATION,** *Specific Rotation* ⟨**781S**⟩
  Sample solution: 5 mg/mL in dioxane
  Acceptance criteria: +56° to +62°
- **LOSS ON DRYING** ⟨**731**⟩
  Analysis: Dry a sample at 105° for 3 h.
  Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Mometasone Furoate RS

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)

USP Monographs