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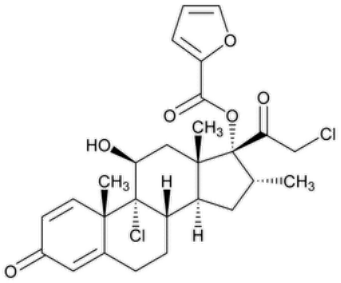
Mometasone Furoate



$C_{27}H_{30}Cl_2O_6$ 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) CAS RN®: 83919-23-7; UNII: 04201GDN4R.

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

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (CN 1-May-2020)

• **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%

• **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

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

Topic/Question	Contact	Expert Committee
MOMETASONE FUROATE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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