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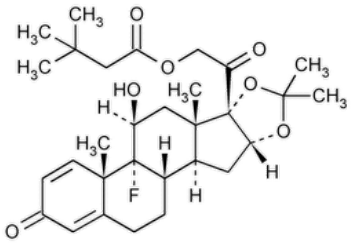
Triamcinolone Hexacetonide



$C_{30}H_{41}FO_7$ 532.64

Pregna-1,4-diene-3,20-dione, 21-(3,3-dimethyl-1-oxobutoxy)-9-fluoro-11-hydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (11β,16α)-; 9-Fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone 21-(3,3-dimethylbutyrate) CAS RN®: 5611-51-8; UNII: I7GT1U99Y9.

DEFINITION

Triamcinolone Hexacetonide contains NLT 97.0% and NMT 102.0% of $C_{30}H_{41}FO_7$, calculated on the dried basis.

IDENTIFICATION

Change to read:

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

ASSAY

• **Procedure**

Mobile phase: Methanol and water (3:1)

System suitability solution: 0.4 mg/mL each of USP Triamcinolone Acetonide RS and USP Triamcinolone Hexacetonide RS in methanol

Standard solution: 0.4 mg/mL of USP Triamcinolone Hexacetonide RS in methanol

Sample solution: 0.4 mg/mL of Triamcinolone Hexacetonide in methanol

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 2 mL/min

Injection size: 10 µL

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for triamcinolone acetonide and triamcinolone hexacetonide are 0.27 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 7.5 between triamcinolone acetonide and triamcinolone hexacetonide

Tailing factor: NMT 1.3 for triamcinolone hexacetonide

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{30}H_{41}FO_7$ in the portion of Triamcinolone Hexacetonide 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 Triamcinolone Hexacetonide RS in the *Standard solution* (mg/mL)

C_U = concentration of Triamcinolone Hexacetonide in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0% on the dried basis

IMPURITIES

Organic Impurities

- **Procedure: Limit of Triamcinolone Acetonide**

Mobile phase, System suitability solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Standard solution: 0.004 mg/mL of USP Triamcinolone Acetonide RS in methanol

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of triamcinolone acetonide in the portion of Triamcinolone Hexacetonide taken:

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

r_U = peak response of triamcinolone acetonide from the *Sample solution*

r_S = peak response of triamcinolone acetonide from the *Standard solution*

C_S = concentration of USP Triamcinolone Acetonide RS in the *Standard solution* (mg/mL)

C_U = concentration of Triamcinolone Hexacetonide in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 1.0%

SPECIFIC TESTS

- **Optical Rotation,** *Specific Rotation*⟨781S⟩

Sample solution: 10 mg/mL in chloroform

Acceptance criteria: +91° to +98°

- **Loss on Drying** ⟨731⟩**:** Dry a sample in a vacuum at 60° for 4 h: it loses NMT 2.0% of its weight.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. Store at room temperature.
- **USP Reference Standards** ⟨11⟩

USP Triamcinolone Acetonide RS

USP Triamcinolone Hexacetonide RS

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

Topic/Question	Contact	Expert Committee
TRIAMCINOLONE HEXACETONIDE	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 36(5)

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