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Triamcinolone Hexacetonide Injectable Suspension

DEFINITION

Triamcinolone Hexacetonide Injectable Suspension is a sterile suspension of Triamcinolone Hexacetonide in a suitable aqueous medium. It contains NLT 90.0% and NMT 115.0% of the labeled amount of triamcinolone hexacetonide ($C_{30}H_{41}FO_7$).

IDENTIFICATION

Change to read:

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

Sample: Place a volume of Injectable Suspension, equivalent to 25 mg of triamcinolone hexacetonide, and 2 mL of water in a membrane filter of 0.20-µm pore size. Apply vacuum to the filter, wash the residue with two 5-mL portions of water, and air-dry the filter and the precipitate. Place the dried filter and precipitate in a small beaker with 5 mL of alcohol, and dissolve the precipitate. Decant the alcohol solution into a small beaker and evaporate with the aid of low heat and a current of air to dryness.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Mobile phase: Methanol and water (3:1)

System suitability solution: 0.3 mg/mL of amcinonide and 0.4 mg/mL of USP Triamcinolone Hexacetonide RS in methanol

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

Sample solution: Using a “to contain” pipet, transfer a volume of Injectable Suspension, equivalent to 40 mg of triamcinolone hexacetonide, to a 100-mL volumetric flask. Rinse the pipet with methanol, collecting the rinse in the volumetric flask. Dilute with methanol to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1.4 mL/min

Injection size: 10 µL

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for amcinonide and triamcinolone hexacetonide are about 0.50 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 10 between amcinonide and triamcinolone hexacetonide

Tailing factor: NMT 1.2 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 Injectable Suspension taken:

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

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

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

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

C_U = nominal concentration of triamcinolone hexacetonide in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

IMPURITIES

Organic Impurities

• **Procedure: Limit of Triamcinolone Acetonide**

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

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

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

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 7.5 between triamcinolone acetonide and triamcinolone hexacetonide

Tailing factor: NMT 1.2 for triamcinolone hexacetonide

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of triamcinolone acetonide in the portion of Injectable Suspension 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 = nominal concentration of triamcinolone hexacetonide in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 1.0%

SPECIFIC TESTS

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 17.2 USP Endotoxin Units/mg of triamcinolone hexacetonide.

• **pH ⟨791⟩:** 4.0–8.0

• **Injections and Implanted Drug Products ⟨1⟩:** Meets the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass. Store at controlled room temperature. Do not freeze.

• **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 INJECTABLE SUSPENSION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

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