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Triamcinolone Acetonide Injectable Suspension

DEFINITION

Triamcinolone Acetonide Injectable Suspension is a sterile suspension of Triamcinolone Acetonide in a suitable aqueous medium. It contains NLT 90.0% and NMT 115.0% of the labeled amount of $C_{24}H_{31}FO_6$.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

Sample: Extract a volume of Injectable Suspension, equivalent to 50 mg of triamcinolone acetonide, with two 10-mL portions of peroxide-free ether, and discard the ether extracts. Filter with the aid of suction, wash with small portions of water, and dry the precipitate at 105° for 1 h.

Acceptance criteria: Meets the requirements

Change to read:

- **B.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-MAY-2020)

Sample solution: 20 µg/mL in methanol, using the triamcinolone acetonide obtained from *Identification* test A

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Mobile phase: Acetonitrile and water (30:70)

Internal standard solution: 84 µg/mL of fluoxymesterone in methanol

Standard stock solution: 200 µg/mL of [USP Triamcinolone Acetonide RS](#) in methanol

Standard solution: 80 µg/mL of [USP Triamcinolone Acetonide RS](#) from the *Standard stock solution* diluted with *Internal standard solution*

Sample stock solution: Dissolve a volume of freshly mixed Injectable Suspension in methanol to obtain a solution containing 200 µg/mL of triamcinolone acetonide.

Sample solution: 80 µg/mL of triamcinolone acetonide from the *Sample stock solution* diluted with *Internal standard solution*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 1.0 mL/min

Injection size: 15–25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between triamcinolone acetonide and fluoxymesterone

Relative standard deviation: NMT 3.0% for five replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{24}H_{31}FO_6$ in the portion of Injectable Suspension taken:

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

R_U = peak response ratio of the triamcinolone acetonide peak to the internal standard peak from the *Sample solution*

R_s = peak response ratio of the triamcinolone acetonide peak to the internal standard peak from the *Standard solution*

C_s = concentration of [USP Triamcinolone Acetonide RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of triamcinolone acetonide in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meets the requirements

SPECIFIC TESTS

- [BACTERIAL ENDOTOXINS TEST \(85\)](#): It contains NMT 4.4 USP Endotoxin Units/mg of triamcinolone acetonide.
- [pH \(791\)](#): 5.0–7.5
- [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, protected from light. Store at controlled room temperature. Do not freeze.
- [USP REFERENCE STANDARDS \(11\)](#).
[USP Triamcinolone Acetonide RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
TRIAMCINOLONE ACETONIDE INJECTABLE SUSPENSION	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](#)

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