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Methylprednisolone Acetate Injectable Suspension

DEFINITION

Methylprednisolone Acetate Injectable Suspension is a sterile suspension of Methylprednisolone Acetate in a suitable aqueous medium. It contains NLT 90.0% and NMT 110.0% of the labeled amount of methylprednisolone acetate ($C_{24}H_{32}O_6$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

Sample: Nominally 100 mg of methylprednisolone acetate from Injectable Suspension

Analysis: Filter the *Sample* through paper. Wash the residue with several 5-mL portions of [water](#), and dry at 105° for 3 h.

Acceptance criteria: Meets the requirements

ASSAY

Change to read:

PROCEDURE

Mobile phase: [n-Butyl chloride](#), water-saturated *n*-butyl chloride, [tetrahydrofuran](#), [methanol](#), and [glacial acetic acid](#) (95:95:14:7:6)

Internal standard solution: 6 mg/mL of [USP Prednisone RS](#) (IRA 1-Dec-2024) prepared as follows. Transfer an appropriate amount of [USP Prednisone RS](#) (IRA 1-Dec-2024) to a suitable volumetric flask. Add 3% of the flask volume of [glacial acetic acid](#), and sonicate. Dilute with [chloroform](#) to volume, slowly adding the [chloroform](#). Sonicate, and shake to dissolve.

Standard solution: 0.2 mg/mL of [USP Methylprednisolone Acetate RS](#) prepared as follows. Transfer an appropriate amount of [USP Methylprednisolone Acetate RS](#) to a suitable volumetric flask, and add 5% of the flask volume of the *Internal standard solution*. Dilute with [chloroform](#) to volume, and shake to dissolve.

Sample solution: $\blacktriangle$ Nominally 0.188 mg/mL of methylprednisolone acetate from Injectable Suspension prepared as follows. $\blacktriangle$ (IRA 1-Dec-2024)
 Swirl Injectable Suspension to ensure uniformity before analysis. Transfer a suitable quantity of Injectable Suspension equivalent to 40 mg of methylprednisolone acetate to a 25-mL volumetric flask, add 10.0 mL of the *Internal standard solution*, dilute with [chloroform](#) to volume, and shake for 15 min or until the aqueous layer is clear. Transfer 4.0 mL of the chloroform layer to a suitable vial, add 30 mL of [chloroform](#) and a small quantity (about 400 mg) of [anhydrous sodium sulfate](#), and shake for 5 min. Use the clear solution.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 25-cm; packing [L3](#)

Flow rate: 1 mL/min

Injection volume: 10 μ L

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for methylprednisolone acetate and prednisone are 1.0 and 1.3, respectively.]

Suitability requirements

Resolution: NLT 2.5 between methylprednisolone acetate and prednisone

Relative standard deviation: NMT 2.0% $\blacktriangle$ for the peak height ratio of methylprednisolone and prednisone $\blacktriangle$ (IRA 1-Dec-2024)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of methylprednisolone acetate ($C_{24}H_{32}O_6$) in the portion of Injectable Suspension taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times F \times 100 \quad (\text{IRA 1-Dec-2024})$$

R_U = peak height ratio of methylprednisolone acetate to prednisone from the *Sample solution*

R_S = peak height ratio of methylprednisolone acetate to prednisone from the *Standard solution*

C_S = concentration of [USP Methylprednisolone Acetate RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of methylprednisolone acetate in the *Sample solution* (mg/mL)

Δ_F = correction factor for the *Internal standard solution*, 0.94▲ (IRA 1-Dec-2024)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

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

SPECIFIC TESTS

- [pH \(791\)](#): 3.0–7.0
- **PARTICLE SIZE**

Analysis: Transfer 1 drop to a microscope slide, and spread it evenly, diluting with [water](#), if necessary, to decrease the density of the field. Examine the slide under a microscope equipped with a calibrated ocular micrometer, using 400× magnification. Scan the entire slide, and note the size of the individual particles.

Acceptance criteria: NLT 99% of the particles are less than 20 µm in length when measured along the longest axis, and NLT 75% of the particles are less than 10 µm

- **OTHER REQUIREMENTS:** It meets the requirements in [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

Change to read:

- **PACKAGING AND STORAGE:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass. ▲Store at controlled room temperature▲

(IRA 1-Dec-2024)

Change to read:

- [USP REFERENCE STANDARDS \(11\)](#)
[USP Methylprednisolone Acetate RS](#)

▲ [USP Prednisone RS](#)▲ (IRA 1-Dec-2024)

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

Topic/Question	Contact	Expert Committee
METHYLPREDNISOLONE ACETATE INJECTABLE SUSPENSION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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