Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Dec-2024
Document Type: USP Monographs
DocId: GUID-86D121EB-156D-43C3-A93D-6990D1111B13_4_en-US
DOI: https://doi.org/10.31003/USPNF_M52866_04_01
DOI Ref: uo8a2

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: ▲Nominally 0.188 mg/mL of methylprednisolone acetate from Injectable Suspension prepared as follows.▲ (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 µL

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% ▲for the peak height ratio of methylprednisolone and prednisone▲ (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:

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

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)

▲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:
Pharmacopeial Forum: Volume No. 50(3)

Current DocID: GUID-86D121EB-156D-43C3-A93D-6990D1111B13_4_en-US

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