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Medroxyprogesterone Acetate Injectable Suspension

DEFINITION

Medroxyprogesterone Acetate Injectable Suspension is a sterile suspension of Medroxyprogesterone Acetate in a suitable aqueous medium. It contains NLT 90.0% and NMT 110.0% of the labeled amount of medroxyprogesterone acetate ($C_{24}H_{34}O_4$).

IDENTIFICATION

Change to read:

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

Sample: Transfer a volume of Injectable Suspension, equivalent to 50 mg of medroxyprogesterone acetate, to a centrifuge tube, centrifuge, decant the supernatant, and wash the solids with two 15-mL portions of water, discarding the water washings. Dissolve the solids in 10 mL of chloroform, transfer to a small beaker, evaporate the chloroform on a steam bath, and dry the residue at 105° for 3 h.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Mobile phase: 700 mL of butyl chloride, 300 mL of hexane, both previously saturated with water, and 80 mL of acetonitrile. The acetonitrile concentration may be varied to meet *System suitability* requirements and to provide elution times of about 12 and 15 min for progesterone and medroxyprogesterone acetate, respectively. Pass the solution through a membrane filter of 1 µm or less pore size.

Internal standard solution: 0.25 mg/mL of progesterone in *Mobile phase*

Standard solution: 0.4 mg/mL of USP Medroxyprogesterone Acetate RS in *Internal standard solution*

Sample solution: Nominally 0.4 mg/mL of medroxyprogesterone acetate in *Internal standard solution*, prepared as follows. Transfer a volume of Injectable Suspension, equivalent to 50 mg of medroxyprogesterone acetate, to a suitable container. Transfer 25 mL of chloroform into the container, shake for 20 min, and centrifuge. Transfer 4 mL of the chloroform layer into a suitable container, and evaporate to dryness. Dissolve the residue in 20 mL of *Internal standard solution*.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 2-mm × 25-cm; 5-µm packing L3

Flow rate: The *Mobile phase* is maintained at a flow rate capable of giving the required resolution and suitable elution times.

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 5.0 between progesterone and medroxyprogesterone acetate

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of medroxyprogesterone acetate ($C_{24}H_{34}O_4$) in the portion of Injectable Suspension taken:

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

R_U = peak area ratio of medroxyprogesterone acetate to the internal standard from the *Sample solution*

R_S = peak area ratio of medroxyprogesterone acetate to the internal standard from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.0–7.0

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

• **USP Reference Standards** ⟨11⟩

USP Medroxyprogesterone Acetate RS

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

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

Chromatographic Database Information: Chromatographic Database

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