Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Aug-2023
Document Type: USP Monographs
DocId: GUID-10B0BC2C-AB7D-42EB-90D9-3BC5D0104EAD_3_en-US
DOI: https://doi.org/10.31003/USPNF_M47950_03_01
DOI Ref: v0elb

Medroxyprogesterone Acetate Tablets

DEFINITION

Medroxyprogesterone Acetate Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of medroxyprogesterone acetate ($C_{24}H_{34}O_4$).

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**

Sample: Triturate a number of Tablets, equivalent to about 25 mg of medroxyprogesterone acetate, with 15 mL of chloroform. Filter, evaporate the chloroform on a steam bath, and dry the residue at 105° for 3 h.

Acceptance criteria: Meet the requirements

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (40:60)

Standard solution: 1 mg/mL of USP Medroxyprogesterone Acetate RS in acetonitrile

Sample solution: Finely powder NLT 20 Tablets. Weigh a portion of the powder, equivalent to 25 mg of medroxyprogesterone acetate, into a 50-mL glass centrifuge tube. Transfer 25 mL of acetonitrile into the tube, shake to wet the powder thoroughly, sonicate for NLT 10 min, and centrifuge. Use the clear supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2

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 Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response 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: 93.0%–107.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.5% sodium lauryl sulfate; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Mobile phase: Acetonitrile and water (60:40)

Sodium lauryl sulfate stock solution: Transfer 180.0 g of sodium lauryl sulfate to a 2000-mL volumetric flask. Add 1500 mL of water, and stir until dissolved. [Note—Several hours of stirring are required.] Dilute with water to volume.

Standard stock solution: 70 mg of USP Medroxyprogesterone Acetate RS in 140 mL of *Sodium lauryl sulfate stock solution*. Dilute with water to 250 mL. [NOTE—It may be necessary to sonicate the solution to bring the Reference Standard into solution before dilution with water.] Prepare the *Standard stock solution* fresh daily.

Standard solution: Transfer a 20-mL aliquot of *Standard stock solution* into a 1-L volumetric flask. Add 40 mL of *Sodium lauryl sulfate stock solution*, and dilute with water to volume. This solution is stable for up to 7 days.

Sample solution: Withdraw 15 mL of the solution under test and filter, discarding the first 5 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 8-cm; packing L7

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.2

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of medroxyprogesterone acetate ($C_{24}H_{34}O_4$) dissolved using the responses from the *Sample solution* and *Standard solution*.

Tolerances: NLT 50% (*Q*) of the labeled amount of medroxyprogesterone acetate ($C_{24}H_{34}O_4$) is dissolved.

Change to read:

• **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** ▲Meet the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

Diluent: Alcohol and water (3:1)

Standard solution: 15 µg/mL of USP Medroxyprogesterone Acetate RS in *Diluent*

Sample solution: Nominally 15 µg/mL of medroxyprogesterone acetate in *Diluent* prepared as follows. Transfer 1 Tablet to a volumetric flask, dilute with *Diluent* to volume, and shake for 15 min. Filter, and quantitatively dilute a portion of the filtrate as needed.

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: Maximum at about 242 nm

Cell: 1 cm

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 Tablet taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

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

▲▲ (CN 1-Aug-2023)

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

• **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 TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 41(3)

Current DocID: GUID-10B0BC2C-AB7D-42EB-90D9-3BC5D0104EAD_3_en-US
DOI: https://doi.org/10.31003/USPNF_M47950_03_01
DOI ref: v0elb