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Methyltestosterone Tablets

DEFINITION

Methyltestosterone Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of methyltestosterone ($C_{20}H_{30}O_2$).

IDENTIFICATION

• **A. Infrared Absorption**

Sample: Evaporate to dryness 25 mL of the *Sample stock solution* from the *Assay*.

Acceptance criteria: The IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima at the same wavelengths as those of a similar preparation of USP Methyltestosterone RS.

ASSAY

• **Procedure**

Standard solution: 10 µg/mL of USP Methyltestosterone RS in alcohol

Sample stock solution: Nominally 0.2 mg/mL of methyltestosterone prepared as follows. Transfer the equivalent to 10 mg of methyltestosterone from NLT 20 powdered Tablets to a 125-mL separator with the aid of about 5 mL of water. Extract with four 25-mL portions of chloroform, filtering each through chloroform-washed cotton. Evaporate the combined extracts on a steam bath, with the aid of a current of air, to dryness. Dissolve the residue in alcohol, transfer to a 50-mL volumetric flask, and dilute with alcohol to volume.

Sample solution: Nominally 10 µg/mL of methyltestosterone in alcohol from the *Sample stock solution*

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 241 nm

Cell: 1 cm

Blank: Alcohol

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of methyltestosterone ($C_{20}H_{30}O_2$) in the portion of Tablets 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 Methyltestosterone RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Disintegration ⟨701⟩**

Time: 30 min

Acceptance criteria: Tablets intended for buccal administration meet the requirements for *Buccal Tablets*.

Change to read:

• **Uniformity of Dosage Units ⟨905⟩:** ▲Meet the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

Standard solution: 0.010 mg/mL of USP Methyltestosterone RS in methanol

Sample stock solution: Transfer 1 finely powdered Tablet to a 100-mL volumetric flask. Add 50 mL of methanol, and shake by mechanical means for 60 min. Dilute with methanol to volume, and filter, discarding the first 20 mL of the filtrate.

Sample solution: Dilute a suitable volume of the *Sample stock solution* with methanol to obtain 0.010 mg/mL of methyltestosterone.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 241 nm

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Cell: 1 cm

Blank: Methanol

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of methyltestosterone ($C_{20}H_{30}O_2$) in the Tablet taken:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times D \times 100$$

A_U = absorbance of methyltestosterone from the *Sample solution*

A_S = absorbance of methyltestosterone from the *Standard solution*

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

L = label claim (mg/Tablet)

V = volume of the *Sample solution* (mL)

D = dilution factor of the *Sample solution*

▲▲ (CN 1-Aug-2023)

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩
  USP Methyltestosterone RS

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

Topic/Question	Contact	Expert Committee
METHYLTESTOSTERONE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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