Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Jan-2025
Document Type: USP Monographs
DocId: GUID-8C2728DA-998C-44A5-951D-CFA162684C60_3_en-US
DOI: https://doi.org/10.31003/USPNF_M53040_03_01
DOI Ref: 95ljd

Methyltestosterone Capsules

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-methyltestosterone-caps-20241227.

DEFINITION

Methyltestosterone Capsules 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 the contents of NLT 20 Capsules to a 125-mL separator with the aid of about 5 mL of water. Extract with four 20-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 Capsules 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

Change to read:

• **Dissolution** ⟨711⟩

▲**Test 1**▲ (RB 1-Jan-2025)

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

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

Sample solution: Filter a portion of the solution under test. Dilute with *Medium* to obtain a solution containing about 10 µg/mL of methyltestosterone.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 248 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Tolerances: NLT 70% (*Q*) of the labeled amount of methyltestosterone ($C_{20}H_{30}O_2$) is dissolved.

▲**Test 2:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N hydrochloric acid; 900 mL, deaerated

Apparatus 1: 10-mesh basket, 100 rpm

Time: 15 min

Buffer: Dissolve 1.36 g of potassium phosphate, monobasic in 1 L of water.

Mobile phase: Acetonitrile and *Buffer* (55:45)

Standard stock solution: 0.28 mg/mL of USP Methyltestosterone RS in methanol. Sonicate to dissolve, if necessary.

Standard solution: 0.011 mg/mL of USP Methyltestosterone RS from *Standard stock solution* in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 1-µm pore size, discarding an appropriate volume of filtrate so that a consistent result can be obtained.

Chromatographic system

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

Mode: LC

Detector: UV 241 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Temperatures

Autosampler: 5°

Column: 30°

Flow rate: 1.5 mL/min

Injection volume: 50 µL

Run time: NLT 1.8 times the retention time of methyltestosterone

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.8

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

r_U = peak response of methyltestosterone from the *Sample solution*

r_S = peak response of methyltestosterone from the *Standard solution*

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

V = volume of the *Medium*, 900 mL

L = label claim (mg/Capsule)

Tolerances: NLT 80% (*Q*) of the labeled amount of methyltestosterone ($C_{20}H_{30}O_2$) is dissolved.▲ (RB 1-Jan-2025)

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

Procedure for content uniformity

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

Sample stock solution: Transfer the contents of 1 Capsule 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

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 Capsule 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/Capsule)

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

D = dilution factor of the *Sample solution*

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

Add the following:

▲• **Labeling:** The labeling states the *Dissolution* test used only if *Test 1* is not used.▲ (RB 1-Jan-2025)

• **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 CAPSULES	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-8C2728DA-998C-44A5-951D-CFA162684C60_3_en-US
DOI: https://doi.org/10.31003/USPNF_M53040_03_01
DOI ref: 95ljd