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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- μ m 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 $\times$ 15-cm; 5- μ m packing [L1](#)

Temperatures

Autosampler: 5°

Column: 30°

Flow rate: 1.5 mL/min

Injection volume: 50 μ L

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:

