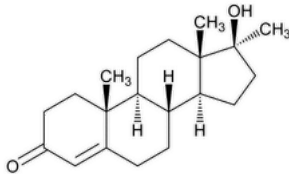


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Methyltestosterone

Change to read:



$C_{20}H_{30}O_2$ Δ 302.46 Δ (USP 1-May-2024)
 Androst-4-en-3-one, 17-hydroxy-17-methyl,(17 β)-;
 17 β -Hydroxy-17-methylandrost-4-en-3-one CAS RN[®]: 58-18-4; UNII: V9EFU16ZIF.

DEFINITION

Methyltestosterone contains NLT 97.0% and NMT 103.0% of methyltestosterone ($C_{20}H_{30}O_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** Δ 197A or Δ (USP 1-May-2024) 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

PROCEDURE

Δ [NOTE—Protect solutions containing methyltestosterone from light.] Δ (USP 1-May-2024)

Mobile phase: [Acetonitrile](#) and [water](#) (55:45)

Standard stock solution: 0.25 mg/mL of [USP Methyltestosterone RS](#) in [methanol](#)

Standard solution: 0.02 mg/mL of [USP Methyltestosterone RS](#) from the *Standard stock solution* in *Mobile phase*

System suitability stock solution: 0.25 mg/mL of [USP Testosterone RS](#) in [methanol](#)

System suitability solution: Δ 0.02 mg/mL each of [USP Methyltestosterone RS](#) and [USP Testosterone RS](#) in *Mobile phase* prepared as follows. Δ (USP 1-May-2024) Dilute 4 mL of the *System suitability stock solution* with the *Standard solution* to 50 mL.

Sample stock solution: 0.50 mg/mL of Methyltestosterone in [methanol](#)

Sample solution: 0.02 mg/mL of Methyltestosterone from the *Sample stock solution* in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 241 nm

Column: 4-mm $\times$ 25-cm; Δ 5- μ m Δ (USP 1-May-2024) packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 50 μ L

System suitability

Samples: *Standard solution* and *System suitability solution*

[NOTE—The relative retention times for testosterone and methyltestosterone are about 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between testosterone and methyltestosterone, *System suitability solution*

Δ Δ (USP 1-May-2024)

Tailing factor: NMT 2.7, *Standard solution*

Relative standard deviation: NMT Δ 1.10%, Δ (USP 1-May-2024) *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of methyltestosterone (C₂₀H₃₀O₂) in the portion of Methyltestosterone taken:

Result = (r_U/r_S) × (C_S/C_U) × 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)

C_U = concentration of Methyltestosterone in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

Change to read:

• **ORGANIC IMPURITIES**

▲[NOTE—Protect solutions containing methyltestosterone from light.]▲ (USP 1-MAY-2024)

Solution A: [Methanol](#) and [water](#) (55:45)

Solution B: [Methanol](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
20	60	40
40	0	100
45	0	100
60	100	0

System suitability solution: ▲0.5 mg/mL of [USP Methyltestosterone RS](#) and 0.005 mg/mL of [USP Testosterone RS](#) in [methanol](#)

Sensitivity solution: 0.25 µg/mL of [USP Methyltestosterone RS](#) in [methanol](#)

Standard solution: 0.5 µg/mL of [USP Methyltestosterone RS](#) in [methanol](#)▲ (USP 1-May-2024)

Sample solution: 0.5 mg/mL of Methyltestosterone in [methanol](#)

Chromatographic system

(See [Chromatography \(621\), System Suitability.](#))

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

▲**Temperatures**

Autosampler: 5°

Column: 30°▲ (USP 1-May-2024)

Flow rate: 1 mL/min

Injection volume: ▲10 µL▲ (USP 1-May-2024)

System suitability

Samples: ▲▲ (USP 1-May-2024) *System suitability solution*, ▲*Sensitivity solution*, and *Standard solution*

[NOTE—The relative retention times in [Table 2](#) are provided as information that could aid in peak assignment.]

Table 2

Name	Relative Retention Time
Androstenedione ^a	0.76