Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Mar-2019
Document Type: USP Monographs
DocId: GUID-E9EBBD6B-3C35-4AE1-8F57-1AD278D295C9_5_en-US
DOI: https://doi.org/10.31003/USPNF_M6484_05_01
DOI Ref: y1mcx



*Add the following:*

# ▲Testosterone Topical Solution

## DEFINITION

Testosterone Topical Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of testosterone ($C_{19}H_{28}O_2$).

## IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

## ASSAY

- **Procedure**

**Solution A:** Acetonitrile, water, and trifluoroacetic acid (10:90:0.05)

**Solution B:** Acetonitrile and trifluoroacetic acid (100:0.05)

**Mobile phase:** See *Table 1*.

**Table 1**

| Time (min) | Solution A (%) | Solution B (%) |
|---|---|---|
| 0 | 80 | 20 |
| 12 | 10 | 90 |
| 13 | 0 | 100 |
| 15 | 0 | 100 |
| 16 | 80 | 20 |
| 21 | 80 | 20 |

[Note—Post time of the gradient may be extended to more than 21 min to allow system to properly re-equilibrate.]

**Diluent:** Absolute alcohol and *Solution A* (50:50)

**Standard stock solution:** 0.8 mg/mL of USP Testosterone RS in absolute alcohol

**Standard solution:** 80 µg/mL of USP Testosterone RS from the *Standard stock solution* in *Diluent*

**Sample solution:** Nominally 80 µg/mL of testosterone from Topical Solution prepared as follows. Dispense a suitable amount of Topical Solution to a screw-cap glass container, seal the container, and sonicate briefly to disperse bubbles. [Note—Do not store sample in an open container.] Transfer a suitable volume of the solution to an appropriate volumetric flask and dilute with *Diluent* to volume. Sonicate the resulting solution. [Note—Sonication for 30–60 s may be suitable.]

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 240 nm. For *Identification B*, use a diode array detector in the range of 210–400 nm.

**Column:** 3.9-mm × 15-cm; 5-µm packing L7. [Note—A guard column with a similar packing may be used.]

**Flow rate:** 0.7 mL/min

**Injection volume:** 10 µL

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Tailing factor:** NMT 1.3

**Relative standard deviation:** NMT 1.0%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of testosterone ($C_{19}H_{28}O_2$) in the portion of Topical Solution taken:

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

$r_U$ = peak response of testosterone from the *Sample solution*

$r_S$ = peak response of testosterone from the *Standard solution*

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

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

**Acceptance criteria:** 90.0%–110.0%

## IMPURITIES

• **Organic Impurities**

**Solution A, Solution B, Mobile phase, Diluent, Standard solution, Sample solution,** and **Chromatographic system:** Proceed as directed in the *Assay*.

**Sensitivity solution:** 0.11 µg/mL of USP Testosterone RS from the *Standard solution* in *Diluent*

**System suitability**

**Samples:** *Standard solution* and *Sensitivity solution*

**Suitability requirements**

**Tailing factor:** NMT 1.3 for the testosterone peak, *Standard solution*

**Signal-to-noise ratio:** NLT 10, *Sensitivity solution*

**Analysis**

**Sample:** *Sample solution*

Calculate the percentage of each individual degradation product in the portion of Topical Solution taken:

$$\text{Result} = (r_U/r_T) \times 100$$

$r_U$ = peak response of each individual degradation product from the *Sample solution*

$r_T$ = peak response of testosterone from the *Sample solution*

**Acceptance criteria:** See *Table 2*.

**Table 2**

| Name | Relative Retention Time | Acceptance Criteria, NMT (%) |
|---|---|---|
| Any individual unspecified degradation product | — | 0.3 |
| Total degradation products | — | 5.0 |

## SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed $10^2$ cfu/mL. The total combined molds and yeasts count does not exceed $10^1$ cfu/mL. It meets the requirements of the tests for the absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

## ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature.

• **USP Reference Standards** ⟨11⟩
USP Testosterone RS

▲2S *(USP41)*

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| TESTOSTERONE TOPICAL SOLUTION | Documentary Standards Support | SM52020 Small Molecules 5 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM52020 Small Molecules 5 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
Pharmacopeial Forum: Volume No. PF 43(4)

**Current DocID: GUID-E9EBBD6B-3C35-4AE1-8F57-1AD278D295C9_5_en-US**
**Previous DocID: GUID-E9EBBD6B-3C35-4AE1-8F57-1AD278D295C9_2_en-US**
**DOI: https://doi.org/10.31003/USPNF_M6484_05_01**
**DOI ref: y1mcx**