



Edition: BP 2025 (Ph. Eur. 11.6 update)

Testosterone Implants

[General Notices](#)

Action and use

Androgen.

DEFINITION

Testosterone Implants are sterile cylinders prepared by the fusion or heavy compression of Testosterone without the addition of any other substance.

The implants comply with the requirements stated under Parenteral Preparations and with the following requirements.

Content of testosterone, $C_{19}H_{28}O_2$

97 to 103%, calculated with reference to the dried substance, and 90 to 110% of the stated amount.

Diameter

Implants containing less than 50 mg, 2.0 to 2.5 mm; implants containing 50 mg or more, 4.25 to 4.75 mm.

Where appropriate, powder the implants before carrying out the following tests.

IDENTIFICATION

- A. The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of testosterone ([RS 329](#)).
- B. Comply with the test for [identification of steroids](#), [Appendix III A](#), using [impregnating solvent II](#) and *mobile phase D*.
- C. To 0.1 g in a stoppered tube add 3 mL of [anhydrous pyridine](#) and 0.6 mL of [acetic anhydride](#). Heat on a waterbath for 3 hours, add [water](#) dropwise until crystals begin to form, then add slowly a further 15 mL of [water](#) and allow to stand until precipitation is complete. Filter the precipitate using a sintered-glass crucible and wash with [water](#) until the washings are neutral to [methyl red solution](#). Recrystallise from [ethanol](#) (96%), adding a few drops of [water](#) if necessary to aid crystallisation, and dry at 105°. The [melting point](#) of the crystals is about 140°, [Appendix V A](#).

TESTS

Melting point

152° to 156°, [Appendix V A](#).

[Specific optical rotation](#)

In a 1% w/v solution in [absolute ethanol](#), +106 to +112, [Appendix V F](#), calculated with reference to the dried substance.

Carbonisation

A 1% w/v solution in [ethanol](#) (96%) is *clear*, [Appendix IV A](#), and *colourless*, [Appendix IV B](#), Method I.

[Loss on drying](#)

When dried to constant weight at 105°, lose not more than 1.0% of their weight. Use 1 g.

[Sulfated ash](#)

Not more than 0.1%, [Appendix IX A](#).

ASSAY

Weigh and powder a single implant. Dissolve 10 mg of the powdered implant in sufficient [absolute ethanol](#) to produce 100 mL, dilute 5 mL to 50 mL with [absolute ethanol](#) and measure the [absorbance](#) of the resulting solution at the maximum at 240 nm, [Appendix II B](#). Calculate the content of $C_{19}H_{28}O_2$ taking 560 as the value of A(1%, 1 cm) at the maximum at 240 nm.

STORAGE

Testosterone Implants should be protected from light.