



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

Testosterone Propionate Injection

[General Notices](#)

Action and use

Androgen.

DEFINITION

Testosterone Propionate Injection is a sterile solution of Testosterone Propionate in Ethyl Oleate or other suitable ester, in a suitable fixed oil or in any mixture of these.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of testosterone propionate, $C_{22}H_{32}O_3$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

Dissolve a volume containing 50 mg of Testosterone Propionate in 8 mL of [petroleum spirit](#) (boiling range, 40° to 60°) and extract with three 8-mL quantities of a mixture of 7 volumes of [glacial acetic acid](#) and 3 volumes of [water](#). Wash the combined extracts with 10 mL of [petroleum spirit](#) (boiling range, 40° to 60°), dilute with [water](#) until the solution becomes turbid, allow to stand for 2 hours in ice and filter. The precipitate, after washing with [water](#) and drying at 105°, complies with the following tests.

- A. The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of testosterone propionate ([RS 332](#)).
- B. Complies with the test for [identification of steroids](#), [Appendix III A](#), using *impregnating solvent III* and *mobile phase F*.

ASSAY

To a volume containing 0.1 g of Testosterone Propionate add sufficient [chloroform](#) to produce 100 mL. Dilute 3 mL to 50 mL with [chloroform](#) and to 5 mL of the solution add 10 mL of [isoniazid solution](#) and sufficient [methanol](#) to produce 20 mL. Allow to stand for 45 minutes and measure the [absorbance](#) of the resulting solution at the maximum at 380 nm, [Appendix II B](#), using in the reference cell a solution prepared by treating 5 mL of [chloroform](#) in the same manner. Calculate the content of $C_{22}H_{32}O_3$ from the [absorbance](#) obtained by repeating the operation using a 0.006% w/v solution of [testosterone propionate BPCRS](#) in [chloroform](#), beginning at the words 'to 5 mL...' and using the declared content of $C_{22}H_{32}O_3$ in [testosterone propionate BPCRS](#).

STORAGE

Testosterone Propionate Injection should be protected from light.

LABELLING

The label states that the preparation is intended for intramuscular injection only.