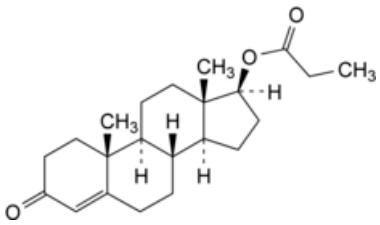
Edition: BP 2025 (Ph. Eur. 11.6 update)

Testosterone Propionate

General Notices

(Ph. Eur. monograph 0297)



$C_{22}H_{32}O_3$ 344.5 *57-85-2*

Action and use

Androgen.

Preparation

Testosterone Propionate Injection

Ph Eur

DEFINITION

3-Oxoandrost-4-en-17β-yl propanoate.

Content

97.5 per cent to 102.0 per cent (dried substance).

CHARACTERS

Appearance

White or almost white powder or colourless crystals.

Solubility

Practically insoluble in water, freely soluble in acetone and in ethanol (96 per cent), soluble in fatty oils.

IDENTIFICATION

Infrared absorption spectrophotometry (2.2.24).

Comparison testosterone propionate CRS.

TESTS

Specific optical rotation (2.2.7)

+ 84 to + 90 (dried substance).

Dissolve 0.250 g in ethanol R and dilute to 25.0 mL with the same solvent.

Related substances

Liquid chromatography (2.2.29).

Test solution Dissolve 20.0 mg of the substance to be examined in methanol R and dilute to 50.0 mL with the same solvent.

Reference solution (a) Dissolve 2 mg of testosterone propionate for system suitability CRS (containing impurities A, B and C) in 5.0 mL of methanol R.

Reference solution (b) Dilute 1.0 mL of the test solution to 100.0 mL with methanol R. Dilute 1.0 mL of this solution to 10.0 mL with methanol R.

Reference solution (c) Dissolve 20.0 mg of testosterone propionate CRS in 50.0 mL of methanol R.

Column:

— *size*: *l* = 0.25 m, Ø = 4.6 mm;

— *stationary phase*: octadecylsilyl silica gel for chromatography R (5 µm).

Mobile phase water R, methanol R (20:80 *V/V*).

Flow rate 1.5 mL/min.

Detection Spectrophotometer at 254 nm.

Injection 20 µL of the test solution and reference solutions (a) and (b).

Run time Twice the retention time of testosterone propionate.

Identification of impurities Use the chromatogram supplied with testosterone propionate for system suitability CRS and the chromatogram obtained with reference solution (a) to identify the peaks due to impurities A, B and C.

Relative retention With reference to testosterone propionate (retention time = about 8 min): impurity C = about 0.4; impurity A = about 0.7; impurity B = about 1.4.

System suitability Reference solution (a):

— peak-to-valley ratio: minimum 3.0, where H_p = height above the baseline of the peak due to impurity B and H_v = height above the baseline of the lowest point of the curve separating this peak from the peak due to testosterone propionate.

Limits:

— *impurity A*: not more than 5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent);

— *impurity C*: not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (0.2 per cent);

— *unspecified impurities*: for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.10 per cent);

— *total*: not more than 7 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.7 per cent);

— *disregard limit*: 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Loss on drying (*2.2.32*)

Maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C for 2 h.

ASSAY

Liquid chromatography (*2.2.29*) as described in the test for related substances with the following modification.

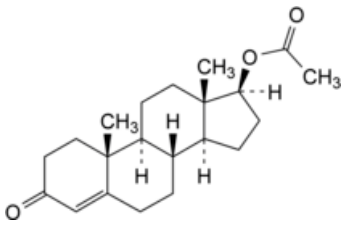
Injection Test solution and reference solution (c).

Calculate the percentage content of $C_{22}H_{32}O_3$ taking into account the assigned content of *testosterone propionate CRS*.

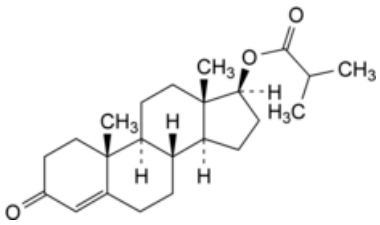
IMPURITIES

Specified impurities *A, C.*

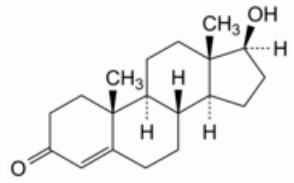
Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph Substances for pharmaceutical use (2034). It is therefore not necessary to identify these impurities for demonstration of compliance. See also 5.10. Control of impurities in substances for pharmaceutical use) *B, D, E.*



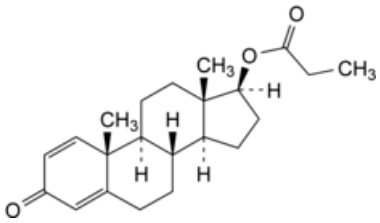
A. 3-oxoandrost-4-en-17β-yl acetate (testosterone acetate),



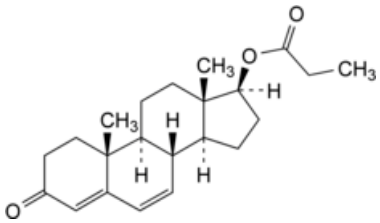
B. 3-oxoandrost-4-en-17β-yl 2-methylpropanoate (testosterone isobutyrate),



C. 17β-hydroxyandrost-4-en-3-one (testosterone),



D. 3-oxoandrosta-1,4-dien-17β-yl propanoate,



E. 3-oxoandrosta-4,6-dien-17β-yl propanoate.

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