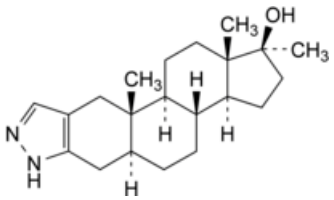
Edition: BP 2025 (Ph. Eur. 11.6 update)

Stanozolol

General Notices

(Ph. Eur. monograph 1568)



$C_{21}H_{32}N_2O$ 328.5 *10418-03-8*

Action and use

Anabolic steroid; androgen.

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DEFINITION

17-Methyl-2′*H*-5α-androst-2-eno[3,2-*c*]pyrazol-17β-ol.

Content

98.5 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance

White or almost white, hygroscopic, crystalline powder.

Solubility

Practically insoluble in water, soluble in dimethylformamide, slightly soluble in ethanol (96 per cent), very slightly soluble in methylene chloride.

It shows polymorphism (*5.9*).

IDENTIFICATION

A. Infrared absorption spectrophotometry (*2.2.24*).

Comparison stanozolol CRS.

If the spectra obtained in the solid state show differences, dissolve the substance to be examined and the reference substance separately in the minimum volume of methylene chloride R, evaporate to dryness at room temperature under an air-stream and record new spectra using the residues.

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

Injection Test solution and reference solution (c).

Results The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (c).

TESTS

Specific optical rotation (2.2.7)

+ 37 to + 41 (dried substance).

Dissolve 60.0 mg in methanol R and dilute to 20.0 mL with the same solvent.

Impurities A and B

Thin-layer chromatography (2.2.27).

Solvent mixture methanol R1, methylene chloride R (10:90 *V/V*).

Test solution Dissolve 20 mg of the substance to be examined in 1.0 mL of the solvent mixture.

Reference solution Dissolve 2 mg of stanozolol CRS, 2.0 mg of stanozolol impurity A CRS and 2.0 mg of stanozolol impurity B CRS in 1.0 mL of the solvent mixture. Dilute 0.1 mL of the solution to 2.0 mL with the solvent mixture.

Plate TLC silica gel plate R.

Mobile phase glacial acetic acid R, ethyl acetate R, cyclohexane R (2:48:50 *V/V/V*).

Application 10 µL.

Development Over 3/4 of the plate.

Drying In air.

Detection Spray with vanillin reagent R and heat at 120 °C.

System suitability Reference solution:

— the chromatogram shows 3 clearly separated spots, due to stanozolol, impurity A and impurity B, in order of increasing R_F value.

Limits:

— *impurity A*: any spot due to impurity A is not more intense than the corresponding spot in the chromatogram obtained with the reference solution (0.5 per cent);

— *impurity B*: any spot due to impurity B is not more intense than the corresponding spot in the chromatogram obtained with the reference solution (0.5 per cent).

Related substances

Liquid chromatography (2.2.29).

Test solution Dissolve 15.0 mg of the substance to be examined in methanol R and dilute to 5.0 mL with the same solvent.

Reference solution (a) 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 (b) Dissolve 1 mg of *stanozolol CRS* and 1 mg of *stanozolol impurity B CRS* in *methanol R* and dilute to 20 mL with the same solvent.

Reference solution (c) Dissolve 15.0 mg of *stanozolol CRS* in *methanol R* and dilute to 5.0 mL with the same solvent.

Column:

— *size*: *l* = 0.15 m, *Ø* = 4.6 mm;

— *stationary phase*: *end-capped octadecylsilyl silica gel for chromatography R1* (5 µm).

Mobile phase 1 g/L solution of *sodium dihydrogen phosphate R* adjusted to pH 3.0 with *phosphoric acid R*, *methanol R1* (30:70 *V/V*).

Flow rate 1.5 mL/min.

Detection Spectrophotometer at 228 nm.

Injection 25 µL of the test solution and reference solutions (a) and (b).

Run time 3 times the retention time of stanozolol.

Identification of impurities Use the chromatogram obtained with reference solution (b) to identify the peak due to impurity B.

Relative retention With reference to stanozolol (retention time = about 12 min): impurity B = about 1.3.

System suitability Reference solution (b):

— *resolution*: minimum 4.0 between the peaks due to stanozolol and impurity B.

Limits:

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

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

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

Loss on drying (*2.2.32*)

Maximum 1.0 per cent, determined on 1.000 g by drying at 105 °C at a pressure not exceeding 0.7 kPa.

ASSAY

Dissolve 0.250 g in 50 mL of *anhydrous acetic acid R*. Titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (*2.2.20*).

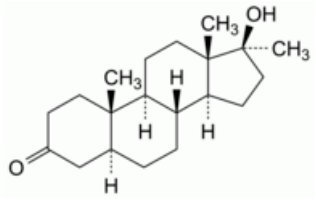
1 mL of *0.1 M perchloric acid* is equivalent to 32.85 mg of $C_{21}H_{32}N_2O$.

STORAGE

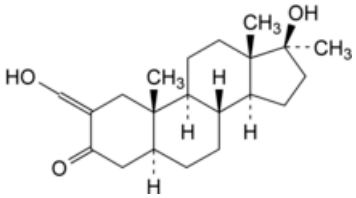
In an airtight container, protected from light.

IMPURITIES

Specified impurities *A, B.*



A. 17β-hydroxy-17-methyl-5α-androstan-3-one (mestanolone),



B. 17β-hydroxy-2-(hydroxymethylene)-17-methyl-5α-androstan-3-one (oxymetholone).

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