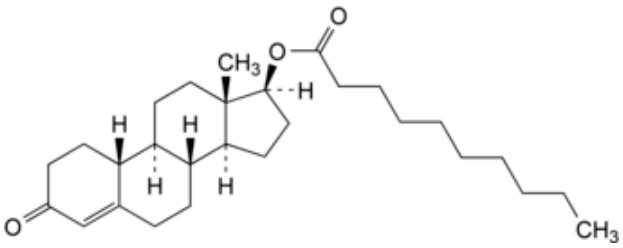
Edition: BP 2025 (Ph. Eur. 11.6 update)

Nandrolone Decanoate

General Notices

(Ph. Eur. monograph 1992)



$C_{28}H_{44}O_3$ 428.7 *360-70-3*

Action and use

Anabolic steroid; androgen.

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DEFINITION

3-Oxoestr-4-en-17β-yl decanoate.

Content

97.0 per cent to 103.0 per cent (dried substance).

CHARACTERS

Appearance

White or almost white, crystalline powder.

Solubility

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

IDENTIFICATION

A. Melting point (2.2.14): 34 °C to 38 °C.
B. Infrared absorption spectrophotometry (2.2.24).

Comparison nandrolone decanoate CRS.

TESTS

Appearance of solution

The solution is clear (2.2.1) and not more intensely coloured than reference solution Y_6 (2.2.2, Method II).

Dissolve 0.20 g in 10 mL of methanol R.

Specific optical rotation (2.2.7)

+ 35.0 to + 40.0 (dried substance).

Dissolve 0.200 g in anhydrous ethanol R and dilute to 20.0 mL with the same solvent.

Impurities A, B, C

Thin-layer chromatography (2.2.27).

Test solution Dissolve 50 mg of the substance to be examined in methylene chloride R and dilute to 5.0 mL with the same solvent.

Reference solution (a) Dilute 1.0 mL of the test solution to 10.0 mL with methylene chloride R.

Reference solution (b) Dilute 1.0 mL of reference solution (a) to 10.0 mL with methylene chloride R.

Reference solution (c) Dilute 1.0 mL of reference solution (a) to 20.0 mL with methylene chloride R.

Reference solution (d) Dissolve 5 mg of nandrolone decanoate for system suitability CRS (containing impurities A, B, C) in 0.5 mL of methylene chloride R.

Plate TLC silica gel plate R.

Mobile phase acetone R, heptane R (30:70 *V/V*).

Application 10 µL of the test solution and reference solutions (b), (c) and (d).

Development Over 2/3 of the plate.

Drying In air.

Detection Treat with alcoholic solution of sulfuric acid R and heat at 130 °C until the spots appear. Examine in ultraviolet light at 366 nm.

Retardation factors Nandrolone decanoate = about 0.37; impurity A = about 0.45; impurity B = about 0.55; impurity C = about 0.58.

System suitability Reference solution (d):

— the chromatogram shows 4 clearly separated spots.

Limits:

— *impurity A*: any spot due to impurity A is not more intense than the principal spot in the chromatogram obtained with reference solution (b) (1.0 per cent);

— *impurities B, C*: any spot due to impurity B or C is not more intense than the principal spot in the chromatogram obtained with reference solution (c) (0.5 per cent).

Related substances

Liquid chromatography (2.2.29).

Test solution Dissolve 25 mg of the substance to be examined in methanol R and dilute to 10.0 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 5 mg of nandrolone decanoate for peak identification CRS (containing impurities D, F, G, H, I, K, L) in methanol R and dilute to 2.0 mL with the same solvent.

Column:

— *size*: *l* = 0.15 m, Ø = 3.9 mm;

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

Mobile phase:

— *mobile phase A*: water for chromatography R;

— *mobile phase B*: acetonitrile R;

Time (min)	Mobile phase A (per cent *V/V*)	Mobile phase B (per cent *V/V*)
0 - 5	35	65
5 - 40	35 → 0	65 → 100
40 - 75	0	100
75 - 80	0 → 35	100 → 65

Flow rate 1.0 mL/min.

Detection Spectrophotometer at 254 nm.

Injection 20 µL.

Relative retention With reference to nandrolone decanoate (retention time = about 30 min): impurity D = about 0.05; impurity F = about 0.6; impurity K = about 0.7; impurity L = about 0.9; impurity G = about 0.97; impurity H = about 1.1; impurity I = about 1.2.

System suitability Reference solution (b):

— peak-to-valley ratio: minimum 1.5, where H_p = height above the baseline of the peak due to impurity G and H_v = height above the baseline of the lowest point of the curve separating this peak from the peak due to nandrolone decanoate.

Limits:

— *correction factors*: for the calculation of contents, multiply the peak areas of the following impurities by the corresponding correction factor: impurity D = 0.5; impurity F = 0.6; impurity H = 1.1; impurity I = 1.3; impurity K = 0.8;

— *impurities D, F, G, H, I, K, L*: for each impurity, not more than 5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent);

— *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 15 times the area of the principal peak in the chromatogram obtained with reference solution (a) (1.5 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 0.5 per cent, determined on 1.000 g by drying *in vacuo* at a pressure not exceeding 0.7 kPa for 4 h.

Sulfated ash (*2.4.14*)

Maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 10.0 mg in *anhydrous ethanol R* and dilute to 100.0 mL with the same solvent. Dilute 5.0 mL of this solution to 50.0 mL with *anhydrous ethanol R*. Measure the absorbance (*2.2.25*) at the absorption maximum at 240 nm. Calculate the content of $C_{28}H_{44}O_3$ taking the specific absorbance to be 407.

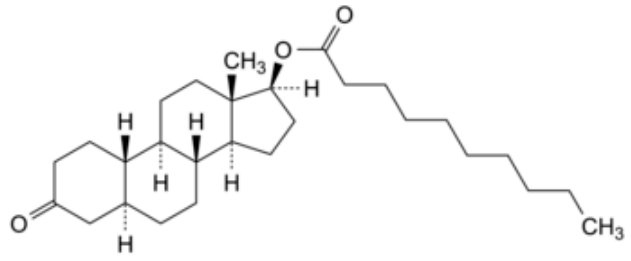
STORAGE

Under nitrogen, protected from light and at a temperature of 2 °C to 8 °C.

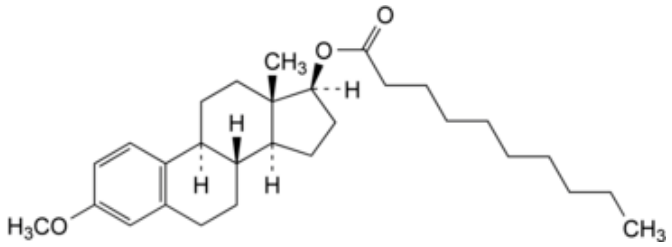
IMPURITIES

Specified impurities A, B, C, D, F, G, H, I, K, L.

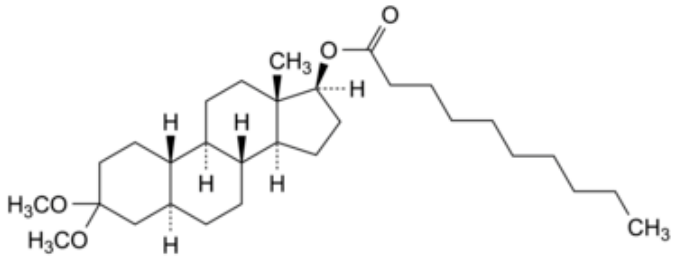
Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph Substances for pharmaceutical 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) E, J.



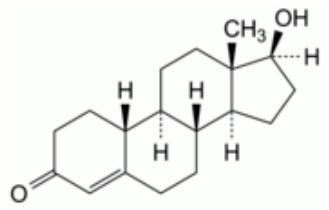
A. 3-oxo-5α-estran-17β-yl decanoate,



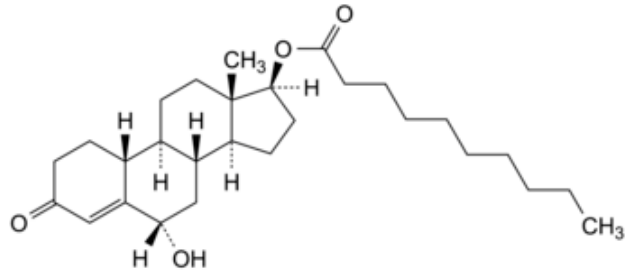
B. 3-methoxyestra-1,3,5(10)-trien-17β-yl decanoate,



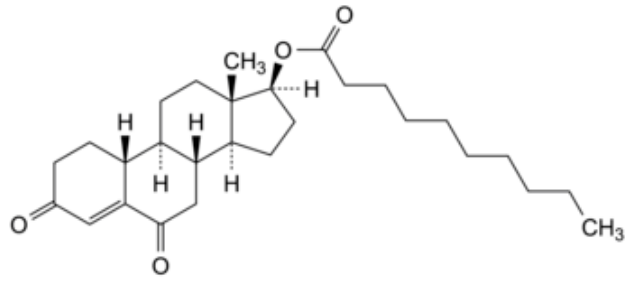
C. 3,3-dimethoxy-5α-estran-17β-yl decanoate,



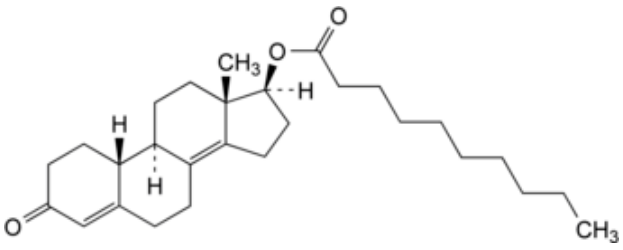
D. 17β-hydroxyestr-4-en-3-one,



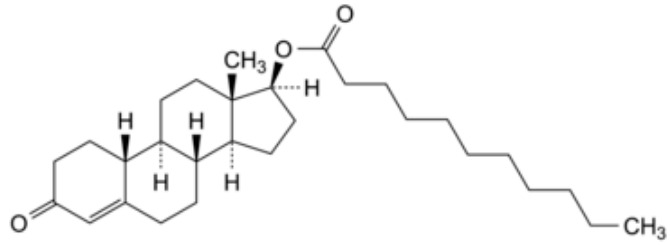
E. 6α-hydroxy-3-oxoestr-4-en-17β-yl decanoate,



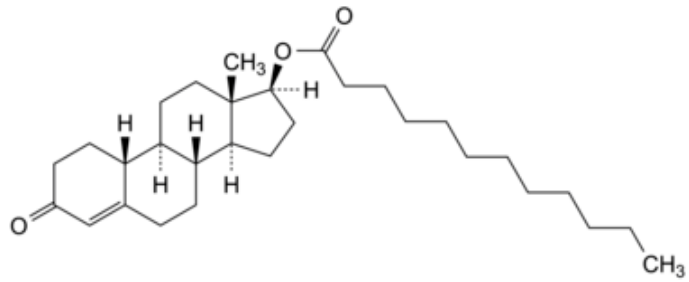
F. 3,6-dioxoestr-4-en-17β-yl decanoate,



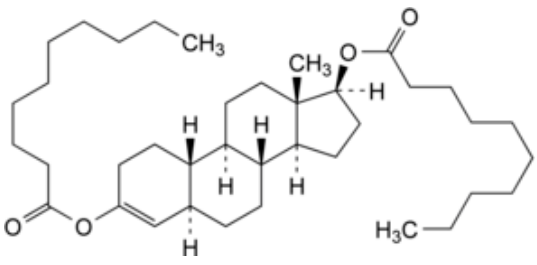
G. 3-oxoestra-4,8(14)-dien-17β-yl decanoate,



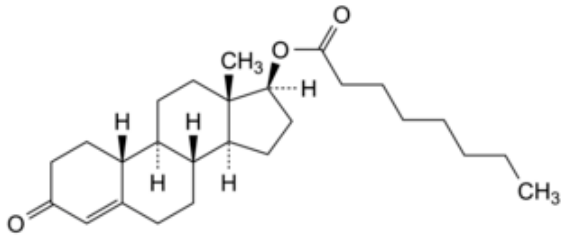
H. 3-oxoestr-4-en-17β-yl undecanoate,



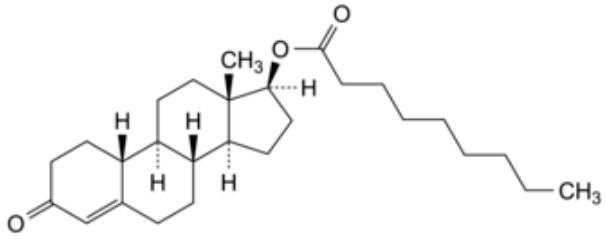
I. 3-oxoestr-4-en-17β-yl dodecanoate,



J. 5α-estr-3-ene-3,17β-diyl didecanoate,



K. 3-oxoestr-4-en-17β-yl octanoate,



L. 3-oxoestr-4-en-17β-yl nonanoate.

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