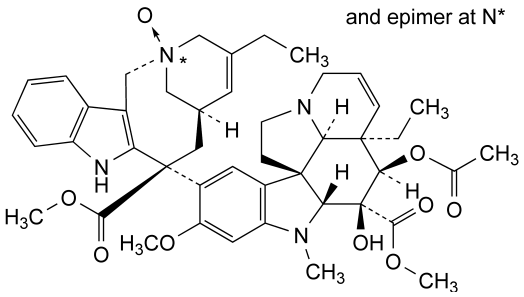
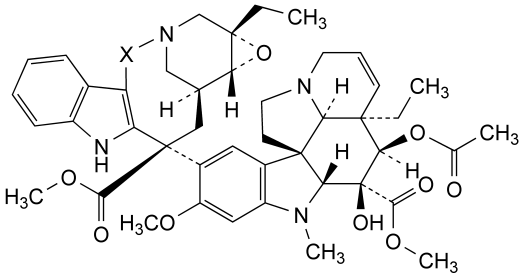
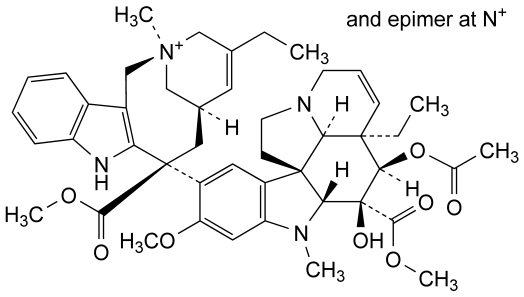



D. methyl (3a*R*,4*R*,5*S*,5a*R*,10b*R*,13a*R*)-4-(acetyloxy)-3a-ethyl-9-[(2*RS*,6*R*,8*S*)-4-ethyl-8-(methoxycarbonyl)-2-oxido-1,3,6,7,8,9-hexahydro-2,6-methano-2*H*-azacyclodecino[4,3-*b*]indol-8-yl]-5-hydroxy-8-methoxy-6-methyl-3a,4,5,5a,6,11,12,13a-octahydro-1*H*-indolizino[8,1-*cd*]carbazole-5-carboxylate,

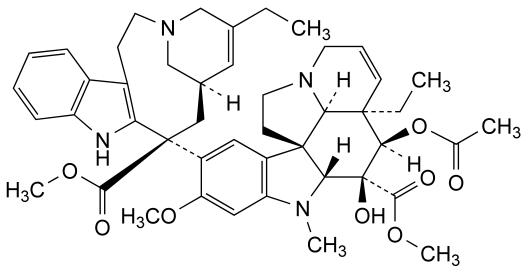


E. X = $CH_2$-$CH_2$: methyl (1a*S*,11*S*,13*S*,13a*R*)-11-[(3a*R*,4*R*,5*S*,5a*R*,10b*R*,13a*R*)-4-(acetyloxy)-3a-ethyl-5-hydroxy-8-methoxy-5-(methoxycarbonyl)-6-methyl-3a,4,5,5a,6,11,12,13a-octahydro-1*H*-indolizino[8,1-*cd*]carbazol-9-yl]-1a-ethyl-1a,4,5,10,11,12,13,13a-octahydro-2*H*-3,13-methanooxireno[9,10]azacycloundecino[5,4-*b*]indole-11-carboxylate (leurosine),

G. X = $CH_2$: methyl (1a*S*,10*S*,12*S*,12a*R*)-10-[(3a*R*,4*R*,5*S*,5a*R*,10b*R*,13a*R*)-4-(acetyloxy)-3a-ethyl-5-hydroxy-8-methoxy-5-(methoxycarbonyl)-6-methyl-3a,4,5,5a,6,11,12,13a-octahydro-1*H*-indolizino[8,1-*cd*]carbazol-9-yl]-1a-ethyl-1a,2,4,9,10,11,12,12a-octahydro-3,12-methano-3*H*-oxireno[8,9]azacyclodecino[4,3-*b*]indole-10-carboxylate,




F. (2*RS*,6*R*,8*S*)-8-[(3a*R*,4*R*,5*S*,5a*R*,10b*R*,13a*R*)-4-(acetyloxy)-3a-ethyl-5-hydroxy-8-methoxy-5-(methoxycarbonyl)-6-methyl-3a,4,5,5a,6,11,12,13a-octahydro-1*H*-indolizino[8,1-*cd*]carbazol-9-yl]-4-ethyl-8-(methoxycarbonyl)-2-methyl-1,3,6,7,8,9-hexahydro-2,6-methano-2*H*-azacyclodecino[4,3-*b*]indolium,

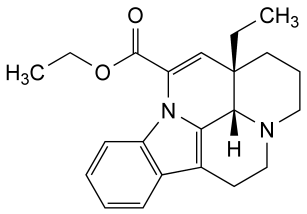


J. methyl (3a*R*,4*R*,5*S*,5a*R*,10b*R*,13a*R*)-4-(acetyloxy)-3a-ethyl-9-[(7*R*,9*S*)-5-ethyl-9-(methoxycarbonyl)-1,4,7,8,9,10-hexahydro-2*H*-3,7-methanoazacycloundecino[5,4-*b*]indol-9-yl]-5-hydroxy-8-methoxy-6-methyl-3a,4,5,5a,6,11,12,13a-octahydro-1*H*-indolizino[8,1-*cd*]carbazole-5-carboxylate.

**01/2008:2139**

# VINPOCETINE

## Vinpocetinum



$C_{22}H_{26}N_2O_2$ $M_r$ 350.5
[42971-09-5]

DEFINITION

Ethyl (13a*S*,13b*S*)-13a-ethyl-2,3,5,6,13a,13b-hexahydro-1*H*-indolo[3,2,1-*de*]pyrido[3,2,1-*ij*][1,5]naphthyridine-12-carboxylate.

*Content*: 98.5 per cent to 101.5 per cent (dried substance).

CHARACTERS

*Appearance*: white or slightly yellow, crystalline powder.

*Solubility*: practically insoluble in water, soluble in methylene chloride, slightly soluble in anhydrous ethanol.

IDENTIFICATION

A. Specific optical rotation (see Tests).

B. Infrared absorption spectrophotometry (*2.2.24*).
*Comparison*: *vinpocetine CRS*.

TESTS

**Specific optical rotation** (*2.2.7*): + 127 to + 134 (dried substance).

Dissolve 0.25 g in *dimethylformamide R* and dilute to 25.0 ml with the same solvent.

**Related substances**. Liquid chromatography (*2.2.29*).

*Test solution*. Dissolve 50.0 mg of the substance to be examined in the mobile phase and dilute to 50.0 ml with the mobile phase.

*Reference solution (a)*. Dilute 1.0 ml of the test solution to 50.0 ml with the mobile phase.

*Reference solution (b)*. Dissolve 5.0 mg of *vinpocetine impurity B CRS*, 6.0 mg of *vinpocetine impurity A CRS*, 5.0 mg of *vinpocetine impurity C CRS* and 5.0 mg of *vinpocetine impurity D CRS* in the mobile phase and dilute to 50.0 ml with the mobile phase.

*Reference solution (c).* Dilute 1.0 ml of reference solution (a) and 1.0 ml of reference solution (b) to 20.0 ml with the mobile phase.

*Column*:

– *size*: *l* = 0.25 m, Ø = 4.6 mm;

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

*Mobile phase*: 15.4 g/l solution of *ammonium acetate R*, *acetonitrile R* (45:55 *V/V*).

*Flow rate*: 1.0 ml/min.

*Detection*: spectrophotometer at 280 nm.

*Injection*: 15 µl.

*Run time*: 3 times the retention time of vinpocetine.

*Relative retention* with reference to vinpocetine (retention time = about 16 min): impurity A = about 0.4; impurity D = about 0.68; impurity B = about 0.75; impurity C = about 0.83.

*System suitability*: reference solution (c):

– *resolution*: minimum 2.0 between the peaks due to impurities B and D.

*Limits*:

– *impurity A*: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (c) (0.6 per cent);

– *impurity B*: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (c) (0.5 per cent);

– *impurity C*: not more than 0.6 times the area of the corresponding peak in the chromatogram obtained with reference solution (c) (0.3 per cent);

– *impurity D*: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (c) (0.5 per cent);

– *unspecified impurities*: for each impurity, not more than the area of the peak due to vinpocetine in the chromatogram obtained with reference solution (c) (0.10 per cent);

– *total*: not more than 10 times the area of the peak due to vinpocetine in the chromatogram obtained with reference solution (c) (1.0 per cent);

– *disregard limit*: 0.5 times the area of the peak due to vinpocetine in the chromatogram obtained with reference solution (c) (0.05 per cent).

**Loss on drying** (*2.2.32*): maximum 0.5 per cent, determined on 1.000 g by drying *in vacuo* in an oven at 100 °C for 3 h.

**Sulphated ash** (*2.4.14*): maximum 0.1 per cent, determined on 1.0 g.

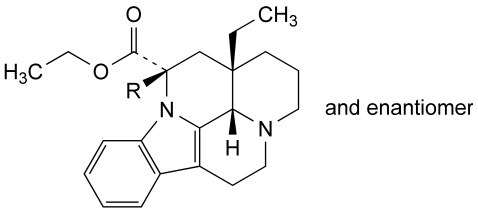
ASSAY

Dissolve 0.300 g in 50 ml of a mixture of equal volumes of *acetic anhydride R* and *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 35.05 mg of $C_{22}H_{26}N_2O_2$.

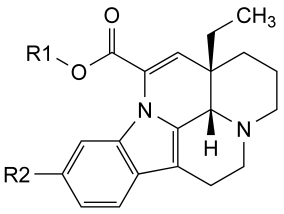
IMPURITIES

*Specified impurities*: *A, B, C, D.*




A. R = OH: ethyl (12*RS*,13a*SR*,13b*SR*)-13a-ethyl-12-hydroxy-2,3,5,6,12,13,13a,13b-octahydro-1*H*-indolo[3,2,1-*de*]pyrido[3,2,1-*ij*][1,5]naphthyridine-12-carboxylate (ethyl vincaminate),

D. R = H: ethyl (12*RS*,13a*RS*,13b*RS*)-13a-ethyl-2,3,5,6,12,13,13a,13b-octahydro-1*H*-indolo[3,2,1-*de*]pyrido[3,2,1-*ij*][1,5]naphthyridine-12-carboxylate (dihydrovinpocetine),




B. R1 = $CH_3$, R2 = H: methyl (13a*S*,13b*S*)-13a-ethyl-2,3,5,6,13a,13b-hexahydro-1*H*-indolo[3,2,1-*de*]pyrido[3,2,1-*ij*][1,5]naphthyridine-12-carboxylate (apovincamine),

C. R1 = $C_2H_5$, R2 = $OCH_3$: ethyl (13a*S*,13b*S*)-13a-ethyl-9-methoxy-2,3,5,6,13a,13b-hexahydro-1*H*-indolo[3,2,1-*de*]pyrido[3,2,1-*ij*][1,5]naphthyridine-12-carboxylate (methoxyvinpocetine).

**01/2008:0034**
**corrected 6.0**

# VISCOSE WADDING, ABSORBENT

## Lanugo cellulosi absorbens

DEFINITION

Absorbent viscose wadding consists of bleached, carefully carded, new fibres of regenerated cellulose obtained by the viscose process, with or without the addition of titanium dioxide, of linear density 1.0 dtex to 8.9 dtex (dtex = mass of 10 000 m of fibre, expressed in grams) and cut to a suitable staple length. It does not contain any compensatory colouring matter.

CHARACTERS

It is white or very slightly yellow, has a lustrous or matt appearance, and is soft to the touch.

IDENTIFICATION

A. Viscose rayon fibres may be solid or hollow; hollow fibres may have a continuous lumen or be compartmented. The fibres have an average length of 25 mm to 80 mm and when examined under a microscope in the dry state, or when mounted in *alcohol R* and *water R*, the following characters are observed. They are usually of a more or less uniform width, with many longitudinal parallel lines distributed unequally over the width. The