



TECHNICAL DOCUMENTATION

Revision: 27.04.2009

VINPOCETINE (JP 1993 - EP 6)

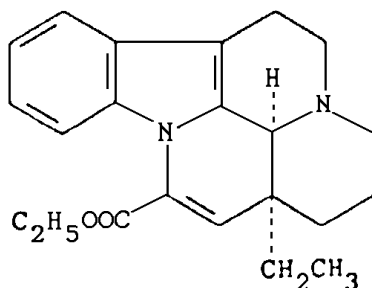
FORMULA: C₂₂H₂₆N₂O₂

DRUG MASTER FILE (DMF): Available in EU CTD Format

IUPAC NAME: Eburnamenine-14-carboxylic acid ethylester

SYNONYMS: Ethyl-apovincaminat; 3 α, 16 α -apovincaminic acid-ethyl-ester

STRUCTURAL FORMULA:



MOLECULAR WEIGHT: 350.46

C.A.S.. REGISTRY NUMBER: 42971-09-5

TECHNICAL DESCRIPTION:

<p>APPEARANCE: White to slightly yellow crystals, or crystalline powder, odourless</p> <p>SOLUBILITY: Practically insoluble in water, soluble in methylene chloride, slightly soluble in anhydrous ethanol</p> <p>MELTING POINT: Between 150° and 153°C</p> <p>IDENTIFICATION : IR</p> <p>LOSS ON DRYING: Not more than 0.2 %</p> <p>SPECIFIC OPTICAL ROTATION: Between + 127 and + 134</p> <p>SULPHATED ASH: Not more than 0.1 %</p> <p>HEAVY METALS: Not more than 10 ppm</p> <p>SULPHATES: Not more than 0.03 %</p>	<p>ASSAY: Perchloric acid titration UV E 1% - 1 cm</p> <p>IMPURITIES (HPLC):</p> <table border="0"> <tr> <td>Apovincamine:</td> <td>Max. 0.4 %</td> </tr> <tr> <td>Related compound (total):</td> <td>Max. 0.4 %</td> </tr> <tr> <td>-Methoxyvinpocetine:</td> <td>Max. 0.1 %</td> </tr> <tr> <td>-Ethyl vincaminat:</td> <td>Max. 0.2 %</td> </tr> <tr> <td>-Others:</td> <td>Max. 0.1 %</td> </tr> </table> <p>MICROBIOLOGY: Complies with EP</p> <p>STORAGE: Sealed container and protected from light</p>	Apovincamine:	Max. 0.4 %	Related compound (total):	Max. 0.4 %	-Methoxyvinpocetine:	Max. 0.1 %	-Ethyl vincaminat:	Max. 0.2 %	-Others:	Max. 0.1 %	<p>Between 99.0 % and 101.0 % Between 330 and 343</p>
Apovincamine:	Max. 0.4 %											
Related compound (total):	Max. 0.4 %											
-Methoxyvinpocetine:	Max. 0.1 %											
-Ethyl vincaminat:	Max. 0.2 %											
-Others:	Max. 0.1 %											

PRODUCT APPLICATIONS: Vinpocetine is a vasodilator and anti- ischemic that increases blood flow to the brain. It is used primarily as a treatment for dementia and as a nootropic or “smart drug”.

THERAPEUTIC CATEGORY: Vasodilator, anti-ischemic, nootropic.

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