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

Naftidrofuryl Capsules

General Notices

Action and use

Vasodilator.

DEFINITION

Naftidrofuryl Capsules contain Naftidrofuryl Oxalate.

The capsules comply with the requirements stated under Capsules and with the following requirements.

Content of naftidrofuryl oxalate, $C_{26}H_{35}NO_7$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Shake, with the aid of ultrasound, a quantity of the powdered contents of the capsules containing 0.1 g of Naftidrofuryl Oxalate with 5 mL of *water* and filter (Whatman GF/C filter paper is suitable). Add 5 mL of 2M *sodium hydroxide* to the filtrate, extract with two 10 mL quantities of *chloroform*, wash the combined chloroform extracts with two 10 mL quantities of *water*, evaporate to dryness using a rotary evaporator and dry the oily residue over *phosphorus pentoxide* at a pressure of 2 kPa for 18 hours. The *infrared absorption spectrum* of the oily residue, Appendix II A, is concordant with the *reference spectrum* of naftidrofuryl *(RS 240)*.
B. Mix a quantity of the powdered contents of the capsules containing 0.25 g of Naftidrofuryl Oxalate with 5 mL of *water*, shake for 10 minutes and filter. Add *calcium chloride solution* to the filtrate; a white precipitate is produced. The residue dissolves in mineral acids but is practically insoluble in 2M *acetic acid* and in 6M *ammonia*.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using 20 µL of the following solutions. For solution (1) mix with the aid of ultrasound a quantity of the powdered contents of the capsules with sufficient of the mobile phase to produce a solution containing 0.1% w/v of Naftidrofuryl Oxalate and filter (Whatman GF/C filter paper is suitable). Solution (2) contains 0.001% w/v of *3-(1-naphthyl)-2-tetrahydrofurfurylpropionic acid BPCRS* in the mobile phase. Solution (3) contains 0.0002% w/v of *2-diethylaminoethyl-3-(1-naphthyl)-2-(1-naphthylmethyl)propionate oxalate BPCRS* in the mobile phase. Solution (4) contains 0.01% w/v of *naftidrofuryl oxalate BPCRS* and 0.005% w/v of *2-diethylaminoethyl-3-(1-naphthyl)-2-(1-naphthylmethyl)-propionate oxalate BPCRS* in the mobile phase.

The chromatographic conditions described under Assay may be used.

The test is not valid unless in the chromatogram obtained with solution (4) the *resolution factor* between the two principal peaks is at least 4.

Inject solution (1) and record the chromatography for twice the retention time of the principal peak. In the chromatogram obtained with solution (1) the area of any peak corresponding to 3-(1-naphthyl)-2-tetrahydrofurfurylpropionic acid is not greater than the area of the peak in the chromatogram obtained with solution (2) (1%), the area of any peak corresponding to 2-diethylaminoethyl-3-(1-naphthyl)-2-(1-naphthylmethyl)-propionate oxalate is not greater than the area of the peak in the chromatogram obtained with solution (3) (0.2%), the area of any other *secondary peak* is not greater than half the area

of the peak in the chromatogram obtained with solution (3) (0.1%) and the sum of the areas of all the *secondary peaks* other than those corresponding to the named impurities is not greater than 1.5 times the area of the peak in the chromatogram obtained with solution (3) (0.3%).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using 20 µL of the following solutions. For solution (1) finely powder the contents of 10 capsules, mix with the aid of a spatula, dissolve with the aid of ultrasound in sufficient of the mobile phase to produce a solution containing 1% w/v of Naftidrofuryl Oxalate, filter (Whatman GF/C filter paper is suitable) and dilute 1 volume of the filtrate to 10 volumes with the mobile phase. Solution (2) contains 0.1% w/v of *naftidrofuryl oxalate BPCRS* in the mobile phase.

The chromatographic procedure may be carried out using (a) a stainless steel column (25 cm × 4.6 mm) packed with particles of silica the surface of which has been modified by chemicallybonded phenyl groups (5 µm) (Spherisorb Phenyl is suitable), (b) a mixture of 40 volumes of 0.05M *sodium acetate*, adjusted to pH 4.0 with an 85% v/v solution of *orthophosphoric acid*, and 60 volumes of *acetonitrile* as the mobile phase with a flow rate of 1 mL per minute and (c) a detection wavelength of 283 nm.

Calculate the content of $C_{26}H_{35}NO_7$ in the capsules using the declared content of $C_{26}H_{35}NO_7$ in *naftidrofuryl oxalate BPCRS*.