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

Vigabatrin Tablets

General Notices

Action and use

Antiepileptic.

DEFINITION

Vigabatrin Tablets contain Vigabatrin.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of vigabatrin, $C_6H_{11}NO_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

To a quantity of the powdered tablets containing 0.5 g of Vigabatrin add 10 mL of *water*, shake and filter through a 0.7 µm filter (Whatman GF/F is suitable). To 0.2 mL of the filtrate add 5 mL of *acetone* and allow the solvent to evaporate in a current of nitrogen. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of vigabatrin (*RS 360*).

TESTS

5-Vinyl-2-pyrrolidone

In the Assay, the area of any peak corresponding to 5-vinyl-2-pyrrolidone in the chromatogram obtained with solution (1) is not greater than the area of the peak in the chromatogram obtained with solution (3) (0.5%).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, injecting 20 µL of each of the following solutions. For solution (1) add 800 mL of the mobile phase to 10 whole tablets, stir vigorously until all of the tablets are uniformLy dispersed into fine particles, add sufficient of the mobile phase to produce 1000 mL, mix well and filter through a 0.2 µm nylon-66 filter. Dilute 10 mL of the filtrate to 50 mL with the mobile phase. Solution (2) contains 0.10% w/v of *vigabatrin BPCRS* in the mobile phase. Solution (3) contains 0.0005% w/v of *5-vinyl-2-pyrrolidone BPCRS* in the mobile phase. Solution (4) contains 0.0005% w/v of *5-vinyl-2-pyrrolidone BPCRS*, 0.1% w/v of *povidone* and 0.1% w/v of *vigabatrin 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 cation exchange resin (10 µm) (Whatman Partisil SCX is suitable), (b) as the mobile phase with a flow rate of 1.5 mL per minute, a mixture of 4 volumes of *acetonitrile*, 40 volumes of *methanol* and 1000 volumes of a 0.34% w/v solution of

potassium dihydrogen orthophosphate, adjusting the pH to 2.8 with *orthophosphoric acid* and (c) a detection wavelength of 210 nm.

In the chromatogram obtained with solution (4), the retention times are about 4 minutes for povidone, about 5 minutes for 5-vinyl-2-pyrrolidone and about 8 minutes for vigabatrin. The test is not valid unless the *resolution factor* between the peaks corresponding to 5-vinyl-2-pyrrolidone and vigabatrin in the chromatogram obtained with solution (4) is at least 1.5 and the *resolution factor* between the peaks corresponding to povidone and 5-vinyl-2-pyrrolidone is at least 1.5.

Calculate the percentage content of $C_6H_{11}NO_2$ in the tablets from the areas of the peaks for vigabatrin in the chromatograms obtained with solutions (1) and (2) and from the declared content of $C_6H_{11}NO_2$ in *vigabatrin BPCRS*.