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

Vigabatrin Oral Powder

General Notices

Action and use

Antiepileptic.

DEFINITION

Vigabatrin Oral Powder contains Vigabatrin.

The oral powder complies with the requirements stated under Oral Powders and with the following requirements.

Content of vigabatrin, $C_6H_{11}NO_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of vigabatrin (*RS 360*).
B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is the same as that of the principal peak in the chromatogram obtained with solution (2).

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, using the following solutions. For solution (1) dissolve a quantity of the mixed contents of 20 sachets containing 0.2 g of Vigabatrin in sufficient of the mobile phase to produce 100 mL. Solution (2) contains 0.2% w/v of *vigabatrin BPCRS* in the mobile phase. Solution (3) contains 0.001% w/v of *5-vinyl-2-pyrrolidone BPCRS*. Solution (4) contains 0.002% w/v of *5-vinyl-2-pyrrolidone BPCRS*, 0.2% w/v of *povidone* and 0.2% 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*, adjusted to pH 2.8 with *orthophosphoric acid* and (c) a detection wavelength of 210 nm.

Inject 20 µL of solution (4). When the chromatogram is recorded under the prescribed conditions, the retention times are povidone, about 4 minutes, 5-vinyl-2-pyrrolidone, about 5 minutes and vigabatrin, about 8 minutes. The test is not valid unless the *resolution factor* between the peaks corresponding to 5-vinyl-2-pyrrolidone and vigabatrin 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.

Inject separately 20 µL of solutions (1) and (2). Calculate the content of $C_6H_{11}NO_2$ in one sachet from the areas of the peaks and using the declared content of $C_6H_{11}NO_2$ in *vigabatrin BPCRS*.