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Development and Validation of Stability Indicating RP-HPLC Method for Simultaneous Estimation of Epalrestat and Pregabalin in Bulk and Tablet Dosage Form

Md. Shabana Sulthana[1], V. Anuradha[2]* and Mandava V Basaveswara Rao[3]

1. Department of Chemistry, Acharya Nagarjuna University, Nagarjuna Nagar -522 510, A.P. **INDIA**
2. Department of Chemistry, Vignan Degree and PG College, Nagarjuna Nagar -522 510, A.P. **INDIA**
3. Department of Chemistry, Krishna University, Machilipatnam-521 001, A.P. **INDIA**

Email: vchema2013@gmail.com

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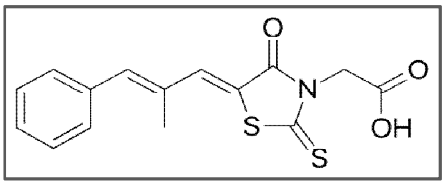
ABSTRACT

The purpose of the investigation was to develop a new RP-HPLC method for simultaneous estimation of Epalrestat at and Pregabalin in pharmaceutical dosage forms. Chromatography was carried out on Kromasil 250 C-18 column (4.6 x 250mm, 5µ particle size) with a isocratic mobile phase composed of ortho phosphoric acid buffer, Acetonitrile, 47:53v v^{-1}) at a flow rate of 1 mL min^{-1}. The column temperature was maintained at 30°C and the detection was carried out using a PDA detector at 210 nm. Validation parameters such as system suitability, linearity, precision, accuracy, specificity, limit of detection (LOD), limit of quantification (LOQ), Stability of sample and standard stock solutions and robustness were studied as reported in the International Conference on Harmonization guidelines. The retention times for Epalrestat and Pregabalin and were 2.575 min and 3.406 min respectively. The percentage recoveries of Epalrestat and Pregabalin were 99.29 % and 100.34 % respectively. The relative standard deviation for assay of tablets was found to be less than 2 %. The method was fast, accurate, precise and sensitive hence it can be employed for routine quality control of tablets containing both drugs in quality control laboratories and pharmaceutical industries.

Graphical Abstract



Chemical Structure of Epalrestat

Keywords: Epalrestat, Pregabalin, High performance liquid chromatography, Acetonitrile, Ortho-phosphoric acid, Terbutaline.