Development and validation of a new method for determination of topiramate in bulk and pharmaceutical formulation using high performance liquid chromatography-UV detection after pre-column derivatization

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ABSTRACT

In published high performance liquid chromatographic (HPLC) methods for analysis of topiramate (TPM) in pharmaceutical dosage forms and raw materials Refractive Index Detector (RID) has been used which is not available in many laboratories and has low sensitivity. We described a new, sensitive and simple HPLC method for determination of topiramate in pharmaceutical forms and Invirto dissolution studies which avoids the use of RID detector. The method is based on derivatization of topiramate and an internal standard by reaction with 4-chloro-7-nitrobenzofurazan (NBD-CL), and reverse-phase chromatography using phenyl column and spectrophotometer detection at 264 nm. A mixture of phosphate buffer (0.05 M) containing triethylamine (0.1½ V/V; pH=2.3) and methanol (28:72, V/V) at a flow rate of 2.2 ml/min was used as mobile phase. The analysis performance was studied and the method was shown to be selective and linear for determination of topiramate in pharmaceutical forms and dissolution studies.

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