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Method Development and Validation by RP-HPLC for Estimation of Topiramatein Bulk and Pharmaceutical Dosage form

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Abstract:A simple, precise, reliable, rapid and reproducible reversed-phase high performance liquid chromatographic (RP-HPLC) method has been developed and validated for the estimation of Topiramate(TPM). Chromatography was carried out Younglin (S.K) Gradient System UV Detector on C18(4.6X250 mm) column with a mobile phase composed of Methanol: Distill water (90:10 v/v) at a flow rate of 1 ml/min. The pH of mobile was adjusted by 0.05% ortho phosphoric acid (pH-3). Detection was carried out using a UV detector at 263 nm.Parameters such as linearity, precision, accuracy, ruggedness, LOD and LOQ were studied as per the ICH Q2(R1) guidelines. The retention times of TPM was4.35min. The linearity range for Topiramate 10-50µg/ml. The correlation coefficients of Topiramatewas found to be 0.999. Developed method was found to be accurate, precise, selective and rapid for simultaneous estimation of Topiramate in pharmaceutical dosage forms. The proposed method can be useful in quality control of bulk manufacturing and pharmaceutical dosage forms.
Keywords: Topiramate, method validation, RP-HPLC, ICH guidelines.

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