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Validated RP HPLC Method for the Determination of Related Substance of Oxcarbazepine an Antiepileptic DRUG

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Abstract: A reverse phase high performance liquid chromatography (RP-HPLC) method has been developed and validated for the quantitative estimation of Oxcarbazepine and its impurities (related substances). The chromatographic separation was performed on a Inertsil ODS3V column, with a particle size of 5µ (250 mmX4.6 mm id.) and a mixture of 0.1% NH_4OH in water adjusted to pH 5.0with glacial acetic acid, acetonitrile as mobile phase at flow rate of 1.0 mL/min. Calibration showed that the response of impurity and Oxcarbazepine was a linear function of concentration over the range 0.25–0.75 µg/mL and 2.5-7.5 µg/mL respectively ($r^2 \geq 0.999$) and the method was validated over this range for precision, accuracy, linearity and specificity. For precision study, RSD of each impurity and drug substance was found to be in prescribed limit. The method was found to be precise, accurate, linear and specific. The proposed method was successfully employed for related substances analysis of Oxcarbazepine. A simple gradient method with 15 minutes run time for determination of all three critical parameters is an added advantage of getting quality product.
Keywords: Antiepileptic agent, Oxcarbazepine, RP-HPLC, Validation.

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