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Stability Indicating Thin-Layer Chromatographic Determination of Brivarecetam as Bulk Drug: Application to Forced Degradation Study

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Abstract : A new, accurate, selective, simple and precise HPTLC method for estimation of briveracetam in bulk drug as well as tablet dosage form was developed and validated. The drug was well separated using mobile phase of ammonium acetate: methanol:n-propanol (8:1.6:1.6 v/v/v) with densitometric quantification of brivaracetam at 242nm. The TLC parameters were standardized and the R*f*of brivaracetam was determined to be 0.40. The values of Linearity (200-1200ng/spot), Method precision (intra-day RSD 0.5-0.8% and inter-day RSD 0.25-0.46%), Accuracy (% recovery 97.53%-102.84%)and specificity were determined according to ICH guidelines. Brivaracetam was exposed to various stress condition to study degradation profile. Degradation was seen in acidic, basic and oxidative condition. Brivaracetam was found to be stable in photolytic condition. The experiment gives us satisfactory result for method validation and development indicates the successful validation of HPTLC method for quantitative determination of brivaracetam. The HPTLC method is simple, rapid, economic andmore suitable for routine analysis of brivaracetamin bulk and tablet dosage forms.

Keywords : Brivaracetam**,** HPTLC, Densitometric estimation, Method development, Validation, Stability indicating method.

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