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Development and validation of determination of genotoxic impurity bromoethane in vigabatrin drug substance using head space gas chromatographic method [HS-GC]

A specific HS-GC method has been developed, optimized and validated for the determination of

genotoxic impurity Bromoethane in Vigabatrin (VGB) drug substance. Chromatographic separation of genotoxic Bromoethane impurity was achieved on DB-1 column (30m × 0.53 mm, 5.0 μm), consists of 100% dimethyl polysiloxane as stationary phase and passing nitrogen carrier gas. The performance of the method was assessed by evaluating the specificity, linearity, sensitivity, precision, and accuracy experiments. The established limit of detection and limit of quantification values for the genotoxic impurity was in the range of 3.57–10.80 μg/ mL. The correlation coefficient value of the linearity experiment was 0.9880. The average recoveries for the accuracy were in the range of 95.3–106.8%. The results proved that the method is suitable for the determination of Bromoethane content in Vigabatrin.

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Biography

Narapereddy Krishna Prasad has completed his master's degree in Pharmacognosy from Manipal college of pharmaceutical science, Manipal University. He is currently working as Senior Formulation Scientist in Research and Development, Reckitt Benckiser LLC. He has more than 10 years of industrial research and development experience at both Formulation and Analytical chemistry.

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