

Development and validation of rapid and sensitive RP-HPLC method for estimation of memantine in tablets by using FMOc derivatization and UV-detection

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Analytical method development and validation is a process used to confirm the analytical procedure employed for a specific test suitable for its intended use. It helps to improve reliability, consistency and accuracy of analytical data. We have found that the excipient in the tablet dosage forms does not interfere in the quantification of active drug by proposed method. This study involves development and validation of chromatographic method of estimation of memantine Hcl in tablet dosage form as per ICH guidelines with a validated reverse phase high performance chromatographic technique. Chromatography was performed on Kromasil RP Column C₁₈ (150 mmx4.6 mm i.d.5 µm particle size) with mobile phase containing Acetonitrile (ACN). The flow rate was 2 ml/min and eluent was detected at 263 nm at ambient temperature. The selected and proposed chromatographic conditions were found effectively with retention time (RT- 1.766 min.) Linearity of memantine was found in the range of 80-120 mg/ml. This method is fast, accurate, precise, reproducible and rugged and used for estimation of memantine in any type of pharmaceutical dosage formulation. In this study, the RP-HPLC method of estimation of memantine has been performed according to the current ICH guidelines. The results obtained in this study are statistically significant and found within the acceptance limit. This simplified developed method was validated which reduces time, cost ultimately with better chromatographic separation as considered with the other available known methods. Therefore the method is suitable for its intended use.

Keywords: Memantine Hcl, RP-HPLC (Reverse Phase HPLC), Validation.

Biography

Vinod Jagannathrao Mokale has completed Master's in Pharmacy at the age of 22 years from AISSMS College of Pharmacy, University of Pune, Pune and submitted Ph.D. synopsis to North Maharashtra University, Jalgaon, India. He is the head of Department of Pharmaceutical Technology, UICT, NMU, Jalgaon. He has published more than 13 papers in reputed journals and serving as guide for than 25 M. Tech. (Pharma. Tech.) Students and given invited talk/lecture in international conferences.

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