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Development and Validation of a RP-HPLC Method for Determination of Citicoline Monosodium in Human Plasma

Shailendra K. BINDAIYA, Kapendra SAHU, Mukesh BHAISARE, C. KARTHIKEYAN, N.S.H.N. MOORTHY, Farhad F. MEHTA & Piyush TRIVEDI*

School of Pharmaceutical Sciences, Rajiv Gandhi Proudyogiki Vishwavidyalaya, Bhopal-462036, India

***SUMMARY*. A sensitive and specific high performance reversed phase liquid chromatographic method was developed for quantification of citicoline monosodium (CTM) in human plasma. The active drug was isocratically eluted at a flow rate of 1 ml/min at ambient temperature in a nucleosil C18 analytical column with a mobile phase composed of tetrabutyl ammonium hydrogen sulfate buffer (0.005 M, pH 5.0):methanol (95:05, v/v). Photodiode array (PDA) was performed at 270 nm and the retention time of the drug was found to be 6.64 min. The lowest limit of quantification (LLOQ) and of detection (LOD) were found to be 30 and 10 ng/ml, respectively. The method was validated and the response was found to be linear in the drug (CTM in spiked plasma) concentration range 150-900 ng/ml. The method was found to be accurate, with ranging from 96.38 to 98.65 % and precise, with intra-day, inter-day as well as analyst-to-analyst precision. The total recoveries of the method ranged between 95.69 and 97.89 %. Stability data revealed that the drug is stable in human plasma under various test conditions and the method can be successfully used for analysis of CTM in human plasma and in pharmacokinetic studies.**

KEY WORDS: Human plasma, HPLC, Validation, Citicoline monosodium.

* Author to whom correspondence should be addressed. *E-mail:* prof_piyushtrivedi@yahoo.com, piyush.trivedi@rgtu.net

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