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Quantification of Clofarabine and its Impurity Substances by RP-HPLC Method in Parenteral Formulation

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ABSTRACT

A simple, accurate and precise stability-indicating RP-HPLC method was developed for estimation of clofarabine in parenteral formulation. Some known impurities like, alpha-anomer, 2-chloroadenine and monobenzoate are used which are related substances of clofarabine, for the analysis of the marketed formulation. Inertsil C_{18} (150 mm × 4.6 mm) 5µ (particle size) was used as stationary phase and Buffer: Acetonitrile 90:10 v/v was used as mobile phase with flow rate 1 ml/min at 263 nm UV detection. The retention time of clofarabine was found to be 3.07 minutes. Linearity was observed over the concentration range of 5-25 µg/ml for clofarabine in which correlation coefficient value was found to be 0.999. Force degradation study was perform and maximum degradation of Standard and Test of Clofarabine was found to be 18.8% and 17.5% respectively in Acidic condition. The LOD and LOQ was found to be 0.071 µg/mL and 0.21 µg/mL, respectively for clofarabine. Moreover, the % RSD for repeatability, inter and intra day precision was found to be within the range, which reveals that the method is precise. Accuracy study of the drug in marketed preparation also reported within the limits. In conclusion, the assay is useful for estimation of clofarabine in parenteral formulations.

KEYWORDS: Clofarabine; alpha-anomer; 2-chloroadenine; monobenzoate; RP-HPLC.