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Research article

Stability indicating method development and validation of Deferiprone in pharmaceutical dosage form by RP-HPLC

P. Vamsi Reddy[*1], V. Asha Ranjani[2], R.Chandra Sekhar[3], M. Shyam Sundar[3]

[1]*Centre for Pharmaceutical Sciences, IST, JNTU, Hyderabad -500085.*
[2]*MLR Institute of Pharmacy, Dundigal (v),Hyderabad-500043*
[3]*Department of Pharmaceutical analysis& Quality assurance, OU, Hyderabad-500007*

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***Corresponding Author: P. Vamsi Reddy,** Centre for Pharmaceutical Sciences, IST, JNTU, Hyderabad -500085.

Abstract

The objective of this present is to develop a simple, precise, accurate stability indicating method for the estimation of deferiprone in formulation by using RP-HPLC. The separation was achieved on Inertsil ODS C18, 250x 4.6mm, 5µm i.d. column using 60 volumes of Mixed Phosphate buffer(KH_2PO_4+K_2HPO_4) pH 3.0 and 40 volumes of methanol as mobile phase and at a flow rate of 1.0 mL/min. Detection was carried out using a PDA detector at 280nm. The method was validated for accuracy, precision, specificity, linearity and sensitivity. The total chromatographic analysis time per sample was about 5 min with deferiprone eluting at retention time of about 4.980 min. The method was validated as per ICH guide lines. Stability studies reported absence of impurities at the peak retention time. The drug was stable to different conditions like acidic, alkali, thermal, oxidative and photolytic conditions. Validation studies demonstrated that the proposed HPLC method is simple, specific, rapid, reliable and reproducible. The standard curves were linear over the concentration range of 75-125µg/mL. The LOD and LOQ values for deferiprone were 3.91 and 11.8 µg/mL, respectively. The percentage recovery was found to be 97.3 to 98.0 and the %RSD for precision was found to be 0.5. The high recovery and low relative standard deviation confirm the suitability of the proposed method for the determination of deferiprone in bulk and capsule dosage forms.

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