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Method development and optimization for determination of Acemetacin and its toxic impurities using design of experiment

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An isocratic RP-HPLC-DAD method has been developed and optimized for the first time by the aid of statistical approaches for simultaneous determination of acemetacin (ACM) and its official impurities (A and B), 4-chlorobenzoic acid (IMP-A) and indometacin (IMP-B). In this study, two level full factorial design was used to optimize the used mobile phase where three chromatographic variables were studied, % acetonitrile (ACN), % H_3PO_4 acid and mobile phase flow rate (FR). The selected responses were the analysis time (t) and the chromatographic resolution (Rs) among the most adjacent peaks (peaks IMP-B and ACM). The impacts of % acetonitrile and mobile phase flow rate individually were significant on analysis time (P=0.0277 and 0.0424, respectively). Also %acetonitrile had a meaningful effect on the chromatographic resolution (P=0.0085). Finally the chromatographic separation has been performed on Zorbax® Eclipse C18 column using acetonitrile: Water (containing 0.05% H3PO4) [55:45, v/v], FR=1.5 mL/min as an optimized mobile phase using full factorial experimental design with UV detection at 230nm. IMP-A appeared at 3.29 minute, IMP-B at 9.07 minute and ACM at 10 minutes. The method fulfilled USP validation standards concerning linearity, accuracy and precision. In addition, system suitability parameters have been calculated and the results were within the acceptance criteria. The commercially available ACM tablets were analyzed, good %recovery and %RSD values were resulted. Also, statistical comparison of the developed method with the reported one showed no significant difference within probability of 95%.

Biography

Nada Sayed Abdelwahab has completed her PhD and is an Associate Professor of Analytical Chemistry at Faculty of Pharmacy Beni Suef University, Egypt. She has published more than 40 papers in different chromatographic and spectroscopic methods of analysis. She has also attended different international conferences and is a potential Reviewer in many international journals.

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