Abstract

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A rapid and sensitive HPLC method for simultaneous determination of Rosuvastatin and Candesartan in human plasma: A useful tool for pharmacokinetic studies

Charmy Kothari *

***Corresponding author:** Department of Pharmaceutical Analysis, Institute of Pharmacy, Nirma University, Ahmedabad-382481, Gujarat, India

Abstract

A rapid and sensitive high-performance liquid chromatography (HPLC) method was developed and validated in human plasma for simultaneous determination of rosuvastatin and candesartan, using atorvastatin as internal standard. Chromatographic separation was achieved on a Waters C18 column (250 × 4.6 mm, 5 µm). A response surface methodology based 3 2 full factorial design was employed to optimize critical chromatographic conditions viz. pH and composition of mobile phase for achieving good resolution between the desired analytes. The optimised chromatographic conditions consisted of mobile phase of sodium acetate buffer (5 mM) with 0.1% acetic acid (pH 3.5)-acetonitrile (30:70, v/v), which was pumped at a flow rate of 1 mL/min. The detection was conducted at 254 nm for all the analytes. The calibration curves were linear over the concentration ranges of 10–150 ng/ml for both rosuvastatin and candesartan. The overall data of precision and accuracy were in accordance with US-FDA guidelines for bioanalytical method validation. Mean % extraction recovery observed for both analytes was above 80% as well as reproducible and consistent. No significant matrix effect was observed while carryover effect was deemed insignificant. Stability studies showed that the samples are stable over a long period which covers from sample collection to final analysis. Hence, the proposed method could be applied for routine laboratory analysis of rosuvastatin and candesartan in human plasma samples, clinical trials and pharmacokinetic studies.

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Biography

Dr. Charmy S. Kothari has 18 years of teaching and research experience. Her research areas of interest are analytical and bioanalytical method development and validation, impurity profiling and stability studies as well as Isolation, identification and characterization of marker compounds from plants and formulations. Her research area also includes regulatory guidelines, registration procedures, evaluation and approval procedures of various regulatory agencies worldwide as well as Pharmacovigilance system. She has more than 50 research and review papers published in reputed Indian and International journals. Key papers published in prestigious Elsevier journals like Trends in Analytical Chemistry (IF=9.8), Food chemistry (7.5), Arabian J of Chemistry (5.165). She has presented a paper as well as various posters at international, national and state level conferences and received several awards for best oral and poster presentation. She is twice recipient of Dr. P. D. Sethi memorial annual national award for research paper certificate for the year 2007 and 2017. She is actively involved in various capacities in organizing National and International Conferences/Workshops. She has also received financial assistance from GUJCOST for organizing workshop and National seminar. She is a life member of various organisations like RAPS, ACS, APTI, IPA & ISTE. She is a recognized Post Graduate and Ph. D. Guide at Institute of Pharmacy, Nirma University. Under her guidance, three PhD students were awarded ICMR-SRF research grant; while one PhD. student received prestigious CM fellowship-SHODH from Government of Gujarat for research work. She received research grants from government funding agencies like GUJCOST, ICMR, DST-BDTD. She also received DST-SERB International Travel Grant to attend International Conference AOAC at Toronto, Canada. She is reviewer of several national & international journals in her researchareaofinteres