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Stability indicating RP-HPLC method development and validation for the simultaneous estimation of darunavir and cobicistat in pharmaceutical dosage form

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Darunavir is a protease inhibitor medication used to treat HIV infection. Cobicistat is a pharmacokinetic enhancer used along with anti HIV agents. The US Food and Drug Administration has approved a fixed-dose combination of Darunavir (800 mg) and Cobicistat (150 mg) for HIV treatment in 2015. In the present work, we planned to develop a simple, fast, accurate and precise RP-HPLC method for the simultaneous estimation of Darunavir and Cobicistat in pharmaceutical dosage form. The chromatographic method was developed by using Kromosil C18 column (250mm x 4.6mm, 5µm) and the mobile phase was pumped with acetonitrile and water (pH was adjusted to 3.2 by using ortho phosphoric acid) in the ratio of 70:30 v/v. The mobile phase was pumped at 1ml/min flow rate and the temperature was maintained at 30°C. The retention times of Darunavir and Cobicistat were found to be 3.5 min and 2.7 min, respectively. The method developed was validated in accordance with ICH guidelines with respect to the stability indicating capacity of the method including system suitability, accuracy, precision, linearity, range, limit of detection, limit of quantification, solution stability and robustness. Darunavir and Cobicistat were found to be linear in the range of 40-240 µg/ml and 7.5-45 µg/ml, respectively. The assay results of Darunavir and Cobicistat in PREZCOBIX were found to be 100.4% and 100.9%, respectively. The sample solution was tested for degradation studies in acidic, basic, neutral, peroxide, heat, photolytic conditions and the percentage degradation was found to be within the limits. The developed methods can be used for the routine analysis of the drugs in pharmaceutical dosage forms.

Biography

Sridhar Siddiraju has completed his PhD from Berhampur University, India. He is working as Associate Professor in Department of Pharmaceutical Chemistry, Malla Reddy College of Pharmacy, Hyderabad, India. He has published more than 30 papers in reputed journals and is serving as Editor-in-Chief of *International Journal of Pharmacy.*

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