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Development and Validation of A Simultaneous Estimation of Darunavir and Cobicistat in Pharmaceutical Dosage Forms Using Micellar Liquid Chromatography

Viswanadha N N Murthy and Rama Krishna Karipeddi*

*Department of Chemistry, Institute of Science, GITAM University, Visakhapatnam, Andhra Pradesh, INDIA

Email: karipeddirk@gmail.com

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ABSTRACT

A rapid, simple and sensitive liquid chromatographic procedure that use micellar mobile phase is reported for the simultaneous estimation of Darunavir and Cobicistat in pharmaceutical dosage forms has been developed and validated. The separation was performed on an Agilent Polaris C18 (5µm; 150 X 4.6mm) column. The composition of the mobile phase is 10:90 % (v/v) of Propan-2-ol and 0.05mM Tween 80 containing 0.1 % glacial acetic acid in water. Quantification was achieved by HPLC-UV detection at 265 nm. The developed method is validated as per ICH Guidelines over a concentration range from 2.45 – 24.55 µg/mL for Darunavir & 2.52 – 25. 22 µg mL⁻¹ for Cobicistat. The method shows excellent linearity and reproducibility. This approach minimizes the usage of organic solvents for analysis.

Keywords: Cobicistat, Darunavir, Micellar liquid chromatography, ICH.