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

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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 & 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 Teen 80 containing 0.1 % glacial acetic acid in water. Quantitation 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 showed excellent linearity and reproducibility. This approach eliminates the usage of organic solvents for analysis.

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