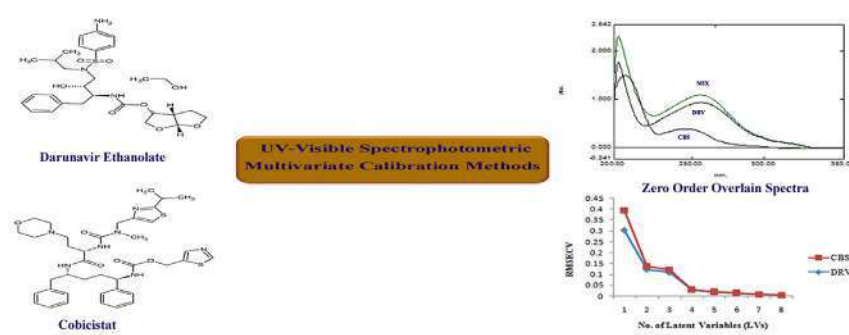# Chemo-metric assisted UV-spectrophotometric methods for simultaneous estimation of Darunavir ethanolate and Cobicistat in binary mixture and their tablet formulation

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HIGHLIGHTS

- Development and validation of chemometric assisted UV–Visible spectrophotometric methods for simultaneous estimation of antiretroviral drug.
- The proposed methods are statistically compared with reported UPLC method.
- These methods are simple, accurate, precise and less expensive, and can be applied for the routine quality control analysis of selected drugs and their combined tablet dosage form.

GRAPHICAL ABSTRACT

ABSTRACT

Darunavir ethanolate (DRV) and Cobicistat (CBS) is a combination of antiretroviral drugs used for the treatment of human immunodeficiency virus (HIV) infections. Two Chemo-metric assisted UV-spectrophotometric methods were developed for simultaneous estimation of DRV and CBS in tablet dosage form, namely; partial least square (PLS) and Classical least square method (CLS). The proposed methods were successfully applied for simultaneous determination of DRV and CBS in a laboratory mixture and their tablet formulation to achieve maximum sensitivity and lowest error. The applied methods were validated as per ICH guidelines and found to be linear in the concentration range of 5-30µg/mL for DRV and 5-30µg/mL for CBS. The developed methods were statistically comared with reported UPLC method where no significant difference was found relating to both accuracy and precision. Thus, the proposed methods can be effectively utilized for the routine quality control assessment of these drugs in commercial tablet dosage form.

1. Introduction

Darunavir Ethanolate (DRV) is protease inhibitors. It is chemically designed as (3R, 3AS, 6ar) - hexahydrofuro [2, 3-b] furan-3-yl, N-((1S, 2R)-1-benzyl-2-hydroxy-3-(N (1) - iso butyl sulfanil amido) propyl) carbamate [1]. Cobicistat (CBS) is potent CYP3A inhibitor and pharmacokinetic enhancer. It is designed as 1,3-Thiazol-5-ylmethy [(2R,5R)-5-{[(2S)-2-[(methyl {[2- (propan-2-yl)- 1,3-thiazol-4-yl] methyl} carbamoyl) amino]-4-(morpholin-4-yl) butanoyl] amino}- 1,6-diphenylhexan-2-yl] carbamate [2]. The structures of DRV and CBS were shown in Fig. 1(a) and (b) respectively. Prezcobix® (Janssen-Cilag, Beerse, Belgium) is combination of DRV and CBS used for the treatment of human

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