Optimization of UV Spectrophotometric Method for Estimation of Darunavir in Bulk Drug and Tablet Formulations

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ABSTRACT
A simple and cost effective spectrophotometric method has been developed and subsequent validation of Darunavir in its bulk and formulation with good accuracy and precision. An absorption maximum was determined at 254 nm. Beer’s law was obeyed in the concentration range of 10-35μg/ml with correlation coefficient of 0.998. Darunavir is a protease inhibitor, is a retroviral drug used in treatment of (HIV) Type-1 infection. The % assay for Darunavir ranged from 98.4-102.1% in tablet dosage form. Hence the developed method can be used for routine analysis of Darunavir in pharmaceutical formulations.

KEYWORDS: Validation, Simultaneous Estimation, Darunavir, UV Spectrophotometry, Beer’s Law.

Introduction
Darunavir is a protease inhibitor used to treat HIV infection (Fig. 1). Darunavir is an OARAC recommended treatment option for treatment-naïve and treatment-experienced adults and adolescents (Ghosh et al., 2007). It was approved for clinical use in 2006. It is a second-generation protease inhibitor, designed specifically to overcome problems with the older agents in this class. Darunavir was designed to form robust interactions with the protease enzyme from many strains of HIV, including strains from treatment-experienced patients with multiple resistance mutations to protease inhibitors. It is on the WHO’s List of Essential Medicines. Darunavir received attention at the time of its release, as it represents a treatment option for people with drug-resistant HIV. Darunavir is an OARAC recommended treatment option for treatment-naïve and treatment-experienced adults and adolescents. As with other antiretrovirals, darunavir does not cure HIV infection or AIDS, and does not prevent passing HIV to others. Darunavir is a nonpeptidic inhibitor of PR that lodges itself in the active site of PR through a number of hydrogen bonds

In this study, we attempted to optimized a simple UV-spectrophotometric method for analysis of darunavir in bulk and tablet formulations. The work was planned for the selection of solvent and location of \( \lambda_{\text{max}} \) of the drug with simultaneous study of Beer’s Lambert’s Law for the determination of UV spectrophotometry for the estimation of Darunavir in the bulk dosage formulations of the marketed drugs (Erwing et al., 1960). Precision and accuracy of the drug were noted at a selected wavelength and its application for the validation protocol was proposed for its formulation was determined (Jenkins., et al. 1986).

Fig. 1. Chemical structure of Darunavir.

Materials and Methods
Darunavir was obtained as gift sample from Noshce Labs Pvt. Ltd, Hyderabad and formulation brand name is PREZISTA (containing 300 mg of darunavir ethanolate). It was purchased from a Hetero pharmacy.

ABBREVIATIONS: RSD: Relative Standard Deviation; SD: Standard Deviation.