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A VALIDATED STABILITY INDICATING RP-HPLC METHOD FOR THE DETERMINATION OF ABACAVIR IN BULK AND TABLET DOSAGE FORMS

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Abstract

A rapid, precise, accurate, specific and simple RP-HPLC method was developed for the estimation of Abacavir in bulk and in tablet dosage form. A High performance liquid chromatograph 10AT SHIMADZU- SPD10A, using Phenomenex - Luna RP-18(2),250X4.6mm, 5 mm column, with a mobile phase composedÂ from water: Acetonitrile [80:20 %(v/v)] were used. The flow rate of 1.0 ml/min and the effluent was detected at 285 nm by using a UV detector. The retention time of Abacavir was 7.761 min. Linearity was observed over concentration range of 100-2800 ng ml^{-1}. The Limit of detection was found to be 21.04 ng ml^{-1}while quantification limit was 63.77 ng ml^{-1}. The accuracy of the proposed method was determined by recovery studies and found to be 98.23 to 100.61 %. Commercial tablet formulation was successfully analyzed using the developed method and the proposed method is applicable to stability studies and routine analysis of Abacavir in bulk and pharmaceutical formulations. The proposed method was validated for various ICH parameters like linearity, limit of detection, limits of quantification, accuracy, precision, range and specificity.

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Abstract
A rapid, precise, accurate, specific and simple RP-HPLC method was developed for the estimation of Abacavir in bulk and in tablet dosage form. A High performance liquid chromatograph 10AT SHIMADZU- SPD10A, using Phenomenex - Luna RP-18(2),250X4.6mm, 5 µm column, with a mobile phase composed from water: Acetonitrile [80:20 %(v/v)] were used. The flow rate of 1.0 ml/min and the effluent was detected at 285 nm by using a UV detector. The retention time of Abacavir was 7.761 min. Linearity was observed over concentration range of 100-2800 ng ml^{-1}. The Limit of detection was found to be 21.04 ng ml^{-1}while quantification limit was 63.77 ng ml^{-1}. The accuracy of the proposed method was determined by recovery studies and found to be 98.23 to 100.61 %. Commercial tablet formulation was successfully analyzed using the developed method and the proposed method is applicable to stability studies and routine analysis of Abacavir in bulk and pharmaceutical formulations.
The proposed method was validated for various ICH parameters like linearity, limit of detection, limits of quantification, accuracy, precision, range and specificity.
Keywords: Abacavir, RP-HPLC, Stability studies, Validation, ICH guidelines

1. Introduction

Abacavir is chemically [(1R)-4-[2-amino-6-(cyclopropylamino) purin-9-yl]-1-cyclopent-2-enyl] methanol (Fig. 1). It is a white crystalline powder used as antiretroviral agents, for the treatment of HIV infection. Abacavir belongs to a class of antiretroviral drugs known as nucleoside reverse transcriptase inhibitor (NRTI) with activity against Human Immunodeficiency Virus Type 1 (HIV-1)[1]. Literature survey reveals that very few analytical methods has been established for the determination of abacavir viz. abacavir, lamivudine and zidovudine in Pharmaceutical Tablets, Human Serum and in Drug Dissolution Studies by HPLC[2], Hypersensitivity reaction to abacavir is strongly associated with the presence of the HLA-B*5701 allele[3], Simple and Reliable HPLC Method of Abacavir Determination in Pharmaceuticals, Human Serum and Drug Dissolution Studies from Tablets[4], Spectrophotometric determination of abacavir sulphate[5], RP-HPLC Method for the simultaneous Estimation of Lamivudine and Abacavir Sulphate in Tablet Dosage Form[6], Development and Validation of RP-HPLC Method for the Estimation of Abacavir , Lamivudine and Zidnovudine in Pharmaceutical Dosage Form[7], Spectrophotometric Estimation of Abacavir Sulphate in Bulk and Tablet Dosage Form[8], Visible spectrophotometric determination of Abacavir sulphate in Bulk Drug and Tablet Dosage Form[9].

Fig. 1: Chemical structure of Abacavir

The stability of a drug substance or drug product is defined as its capacity to remain within established specifications, i.e. to maintain its identity, strength, quality, and purity until the retest or expiry date[10]. Stability testing of an active substance or finished product provides evidence of how the quality of a drug substance or drug product varies with time under a variety of environmental conditions, for example temperature, humidity, and light. Knowledge from stability studies is used in the development of manufacturing processes, selection of proper packaging and storage conditions, and determination of product shelf-life[11-12]. There was no reported stability-indicating analytical method for analysis of abacavir in the presence of its degradation products in bulk and pharmaceutical dosage forms. The objective of this work was to develop a new, simple, economic, rapid, precise, and accurate stability-indicating HPLC

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