A VALIDATED STABILITY INDICATING RP-HPLC METHOD FOR THE DETERMINATION OF EMTRICITABINE IN BULK AND CAPSULES

PRADEEP KUMAR*1, S.C.DWIVEDI1, ASHOK KUSHNOOR2

1School of Pharmacy, Suresh Gyan Vihar University, Jaipur, Rajasthan, India
2Shri Gopichand College of Pharmacy, Baghipat, Uttar Pradesh, India
*corresponding author: pradeep_alpine@yahoo.co.in

Abstract

A rapid, precise, accurate, specific and simple RP-HPLC (reversed phase – high performance liquid chromatography) method was developed for the assay of Emtricitabine from capsules. A High performance liquid chromatograph 10AT SHIMADZU- SPD10A, using Phenomenex - Luna RP-18(2),250X4.6mm, 5 µm column, with a mobile phase composition of buffer : acetonitrile [85:15 (%v/v)] was used. The flow rate of 1.0 mL min\(^{-1}\) and the effluent was detected at 280 nm. The retention time of Emtricitabine was 9.341 minutes. Linearity was observed over the concentration range of 20-600µg mL\(^{-1}\). The limit of detection was found to be 5.539µg mL\(^{-1}\) while the quantification limit was 16.786µg mL\(^{-1}\).

The accuracy of the proposed method was determined by recovery studies and was found to be 99.468% to 101.110 %. The commercial capsule formulation was successfully analyzed using the developed method and the proposed method is applicable to stability studies and routine analysis of Emtricitabine in bulk and pharmaceutical formulations.

The proposed method was validated for various ICH (International Conference on Harmonization) parameters like linearity, limit of detection, limits of quantification, accuracy, precision, range and specificity.

Rezumat

Lucrarea prezintă etapele de elaborare și validare a unei metode RP-HPLC (reversed phase – high performance liquid chromatography) rapidă, specifică și simplă, pentru determinarea cantitativă a Emtricitabinei din tablete. S-a utilizat un sistem cromatografic de tip 10AT SHIMADZU- SPD10A, dotat cu o coloană Phenomenex - Luna RP-18(2),250X4.6mm, 5 µm. Detecția s-a realizat la 280nm, timpul de rețenție al Emtricitabinei a fost de 9.341 minute. Domeniul de linearitate s-a înregistrat pe domeniul de concentrații 20-600 µg mL\(^{-1}\), limita de detecție s-a înregistrat la 5.539µg mL\(^{-1}\), limita de cuantificare a fost 16.786µg mL\(^{-1}\), iar coeficientul de regăsire 99.468%-101.110 %. Metoda a fost validată conform ICH (International Conference on Harmonization).

Keywords: Emtricitabine, RP-HPLC, Stability studies, ICH guidelines

Introduction

Emtricitabine is chemically 4-amino-5-fluoro-1-[(2R, 5S)-2-(hydroxymethyl)-1, 3-oxathiolan-5-yl] pyrimidin-2-one (Fig. 1). It is a white
Acceptance Letter

**Title:** A Validated Stability Indicating RP-HPLC Method for The Determination Of Tenofovir In Bulk And Tablet Dosage Forms

**Authors:** Pradeep Kumar, S.C Dwivedi, Ashok Kushnoor

Dear Pradeep Kumar,

I am very glad to inform you that your paper has been accepted for the publication in Eurasian Journal of Analytical Chemistry (EJAC).

I am grateful to you for the kind consideration.

Sincerely Yours,

Prof. Dr. Huseyin BAG
Editor in Chief
VALIDATION AND STABILITY OF RP-HPLC METHOD FOR THE DETERMINATION OF EFAVIRENZ AS BULK DRUG AND IN PHARMACEUTICAL FORMULATIONS

PRADEEP KUMAR*1, S.C.DWIVEDI1 and ASHOK KUSHNOOR2

1School of Pharmacy, Suresh Gyan Vihar University, Jaipur, Rajasthan, (INDIA)
2Shri Gopichand College of Pharmacy, Baghpat, Uttar Pradesh, (INDIA)

PRADEEP KUMAR
School of Pharmacy, Suresh Gyan Vihar University, Jaipur, Rajasthan, (INDIA)

*Corresponding author

ABSTRACT

A rapid, precise, accurate, specific and simple RP-HPLC method was developed for the estimation of Efavirenz in its tablet form. A High performance liquid chromatograph 10AT SHIMADZU- SPD10A, using Phenomenex - Luna RP-18(2),250X4.6mm, 5 μm column, with mobile phase composition of Acetonitrile: Phosphate Buffer [58:42 %(v/v)] was used. The flow rate of 1.0 ml min⁻¹ and effluent was detected at 247 nm. The retention time of Efavirenz was 4.611 minutes. Linearity was observed over concentration range of 500-10000ng ml⁻¹. The Limit of detection and limit of quantification was found to be 157.63ng ml⁻¹ and 477.68ng ml⁻¹ respectively. The accuracy of the proposed method was determined by recovery studies and found to be 98.240 to 101.170 %. The proposed method is applicable to stability studies and routine analysis of Efavirenz 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.
Development and validation of stability indicating RP-HPLC method for the estimation of Nelfinavir in bulk and pharmaceutical formulations

Pradeep Kumar1*, S.C. Dwivedi1, Ashok Kushwaha2
1School of Pharmacy, Suresh Gyan Vihar University, Jaipur, Rajasthan, India.
2Shri Gopalchand College of Pharmacy, Baghpat, Uttar Pradesh, India.

Received on: 19-06-2011; Revised on: 08-07-2011; Accepted on: 01-10-2011

ABSTRACT

A rapid, precise, accurate, specific and simple RP-HPLC method was developed for the estimation of Nelfinavir in Its tablet form. A high performance liquid chromatograph (HPLC; Shimadzu, SPD-10A, using Phenomenex - Luna RP-C18, 250 x 4mm column, with mobile phase composition of A (0.1M monobasic potassium phosphate buffer pH=2.0) and B (acetonitrile). Phosphate Buffer [8:15 v/v] was used. The flow rate of 1.0 ml/min and effluent was detected at 220 nm. The retention time of Nelfinavir was 6.75 minutes. Linearity was observed over concentration range of 50-2000ng/ml. The Limit of detection and Limit of quantification was found to be 0.26ng/ml and 18.90ng/ml respectively. The accuracy of the proposed method was determined by recovery studies and found to be 98.931 to 100.419%. The proposed method is applicable to stability studies and routine analysis of Nelfinavir in bulk and pharmaceutical formulations. The proposed method was validated for various ICH parameters like linearity, limit of detection, limits of quantification, accuracy, precision and specificity.

Key words: Nelfinavir, RP-HPLC, Stability studies, Validation, ICH guidelines

INTRODUCTION

Nelfinavir is chemically (3S,4S)-8a-N-tert-butyl-2,4-[(2R,3R)-2-hydroxy-3-[3,4,6,7,8-tetrahydro-1H-isquinoline-3]-carboxamide (Fig. 1). It is a white powder form to be used as antiretroviral agent, for the treatment of HIV infection. It has an empirical formula of C23H26N4O8 and molecular weight of 587.42. Nelfinavir belongs to a class of antiretroviral drugs known as protease inhibitor with activity against human Immunodeficiency Virus Type I (HIV-1)1. Literature survey reveals that very few analytical methods has been established for the determination of Nelfinavir viz. Nelfinavir (Viracept) is a potent and orally bioavailable human immunodeficiency virus HIV-1 protease inhibitor and is being widely prescribed in combination with HIV reverse transcriptase inhibitors for the treatment of HIV infection.2 Spectrophotometric estimation of nelfinavir in tablet dosage forms Spectrophotometric method for the determination of Nelfinavir in either bulk form or dosage forms3 HIV-1 Protease inhibitors Nelfinavir and Atazanavir Induced Mitochondrial Glioma Death by Triggering Endoplasmic Reticulum Stress.4 Evaluation of an International Pharmacopeia method for the analysis of Nelfinavir by liquid chromatography5, Stress degradation studies of Nelfinavir by Fourier transform infrared spectroscopy.

There was no reported stability-indicating analytical method for analysis of Nelfinavir in the presence of its degradation products in bulk and pharmaceutical dosage forms. The objective of this work was to develop a new, simple, rapid, precise, and accurate stability-indicating HPLC method for quantative analysis of Nelfinavir, and to validate the method in accordance with ICH guidelines6 with shorter retention time, runtime, and economic mobile phase.

EXPERIMENTAL

MATERIALS AND METHODS

Pure standard of Nelfinavir ( Assigned purity 99.98%) was obtained as a gift sample from Hetero Drugs Ltd, Hyderabad, Andhra Pradesh, India. The gift samples were used as standard without further purification. HPLC grade water, Acetonitrile and methanol (Qualigens), Hydrochloric acid, Sodium hydroxide, Hydrogen peroxide, Anhydrous sodium hydrogen phosphate, citric acid monohydrate (S.D. fine chemicals, Mumbai, India), were used throughout the experiment. Commercial pharmaceutical preparation (Viracept) which was claimed to contain 25.0mg of Nelfinavir was used in analysis. The chemical structure and purity of the sample obtained was confirmed by TLC, IR, melting point studies.

Instrumentation and Chromatographic conditions

High performance liquid chromatograph Shimadzu prepLC-10AT VP equipped with universal injector (Hamilton 25 μl) SPD-10A UV-VIS detector SPD-10A-10A VP (Shimadzu) was used. Isocratic elution of mobile phase comprising of Acetonitrile:Phosphate Buffer in the ratio of 83.15 % (v/v) with flow rate of 1.0 ml/min was performed on C18 column (250x 4.6 mm, 5 μm). The effluent was detected at 220 nm. The retention time of Nelfinavir was 6.75 minutes. The column temperature was maintained at ambient and the volume of injection was 20 μl. Prior to injection of analyte, the column was equilibrated for 30–40 min with mobile phase.

Different kits of equipments viz, Analytical weighing balance (Shimadzu AX 200), Sonicator (model SONICA 2200MFT, Water purification system, Vacuum pump (model XT 592090 of Millipore), Millipore filtration kit for solvents and sample filtration were used throughout the experiment. The Spectrachrom CBR software was used for acquisition, evaluation and storage of chromatographic data.

Preparation of Mobile Phase

The HPLC grade solvents of water and Acetonitrile were used for the preparation of mobile phase Mobile Phase : (Acetonitrile 83% Phosphate Buffer 15%) Solvent A, Acetonitrile 83% Solvent B, Buffer: Dissolve 0.10 g of anhydrous sodium hydrogen phosphate in 500 ml water and adjust the pH to 3.6 with 1.298 g of citric acid monohydrate in sufficient water to produce 1000 ml. The contents of the mobile phase were filtered before use through a 0.45 μm membrane filter, sonicated and pumped from the solvent reservoir to the column at a flow rate of 1 ml/min.

Preparation of Standard Solution

A stock solution of drug was prepared by dissolving 100 mg of Pure Nelfinavir in a 100 ml volumetric flask containing sufficient amount of methanol (HPLC grade) to dissolve the drug, sonicated for about 15 min and then made up to 100 ml with methanol. The solution was filtered through a 0.45 μm membrane filter. The resulting solution was stable for 3 days when stored at room temperature.

Preparation of Mobile Phase

The HPLC grade solvents of water and Acetonitrile were used for the preparation of mobile phase Mobile Phase : (Acetonitrile 83% Phosphate Buffer 15%) Solvent A, Acetonitrile 83% Solvent B, Buffer: Dissolve 0.10 g of anhydrous sodium hydrogen phosphate in 500 ml water and adjust the pH to 3.6 with 1.298 g of citric acid monohydrate in sufficient water to produce 1000 ml. The contents of the mobile phase were filtered before use through a 0.45 μm membrane filter, sonicated and pumped from the solvent reservoir to the column at a flow rate of 1 ml/min.
Validated HPTLC Method for the Determination of Abacavir as Bulk Drug and In Pharmaceutical Dosage Form.

Pradeep Kumar, S.C.Dwivedi, Ashok Kushnoor
1School of Pharmacy, Suresh Gyan Vihar University, Jaipur, Rajasthan, India. 2Shri Gopichand College of Pharmacy, Baghpit, Uttar Pradesh, India.

Abstract
A simple, accurate, precise, and rapid high performance thin layer chromatographic method has been developed and validated for the estimation of Abacavir in tablet dosage forms. The method employed TLC aluminium plates precoated with silica gel 60 F 254 as the stationary phase. The mobile phase used was a mixture of (Chloroform: Methanol 9: 1 v/v). The detection of spot was carried out at 284nm. The calibration curve was found to be linear between 400 to 2400 μg mL⁻¹ with regression coefficient of 0.9992. The proposed method can be successfully used to determine the drug content of marketed formulation. The accuracy of the proposed method was determined by recovery studies and found to be 99.49 to 99.79 %. The proposed method is applicable to routine analysis of Abacavir in bulk and pharmaceutical formulations. The proposed method was validated according to various ICH parameters like linearity, accuracy, precision, specificity, limits of detection and limits of quantification.

Key Words
Abacavir, Validation, ICH guidelines, HPTLC

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. It has an empirical formula of C₉H₁₉N₆O and molecular weight of 286.3323. 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). 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 HPLC², Hypersensitivity reaction to abacavir is strongly associated with the presence of the HLA-B 5701 allele³. Simple and Reliable HPLC Method of Abacavir Determination in Pharmaceuticals, Human Serum and Drug Dissolution Studies from Tablets⁴. Spectrophotometric determination of abacavir sulphate⁵, HPTLC method for simultaneous determination of Lamivudine and Abacavir Sulphate in tablet dosage form⁶ were reported.

*Corresponding Author:
pradeep_alpine@yahoo.co.in

Fig. 1: Chemical structure of Abacavir.

The objective of this work was to develop a new, simple, economic, rapid, precise, and accurate HPTLC method for quantitative analysis of abacavir as bulk drug and in pharmaceutical formulations, and to validate the method in accordance with ICH guidelines⁷.

Materials and Methods
Pure standard of Abacavir (Assayed purity 99.97 %) was obtained as a gift sample from Ranbaxy labs Pvt. Ltd, Jammm (H.P). The gift sample was used as standard without further purification. Silica gel 60 F 254 TLC plates (20x10cm) were used as stationary phase. All chemicals and reagents used were of analytical grade and obtained from Qualigens.

Commercial pharmaceutical preparation (Zingen)
Validated HPTLC Method for the Determination of Tenofovir as Bulk Drug and in Pharmaceutical Dosage Form

Kumar Pradeep¹, Dwivedi S.C.¹ and Kushnoor Ashok²
¹School of Pharmacy, Suresh Gyan Vihar University, Jaipur, Rajasthan INDIA
²Shri Gopichand College of Pharmacy, Baghapar, Uttar Pradesh INDIA

Available online at: www.isca.in
(Received 1st August 2011, revised 11th August, accepted 24th August 2011)

Abstract

A simple, accurate, precise and rapid high performance thin layer chromatographic method has been developed and validated for the estimation of Tenofovir in tablet dosage forms. The method employed TLC aluminium plates precoated with silica gel 60 F 254 as the stationary phase. The mobile phase used was a mixture of (Chloroform: Methanol 8:5: 1.5Vol%). The detection of spot was carried out at 270nm. The calibration curve was found to be linear between 200 to 1200 ng mL⁻¹ with regression coefficient of 0.9994. The proposed method can be successfully used to determine the drug content of marketed formulation. The accuracy of the proposed method was determined by recovery studies and found to be 98.39 to 101.19 %. The proposed method is applicable to routine analysis of Tenofovir in bulk and pharmaceutical formulations. The proposed method was validated according to various ICH parameters like linearity, accuracy, precision, specificity, limits of detection, limits of quantification, range and solution stability.

Key words: Tenofovir, validation, ICH guidelines, HPTLC.

Introduction

Tenofovir is chemically [(2R)-1-(6-aminopurin-9-yl) propan-2-yl] oxymethyl phosphonic acid figure 1. It is a white crystalline powder used as antiretroviral agents, for the treatment of HIV infection. It has an empirical formula of C₁₃H₁₆N₄O₄P and molecular weight of 287.2123. Tenofovir belongs to a class of antiretroviral drugs known as nucleotide analogue reverse transcriptase inhibitors (NRTIs), which block reverse transcriptase, an enzyme crucial to viral production in HIV-infected people. Food and drug administration granted approval to market viread (TENOFOVIR) for the treatment of chronic hepatitis B. Literature survey reveals that very few analytical methods has been established for the estimation of tenofovir and emtricitabine in bulk and in tablet dosage form by spectrophotometric method. Simultaneous determination of emtricitabine and Tenofovir by area under curve and dual wavelength spectrophotometric method, relevance of a combined UV and single mass spectrometry detection for the determination of tenofovir in human plasma by HPLC in therapeutic drug monitoring, segmented polyurethane intravaginal rings for the sustained combined delivery of antiretroviral agents dapivirine and tenofovir, simultaneous quantification of a non-nucleoside reverse transcriptase inhibitor efavirenz, a nucleoside reverse transcriptase inhibitor emtricitabine and a nucleoside reverse transcriptase inhibitor tenofovir in plasma by liquid chromatography positive ion electrospray tandem mass spectrometry, RP-HPLC method for the determination of tenofovir in pharmaceutical formulations and spiked human plasma, spectrophotometric determination of tenofovir disoproxil fumarate after complexation with ammonium molybdate and picric acid, quantitative analysis of tenofovir by titrimetric, extractive ion-pair spectrophotometric and charge-transfer complexation methods.

Figure-1

Chemical structure of Tenofovir
The objective of this work was to develop a new, simple, economic, rapid, precise, and accurate HPTLC method for quantitative analysis of tenofovir, and to validate the method in accordance with ICH guideline.
VALIDATED HPTLC METHOD FOR THE DETERMINATION OF EMTRICITABINE AS BULK DRUG AND IN CAPSULE DOSAGE FORM

Pradeep Kumar 1, S.C. Dwivedi 1, Ashok Kushmoo 2

1 School of Pharmacy, Suresh Gyan Vihar University, Jaipur, Rajasthan, (INDIA)
2 Shri Gopichand College of Pharmacy, Baghpur, Uttar Pradesh, (INDIA)

E-mail of Corresponding Author: pradeep_alpine@yahoo.co.in

Abstract

A simple, accurate, precise, and rapid high performance thin layer chromatographic method has been developed and validated for the estimation of Emtricitabine in capsule dosage forms. The method employed TLC aluminium plates precoated with silica gel 60 F 254 as the stationary phase. The mobile phase used was a mixture of (Chloroform: Methanol 8.5: 1.5v/v). The detection of spot was carried out at 275nm. The calibration curve was found to be linear between 200 to 2200 ng mL\(^{-1}\) with regression coefficient of 0.9992. The proposed method can be successfully used to determine the drug content of marketed formulation. The accuracy of the proposed method was determined by recovery studies and found to be 98.79 to 99.61 %. The proposed method is applicable to routine analysis of Emtricitabine in bulk and pharmaceutical formulations. The proposed method was validated according to various ICH parameters like linearity, accuracy, precision, specificity, limits of detection, limits of quantification, range and solution stability.

Keywords: Emtricitabine, Validation, ICH guidelines, HPTLC

1. Introduction

Emtricitabine is chemically 4-amino-5-fluoro-1-[2[R, 5S]-2-(hydroxymethyl)-1, 3-oxathiolan-5-yl] pyrimidin-2-one (Fig. 1). It is a white crystalline powder used as antiretroviral agents, for the treatment of HIV infection. It has an empirical formula of C\(_9\)H\(_{10}\)FN\(_3\)O\(_2\)S and molecular weight of 247.2470. Emtricitabine 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 estimation of Emtricitabine viz. Simultaneous ultraviolet spectrophotometric estimation of Tenofovir and Emtricitabine in Bulk and in Tablet dosage form 2. A Validated RP-HPLC Method for Simultaneous Estimation of Emtricitabine and Tenofovir in a Tablet Dosage Form 3. A simple HPLC method for quantitation of Emtricitabine in capsule dosage form 4. Simultaneous determination of Emtricitabine and Tenofovir by area under curve and dual wavelength spectrophotometric method 5. Emtricitabine: Inhibitor and substrate of multidrug resistance associated protein 6. Extractive spectrophotometric methods for the determination of emtricitabine in dosage form using safranin 7. Development and validation of Emtricitabine and Tenofovir in Pure and in fixed dose combination by UV Spectrophotometry 8. Low Level Determinations of Methyl Methanesulphonate and Ethyl Methanesulphonate Impurities in Emtricitabine Active Pharmaceutical Ingredient by LC/MS/MS Using Electrospray Ionization 9.
Research Journal of Pharmaceutical, Biological and Chemical Sciences

Development and Validation of HPTLC Method for the Determination of Efavirenz as Bulk Drug and in Tablet Dosage form

Pradeep Kumar¹, SC Dwivedi¹, Ashok Kushnoor²

¹School of Pharmacy, Suresh Gyan Vihar University, Jaipur, Rajasthan, (INDIA)
²Shri Gopichand College of Pharmacy, Baghpur, Uttar Pradesh, (INDIA)

ABSTRACT

A simple, accurate, precise, and rapid high performance thin layer chromatographic method has been developed and validated for the estimation of Efavirenz in tablet dosage forms. The method employed TLC aluminium plates precoated with silica gel 60 F 254 as the stationary phase. The mobile phase used was a mixture of Toluene: Ethyl acetate: Formic acid (10: 3: 1 v/v). The detection of spot was carried out at 254 nm. The calibration curve was found to be linear between 300 to 1800 ng mL⁻¹ with regression coefficient of 0.9991. The proposed method can be successfully used to determine the drug content of marketed formulation. The accuracy of the proposed method was determined by recovery studies and found to be 99.38 to 99.68 %. The proposed method is applicable to routine analysis of Efavirenz in bulk and pharmaceutical formulations. The proposed method was validated according to various ICH parameters like linearity, accuracy, precision, specificity, limits of detection, limits of quantification, range and solution stability.

Keywords: Efavirenz, Validation, ICH guidelines, HPTLC

*Corresponding author
Email: pradeep_alpine@yahoo.co.in
Development and Validation of HPTLC Method for the Determination of Nelfinavir as Bulk Drug and in Tablet Dosage Form

Pradeep Kumar¹, S.C. Dwivedi¹, Ashok Kushnood²

¹School of Pharmacy, Suresh Gyan Vihar University, Jaipur, Rajasthan, (INDIA)
²Shri Gopichand College of Pharmacy, Baghaprat, Uttar Pradesh, (INDIA)

ABSTRACT
A simple, accurate, precise, and rapid high performance thin layer chromatographic method has been developed and validated for the estimation of Nelfinavir in tablet dosage forms. The method employed TLC aluminium plates precoated with silica gel 60 F 254 as the stationary phase. The mobile phase used was a mixture of n-Butanol: Ethyl acetate: Diethyl ether (5: 4: 1 v/v). The detection of spot was carried out at 254nm. The calibration curve was found to be linear between 400 to 2400 ng mL⁻¹ with regression coefficient of 0.9993. The proposed method can be successfully used to determine the drug content of marketed formulation. The accuracy of the proposed method was determined by recovery studies and found to be 99.44 to 100.52 %. The proposed method is applicable to routine analysis of Nelfinavir in bulk and pharmaceutical formulations. The proposed method was validated according to various ICH parameters like linearity, accuracy, precision, specificity, limits of detection, limits of quantification, range and solution stability.

Keywords : HPTLC, Nelfinavir, Validation, ICH guidelines

INTRODUCTION
Nelfinavir is chemically (3S,4αS,8αS)-(N-tert-butyloxycarbonylamino)-4-phenyl-3,4,5,6,7,8,8a-octahydro-1H-squoline-3-carboxamide (Fig. 1). It is a white powder form and used as antiretroviral agent, for the treatment of HIV infection. It has an empirical formula of C₂₀H₂₅N₂O₆S and molecular weight of 567.7820. Nelfinavir belongs to a class of antiretroviral drugs known as protease inhibitors with activity against Human Immunodeficiency Virus Type 1 (HIV-1). Literature survey reveals that very few analytical methods has been established for the determination of Nelfinavir viz. Nelfinavir (Viracept) is a potent and orally bioavailable human immunodeficiency virus HIV-1 protease inhibitor and is being widely prescribed in combination with HIV reverse transcriptase inhibitors for the treatment of HIV infection. Spectrophotometric estimation of nelfinavir in tablet dosage forms, Spectrophotometric Methods for the Determination of Nelfinavir in either bulk form or dosage forms, HIV-1 Protease Inhibitors Nelfinavir and Atazanavir Induces Malignant Gloma Death by Triggering Endoplasmic Reticulum Stress, Evaluation of an International Pharmacopeia method for the analysis of nelfinavir by liquid chromatography, Stress degradation studies of nelfinavir by Fourier transform infrared spectroscopy, Stability indicating high performance thin-layer chromatographic determination of nelfinavir mesylate as bulk drug and in pharmaceutical dosage form.

The objective of this work was to develop a new, simple, economic, rapid, precise, and accurate HPTLC method for quantitative analysis of Nelfinavir, and to validate the method in accordance with ICH guidelines.

EXPERIMENTAL DETAILS
Materials
Pure standard of Nelfinavir (Assigned purity 99.98%) was obtained as a gift sample from Hetero Drugs Ltd, Hyderabad, Andhra Pradesh, India. The gift sample was used as standard without further purification. Silica gel 60 F 254 TLC plates (20x10cm) were used as stationary phase. All chemicals and reagents used were of analytical grade and obtained from Qualigen. Commercial pharmaceutical preparation (Viracept) which was claimed to contain 625mg of Nelfinavir was used in analysis. The chemical structure and purity of the