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Development and validation of assay method for estimation of quetiapine fumarate by RP-HPLC

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Abstract

A simple, rapid, accurate and precise RP-HPLC method has been developed for estimation of Quetiapine Fumarate from tablet dosage form. Assay method was developed using Zorbax ODS C-18, 150 mm x 4.6 mm, 5.0 µm as stationary phase. Buffer:ACN (65:35) was used as mobile phase. % Assay was found to be 98.01-98.06. The method was validated in terms of linearity, precision, accuracy, specificity and robustness. All the validation were done as per ICH guidelines.

Key-Words: Quetiapine Fumarate, RP-HPLC, ICH

Introduction

Quetiapine Fumarate is a White to off-white crystalline powder. Drug having efficacy in the treatment of schizophrenia and bipolar disorder is mediated through a combination of dopamine type 2 (D_2) and serotonin type 2 ($5HT_2$) antagonism. Chemically it is 2-[2-(4-Dibenzo[b,f]-[1,4]thiazepin-11-yl-1-piperazenyl)ethoxy]ethanol fumarate (2:1) salt. Literature survey revealed that, several spectrophotometric and chromatographic methods for estimations of Quetiapine Fumarate in bulk, biological fluids and in their pharmaceutical formulations. But no method was reported for assay development.So here aim was to develop the accurate, precise, rapid and economic assay method for estimation of Quetiapine Fumarate by HPLC.

Material and Methods

Materials

Quetiapine Fumarate: - Working standard and its claimed purity was 98.20%.

Quetiapine Fumarate Sustained Release Tablet (label claim 200 mg) and placebo, which was prepared at Mission Vivacare R&D Center, Pithampur, MP.

Reagents and Chemicals

Acetonitrile: -HPLC grade, Rankem, India.

Methanol: - HPLC grade, Rankem, India.

Milli-Q water: - It was purified by Millipore Corporation's system.

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Instruments, Apparatus and equipment

High Performance Liquid chromatography system (HPLC): Agilant Liquid Chromatography with PDA detector

Chromatographic software:– E Z Crome Elite

A double beam UV-visible spectrophotometer having two matched cells with 1cm light path: - UV- 2450, Shimadzu, Japan.

Analytical Balance: - AD 265S, Mettler Toledo, Schwerzenland.

pH Meter: - Labindia, India.

Sonicator: - 5510, Branson Ultrasonics Corporation, Danbury, CT, USA.

Methods

Estimation of Quetiapine Fumarate by RP-HPLC

Standard preparation

Weigh and transfer about 30 mg of Quetiapine Fumarate reference standard to a 100 mL volumetric flask and dissolve and dilute up to the mark with mobile phase.

Sample preparation

Weigh accurately 20 tablet crush and weigh powder equivalent to 30mg of label amount into 100 mL volumetric flask add about 75 mL of mobile phase, sonicate at for about 15 min with intermittent shaking, keep achieve room temperature make up to volume with mobile phase

Mobile phase Preparation

Mix 350 ml of Acetonitrile and 650ml of buffer solution, sonicate and filter through 0.45µ membrane filter and degas.

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Buffer Preparation

Added 1ml orthophosphoric acid in 1000ml water and adjust Ph 3.0 with triethyl amine.

Blank Solution: Use mobile phase as blank.

Optimized HPLC Parameters

Instrument : Agilant Liquid Chromatography with PDA detector
Column : Zorbax ODS C-18, 150 mm x 4.6 mm, 5.0 µm
Flow Rate : 0.6 mL/min
Injection volume : 10 µL
Column temperature : Ambient
Sample cooler Temperature : Ambient
Detection : 257 nm
Run time : 15 minutes

Procedure: Injection sequence

Description	No of Injection
Blank	01
Standard solution	05
Test solution 1	02
Bracketing standard	01

Estimation of Quetiapine Fumarate by RP-HPLC

$$\%Assay = \frac{AT}{AS} \times \frac{WS}{WT} \times \frac{\text{average wt}}{\text{label claim}} \times P$$

Where,
AT= average area due to quetiapine fumarate in test solution.
AS= average area of peak response of quetiapine fumarate in standard solution.
WS=weight of standard in mg.
WT=weight of sample in mg.
P =purity of standard.

Results and Discussion

The Proposed method was found to be simple, accurate, economical and rapid for estimation of Quetiapine Fumarate. %Assay was found in between 98.01-98.06.The accuracy, precision, robustness and linearity of the method was determined by, calculating mean percentage recovery.

Table 1: Results for Test Solution

S/No.	Label Claimed(mg)	Area of Test Solution	% Assay
1	200	3631432	98.01
2	200	3630342	98.06

Chromatograms

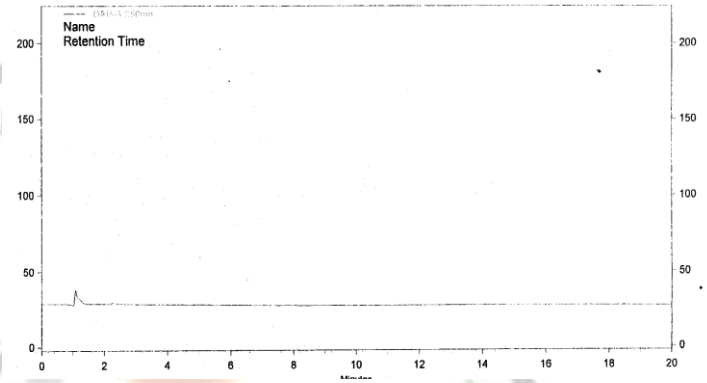


Fig. 1: Chromatogram of blank

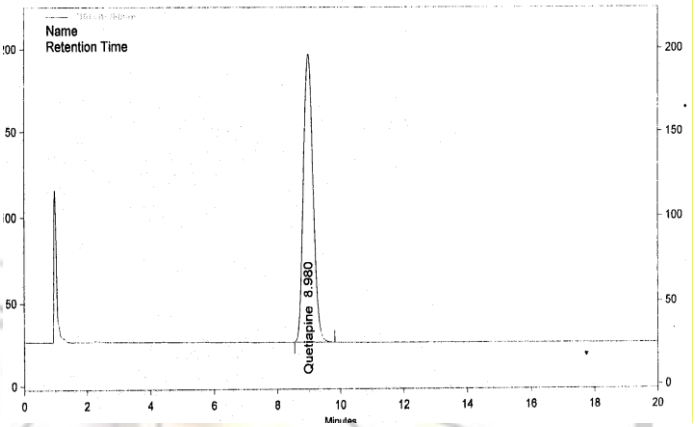


Fig. 2: Chromatogram of Sample Solution

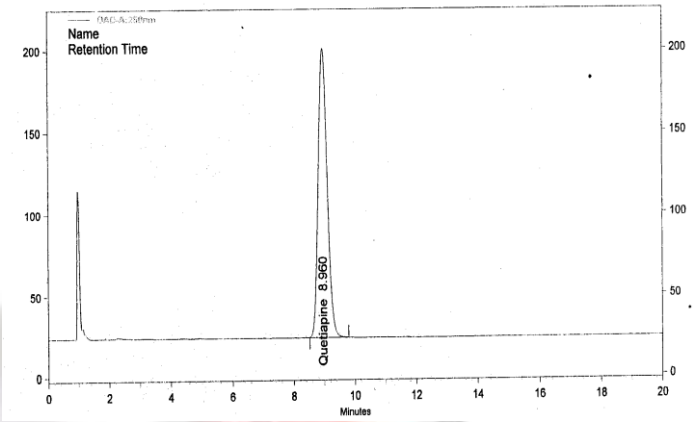
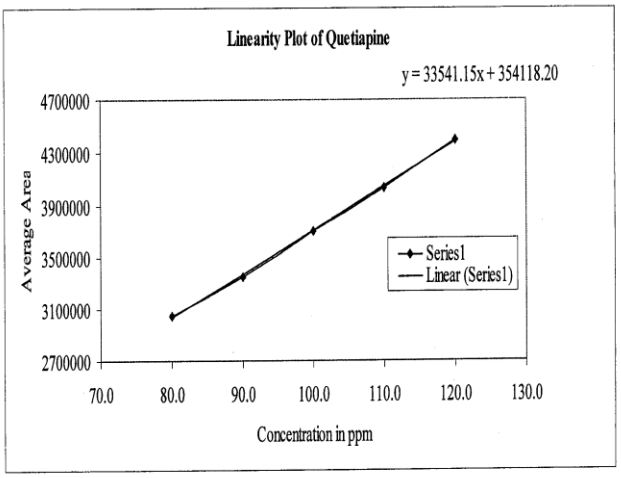


Fig. 3: Chromatogram of Test Solution

Validation parameters

Linearity: Linearity was found to be .9999



Parameters	% Assay	S.D	%R.S.D
Accuracy	98.05	.56	0.056
Method Precision	99.56	0.12	0.012
Intermediate Precision	99.66	0.24	0.024
Robustness	98.46	0.17	0.017

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