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Determination of quetiapine fumarate and cilostazol in bulk and tablet by UV-spectrophotometry

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ABSTRACT

Simple, rapid, sensitive and accurate UV- Spectrophotometric methods have been developed for estimation of Quetiapine fumarate and Cilostazol in pharmaceutical formulation. In water, QTF showed absorbance maxima at 290 nm. In acetonitrile (30% v/v) CLZ showed maximum absorbance at 258 nm. Linearity was observed in the concentration range 6 - 54 µg/ml (r^2= 0.9999) for QTF and 3 - 21 µg/mL (r^2= 0.9993) for CLZ. Amounts of drug estimated from the tablet formulations were in good agreement with label claim. Both the methods were validated statistically and by recovery studies.

Key words: UV- Spectrophotometry; Quetiapine fumarate**,** Cilostazol**.**

INTRODUCTION

Quetiapine fumarate (QTF), 2-[2-(4-(Dibenzo [b, f] [1, 4] thiazepin-11-yl-1-piperazenyl] ethoxy) ethanol] fumarate) is a dibenzothiazepine derivative and used as antipsychotic drug[1]. Cilostazol (CLZ), 6-[4-(1-cyclohexyl-1*H*-tetrazol-5-yl) butoxyl]-3, 4-dihyro-2(1*H*)-quinolinone is a phosphodiestrase inhibitor with antiplatelet and vasodilating activity[1].

Literature survey revealed spectrophotometric[2] and HPLC[3 - 5] methods for estimation of QTF in bulk, formulations and biological fluids. Few chromatographic methods[6 - 9] have been reported for estimation of CLZ in bulk, formulation and biological fluids. Both these drugs are not official in IP, BP and USP. Therefore, an attempt has been made to develop simple UV-Spectrophotometric method and validate it for accuracy, precision and ruggedness[10].

MATERIAL AND METHODS

- All the measurement were made using UV-visible spectrophotometer (Shimadzu-2450 with UV probe 2.21 software), with 10 mm quartz cell and spectral bandwidth 1nm.
- Chemicals used were of analytical grade

Preparation of standard stock solutions QTF and CLZ

Accurately weighed 10 mg of QTF was dissolved in 100 ml of double R.O water to obtain 100 ug/ml of working standard solution. Stock solution 100 ug/ml for CLZ was prepared by dissolving 10 mg of CLZ in 100 ml of acetonitrile (30% v/v). Different aliquots were taken from the stock solutions, diluted to 10 ml mark with respective solvents to obtain series of concentrations. Absorbances were measured at 290 nm for QTF and 258 nm for CLZ against blank. The calibration curve was linear in the concentration range 6-54

µg/ml (Y = 0.0187 X + 0.0044; r^2= 0.9999) for QTF and 3 - 21 µg/ml (Y = 0.04525 X + 0.0055; r^2 = 0.9993) for CLZ.

Preparation of Sample Solution

An accurately weighed amount of tablet powder (QTF) equivalent to 10 mg was dissolved in 100 ml of double R.O. water, sonicated for 15 min and filtered through Whatmann filter paper no.41. After appropriate dilutions, absorbance of sample was recorded at 290 nm and concentration was determined by linear regression equation.

An accurately weighed amount of tablet powder (CLZ) equivalent to 10 mg was dissolved in 100 ml of acetonitrile (30% v/v), sonicated for 15 min and filtered through Whatmann filter paper no 41.After appropriate dilutions, absorbance of sample was measured at 258 nm and concentration was determined by linear regression equation.

The results of analysis for QTF and CLZ are shown in Table 2.

Recovery studies

To study the accuracy of the proposed method, recovery experiments were carried out by adding a known amount of standard drug solution to preanalysed sample solution at three different levels i.e. 80%, 100% and 120% and re-analysed the samples using proposed method. The results are shown in Table 2.

RESULTS AND DISCUSSION

QTF in double R.O. showed λmax at 290

Table 1: Results of assay

Label claim	*Amount found ± SD	Amount found	% RSD
100 mg of QTF	99.61 ± 0.54	99.61	0.55
50 mg of CLZ	50.37 ± 0.89	100.75	0.88

* mean of five estimations

Table 2: Summary of validation

Parameters	QTF	CLZ
Linearity (µg/ml)	6-54	3-21
Accuracy (%Recovery*)	99.23-100.36 %	98.84-100.60
%RSD	0.31	0.43
Precision (%RSD)		
Intra-day [n=3]	0.46 - 0.59	0.32 - 0.62
Inter-day [n=3]	0.44 - 0.60	0.33 - 0.72
Repeatability [n=6]	0.24	1.03
Ruggedness (%RSD)		
Analyst –I [n = 3]	0.32	0.65
Analyst –II [n = 3]	0.43	0.74

* mean of three estimation at each level

nm. CLZ in acetonitrile (30% v/v) showed λmax at 258 nm. QTF and CLZ follows linearity in the concentration range 6 - 54 µg/ml and 3 - 21 µg/ml at respective wavelengths. The analysis of tablet formulation by proposed methods was in good agreement with the label claimed. The methods were validated for accuracy, precision and ruggedness. The low values of %RSD indicate method is accurate and precise. Ruggedness of the proposed methods was studied with the help of two analysts and proven to be rugged. The results from validation studies are shown in Table 2. The proposed methods are simple, rapid, accurate, economical and used for the routine analysis of QTF and CLZ from marketed formulations.

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