ISSN: 2456-9909 (Online)

International Journal of Research in AYUSH and Pharmaceutical Sciences

Research Article

ESTIMATION OF PAROXETINE HYDROCHLORIDE FROM ITS TABLET FORMULATION BY UV SPECTROPHOTOMETRY

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Keywords: Paroxetine, Calibration, Validation, Estimation.

ABSTRACT

A simple, precise and accurate UV Spectrophotometric method was developed for the estimation of Paroxetine hydrochloride. The developed method obeyed Beer-Lambert's law in the concentration range of 5-30 µg/ml with a correlation coefficient of 0.995. The recovery study was carried out at three different levels and was found to be satisfactory. The percent amount of drug estimated by this method is 100%, found to be in good agreement with label claim of marketed tablet formulation. The validation parameters like linearity, precision, accuracy, robustness and ruggedness were studied and were found to be within limits. The proposed method can be adopted for routine quality control analysis of estimation of Paroxetine hydrochloride in pharmaceutical formulation.

INTRODUCTION

Paroxetine hydrochloride is a potent and selective serotonin reuptake inhibitor[1,2]. Chemically Paroxetine hydrochloride is (-)-*trans*-4R-(4'-fluorophenyl)-3*S*-[(3',4'-methylenedioxyphenoxy) methyl] piperidine hydrochloride hemihydrate (Fig. 1)[3]. Paroxetine hydrochloride is indicated for the treatment of depression, obsessive-compulsive disorder, panic disorder and social phobia[4]. Paroxetine acts by potentiation of serotonergic activity in the central nervous system resulting from inhibition of neuronal reuptake of serotonin (5-hydroxy-tryptamine, 5-HT)[5].

Literature survey reveals that very few UV Spectrophotometric methods were reported for the determination of Paroxetine hydrochloride[6]. The present study report a simple, rapid, precise and accurate UV Spectrophotometric method for the estimation of Paroxetine hydrochloride in bulk drug and in tablet dosage form and the developed method was validated as per ICH guidelines[7].

MATERIALS AND METHODS

Chemicals and Reagents

Pharmaceutical grade Paroxetine hydrochloride was obtained as gift sample from Spectrum Pharma Research Solutions, Hyderabad, India. Paroxetine hydrochloride (PARADISE XR 12.5) tablets were purchased from local market. Methanol (AR grade) was purchased from E.Merck (India) Ltd., Mumbai, India and was used as solvent. Fresh purified distilled water was used throughout the experiment.

Instruments

UV Spectrophotometer: Shimadzu-UV1800 Double Beam UV-Visible Spectrophotometer

Weighing balance: Shimadzu-BL220H Digital Weighing Balance

Preparation of standard stock solution

10 mg of Paroxetine hydrochloride was accurately weighed, transferred to 10 ml volumetric flask and dissolved in 7 ml of methanol. Sonicated the solution for few minutes and dissolved the drug completely. Then it was filtered through 0.45 µ filter and the volume was made up to 10 ml with methanol to get a concentration of 1 mg/ml stock solution. Further pipetted 1.0 ml of the above stock solution into a 10 ml volumetric flask and diluted up to the mark with diluent to obtain the concentrations of 100 µg/ml. Different aliquots were taken from standard stock solution and diluted with methanol separately to prepare series of concentrations from 5-30 µg/ml.

Preparation of sample solution

Twenty tablets of Paroxetine hydrochloride were weighed, finely powdered and calculated the average weight. An accurately weighed portion of powder sample equivalent to 10 mg of Paroxetine hydrochloride was transferred to 10 ml volumetric flask and dissolved in 7 ml of the methanol. Sonicated the solution for few minutes and dissolved the drug completely. Then it was filtered through 0.45 µ filter and the volume was made up to 10 ml with methanol. Further pipetted 2 ml of the above stock solution into a 10 ml volumetric flask and diluted up to the mark with methanol to obtain the concentration of 20 µg/ml.

Selection of solvent

The solubility of Paroxetine hydrochloride was determined in a variety of polar and non-polar solvents. Based on the solubility of the compound finally methanol was selected due to its positive results. Absorbance was measured at selected maximum wave length (200 nm to 400 nm) based on the overlain spectra of drug spectrum.

Selection of wave length

The selection of wave length for the estimation of Paroxetine hydrochloride, a suitable diluted stock solution contains 20 µg/ml and the solution were scanned between 200-400 nm by using methanol as blank. From the overlain spectra, by the observation of spectral characteristics of Paroxetine hydrochloride, the wave length selected was 235 nm. The stability was performed by measuring the absorbance of same solution at different intervals. It was observed that Paroxetine hydrochloride in methanol were stable for more than 4 hours at all the selected wave length.

Specificity

The wave length was specific for Paroxetine hydrochloride according to its structure. A study conducted to establish specificity of blank and placebo using the spectrophotometric conditions defined for the proposed method. It was found that there is no interference due to excipients in the tablet formulation and also found good correlation between the absorbances of standard and sample.

Linearity

Working standard solutions of Paroxetine hydrochloride were prepared from the standard solution of 100 µg/ml. Different aliquots were taken from standard stock solution and diluted with methanol separately to prepare 5 µg/ml, 10 µg/ml, 15 µg/ml, 20 µg/ml, 25 µg/ml and 30 µg/ml solutions respectively. Linearity was evaluated by taking different concentrations in the range of 5-30 µg/ml and the absorbances were measured. Each measurement was carried out in triplicate. The correlation coefficient was found to be 0.995. Linearity was proven by linear regression analysis by the least square method. By taking the concentration and absorbance values calibration curve was plotted taking concentration on x-axis and absorbance on y-axis which showed a straight line in the calibration curve obeyed linearity. The calibration curve of Paroxetine hydrochloride was shown in Fig. 2. The linearity results were furnished in Table 1.

Precision

The concentration used for the precision studies is 20 µg/ml and was assumed as 100%. The precision of the method was determined by intra-day and inter-day analysis i.e., the analysis of formulation was repeated six times in the same day and on six consecutive days. The amount of drug was determined and %RSD was calculated. The %RSD of Paroxetine hydrochloride should not be more than 2.0. The intra-day and inter-day precision results were furnished in Table 2 and Table 3.

Accuracy

The accuracy of the method was determined by standard addition method. A known amount of standard drug was added to the fixed amount of pre-analyzed tablet formulation solution of Paroxetine hydrochloride and the procedure was followed as per the analysis of formulation. Percent recovery was calculated by comparing the absorbance before and after the addition of the standard drug. The standard addition method was performed at three concentration levels of 50%, 100% and 150%. The solutions were analyzed in triplicate at each level as per the proposed method. Each recovery was made three times and the average value was considered. The percent recovery at each level was calculated. The results of recovery studies of Paroxetine hydrochloride were furnished in Table 4.

Robustness

The robustness study was performed by slight modification in method parameters of Paroxetine hydrochloride. Sample of Paroxetine hydrochloride at 20 µg/ml concentration were analyzed under these changed experimental conditions. It was observed that there were no marked changes in absorbances, which demonstrated that the developed method was robust in nature.

Ruggedness

Ruggedness of the method was confirmed by the analysis of formulation was done by different analysts. Sample of Paroxetine hydrochloride at 20 µg/ml concentration were analyzed by different

analysts. It was observed that there were no marked changes in absorbances, which demonstrated that the developed method was rugged in nature.

Assay

Instrument was allowed to stand for 10 minutes to stabilize. Then the instrument parameters viz. start wavelength, end wavelength data interval, scan speed, slit width and sample information were entered in the instrument. Then base line correction was performed by keeping the blank in both the sample and reference compartments. The absorbances of standard solutions and sample solutions were determined against blank (methanol) at 235 nm. Paroxetine hydrochloride was assayed from the commercial tablet formulations by calibration curve drawn between absorbance and concentration of Paroxetine hydrochloride with label claim of 10 mg. Sample of Paroxetine hydrochloride at 20 µg/ml concentration was used for estimation. The assay results were furnished in Table 5.

RESULTS AND DISCUSSION

The absorption spectrum of Paroxetine hydrochloride in methanol was found to be 235 nm. Paroxetine hydrochloride was linear with the concentration range of 5-30 µg/ml. The regression equation of the linearity plot of concentration of Paroxetine hydrochloride over its peak area was found to be y=0.01x+0.009 (R^2=0.995), where x is the concentration of Paroxetine hydrochloride (µg/ml) and y is the corresponding absorbance. The %RSD for intra-day precision and inter-day precision of Paroxetine hydrochloride was found to be 1.10 and 1.74. The percent recovery of Paroxetine hydrochloride was in the range of 97.2% to 101.3% and the % mean recovery was found to be 98.93% by the proposed method. The high percentage of recovery indicates that the proposed method is highly accurate. The % assay of Paroxetine in commercial tablet formulations was 100%, indicating that excipients used in tablet formulations did not interfere with the estimation of the drug Paroxetine hydrochloride by the proposed UV spectrophotometric method. The assay showed that the drug content of this product to be in accordance with the labeled claim.

CONCLUSION

In the present investigation, an attempt has been made to develop simple, sensitive, precise and accurate UV spectrophotometric method for the determination of Paroxetine hydrochloride in bulk sample and pharmaceutical formulations. The advantage of proposed method was its simple procedure for its sample preparation and more economical. The method was validated as per International Conference on Harmonization Guidelines. The satisfying recoveries, low coefficient of variation and assay results confirmed the suitability of proposed method for the routine quality control analysis of Paroxetine hydrochloride in pharmaceutical formulations.

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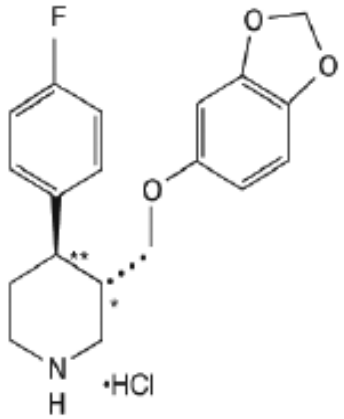

Fig. 1: Chemical structure of Paroxetine hydrochloride

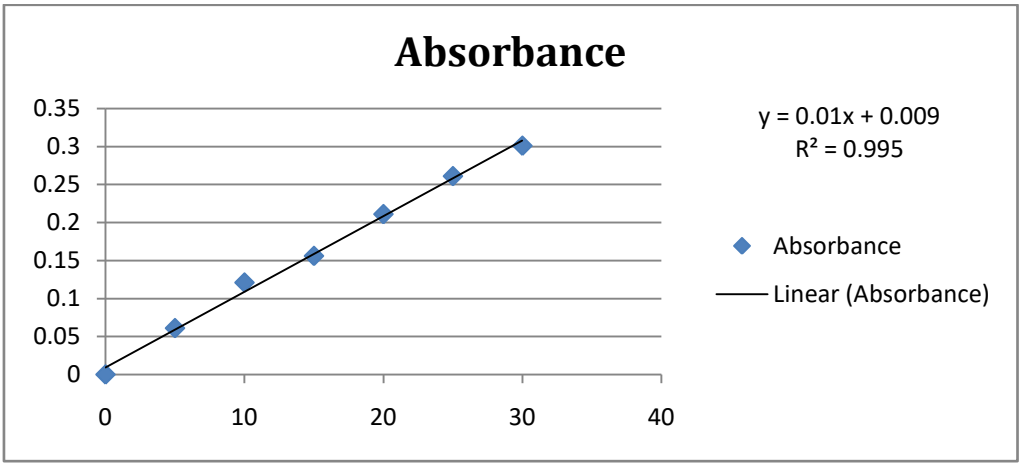

Fig.2: Calibration curve of Paroxetine hydrochloride

Table 1: Linearity results of Paroxetine hydrochloride

S. No.	Concentration (µg/ml)	Absorbance
1.	0	0
2.	5	0.061
3.	10	0.121
4.	15	0.156
5.	20	0.211
6.	25	0.261
7.	30	0.301
	Slope	0.01
	Intercept	0.009
	Correlation Coefficient	0.995

Table 2: Intra-day precision results of Paroxetine hydrochloride

S. No.	Time (Hours)	Absorbance
1	0	0.214
2	3	0.217
3	6	0.213
4	9	0.215
5	12	0.211
6	15	0.211

Mean	0.213
SD	0.00235
%RSD	1.10

Table 3: Inter-day precision results of Paroxetine hydrochloride

S. No.	Time (Days)	Absorbance
1	1	0.213
2	2	0.209
3	3	0.215
4	4	0.211
5	5	0.219
6	6	0.217
Mean		0.214
SD		0.00374
%RSD		1.74

Table 4: Recovery studies for Paroxetine hydrochloride

Level	Standard concentration (µg/ml)	Concentration added (µg/ml)	Concentration found (µg/ml)	% Recovery	% Mean recovery
50%	10	5	4.86	97.2	98.93
100%	10	10	10.33	101.3	
150%	10	15	14.7	98.0	

Table 5: Assay results of Paroxetine hydrochloride

Formulation	Label claim	Amount found	%Assay
PARADISE XR 12.5	12.5 mg	12.5 mg	100%

Cite this article as:
A. Lakshmana Rao, A.B. Hima Bindu, G. Jyothi Stella, Y. Prema Latha and K. Kiranmai. Estimation of Paroxetine Hydrochloride from its Tablet Formulation by Uv Spectrophotometry. International Journal of Research in AYUSH and Pharmaceutical Sciences, 2019;3(8):359-363.
Source of support: Nil, Conflict of interest: None Declared

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