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Research Article

DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC DETERMINATION OF ARIPIPRAZOLE IN BULK AND TABLET FORMULATION

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ABSTRACT

Simple, sensitive and reliable UV-spectroscopic methods for estimation of Aripiprazole have been attempted. Method was developed at Wavelength 216nm.This method was developed for the determination of Aripiprazole in pure form and formulation. It has absorption maximum at 216 nm and obeys beer's law. Results of analysis were validated statistically and by recovery study. This method is successful employed for the determination of Aripiprazole in tablet formulation.

Keywords: UV spectrophotometer, Methanolic HCL, Aripiprazole, Recovery, Validation.

INTRODUCTION

Aripiprazole (7-{4-[4-(2, 3-dichlorophenyl) piperazin-1-yl] butoxy}-3, 4- dihydroquinolin - 2(1*H*)-one) is a psychotropic agent belonging to the chemical class of benzisoxazole derivatives and is indicated for the treatment of schizophrenia. The structural formula of aripiprazole is shown in fig. no. 1. Methods reporter are simple hence need arises to develop a simple, accurate UV method for analysis of aripiprazole in formulation.

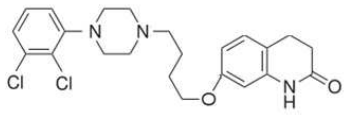

Fig. 1: Structure of Aripiprazole

MATERIAL AND METHODS

Pure drugs of Aripiprazole was obtained from VAMA Pharma, Nagpur, India. The commercial formulations of Aripiprazole used for analysis is Aripraz 15mg (VAMA Pharma). A Shimadzu UV/VIS (1700) spectrophotometer with 1cm matched quartz cells were used for all the special measurements. All the chemicals used were of A.R Grade. Stock solution was prepared by An accurately weighed quantity of Aripiprazole 10 mg was transferred to the 100 ml volumetric flask and dissolved in 10 ml of 0.1N Methanolic HCL and sonicate for 5 min. The volume was made up to the mark with Distilled water (100 µg/ml). 2 ml solution was diluted up to 10 ml to get 20 µg/ml concentration for selection of analytical wavelength. Solution was scanned and 216 nm was selected (Fig. no. 2)

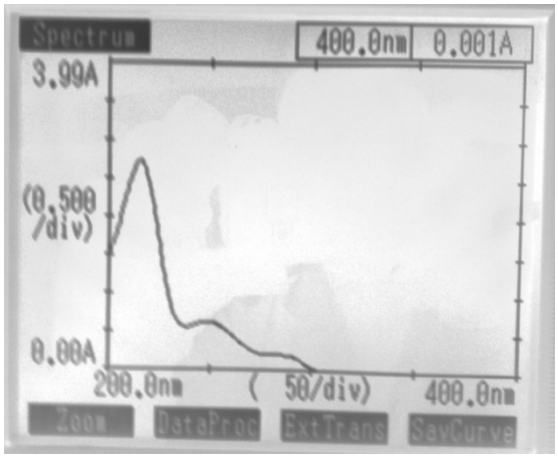

Fig. 2: Absorbance spectrum of Aripiprazole

The aliquot portion of stock standard solutions of Aripiprazole was diluted appropriately with solvent to get a series of concentration between 4-20 (µg /ml) of Aripiprazole to plot calibration curve.

Table 1: Observations of Beer-Lambert's study for Aripiprazole (Standard)

Sr.No.	Conc. In µg /ml	Absorbance at 216 nm
1.	4	0.536
2.	8	1.075
3.	12	1.61
4.	16	2.144
5.	20	2.67

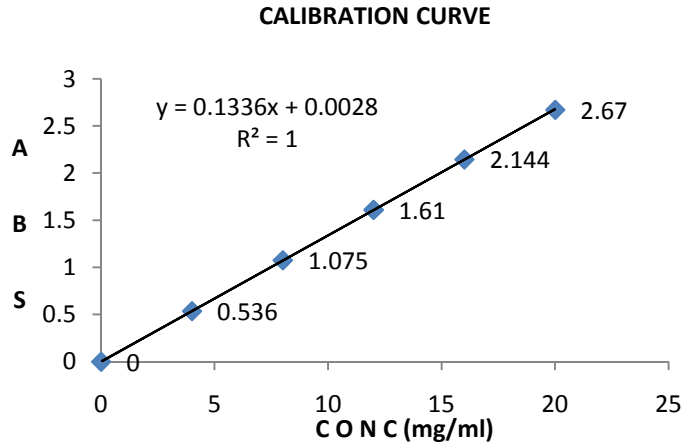

Fig. 3: Calibration curve

Procedure for tablet

20 tablets were crushed and accurately weighed quantity of Aripiprazole equivalent to 10 mg was transferred to the 100 ml volumetric flask and dissolved in 10 ml of 0.1N Methanolic HCL and sonicate for 5 min. The volume was made up to the mark with Distilled water (100 µg/ml) and filtered with Whatman filter paper no. 41.

The aliquot portion of stock solutions of Aripiprazole tablets was diluted appropriately with solvent to get a series of concentration 10µg/ml of Aripiprazole.

Table 2: Result of estimation in tablet formulation

Sr.No.	Weight of tablet powder (mg)	Absorbance at 216 nm	% Label claim
1.	76.3	1.345	100.00
2.	76.2	1.347	100.15
3.	76.2	1.344	99.93
		Mean	100.03
		± S.D.	0.1125
		%R.S.D	0.1124

Validation of the proposed method

Accuracy: Accuracy of the proposed method was ascertained on the basis of recovery studies performed by Standard addition method. The procedure for mixed standard solution is same as given in Table No. 4.

Precision: It is expressed as ±SD and % RSD of any measurements. Precision of estimation of Aripiprazole by proposed method was ascertained by replicate analysis of homogenous samples of tablet powder. The results are also shown in Table No. 3.

Ruggedness: The studies were carried out for different parameters i.e. different elapsed times (intraday and interday) different analysts.

Linearity and range

Accurately weighed quantities of tablet powder equivalent to 80, 90, 100, 110, 120 % of label claim were taken and dilutions were done appropriately to obtain a concentration in the range of 80-120% of the test concentration and absorbance were recorded 219 nm and 282 nm. RIS and THP were found to be linear in 80% - 120% of the test concentration. The plot of linearity and range is shown in Fig. No. 6.3

Table 3: Ruggedness study

Sr.No.	Parameters	Interday	Intraday	Different analyst
1.	Mean	98.50	98.57	98.64
2.	± S.D.	0.2677	0.3416	0.2451
3.	%R.S.D	0.2717	0.3466	0.2485

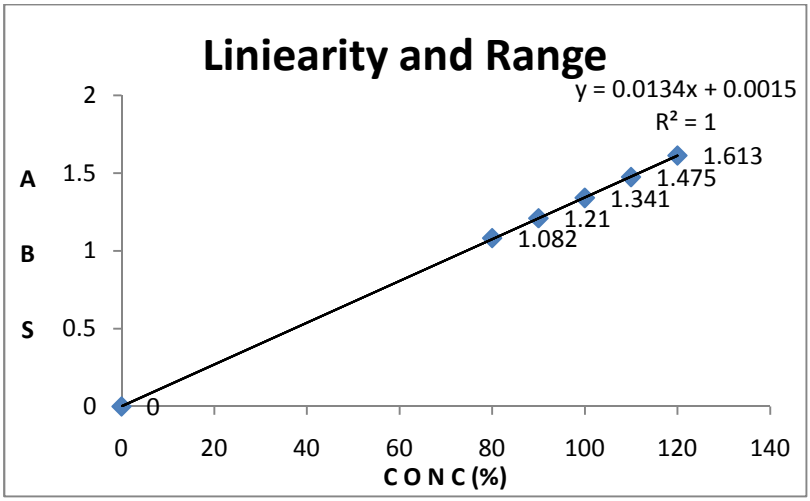

Fig. 4: Plot of linearity and range for Aripiprazole

Table 4: Results of recovery studies of Aripiprazole

Sr. No	Weight of tablet powder (mg)	Amount Added in µg.	Absorbance	Amount Recovered in µg	% Recovery
1		2	1.607	1.99	99.91
2		2	1.605	1.97	99.75
3	76.1	4	1.874	3.98	99.85
4		4	1.873	3.97	99.78
5		6	2.138	5.95	99.68
6		6	2.141	5.97	99.81
				Mean	99.79
				± S.D.	0.080
				%R.S.D	0.080

Recovery study

To check the accuracy of the developed methods and to study the interference of formulation additives, analytical recovery experiment was carried out by standard addition method. From the total amount of drug found, the percentage recovery was calculated. The results are reported in Table 5.

RESULTS AND DISCUSSION

The UV spectrum of standard solution of Aripiprazole was illustrated in Fig. no. 2.The method was validated as per ICH guidelines. Linearity study was performed in the range 4-20 µg/ml. All validation parameters were within the range. To study the accuracy and precision of the above proposed methods, recovery studies were

carried out by addition of known of standard drugs solution of aripiprazole to preanalysed tablet solution. The proposed method was found to be simple, accurate, economical and rapid for routine estimation of drugs.

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