

A Simple and Rapid Spectrophotometric Determination of Aripiprazole in Pharmaceutical Dosage Form

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Abstract

A new simple, sensitive, spectrophotometric method in ultraviolet region for the determination of aripiprazole in bulk and pharmaceutical dosage forms was developed. Spectroscopic determination was carried out at an absorption maximum of 256 nm using 95% ethanol as solvent. In the UV spectroscopic method linearity over the concentration range of aripiprazole was found to be 5 – 30 µg/ml with a correlation coefficient 0.9995. Results of the analyses were validated statistically and by recovery studies. The developed method was found to be precise, selective and rapid for the estimation of aripiprazole in solid dosage form.

How to Cite this Paper:

Samiran Dey, Nitesh Chauhan, Dr. P. Malairajan, R. Murugan, Rakhal Chandra Das, Shafique Ahmad "A Simple And Rapid Spectrophotometric Determination Of Aripiprazole In Pharmaceutical Dosage Form", Int. J. Drug Dev. & Res., Jan-March 2011, 3(1): 205-208

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Article History:-----

Date of Submission: 23-10-2010

Date of Acceptance: 25-01-2011

Conflict of Interest: NIL

Source of Support: NONE

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Introduction

Aripiprazole is chemically 7-[4-[4-(2,3-dichloro)phenyl]piperazine -1-yl] butoxy]-3,4-dihydro-1H-quinolin-2-one and the molecular formula is C₂₃H₂₇Cl₂N₃O₂. It is the sixth and most recent second-

generation antipsychotic agent, used in the treatment of acute, manic and mixed episodes associated with bipolar disorder [1, 2]. Aripiprazole appears to mediate its antipsychotic effect primarily by partial agonism at the D₂ receptor that has been shown to modulate dopaminergic activity in areas where activity may be high or low. It shows partial agonism at the 5-HT_{1A} receptor and antagonist profile at the 5-HT_{2A} receptor [3]. Only a few authors have described the validation methods for aripiprazole among which UV and HPLC methods have been developed for the drug in rat plasma, human plasma and pharmaceutical formulations [4, 5, 6, 7]. As these methods are expensive and not reproducible, we have made an attempt to develop a more precise, simple and economical spectrophotometric method with greater precision, accuracy and sensitivity for the analysis of aripiprazole in bulk and dosage forms.

EXPERIMENTAL

Materials

Aripiprazole bulk drug (Orchid Health Care, Chennai, India) and ethyl alcohol (S.D. Fine Chemicals Ltd., Mumbai, INDIA) were used for the study.

METHOD

Selection of wavelength

The drug was found to have a maximum absorbance at 255.92 nm in ethyl alcohol and hence this λ_{\max} was selected for further studies (Figure 1).

Standard stock solution

A stock solution of 1000 $\mu\text{g/ml}$ of aripiprazole was prepared freshly by dissolving 10.0000 mg of the drug in 10 ml of ethyl alcohol.

Sample solution

For the analysis of aripiprazole in tablets, a commercial brand, Arip-MT (Torrent Pharmaceuticals Ltd., Ahmedabad, India) of 10 mg strength was taken. Twenty tablets were weighed and powdered. The tablet powder equivalent to 10 mg of

aripiprazole was weighed accurately and dissolved in 10 ml of ethyl alcohol. The solution was filtered through Whatman filter paper number 40 and the filtrate was diluted to 100 ml with water. An aliquot corresponding to 10 $\mu\text{g/ml}$ was analyzed by the proposed method.

Procedure for calibration and assay

The stock solution was diluted in such a way with double distilled water to get the required concentrations, 5, 10, 15, 20, 25 or 30 $\mu\text{g/ml}$. The absorbance was measured at 255.92 nm using a UV visible spectrophotometer (Perkin Elmer, Massachusetts 02451 USA) lambda 25 model with 1 cm matched quartz cell against ethyl alcohol as a blank (Figures 2 & 3).

Recovery study

Recovery experiments were carried out to study the accuracy, reproducibility and precision of the proposed method. Percentage recovery was calculated from the amount of the drug found (Table 1 & 2).

Statistical Analysis

Statistical analyses were carried out using Graph pad Prism 2.01 statistical software (Graph pad software, San Diego, CA, USA). Experiments were repeated for confirmation of results and to determine its reproducibility. The data of each experiment did not differ from each other significantly and hence all the data have been combined and means calculated.

RESULTS AND DISCUSSION

The proposed method for the determination of aripiprazole in solid dosage form was found to be precise, selective, rapid and economical. Aripiprazole exhibited maximum absorption at 255.92 nm and obeyed Beer's law in the concentration range of 5-30 $\mu\text{g/ml}$. the proposed method for the determination of aripiprazole showed molar absorptivity of 0.74023 x

10⁻⁴, linear regression $Y = 0.031X + 0.0156$ with a correlation coefficient(r^2) of 0.9995 (Figure 3). Similar results were obtained for granisetron hydrochloride, famciclovir, gatifloxacin in tablets and bulk dosage forms. A relative standard deviation of 0.330 % was observed on analysis of six replicate samples. Kumar et al., (2007) have described spectrophotometric, RP-HPLC and solvation (acetonitrile and 0.1 M HCl for dissolution and dilution respectively) methods for determination of aripiprazole. Our studies revealed a recovery percentage of 100.12 ± 0.52 %, which indicates that the developed method was simple, rapid and precise. Similar results were obtained in the studies of Kumar et al (2007). But most important of all, our method proves to be more economical than the published standard methods.

ACKNOWLEDGEMENT

The authors are grateful to Orchid Pharmaceuticals Private Limited, Chennai for providing authentic sample of aripiprazole, S.D. Fine Chemicals Ltd., Mumbai, India for providing solvents and reagents and Shree Samanvay Institute of Pharmaceutical Education and Research, India for providing necessary facilities and encouragement.

Table 1: Optical Characteristics, Precision and Accuracy

PARAMETERS	METHOD
λ_{max} (nm)	255.92
Beers law limit ($\mu\text{g/ml}$)	5 – 30
Molar absorptivity(1mol/cm)	0.74023×10^{-4}
Sandell's sensitivity (($\mu\text{g}/\text{cm}^2/0.001$ abs. unit)	0.035
Co-relation co-efficient (r)	0.9995
Regression equation (Y)*	
Slope (B) μg	0.031
Intercept (A)	0.0156
Relative standard deviation** (%)	0.330
%Range of error	
Confidence limit with 0.05 level (95%)	± 0.4329
Confidence limit with 0.01 level (99%)	± 0.6897

* $Y = a + bX$, where X is concentration in $\mu\text{g/ml}$ and Y is absorbance unit.

** Average of Six determinations.

Table 2: Estimation of Aripiprazole

Formulation	Labelled Amount (mg/tablet)	Amount Obtained* (mg)	Percentage Recovery* (%)
Arip MT	10	10.385	100.12

*Each value is average of five estimations.

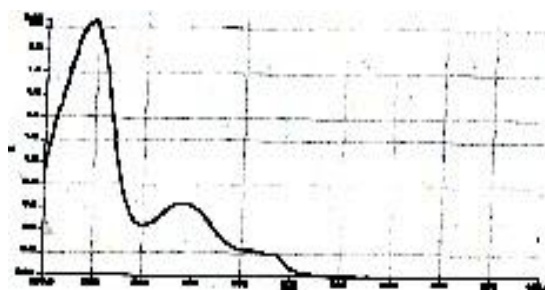


Figure 1: uv λ_{max} of aripiprazole in ethyl alcohol at 255.92 nm.

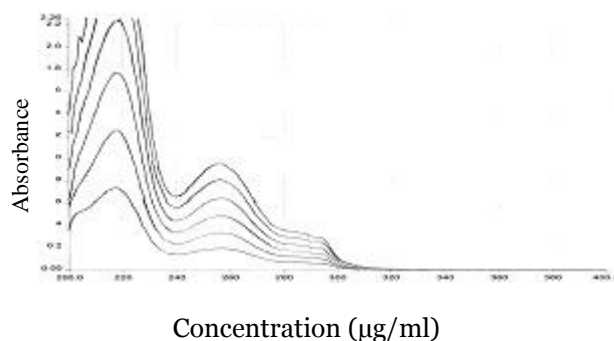


Figure 2: Overlain Spectra of different Concentrations of Aripiprazole in Ethyl Alcohol

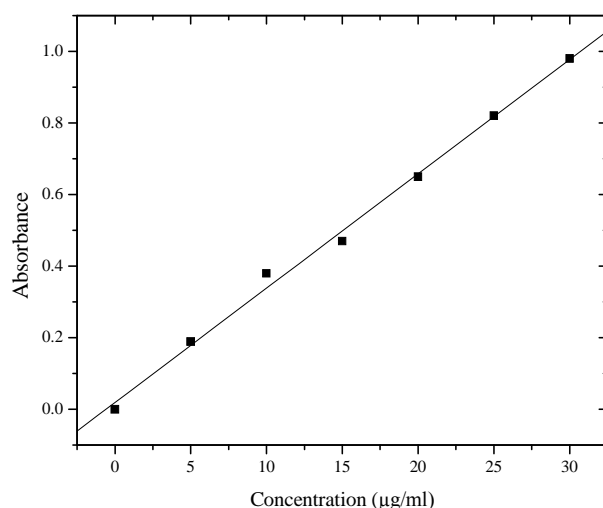


Figure 3: Calibration Graph of Aripiprazole (5-30 $\mu\text{G}/\text{ML}$)

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