Journal of Chemical, Biological and Physical Sciences

An International Peer Review E-3 Journal of Sciences

Available online at www.jcbsc.org

Section B: Biological Science

ISSN 2249 –1929

Research Article

Visible spectrophotometric method development and validation of aripiprazole in pure form

Mrs..V.V.Dhanu Radha* ; K.Rama Krishna

*Department of Chemistry, Gitam Institute of Technology, Gitam University, Visakhapatnam

Department of Chemistry, Gitam Institute of Sciences, Gitam University, Visakhapatnam

Received: 29 May 2011; Revised: 6 June 2011; Accepted: 21 June 2011

ABSTRACT

Two simple, economical and precise visible spectrophotmetric methods have been developed for the estimation of aripiprazole in pure form. These developed methods are based on the formation of yellow complex with sodium nitro prusside and bluish green complex with cobalt thio cyanate by using double distilled water. The maximum absorbance was observed at 430 nm and 625 nm for method 1 and method 2 respectively. Thus statistical analysis proves that the methods developed are reproducible and selective for the routine analysis of the said drug.

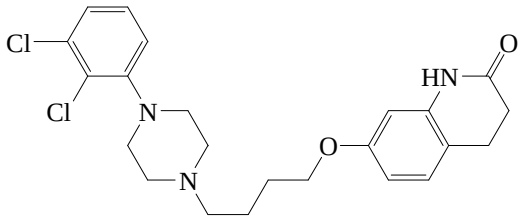
Keywords: UV-Visible Spectrophotometry, Ultra Sonicator, Electronic balance, Millipore double distilled water, Aripiprazole, Sodium Nitro Prusside, Hydroxyl amine hydro chloride, Cobalt thio cyanate.

INTRODUCTION

Aripiprazole is chemically a quinolinone derivative used as a typical antipsychotic and antidepressant used in the treatment of schizophrenia, bipolar disorder, and clinical depressi

on[1-2]. It has potent partial agonist activity at dopamine 2 receptors, partial agonist activity at serotonin A receptors and antagonist activity at 5HTZA receptors[3]. Knowldege of pharmacokinetics of aripiprazole in patients suffering from schizophrenia is limited.

Aripiprazole, Its structure is :



(**Fig.No.1:** Aripiprazole)

7-(4-(4-(2,3-dichlorophenyl)piperazin-1-yl)butoxy)
-3,4-dihydroquinolin-2(1*H*)-one

EXPERIMENTAL

Literature survey reveals that few analytical methods have been developed for the estimation of aripiprazole in tablet and bulk formulation 3-11. Most of the methods reported for the estimation of aripiprazole are from tablet form. Hence this paper reports a simple, precise, rapid and method for the estimation of Aripiprazole in its pure form.

Objective: The objective of the present investigation is to develop a simple, accurate and economical visible spectrophotometric method for estimation of aripiprazole in pure form.

MATERIALS AND METHODS

Instrumentation: ELICO UV 177, UV/Vis Spectrophotometer wavelength accuracy of ± 0.3 nm and 1.0 cm matched quartz cells was used for analytical method development.

Preparation of stock solution and experimental solution: Standard solution of Aripiprazole was prepared by dissolving 50 mg in 50 ml of ethanol and diluting 10 mLof this solution to 100 mL with ethanol (100µg/mL). 50 mg of pure Aripiprazole is transferred into a 50 mL volumetric flask containing 20 mL of ethanol and flask was kept for ultrasonication for 3 min, then it is diluted up to the mark with ethanol and the solution. From the above solution 10 mL is pipetted out into a 100 mL volumetric flask and the volume was made up to the mark with ethanol. This final concentration of Aripiprazole was used for the analysis.

Method I: In this method aliquots of Aripiprazole ranging from 0.5-2 mL of standard solution are transferred to each 25 mL volumetric flask, 1 mL of 5% w/v sodium nitroprusside solution and 2 mL of 5% w/v $NH_2OH.HCl$ solution are added and waited for 2min. Then 1mL of 10% w/v sodium carbonate solution is added, shaken for 15 minutes and

the volume is made upto the mark with double distilled water. The absorbance is measured at 430 nm against the reagent blank prepared simultaneously without the drug. The decrease in absorbance corresponds to the consumed sodium nitro prusside, which in turn to the drug quantity was obtained by subtracting the absorbance of the blank solution from the test solution .The calibration graph is drawn by plotting the decrease in the absorbance.

Method II: ***Preparation of CTC solution (2.5X10-1 M) :*** 3.625 g of cobalt nitrate and 1.9 g of ammonium thio cyanate are dissolved in 50 ml of Double distilled water.

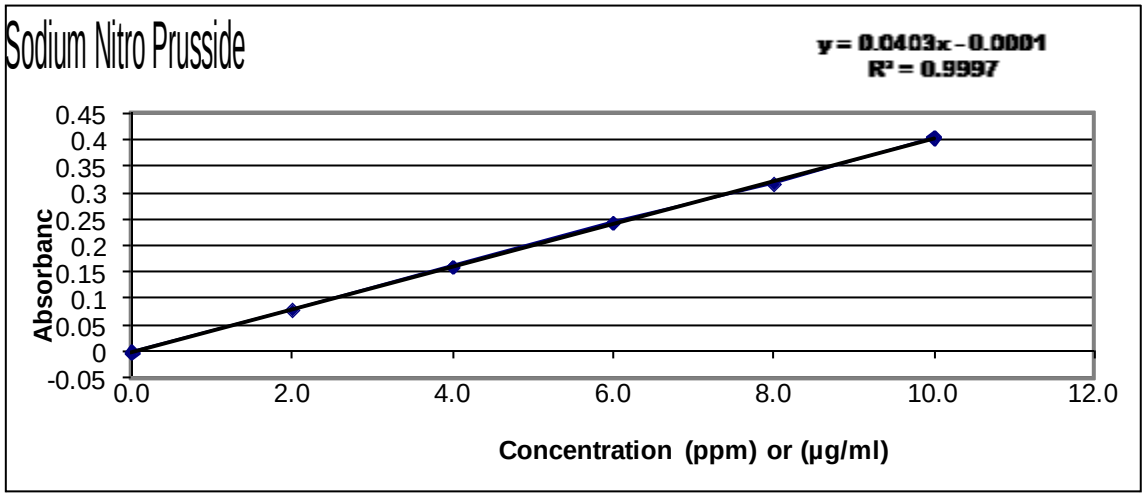
Buffer solution (pH 2.0) 306 ml of Tri sodium nitrate of 0.1M is mixed with 694ml of 0.1M HCL.

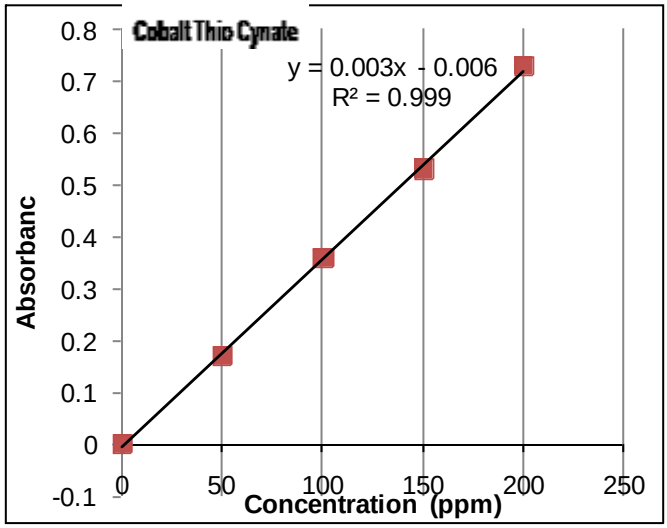
In the second method aliquots of Aripiprazole ranging from 1.2- 5 mL of 1000 ppm standard solution is transferred in to a series of calibrated tubes and the solvent was completely removed by heating on a boiling water bath. To the residue in each tube, 2.0 mL of buffer of pH 2.0 and 5.0 mL of Cobalt thio cynate solution are added and the total volume is adjusted by using double distilled water to 15 mL. These solutions are transferred into a series of 125 mL separating funnels, then to each separating funnel 10.0mL of nitro benzene is added and the contents are shaken for 2min. The two phases are allowed to separate and the absorbance of each separated nitro benzene layer was measured after 20 min at 625 nm against the reagent blank prepared simultaneously without the drug. The calibration graph is drawn by plotting the increase in the absorbance.

Table 1: Spectral Characteristics of Aripiprazole

Parameters	Values	Values
Wave length	430nm	625nm
Beer's law limit (µg/ml)	2-10	50-200
Correlation coefficient, r2	0.9997	0.9994
Regression equation	y = 0.0403x - 0.0001	y = 0.0036x - 0.0066
Slope	0.0403	0.0036
Intercept	0.0001	0.0066
Molar Absorptivity	1.83X104	1.61X104
Sandell's Senstivity (g/cm2/ 0.001 abs unit)	2.45X10-2	2.80X10-2

GRAPHS





RESULTS AND DISCUSSION

The absorption spectral analysis shows that the maximum wavelength of Aripiprazole was found to be 430 nm and 625nm for the above proposed methods. These proposed methods obey Beer's law in the concentration range of 2-10 µg/mL, 50-200 µg/mL with sodium nitroprusside and cobalt thio cyanate. It was found to be linear and henceforth, suitable for the estimation of the drug. The slope, intercept, correlation coefficient, molar absorptivity and Sandell's Senstivity are summarized in Table 1. The recovery studies were carried out by standard addition method and were found close to 100 %.Hence the developed methods could be used for routine estimation of aripiprazole in pure form.

Recovery Studies

The recovery was in the range: 99-100 %

CONCLUSION

Thus it can be concluded that the methods developed in the present investigation are simple, sensitive, accurate and precise. Hence, the above said methods can be successfully applied for the estimation of aripiprazole in pure form.

REFERENCES

1. Merck index, 13th ed., *Merck. In. Co*., NJ-USA: 2001, p. 134
2. Aripiprazole- *Wikipedia, the fre Encyclopedia*
3. J.K.McGavin ,K.L. Goa ,.*Ingenta connect., 2002,* **16,** 11, 779
4. A.Musenga and M.A. Saracino , *Anal chim Acta*.,2008, **612,** 2, .204.
5. N. Attri ,S. Yada and A. Goyal. A., *www.scientificipca.org/paper/2009/09/13/200909131216450A.doc*
6. R. Kalaichelvi, B.Thangabalan, D. Srinivasarao and E. Jayachandran, *E-Journal of Chemistry* 2009., **6(S1),** S87-S90
7. Anthony de Leon., Nick, C.Patel.,Lynn Crimson,M.,*Clinical Therapeutics*., 2004, **26**,5.
8. Suresh Mallikararjun, Daniel, E.Salazar and Steven.L., *Journal of Clinical Pharmacology*., 2004, 44, 179-187
9. Vijaya kumar.M and Muley., *The Indian Pharmacist*., 2005, April, 71
10. A. Suganthi, P. Ravimathi*, Sapna Shrikumar, and T.K. Ravi. *Pharmainfo.net*
11. Shailesh, S.Vengurlekhar., Simultaneous LC-MS/MS Determination of Aripiprazole (OPC-14597) and its five major metabolites in Human Urine
12. Becket A H and Stenlake J B, *Practical Pharmaceutical Chemistry*, 4th Edition; CBS Publishers and distributors, New Delhi, Part 2, 304
13. J.M.Green , A *Practical guide to analytical method validation*, Anal Chem., News Feat 305A/309A, 1996, May 1.

*Correspondence Author: **Mrs..V.V.Dhanu Radha,** Dpartment of Chemistry, Gitam Institute of Technology, Gitam University, Visakhapatnam