



# RP-HPLC Method Development and Validation for Estimation of Aripiprazole in Bulk and Dosage Form

Sonali N. Kawade\*, Jaiprakash V.Kokane , Bhavana A. Kokane and Rameshwar B. Dhule

Department of Pharmaceutical Chemistry, S.N.D. College of Pharmacy, Babhulgoan, Yeola-423401, India.

Received: 02 Jul 2019 / Accepted: 9 Aug 2019 / Published online: 1 Oct 2019

\*Corresponding Author Email: [kawadesonu123@gmail.com](mailto:kawadesonu123@gmail.com)

## Abstract

A simple, rapid, sensitive, reverse phase high performance liquid chromatographic method was developed for estimation of aripiprazole in bulk & dosage form. The method was validated as per ICH guidelines. Aphenomenex C18 (250mm X 4.6mm,5µm).The mobile phase for estimation is phosphate buffer (PH 4.2)70: Methanol 30 and detection was carried out 255nm.The analysis was performed runtime 7min at a flow rate 1ml/min. Linearity was obtained in concentration range of 10 to 60 µg/ml with correlation coefficient 0.9997 respectively. The method was validated for precision. Limit of detection, limit of quantitation, linearity, robustness and ruggedness. The limit of quantitation and limit of detection was found to be 3.72µg/ml to 1.23µg/ml respectively. Proposed HPLC method was sensitive and reproducible for the analysis of aripiprazole in pharmaceutical dosage form (tablet) with short analysis time.

## Keywords:

### Keywords

Aripiprazole, bulk dosage form, RP-HPLC, Validation.

\*\*\*\*\*

\*\*\*\*\*

## INTRODUCTION

Aripiprazole is chemically 7-(4-(4-(2,3-Dichlorophenyl) - 1- piperainyl) butoxy) - 3, 4-dihydro-2(IH) quinolinone. Aripiprazole is a psychotropic agent belonging to the chemical class of benzisoxazole derivatives and is indicated for the treatment of schizophrenia. It acts as a D<sub>2</sub> partial agonist. Aripiprazole is also a partial agonist at the 5-HT<sub>1A</sub> receptor, and like the other atypical

antipsychotics displays an antagonist profile at the 5-HT<sub>2A</sub> receptor. Literature survey reveals that few spectroscopic and chromatographic methods have been reported for the quantitative estimation of Aripiprazole in bulk drug and pharmaceutical formulation. Therefore, here is an attempt to develop simple, specific and cost-effective method for determination of Aripiprazole as drug substance as well drug product.

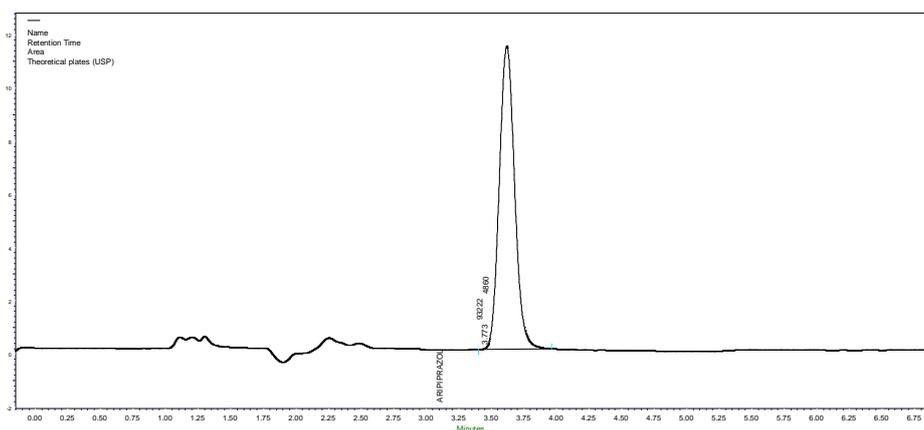


## RESULTS AND DISCUSSION

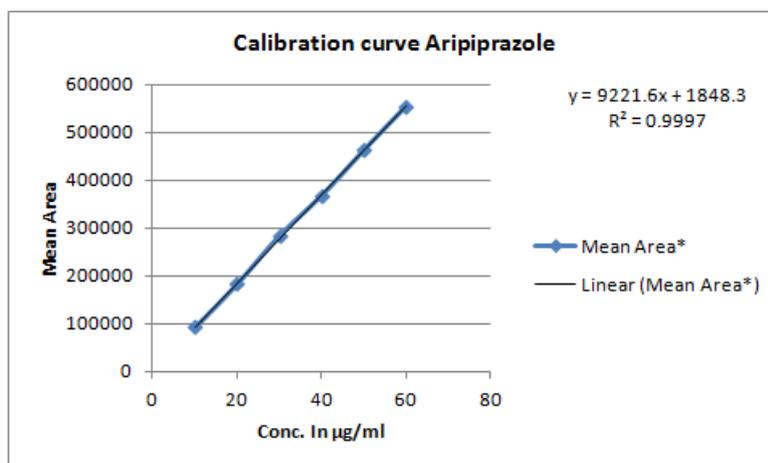
### System suitability testing

**Table 1: Results of system suitability experiment and their correlation with standards**

Sr. No.	Parameter	Mean observations	SD	%RSD	Acceptance criteria	Inference
1	Peak Area	93354.33	746.73	0.80	< 2	Pass
2	Retention time	3.77	0.02	0.46	< 0.5	Pass
3	Number of Theoretical plates	3794	--		> 2000	Pass
4	Tailing factor	1.31	--		< 2	Pass


**Figure 1: ARPZ chromatogram obtained for system suitability testing**

### Linearity


**Figure 2: Calibration curve of Aripiprazole**

### Precision

**Table 2: Observation table for Repeatability and Intermediate precision experiment**

Conc. (µg/ml)	Intra-day precision			Inter-day precision		
	Mean area ± SD	% RSD	Inference	Mean area ± SD	% RSD	Inference
15	131028.67 ± 684.83	0.52	Pass	132857.89 ± 1328.03	1.00	Pass
35	308218.67 ± 5700.07	1.85	Pass	319585.22 ± 4703.50	1.47	Pass
55	514688.33 ± 10350.67	2.01	Pass	513538.33 ± 8596.03	1.67	Pass

## Robustness

**Table 3: Results obtained in Robustness experiment for organic concentration variation**

Methanol Concentration (%)	Standard Conc. ( $\mu\text{g/ml}$ )	Mean peak area*	Mean measured conc. ( $\mu\text{g/ml}$ )	% Assay	Inference (Compendial standard 90-110 %w/w)
30	10	93222	9.91	99.09	Pass
32	10	95899	10.20	101.99	Pass
28	10	91638	9.74	97.37	Pass

**Table 4: Observation table for Flow rate variation for Robustness assessment**

Flow Rate (ml/min)	Standard Conc. ( $\mu\text{g/ml}$ )	Mean peak area*	Mean measured conc. ( $\mu\text{g/ml}$ )	% Assay	Inference (Compendial standard 90-110 %w/w)
1	10	93222	9.91	99.09	Pass
1.1	10	90528	9.62	96.00	Pass
0.9	10	97229	10.34	103.43	Pass

## % Recovery

**Table 5: Results obtained for percent recovery experiment of ARPZ in tablet dosage form**

% Recovery Level	Conc. of standard spiked ( $\mu\text{g/ml}$ )	Conc. of sample ( $\mu\text{g/ml}$ )	Mean peak Area of sample conc.*	Amount recovered ( $\mu\text{g/ml}$ )	% Recovery	Inference (Standards 95-105%w/w)
80	10	8	73527	7.78	97.69	Pass
100	10	10	95067	10.11	101.05	Pass
120	10	12	116771	12.46	103.43	Pass

## LOD and LOQ

**Table 6: Results obtained for LOD and LOQ**

Standard Drug Solution	LOD ( $\mu\text{g/ml}$ )	LOQ ( $\mu\text{g/ml}$ )
Aripiprazole	1.23	3.72

## CONCLUSION

The experiments were started with trial run in order to optimize the chromatographic conditions to get best possible results. Therefore, it was optimized, and final conditions were set as mobile phase composition, flow rate, wavelength, injection volume and temperature as phosphate buffer at pH 4.2 70: Methanol 30 percent, 1ml/min, 255nm, 10 $\mu\text{l}$  and ambient temperature respectively. Therefore, eventually it was concluded that we have attained our objectives by successful development and validation of RP HPLC method for quantification of Aripiprazole. Moreover, the applicability of the method was also proved for schedule analysis of aripiprazole in tablet dosage form.

## REFERENCES:

1. Chatwal, G. R.; Anand, S. K. Instrumental Methods of Chemical Analysis, 5<sup>th</sup> ed.; Himalaya Publishing House: New Delhi, 2004; pp. 2.599-2.605, 2.112, 2.570-2.582, 2.652-2.630.
2. Khopkar S. M. Basic concepts of analytical chemistry, New age International Ltd. Publishers, New Delhi, 1998,2, pp. 178-179.
3. Kasture A.V.; Wadodkar S. G. Pharmaceutical Analysis 7<sup>th</sup> edition vol.2, Nirali Prakashan pp.7
4. Beckett A. H.; Stenlake J. B. Practical Pharmaceutical Chemistry 4<sup>th</sup> edition Vol. 2, CBS Publishers and Distributors, New Delhi, 2007, pp. 95-96, 96, 92-93, 99-100, 275.
5. Thakkar R. S. et al., *Indian J Pharm Sci.* 2011, 73(4), pp. 439-443.
6. Sastry B. S. et al., *Asian J. Chem.* 21(9), 2009, pp. 6643-6646.
7. Pai N. R. et al., *Der Pharmacia Lettre*, 2010, 2(4), pp. 1-10.
8. Vijayabharathi et al., *Asian J Pharm Clin Res*, 2017, 10(5), pp. 379-382.
9. Kalaichelvi R. et al., *E-Journal of Chemistry*, 2010, 7(3), pp. 827-832.
10. Kumari et al., *World Journal of Pharmacy and Pharmaceutical Sciences*, 2016, 5(6), pp. 1168-1179.