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EVALUATION AND VALIDATION OF A UPLC METHOD FOR THE ESTIMATION OF ARIPIPRAZOLE IN BULK DOSAGE FORM

Reshma*[1], Dr. Osman Ahmed[1], Syeda Rakhshinda Zareen[1], Mohammed Sayeed Uddin[1] and Dr. Anas Rasheed[2]

[1]Department of Pharmaceutical Analysis, Deccan School of Pharmacy, Hyderabad.
[2]CSO, Gaelib Medications Private Limited, Hyderabad.

Corresponding Author: Reshma
Department of Pharmaceutical Analysis, Deccan School of Pharmacy, Hyderabad.

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ABSTRACT

An antipsychotic medication, works by changing the actions of chemicals in the brain. It is used to treat the symptoms of psychotic conditions such as schizophrenia and bipolar disorder. Aripiprazole possess a different mechanism of action which is different from other FDA – approved atypical antipsychotics.

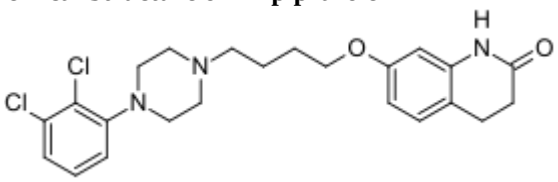
KEYWORDS: Aripiprazole, schizophrenia and FDA.

INTRODUCTION

Aripiprazole is an antipsychotic medication, works by changing the actions of chemicals in the brain. It is used to treat the symptoms of psychotic conditions such as schizophrenia and bipolar disorder (manic depression). Aripiprazole possess a different mechanism of action which is different from other FDA – approved atypical antipsychotics approved by Food and Drug Administration. Instead of acting as an antagonist at D_2 receptor it acts as a partial agonist at the D2 receptor. It also acts as the partial agonist at the 5-HT_1A receptor but exhibits the role of the antagonist at 5-HT_2A receptor similar to that of the other atypical anti-pshycotics.

Aripiprazole also possess high affinity towards 5-HT_7 receptor (acts as antagonist) and 5-HT_2C receptor (acts as a partial agonist). Its action on the 5-HT_7 receptor and 5-HT_2C receptor is found to be the main cause of weight gain of the patient during the treatment period. Aripiprazole also possess moderate affinity for histaminergic, α-adrenergic, dopaminergic receptors and serotonin transporter. It has a very less affinity for muscarinic acetyl choline receptors. The main aim and objective of this work is to perform the physical, chemical characterization (in-vitro dissolution profile) and accelerated stability studies for the optimized lab scale batch to formulate a stable and robust formulation of aripiprazole immediate release tablets of strength 30mg, which is used in the treatment of schizophrenia and bipolar disorders.

Chemical Structure of Aripiprazole



Weight: 383.51 g·mol−1
Chemical Formula $C_{23}H_{27}Cl_2N_3O_2$
IUPAC 7-{4-[4-(2,3-Dichlorophenyl)piperazin-1-yl]butoxy}-3,4-dihydroquinolin-2(1H)-one

EXPERIMENTAL METHODOLOGY

Method Validation

What we mean when we talk about "the analytical technique" is the method by which the analysis is carried out. All of the analytical procedures should be spelled out in great detail. The sample, the reference standard, and the reagents, as well as their preparations, the use of the equipment, the development of the calibration curve, the application of the formulas for the calculation, etc. There has been comprehensive validation of the disclosed technique for its specificity, system appropriateness, linearity, accuracy, precision, limit of detection, limit of quantification, and robustness.

RESULTS

Preparation of Standard Stock Solution

Preparation of Diluent

In arrange to achieve partition beneath ideal circumstances taking after a arrangement of exploratory trials, it is essential to summarize the comes about. A

stationary stage such as the Hypersil BDS C18 (100 mm x 2.1 mm, 1.7 m) column was the foremost fitting since it generated symmetrical crests with tall determination and an awfully great affectability, as well as an awfully great determination and affectability. The stream rate was kept steady at 0.25 mL min-1, coming about in great determination. The response of Aripiprazole to the PDA finder was explored, and it was found that the ideal wavelength was 210 nm, which had the most prominent affectability.

System Precision

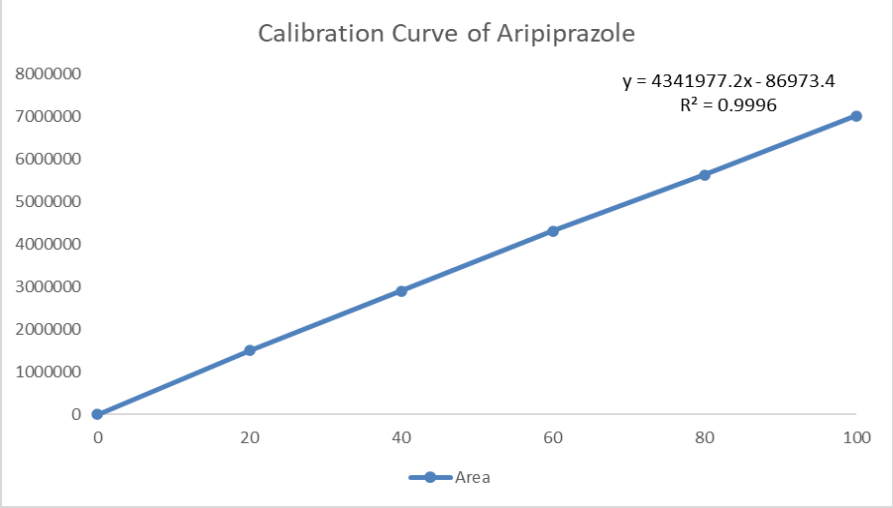
Parameters	**Aripiprazole**
Theoretical plates ± % RSD	2116.94 ± 0.50
Asymmetry ± % RSD	1.05 ± 0.05
Repeatability (% RSD)	0.15

Method Precision

Replicate	***Aripiprazole***		
S. No.	**Concentration Taken (µg/ml)**	**Area**	**%LC**
1	25.68	4546389	98.90%
2		4552071	98.77%
3		4554099	98.71%
4		4556291	98.68%
5		4558244	98.64%
6		4555351	98.70%
Average			98.73%
Std. Dev			0.0920
% RSD			0.09%
Standard weight			25.68mcg
Standard potency			98.90 %

Linearity

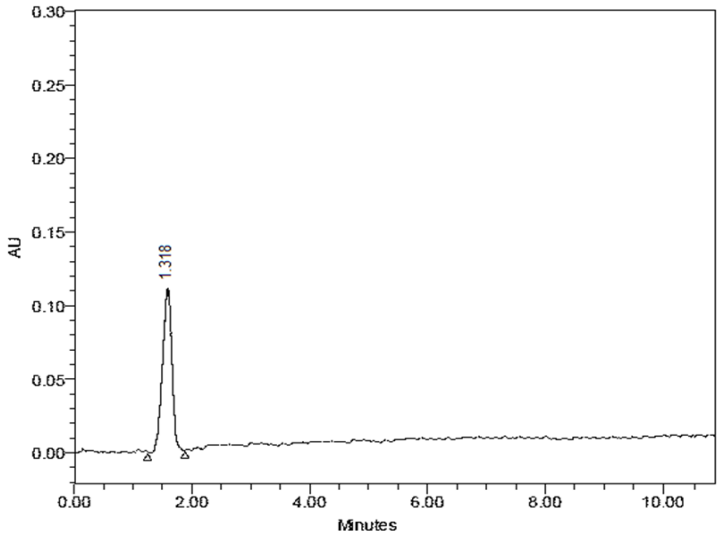
Aripiprazole		
Linearity level	**Concentration in µg/mL**	**Area**
1	20 µg/mL	1496421
2	40 µg/mL	2898629
3	60 µg/mL	4299318
4	80 µg/mL	5618501
5	100 µg/mL	7006219
Correlation co-efficient	0.9996	
Slope	86973.4	
Intercept	4341977.2	



Ruggedness

Aripiprazole			
Ruggedness			
Parameter	**Peak Area**	**% RSD**	**%LC**
Intraday precision	4554134	0.15%	99.75%
	4562308		99.99%
	4567882		100.11%
Inter day precision	4554152	0.14%	99.81%
	4562512		100.02%
	4568042		100.12%
Instrument:1 Acquity HPLC Waters,2695H	4562071	0.13%	99.99%
	4567448		100.11%
	4555194		99.84%
Instrument:2 Agilent Technologies,1290	4562131	0.13%	99.99%
	4567339		100.10%
	4555176		99.85%
Average			**99.97**
Std.Dev			**0.13**
%RSD			**0.13%**

Assay Studies
Sample Control



EVALUATION OF METHODS

Assay Studies
Calculation formula for Aripiprazole

$$\%\ Assay = \frac{AT}{AS} \times \frac{W1}{100} \times \frac{1}{25} \times \frac{100}{W2} \times \frac{25}{1} \times \frac{AW}{LC} \times P$$

Aripiprazole:

$$\%\ Assay\ of\ API = \frac{4558244}{4899318} \times \frac{25.62}{100} \times \frac{1}{25} \times \frac{100}{25.44} \times \frac{25}{1} \times \frac{25.40}{25.42} \times 98.90$$

$= 92.59\%$

$$\%\ Assay\ of\ Market = \frac{4559321}{4899318} \times \frac{25.62}{100} \times \frac{1}{25} \times \frac{100}{25.44} \times \frac{25}{1} \times \frac{25.40}{25.42} \times 98.90$$

$= 92.61\%$

CONCLUSION

A particular, accurate, and precise high weight fluid chromatography (HPLC) method for the assessment of Aripiprazole in bulk medication and measuring form has been developed. The technique was implemented using Hypersil BDS C18 (100 mm x 2.1 mm, 1.7 m) in an angled mode, using methanol and acetonitrile in a 65:35% v/v ratio in the mobile stage and acetonitrile in the stationary stage. At a wavelength of 254 nm, we were able to determine that the stream rate was 0.1 mL/min and the profluent concentration was 0.01%. The upkeep time was calculated to be 1.1300.005 minutes. The process met all of the ICH (International Conference on Harmonization) requirements for linearity, precision, accuracy, restriction of discovery, and limitation of measurement.

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