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EVALUATION AND VALIDATION OF A UPLC METHOD FOR THE STABILITY INDICATING ASSAY OF ARIPIPRAZOLE IN TABLET DOSAGE FORM

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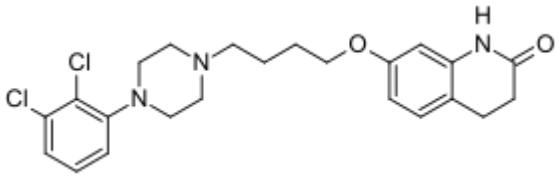
ABSTRACT
A psychosis treatment will change the way that certain chemicals in the brain function in order to get the desired therapeutic effect. Patients who are afflicted with mental illnesses such as schizophrenia and manic depression may find that the drug's capacity to lessen the symptoms of their disease provides them with some degree of comfort. The mechanism of action of the atypical antipsychotic aripiprazole is unique from the mechanisms of action of other atypical antipsychotics that have been authorised for use by the FDA.

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.

Accuracy Procedure

Aripiprazole						
Level %	**Amount added (µg/ml)**	**Amount found (µg/ml)**	**% Recovery**	**Mean recovery (%)**	**Std.Dev**	**% RSD**
50	09.95	09.75	97.98	98.61	0.6977	0.71%
100	19.90	19.60	98.49			
150	29.85	29.66	99.36			

Recovery level	**Set No.**	**Aripiprazole**	
		Wt. Taken (µg/ml)	**Amount found (µg/ml)**
50%	**Set 1**	09.45	09.22
	Set 2	09.75	09.68
	Set 3	09.95	09.81
100%	**Set 1**	19.55	19.33
	Set 2	19.70	19.63
	Set 3	19.90	19.80
150%	**Set 1**	29.44	29.30
	Set 2	29.62	29.57
	Set 3	29.85	29.81

System Precision

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

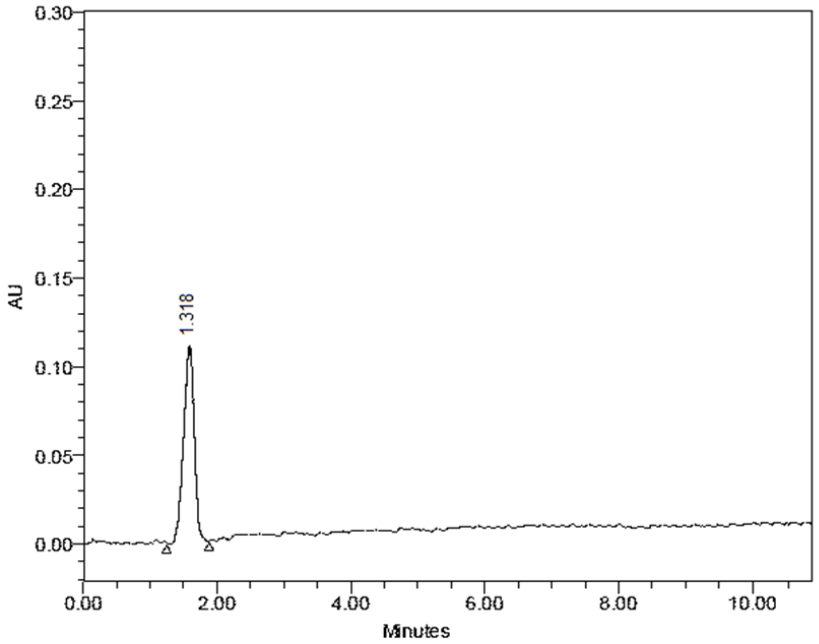
Method Precision

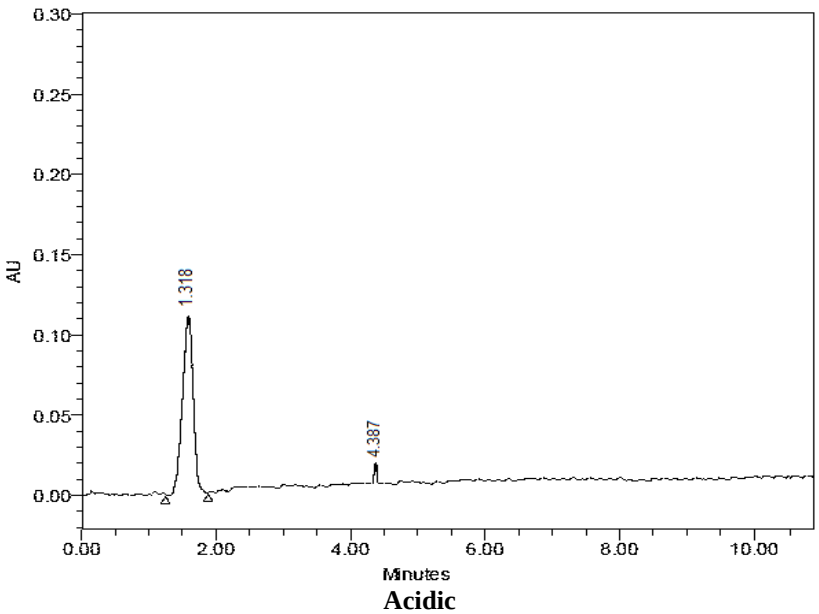
Replicate	***Aripiprazole***		
S.No.	**Concentration Taken (µg/ml)**	**Area**	**%LC**
1	25.68	4546389	98.90%
2		4552071	98.77%
3		4554099	98.71%
4		4556291	98.68%
5		4558244	98.64%
6		4555351	98.70%
Average			98.73%
Std.Dev			0.0920
% RSD			0.09%
Standard weight			25.68mcg
Standard potency			98.90 %

Robustness

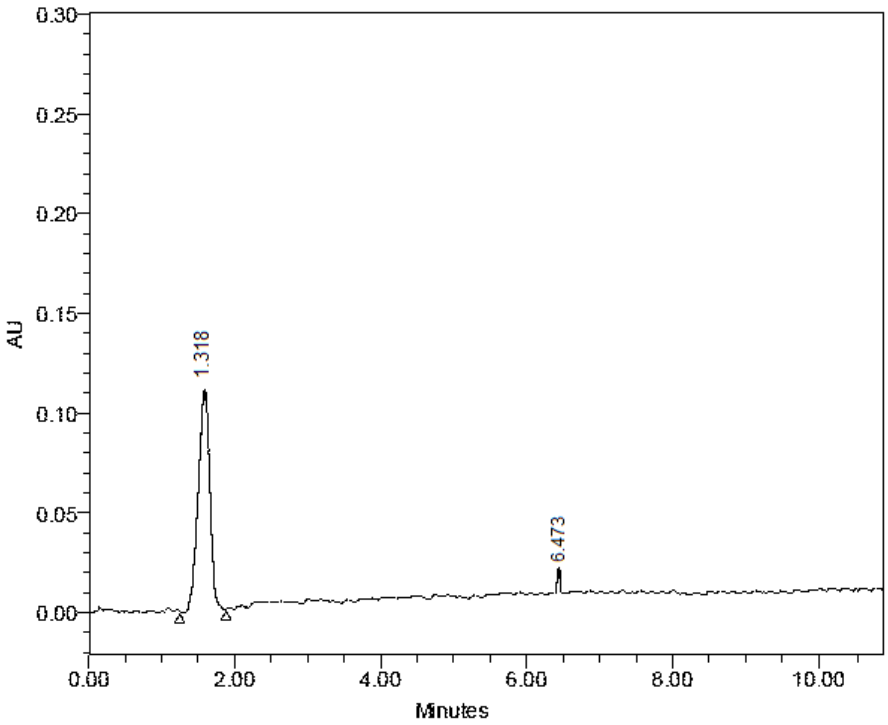
Robustness Studies			
Parameter	**Value**	**Peak Area**	**% RSD**
Flow Rate	**Low**	4557141	0.03%
	Actual	4559365	
	Plus	4560043	
Temperature	**Low**	4558912	0.01%
	Actual	4559724	
	Plus	4560254	
Wavelength	**Low**	4558864	0.01%
	Actual	4559671	
	Plus	4560113	

Stability Assay Studies
Sample Control

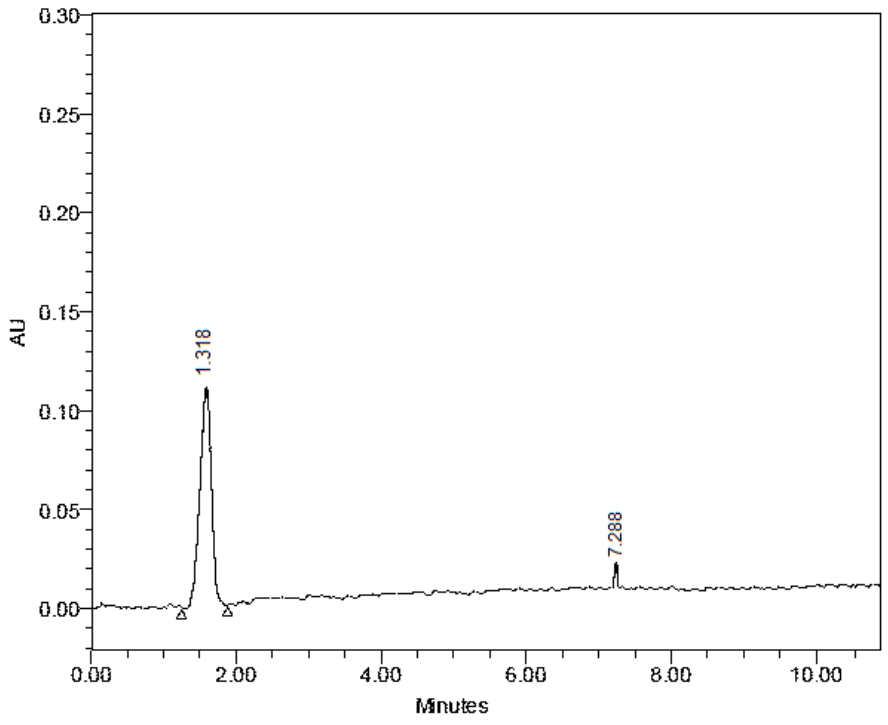




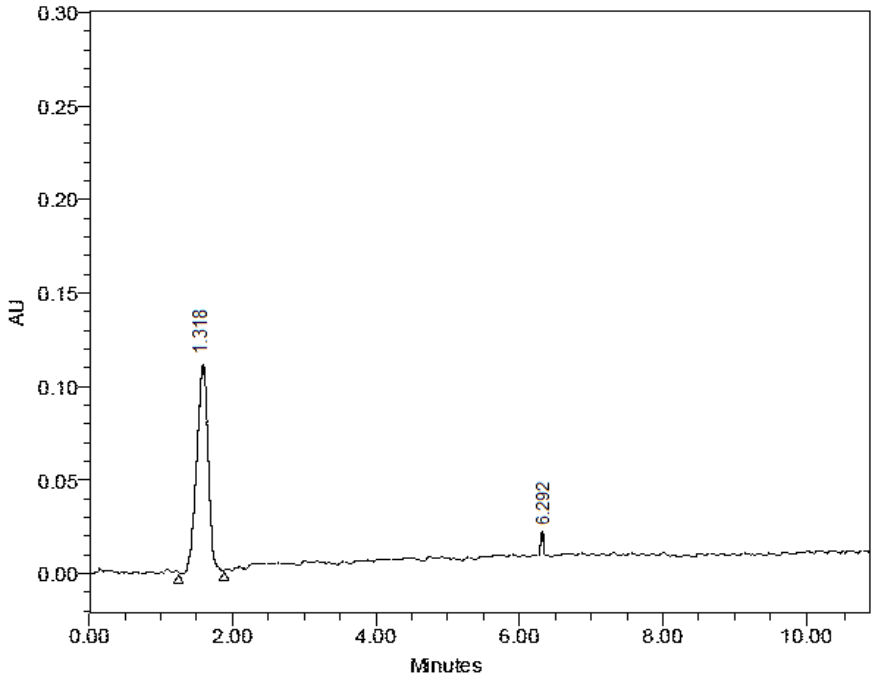
Acidic



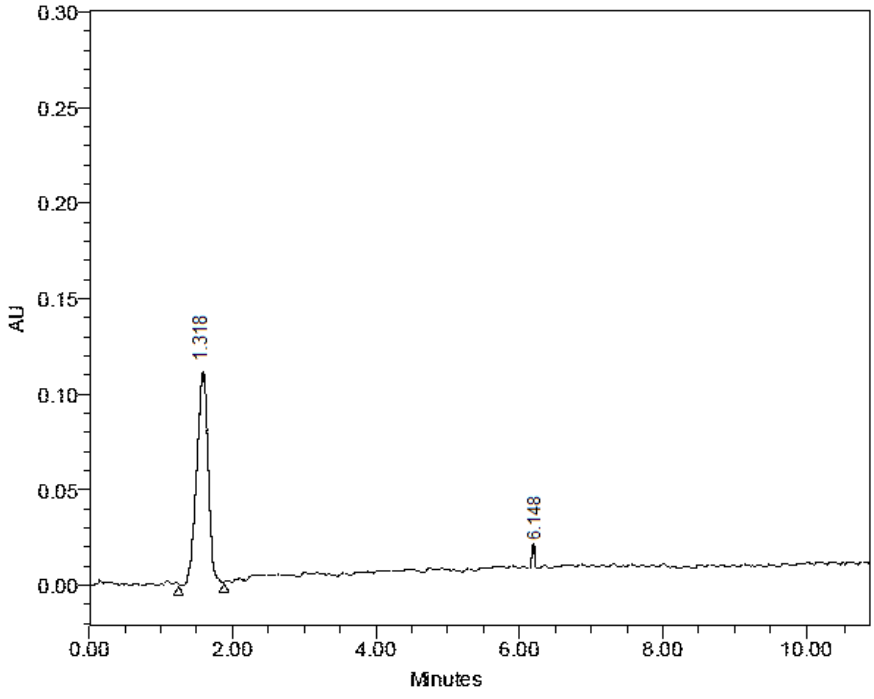
Alkaline



Oxidation



Photolytic



Wet Heat

EVALUATION OF METHODS

Assay Studies

- **Stability Indicating Analysis of ARIPIPRAZOLE**

Conditions	% claim
Sample Control	98.73%
Acidic	95.88%
Alkaline	96.13%
Oxidation	96.44%
Photolytic	95.19%
Wet Heat	96.54%

CONCLUSION

For this drug in particular, a novel, accurate, and specialised ultra chromatographic technique was needed to account for the uneven dosing patterns that occur in bulk pharmaceutical and applications. This was done so that the pattern could be examined. With a simple evaluation method that doesn't get in the way of the treatment, this therapeutic goal may be reached. Since "therapy" has so many negative associations, it allows for this. This strategy is both effective and straightforward to adopt because to its high impact and frequency, as well as the fact that it retains its accuracy. The available information suggested that the method was sufficient for authorising the stated approval criteria.

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