

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

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ABSTRACT

The atypical antipsychotic quetiapine, which is most often known to by its trade name, Seroquel, is a medicine that has had promising outcomes in the treatment of schizophrenia, bipolar disorder, and major depressive disorder. In spite of the fact that the possible negatives of taking it seem to outweigh the benefits of using it, it is often used as a sleep aid due to the sedative qualities that it has.

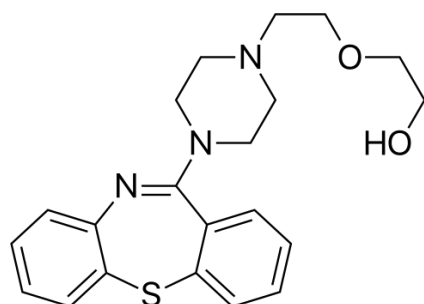
KEYWORDS: Quetiapine, Seroquel and sedative.

INTRODUCTION

Bipolar disorder

Quetiapine is used to treat depressive episodes, short-term manic episodes in people with bipolar I disorder (as a monotherapy or in combination with lithium, valproate, or lamotrigine), short-term mixed episodes, and to keep people with bipolar I disorder from getting worse (as adjunct therapy to lithium or divalproex).

Quetiapine Chemical Structure



Chemical Structure of Quetiapine

Weight: 383.51 g·mol⁻¹

Chemical Formula C₂₁H₂₅N₃O₂S

IUPAC 2-(2-(4-Dibenzo[b,f][1,4]thiazepine-11-yl)-1-piperazinyl) ethoxy)ethanol

Experimental

Methodology

Method Validation

The way the analysis is done is what is meant by "analytical procedure." It should explain in detail how

each analytical test needs to be done. This may include, but is not limited to, preparing the sample, the reference standard, and the reagents, using the equipment, making the calibration curve, using the formulas for the calculations, etc. The described method has been thoroughly tested for specificity, system suitability, linearity, accuracy, precision, limit of detection, limit of quantification, and robustness.

RESULTS

Preparation of Standard Stock Solution

Preparation of Diluent

After a set of exploratory trials, the results need to be summed up so that a separation can be made under the best possible conditions. A stationary phase like the Hypersil BDS C18 (100 mm x 2.1 mm, 1.7 m) column was best because it made symmetrical crests with high determination and a lot of flexibility. It also had a lot of determination and flexibility. The flow rate stayed the same at 0.5 mL min⁻¹, which was done with great determination. The PDA finder's reaction to Quetiapine was looked at, and it was found that the best wavelength was 210 nm, which showed that it could be affected.

Using a slope programming strategy, a mixture of two arrangements (Dimethylformamide and Acetonitrile in a ratio of 30:70 percent v/v) was used as the mobile phase at a flow rate of 0.5mL/min. This was found to be a good mobile phase for the separation of Quetiapine. The column was kept at the same temperature as the room.

Internal standard arrangement: Weighed exactly about 10 mg of Testosterone working standard and put it

in a 100-ml volumetric carafe. We added 50 ml of portable phase and sonicated it to completely break it up. We then added portable phase to bring the volume up to the right level to get a standard stock arrangement of working standard with 100 micrograms per millilitre (g/mL). After that, it was handled with ultrasonic waves for 10 minutes before being put through a 0.20-micron layer channel and sifted.

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Planning of Quetiapine standard arrangement incorporates the taking after steps: Weighed exactly

Accuracy Procedure

Quetiapine						
Level %	Amount added (µg/ml)	Amount found (µg/ml)	% Recovery	Mean recovery (%)	Std.Dev	% RSD
50	02.04	02.03	99.56	99.47	0.1112	0.10%
100	04.05	04.04	99.53			
150	06.07	06.03	99.37			

Recovery level	Set No.	Quetiapine	
		Wt. Taken (µg/ml)	Amount found (µg/ml)
50%	Set 1	02.07	02.04
	Set 2	02.03	02.01
	Set 3	02.05	02.03
100%	Set 1	04.03	04.02
	Set 2	04.07	04.02
	Set 3	04.11	04.08
150%	Set 1	06.04	06.02
	Set 2	06.08	06.04
	Set 3	06.13	06.08

System Precision

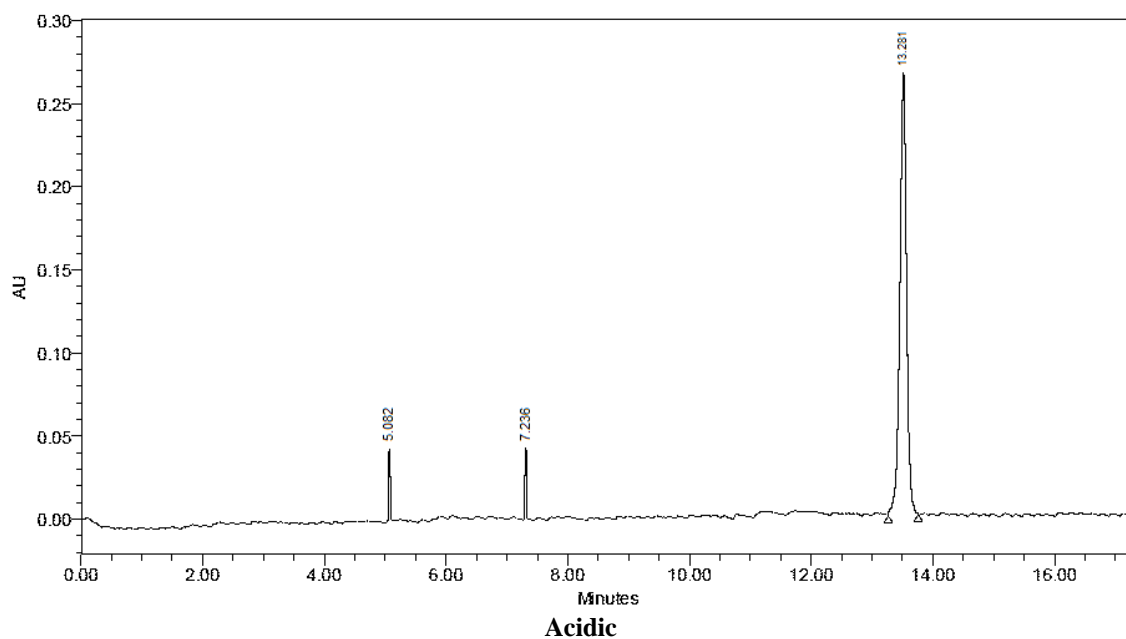
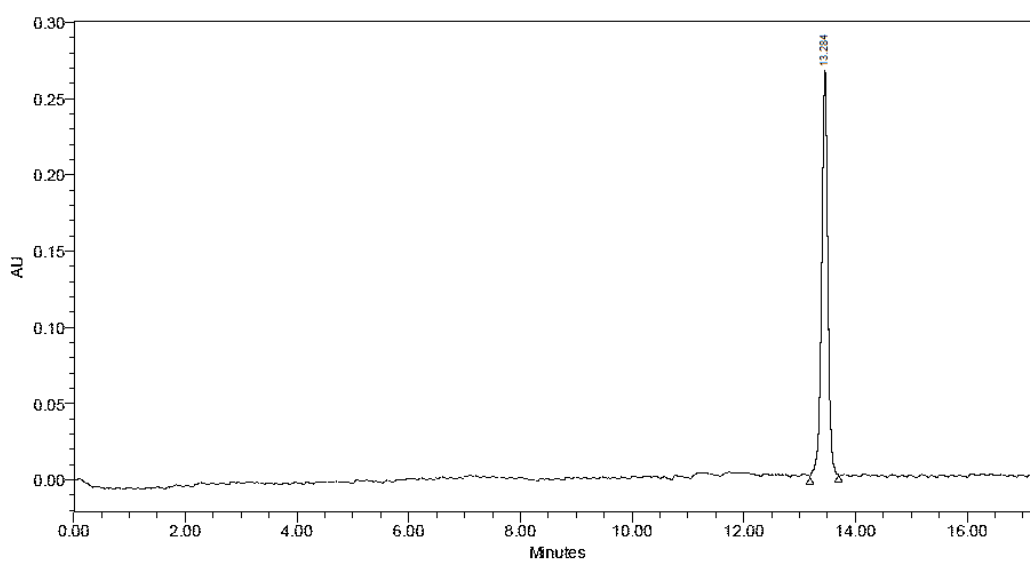
Parameters	Quetiapine
Retention time (min) ± % RSD	13.274 ± 0.05
Theoretical plates ± % RSD	6795.26 ± 0.75
Asymmetry ± % RSD	1.07 ± 0.06
Repeatability (% RSD)	0.09

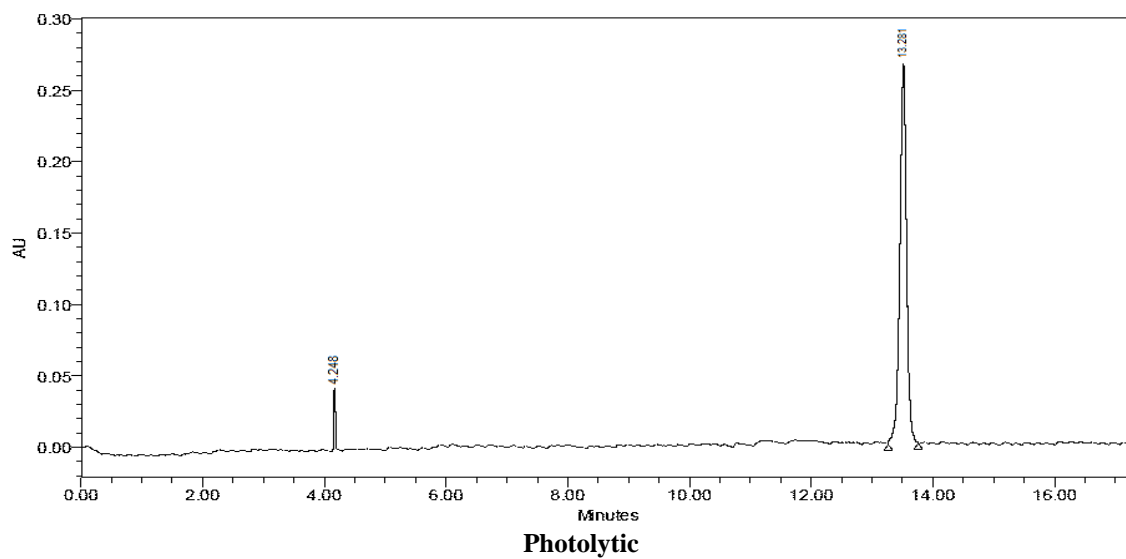
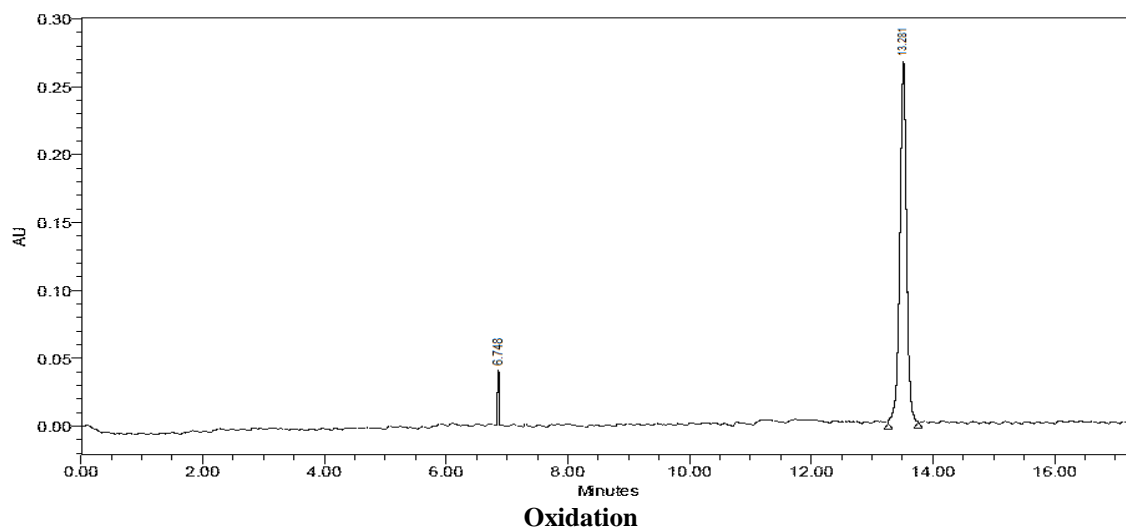
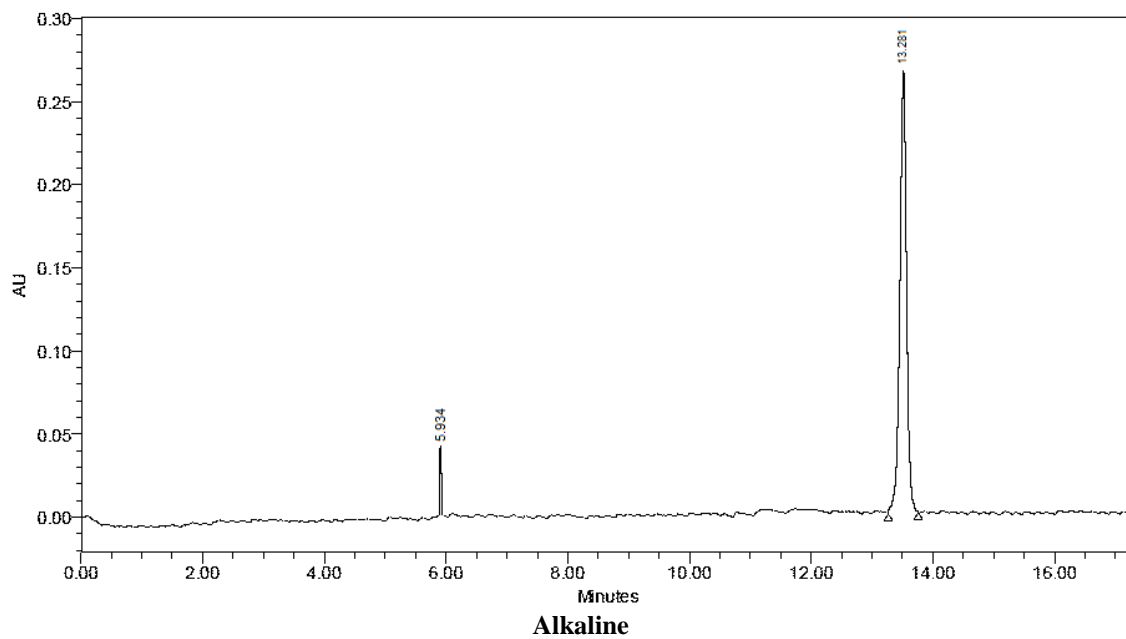
Method Precision

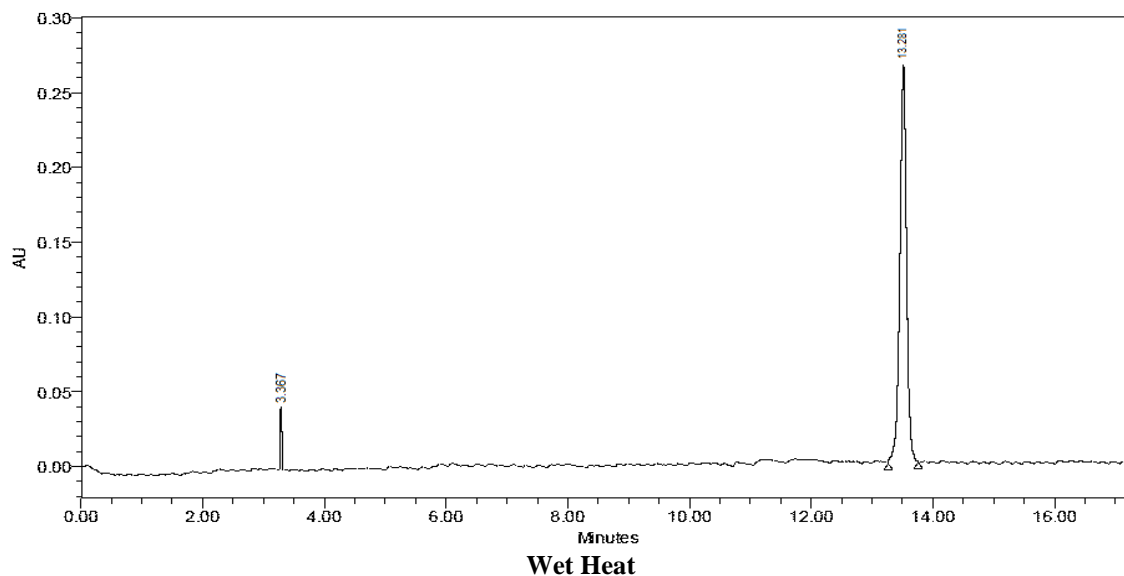
Replicate	Quetiapine			
	S.No.	Concentration Taken (µg/ml)	%LC	
	1	04.00	34297	99.43%
	2		34395	99.27%
	3		34284	99.56%
	4		34464	98.95%
	5		34432	98.85%
	6		34448	98.87%
	Average			99.76%
	Std.Dev			0.2275
	% RSD			0.24%
	Standard weight			4mg
	Standard potency			99.87%

Robustness

Robustness Studies			
Parameter	Value	Peak Area	% RSD
Flow Rate	Low	34556	0.7%
	Actual	34584	
	Plus	34624	
Temperature	Low	34694	0.04%
	Actual	34773	
	Plus	34785	
Wavelength	Low	34567	0.05%
	Actual	34598	
	Plus	34556	

Stability Assay Studies**Sample Control**





EVALUATION OF METHODS

Assay Studies

➤ Stability Indicating Analysis of Quetiapine

Conditions	% claim
Sample Control	96.97%
Acidic	92.45%
Alkaline	93.87%
Oxidation	93.54%
Photolytic	95.58%
Wet Heat	96.43%

CONCLUSION

Ultra chromatography was used to come up with a new, accurate, and special way to look at the dosage distribution pattern in bulk pharmaceutical and applications, and especially for this medicine. Because it has to do with treatment, this goal can be reached by using a simple evaluation method that doesn't interfere with how the approach is actually used. This strategy is effective and easy to use because it has a big effect and is repeated in a precise way. Based on what was known, it seemed like the method was a good way to approve the given approval criteria.

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