EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 10
Issue: 2
173-178
Year: 2023

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

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Article Received on 09/12/2022 **Article Revised on 29/12/2022** **Article Accepted on 19/01/2023**

ABSTRACT
Quetiapine, widely known by its brand name Seroquel, is an atypical antipsychotic drug that has demonstrated useful in the treatment of schizophrenia, bipolar disorder, and major depressive disorder. It is often used as a sleep aid because to its sedative qualities, despite the fact that the benefits seem to be outweighed by the negatives.

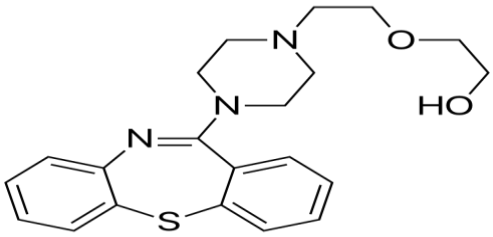
KEYWORDS: Quetiapine, Seroquel and Sedative.

INTRODUCTION

Bipolar disorder

Depressive episodes, acute manic episodes related to bipolar I illness (as monotherapy or adjunct therapy to lithium, valproate, or lamotrigine), and acute mixed episodes, together with maintenance treatment for bipolar I disorder, may all be treated with quetiapine (as adjunct therapy to lithium or divalproex).

Quetiapine chemical structure



Chemical structure of quetiapine
Weight: 383.51 g·mol−1
Chemical formula: $C_{21}H_{25}N3O_2S$
IUPAC: 2-(2-(4-Dibenzo [b,f][1,4]thiazepine-11-yl-1-piperazinyl)ethoxy)ethanol

EXPERIMENTAL METHODOLOGY

Method validation

The phrase "analytical process" refers to the manner in which the analysis is carried out. It should include a detailed description of the procedures that are required to carry out each analytical test. This may include, but is not limited to, the preparation of the sample, the reference standard, and the reagents; the use of the equipment; the development of the calibration curve; the application of the equations for the computation; and other such things. The technique that has been presented has undergone considerable testing to confirm its specificity, system appropriateness, linearity, accuracy, precision, limit of detection, limit of quantification, and robustness.

RESULTS

Preparation of standard stock solution

Preparation of diluent

It is necessary to summarise the results in order to make preparations for achieving partition under optimal conditions after a series of exploratory attempts. Because it formed symmetrical crests with high determination and an amazingly great affectability, as well as an awfully great determination and affectability, a stationary phase like the Hypersil BDS C18 (100 mm x 2.1 mm, 1.7 m) column was the most appropriate choice. The flow rate was maintained constant at 0.5 mL min-1, which was accomplished with an incredible amount of determination. After analysing the response of Quetiapine's PDA detector, researchers discovered that the best wavelength, which exemplified affectability, was 210 nm. This finding demonstrates that Quetiapine may be affected.

Using a slope programming strategy, a combination of two arrangements (Dimethylformamide and Acetonitrile in a proportion of 30:70 percent v/v) was utilised as the portable phase at a stream rate of 0.5mL/min. This combination of two arrangements was found to be a worthy versatile phase for the division of Quetiapine.

The column's temperature was maintained at a constant of 20 degrees Celsius (68 degrees Fahrenheit).

Internal standard arrangement: Weighed precisely approximately 10 mg of testosterone working standard and transferred it to a 100-ml volumetric carafe. Next, we added 50 ml of portable phase and sonicated it to completely break it up. Finally, the volume was made up to the required level with portable phase to obtain a standard stock arrangement of working standard containing 100 micrograms per millilitre (g/mL). After that, it was treated with ultrasonic vibrations for ten minutes at some point in the recent past while it was being sieved via a 0.20-micron layer channel.

Planning of quetiapine standard arrangement incorporates the taking after steps: Approximately 10 mg of Quetiapine was precisely weighed into a 100-mL volumetric carafe. After that, 50 mL of portable phase was added, and the mixture was sonicated to completely break down the Quetiapine. Finally, the volume was brought up to the specified level with portable phase so that the working standard would have a standard stock arrangement of 100 g/mL. After that, it was ultrasonically prepared for ten minutes prior to being filtered via a film channel with a 0.20-micron opening.

Accuracy procedure

Quetiapine						
Level %	**Amount Added (µg/ml)**	**Amount Found (µg/ml)**	**% Recovery**	**Mean Recovery (%)**	**Std.Dev**	**% RSD**
50	02.02	02.01	99.54	99.45	0.1115	0.11%
100	04.04	04.02	99.50			
150	06.06	06.02	99.33			

Recovery level	**Set No.**	**Quetiapine**	
		Wt. Taken (µg/ml)	**Amount found (µg/ml)**
50%	Set 1	02.02	02.01
	Set 2	02.04	02.03
	Set 3	02.06	02.04
100%	Set 1	04.04	04.03
	Set 2	04.08	04.05
	Set 3	04.12	04.09
150%	Set 1	06.06	06.03
	Set 2	06.09	06.07
	Set 3	06.12	06.10

System precision

Parameters	**Quetiapine**
Retention time (min) ± % RSD	13.385 ± 0.07
Theoretical plates ± % RSD	6783.67 ± 0.50
Asymmetry ± % RSD	1.03 ± 0.02
Repeatability (% RSD)	0.09

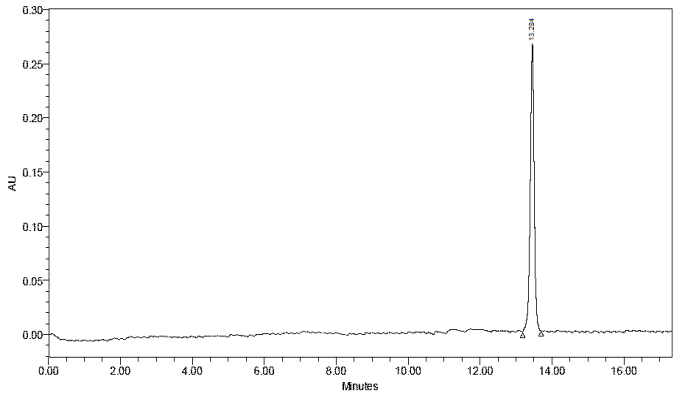
Method precision

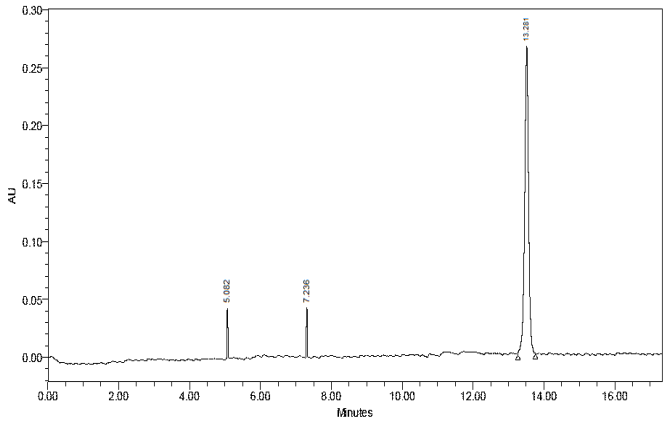
Replicate	***Quetiapine***		
S. No.	**Concentration Taken (µg/ml)**	**Area**	**%LC**
1	04.00	34281	99.39%
2		34388	99.08%
3		34275	99.41%
4		34453	98.90%
5		34422	98.99%
6		34437	98.94%
Average			99.11%
Std.Dev			0.2263
% RSD			0.23%
Standard weight			4mcg
Standard potency			99.80%

Robustness

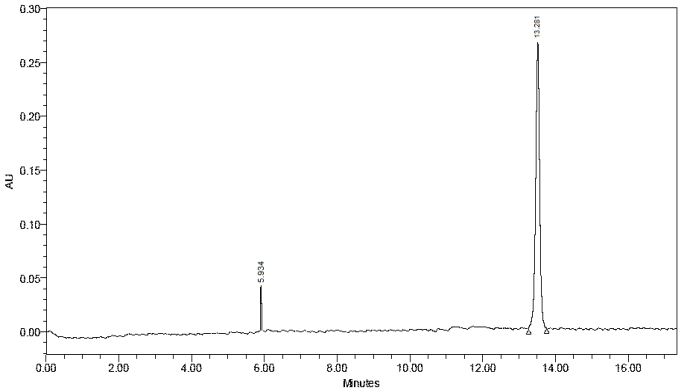
Robustness Studies			
Parameter	**Value**	**Peak Area**	**% RSD**
Flow Rate	Low	34556	0.7%
	Actual	34589	
	Plus	34607	
Temperature	Low	34687	0.04%
	Actual	34702	
	Plus	34717	
Wavelength	Low	34559	0.05%
	Actual	34580	
	Plus	34596	

Stability assay studies
Sample control

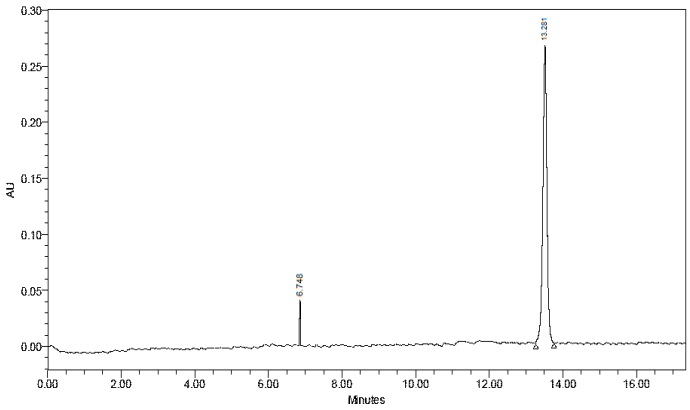




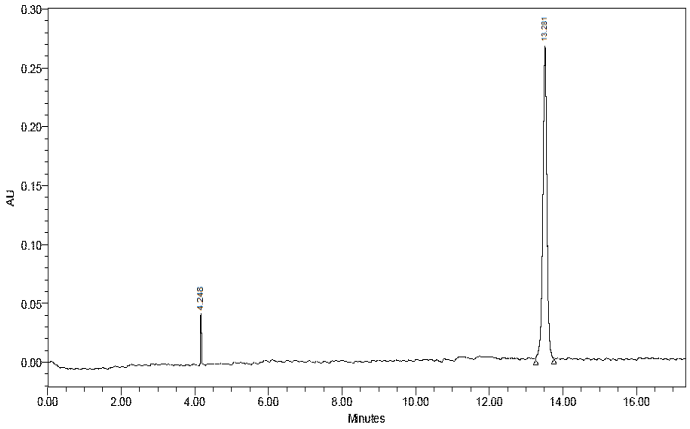
Acidic



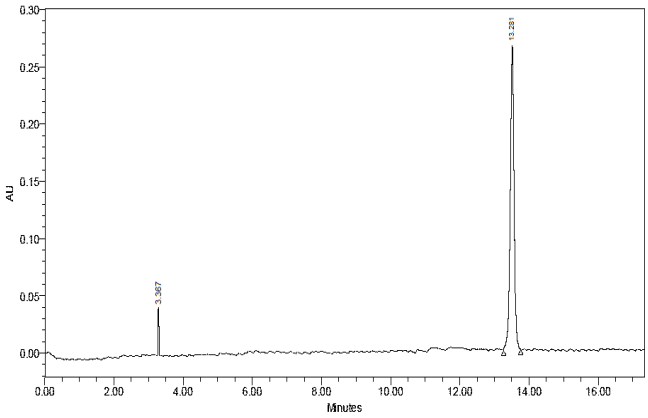
Alkaline



Oxidation



Photolytic



Wet Heat

Evaluation of methods

Assay studies

- **Stability indicating analysis of quetiapine**

Conditions	% claim
Sample control	96.95%
Acidic	92.29%
Alkaline	93.67%
Oxidation	93.48%
Photolytic	95.37%
Wet heat	96.28%

CONCLUSION

The dose distribution pattern in bulk pharmaceutical and applications, and in particular for this medication, required the development of an innovative, precise, and specialised ultra chromatographic technology. This was done in order to analyse the pattern. This aim, which has connotations of therapy, may be accomplished by using a basic assessment technique that does not interfere with the actual application of the approach. This is possible because of the connotations treatment has. The high impact and recurrence of this tactic, together with the fact that it maintains its accuracy, make it an efficient and easy method to implement. It appeared, on the basis of the evidence that was at hand, that the procedure was adequate for authorising the particular approval criteria that were given.

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