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

ISSN 2349-8870
Volume: 10
Issue: 2
179-184
Year: 2023

EVALUATION AND VALIDATION OF A UPLC METHOD FOR THE STABILITY INDICATING ASSAY OF QUETIAPINE IN TABLET DOSAGE FORM USING UPLC-MS/MS^N

Syeda Rakhshinda Zareen[1]*, Dr. Osman Ahmed[1], Reshma[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: Syeda Rakhshinda Zareen**
Department of Pharmaceutical Analysis, Deccan School of Pharmacy, Hyderabad.

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

ABSTRACT
With promising results in the treatment of schizophrenia, bipolar disorder, and major depressive disorder, the atypical antipsychotic quetiapine is better known by its brand name, Seroquel. Due to its sedative properties, it is often used as a sleep aid, despite the fact that the risks of using it seem to exceed the benefits.

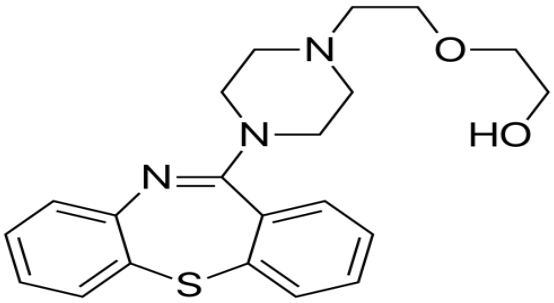
KEYWORDS: Quetiapine, Seroquel and Sedative.

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

$C_{21}H_{25}N3O_2S$

IUPAC

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

EXPERIMENTAL

METHODOLOGY

Method validation

The 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.

Planning of quetiapine standard arrangement incorporates the taking after steps: 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.

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

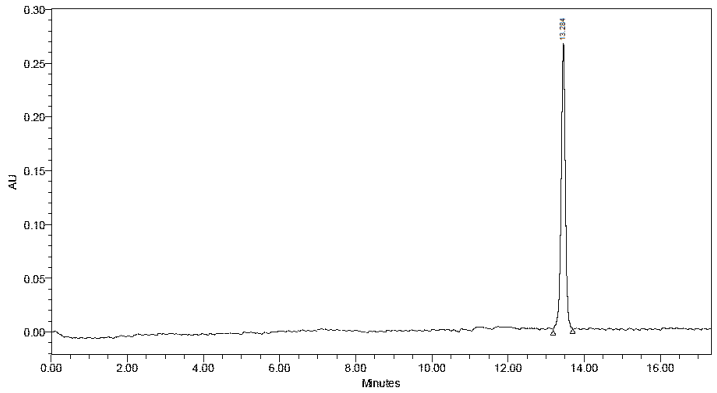
Method precision

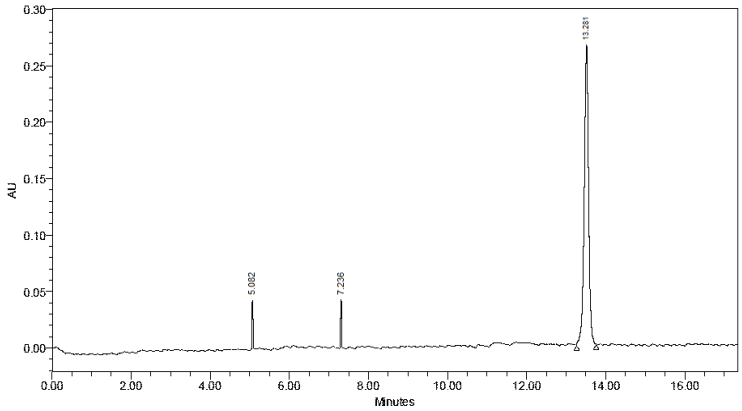
Replicate	***Quetiapine***		
S.No.	**Concentration Taken (µg/ml)**	**Area**	**%LC**
1	04.00	34297	99.43%
2		34395	99.27%
3		34284	99.56%
4		34464	98.95%
5		34432	98.85%
6		34448	98.87%
Average			99.76%
Std.Dev			0.2275
% RSD			0.24%
Standard weight			4mg
Standard potency			99.87%

Robustness

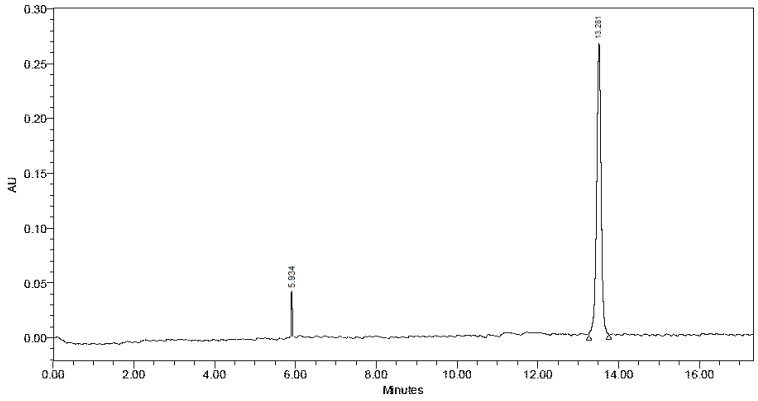
Robustness Studies			
Parameter	**Value**	**Peak Area**	**% RSD**
Flow Rate	Low	34556	0.7%
	Actual	34584	
	Plus	34624	
Temperature	Low	34694	0.04%
	Actual	34773	
	Plus	34785	
Wavelength	Low	34567	0.05%
	Actual	34598	
	Plus	34556	

Stability assay studies
Sample control

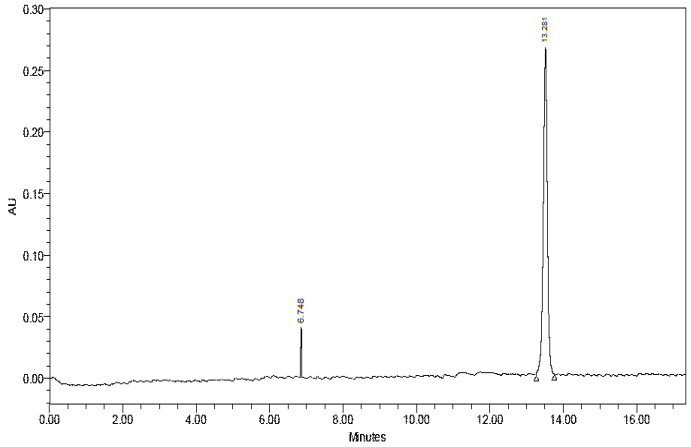




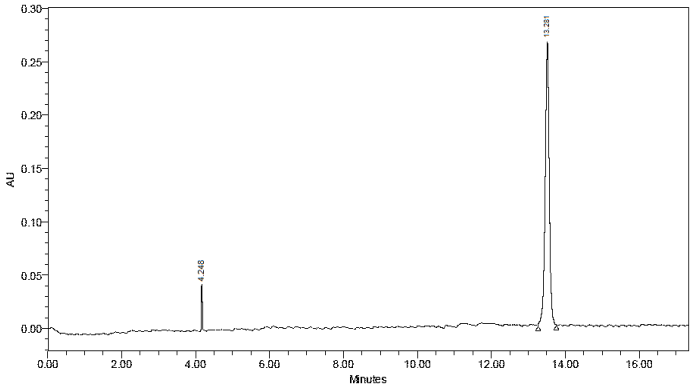
Acidic



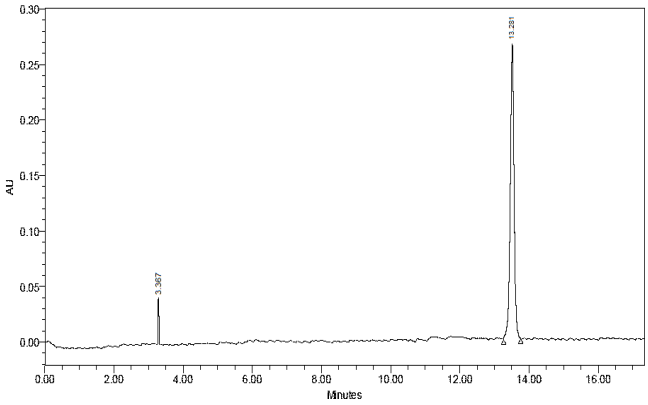
Alkaline



Oxidation



Photolytic



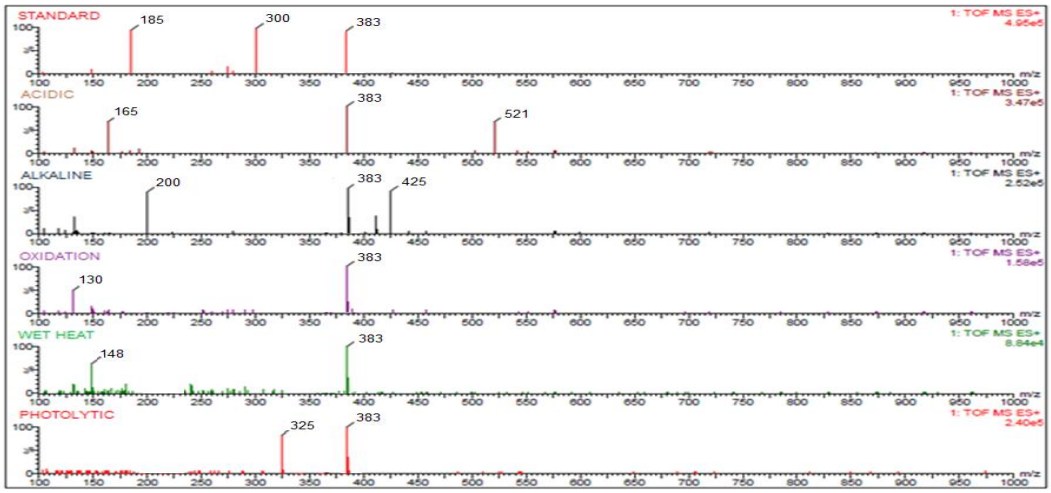
Wet heat

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%



Analyte	Observed ion mass (Da)	Proposed formula	Calculated mass (Da)
Unknown	148.38	C8H22NO	148.27
Unknown	185.54	C9H18N2O2	186.25
Unknown	200.02	C10H20N2O2	200.28
Unknown	300.42	C13H23N3O3S	301.40
Unknown	325.46	C14H19N3O4S	325.38
Quetiapine	383.50	C21H25N3O2S	383.51
Unknown	425.45	C17H23N5O4S2	425.52
Unknown	426.87	C17H24N5O4S2	426.53
Unknown	521.72	C17H27N7O6S3	521.63

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.

REFERENCES

1. Y. C. Mayur*, Osman Ahmad, V. V.S. Rajendra Prasad, M. N. Purohit, N. Srinivasulu, S. M. Shanta Kumar, "Synthesis of 2-Methyl N^{10}-Substituted Acridones as Selective Inhibitors of Multidrug Resistance (MDR) Associated Protein in Cancer Cells". Medicinal Chemistry, Bentham Science Publishers, 2008; 4, 5: 457-465(9).
2. Osman Ahmed*, Pankaj Sharma, Jaya Sharma, "Synthesis and Pharmacological Study of Azetidinone Derivatives" International Journal of Pharmaceutical Science & Education, 2013; 11-18.
3. Osman Ahmed*, Pankaj Sharma, Jaya Sharma, Dr. Indrajeet Singhvi, "Synthesis and Anticonvulsant Activity of Some Substituted Azetidinone Derivatives" Asian Journal of Pharmaceutical Research and Development, 2013; 5.
4. Osman Ahmed*, Dr. Md Salahuddin, Vinutha. K, Pankaj Sharma. "Design, Synthesis and Biological Evaluation of Some Novel Substituted Thiazolidinone Derivatives as Potent Antihyperglycemic Agents". International Journal of Pharmaceutical Research Scholars, 2013; 2: 3.
5. Osman Ahmed*, Md Salahuddin, Pankaj Sharma, Indrajeet Singhvi "Synthesis and biological investigations of some new thiazolidinone derivatives as anti-tubercular agents", American Journal of Pharmtech Research, 2013; 3: 193-201.
6. Osman Ahmed*, Md. Salahuddin, Iffath Rizwana, M.A.Aleem, Pankaj Sharma, "Synthesis, Characterization and Biological Evaluation of Novel thiazolidinone derivatives as Anti-inflammatory Agents", Indo American Journal of Pharmaceutical Research, 2013; 3(10): 8121-8126.
7. Osman Ahmed*, Pankaj Sharma, Indrajeet Singhvi. "Synthesis and Anti-Hyperglycemic activity of Some Novel Thiazolidinone Derivatives". Indo

American Journal of Pharmaceutical Research, 2014; 4(02): 1008-1014.
8. Osman Ahmed*, Pankaj Sharma, Indrajeet Singhvi. "Anticonvulsant Activity of Some Novel Substituted Thiazolidinone Derivatives against Maximal Electro Shock Induced Seizure". International Journal of Pharmaceutical Research Scholars, 2014; 3, 1: 289-294.
9. Osman Ahmed*, Mohd Haseeb Ur Rahman, Abdul Najeeb, Sk. Md. Noorullah, S.A.Azeez Basha, Design, "Synthesis and Anti- inflammatory activity of certain fused Novel Thienopyrimidines Derivatives", International Journal of Pharmaceutical Research Scholars, 2013; 2, 4: 82-87.
10. Syed Aamer Ali, SK Danda, Syed Abdul Azeez Basha, Rasheed Ahmed, Osman Ahmed, Mohd Muqtader Ahmed. "Comparision of uroprotective activity of reduced glutathione with Mesna in Ifosfamide induced hemorrhagic cystitis in rats". Indian Journal of Pharmacology, 2014; 46: 105-108.
11. Osman Ahmed*, Syed Azeemuddin Razvi, T K Md Rayees, M A Nafay Shoeb, Md Salahuddin. "Synthesis Characterization and Anti-inflammatory activity of some substituted pyrimidine derivatives". Indo American Journal of Pharmaceutical Research, 2014; 4(05): 2301-2306. DOI: 10.1044/1980-iajpr.14369.
12. Osman Ahmed*, Farhana Begum, Nishat Fatima, Md. Salahuddin. "Synthesis and Biological Activity of Some Novel Pyrimidine Derivatives". International Journal of Pharmaceutical Research Scholars, 2014; 3, 4: 103-108.
13. Ms. Farhana Begum, Osman Ahmed, Md. Salahuddin, Nishat Fatima. "Synthesis, Characterization and Anti-Hyperglycemic Activity of Novel Pyrimidine Derivatives". Indo American Journal of Pharm Research, 2014; 4(11): 5501-5506. DOI: 10.1044/19 80-iajpr.141042
14. Osman Ahmed*, Mehruq Fatima, Juveriya Parveen, Asma Farheen, Ayesha Binth Saleh, Dr. Syed Mahmood Ahmed. Changes in Pulmonary Function Test (PFT) Before and After Adding Tiotropium Bromide to the Ongoing Therapy of Severe Persistant Asthamatics. Indo American Journal of Pharm Research, 2015; 5(01). DOI: 10.1044/1980-iajpr.141266.
15. Mohd Khader, Mohd Mahboob Shareef, Syeda Huda Noorain, Osman Ahmed. Synthesis, Characterization and Biological Activity of Some Novel Pyrimidine Derivatives. Indo American Journal of Pharm Research, 2015; 5(03).
16. Fayeza Batool, Osman Ahmed, Anas Rasheed. An Assay Method for the Simultaneous Estimation of Acetaminophen and Tramadol using RP-HPLC Technology. Indo American Journal of Pharmaceutical Research, 5(7): 2605-2610.
17. Fayeza Batool, Osman Ahmed, Anas Rasheed. A Stability Indicating Method for the Simultaneous Estimation of Acetaminophen and Tramadol in Pharmaceutical Dosage Form. American Journal of PharmTech Research, 2015; 5(04): 674-683.
18. Humeera Rafeeq, Talath Fatima, Afiya Ansari, Osman Ahmed. Personalized Medicine - A Boon For Treating Rheumatoid Arthritis. Indo American Journal of Pharmaceutical Research, 5(8).
19. Humeera Rafeeq, Osman Ahmed, M.A Khaleq, Samee A, Amer M. Progress In The Treatment of Neuroblastoma. Indo American Journal of Pharmaceutical Research, 5(8).
20. Talath Fatima, Osman Ahmed, Amer Mahboob, Afiya Ansari, Amatullah Fathimah. Personalized Medicine - A Review – Progress In The Treatment of Non Small Cell Lung Cancer (NSCLC) In A New Era of Personalised Medicine. Indo American Journal of Pharmaceutical Research, 5(8).
21. Talath Fatima*, Osman Ahmed, Afiya Ansari, Amatullah Fathimah, Amer Mahboob. Novel Therapeutic Approaches to a Chronic Inflammatory Disorder – Asthma. International Journal of Pharmaceutical Research Scholars, 2015; V-4, I-3, 112-117.
22. Humeera Rafeeq*, Osman Ahmed, Sohail Ali, Mohd Younus, Mohd Bilal. A Review on Mowat-Wilson Disorder, International Journal of Pharmaceutical Research Scholars, 2015; V-4, I-3, 176-181.
23. Humeera Rafeeq*, Osman Ahmed, Fayeeza Ameen, Amreen Sultana, Maryam Fatima. A Review on Harlequin Ichthyosis. International Journal of Pharmaceutical Research Scholars, 2015; V-4, I-3, 189-193.
24. Anees Begum*, Osman Ahmed. An Assay Method for the Simultaneous Estimation of Albuterol and Ipratropium Bromide using RP- HPLC Technology. International Journal of Pharmaceutical Research Scholars, 2016; V-5, I-4, 33-37.
25. Anas Rasheed*, Osman Ahmed. UPLC Method Optimisation and Validation for the Estimation of Sodium Cromoglycate in Pressurized Metered Dosage Form, International Journal of Applied Pharmaceutical Sciences and Research, 2017; 2(2): 18-24. http://dx.doi.org/10.21477/ijapsr.v2i2.7774