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EVALUATION AND VALIDATION OF A UPLC METHOD FOR THE ESTIMATION OF QUETIAPINE IN TABLET DOSAGE FORM

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ABSTRACT

Atypical antipsychotic quetiapine, most often referred to by its brand name Seroquel, is a medication that has shown promising results in the treatment of schizophrenia, bipolar disorder, and major depressive disorder. Because of its sedative properties, it is often used as a sleep aid, despite the fact that the potential drawbacks seem to exceed the advantages of using it.

KEYWORDS: Quetiapine, Seroquel and sedative.

INTRODUCTION

In the treatment of major depressive disorder, quetiapine is beneficial both when used on its own and in combination with other drugs (MDD). Sedation, on the other hand, is often an unwelcome side effect.

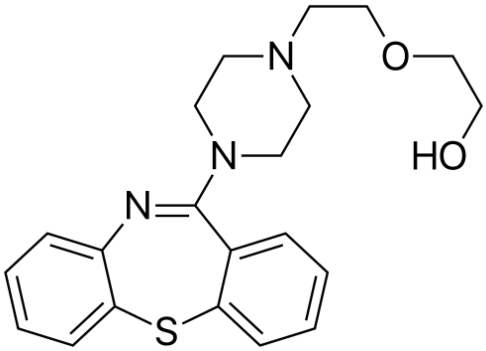
In the United States, the United Kingdom, and Australia, quetiapine is authorised for use as an add-on medication in major depressive disorder (MDD), despite the fact that it is not subsidised by the Australian Pharmaceutical Benefits Scheme for the treatment of MDD.

Quetiapine Drug Information

Quetiapine is an atypical antipsychotic medicine that is used for the treatment of schizophrenia, bipolar disorder, and major depressive disorder, among other conditions. The medication is offered under the brand name Seroquel, among other names. In spite of the fact that it has a sedative effect and is thus often used as a sleep aid, it would seem that the advantages of such usage do not, on average, exceed the adverse effects. It is consumed via the mouth.

The most often seen adverse effects include drowsiness, constipation, weight gain, and dry mouth. A low blood pressure reading upon standing, seizures, a prolonged erection, high blood sugar level, tardive dyskinesia, and neuroleptic malignant syndrome are some of the other adverse effects. The usage of this drug raises the chance of mortality in elderly patients suffering from dementia. When used during the third trimester of pregnancy, there is an increased risk that the infant will have mobility disorders for some time after delivery. It is thought that quetiapine achieves its therapeutic effect by inhibiting a variety of receptors, including those for serotonin and dopamine.

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: I used a volumetric carafe with a 100-milliliter capacity to measure out exactly 10 milligrammes of testosterone, the industry standard. Then, 50 ml of portable phase was added, and it was sonicated to pulverise the mixture into tiny pieces. Finally, the volume was brought up to the appropriate level using portable phase to create a working standard stock arrangement of 100 g/mL. After that, it was sieved through a 0.20 micron layer channel and subjected to ultrasonic vibrations for 10 minutes.

Planning of Quetiapine standard arrangement incorporates the taking after steps: To prepare a 100-g/mL standard stock arrangement of the working standard, about 10 mg of Quetiapine was carefully weighed into a 100-mL volumetric carafe, and then 50 mL of portable phase was added and sonicated to completely break down the Quetiapine. After that, a 0.20 micron film channel was used to sieve the mixture before ultrasonically preparing it for 10 minutes.

System Precision

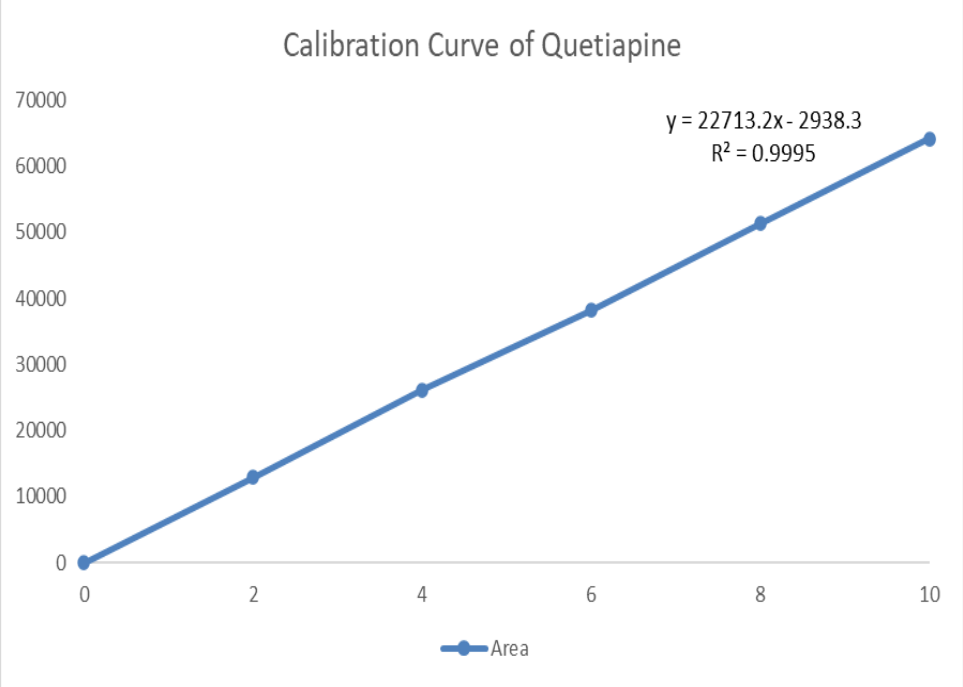
Parameters	**Quetiapine**
Retention time (min) ± % RSD	12.289 ± 0.09
Theoretical plates ± % RSD	6854.21 ± 0.55
Asymmetry ± % RSD	1.24 ± 0.08
Repeatability (% RSD)	0.07

Method Precision

Replicate	***Quetiapine***		
S.No.	**Concentration Taken (µg/ml)**	**Area**	**%LC**
1	04.00	34276	99.41%
2		34354	99.76%
3		34265	99.54%
4		34427	98.88%
5		34443	98.94%
6		34487	98.97%
Average			99.35%
Std.Dev			0.2274
% RSD			0.26%
Standard weight			4mg
Standard potency			99.73%

Linearity

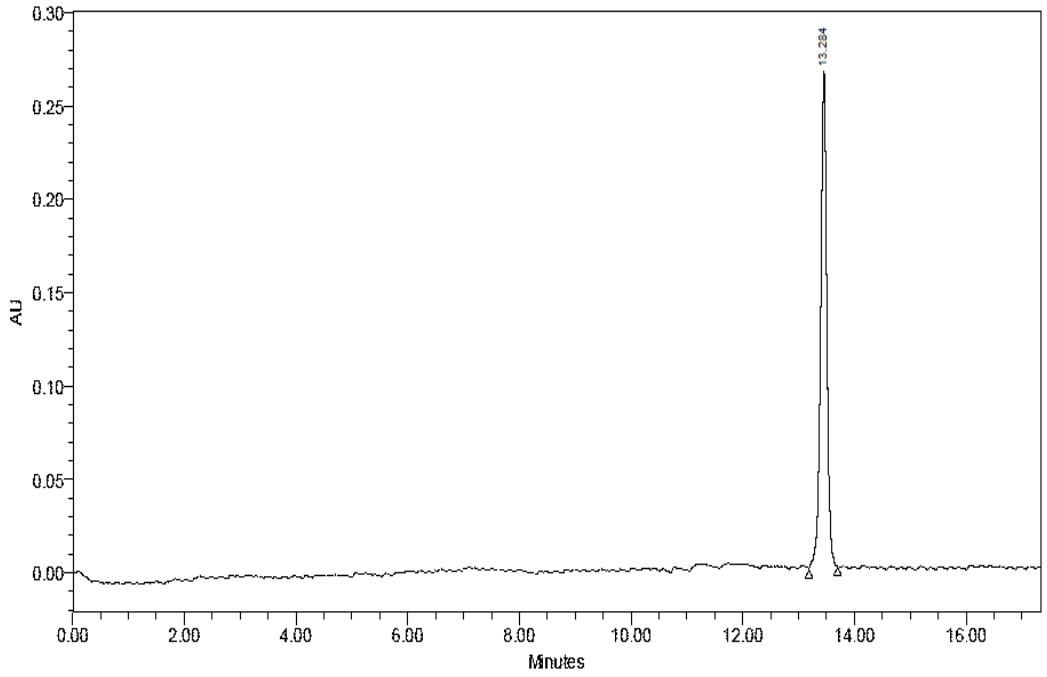
Quetiapine		
Linearity level	**Concentration in µg/mL**	**Area**
1	2 µg/mL	12936
2	4 µg/mL	26078
3	6 µg/mL	38184
4	8 µg/mL	51335
5	10 µg/mL	64184
Correlation co-efficient	0.9995	
Slope	2938.3	
Intercept	22713.2	



Ruggedness

Quetiapine			
Ruggedness			
Parameter	**Peak Area**	**% RSD**	**%LC**
Intraday precision	34397	0.09%	99.98%
	34455		99.83%
	34434		99.84%
Inter day precision	34393	0.1%	99.96%
	34456		99.85%
	34448		99.87%
Instrument:1 Acquity HPLC Waters,2695H	34554	0.09%	99.54%
	34553		99.52%
	34604		99.33%
Instrument:2 Agilent Technologies,1290	34558	0.1%	99.54%
	34559		99.56%
	34614		99.38%
Average			**99.65%**
Std. Dev			**0.2267**
%RSD			**0.24%**

Assay Studies
Sample Control



Evaluation of Methods
Assay Studies

- **Analysis of Quetiapine**

Conditions	Sample Amount (µg/ml)	Peak Area	% claim
Sample Control	04.15	34458	96.13%
Market	04.12	34215	96.22%

Calculation formula for Quetiapine

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

Sample Control (Quetiapine)

$$\%\ Assay = \frac{34453}{34859} \times \frac{04.27}{100} \times \frac{1}{25} \times \frac{100}{04.35} \times \frac{25}{1} \times \textbf{Error!} \times$$

99.80
= 96.96%

CONCLUSION

For the purpose of analysing the dosage distribution pattern in bulk pharmaceutical and applications, and in particular for this medicine, a novel, accurate, and unique ultra chromatographic technique was created. Due to the connotations with healthcare, this objective may be reached by a straightforward evaluation process that does not hamper the usefulness of the approach. Due of its widespread applicability and possibility for repeated accuracy, this strategy is both effective and convenient. According to the available data, the approach was effective in approving the predetermined approval criteria.

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