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

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ABSTRACT
Quetiapine, also known by its brand name Seroquel, is an atypical antipsychotic medicine that has shown effective in the treatment of schizophrenia, bipolar disorder, and major depressive disorder. Due to its sedative properties, it is often used as a sleep aid, however the benefits seem to not exceed the cons.

KEYWORDS: Quetiapine, Bipolar Disorder and Sedative.

INTRODUCTION

When treating major depressive illness, quetiapine works well both alone and in combination with other drugs (MDD). On the other hand, sedation is frequently a negative adverse consequence.

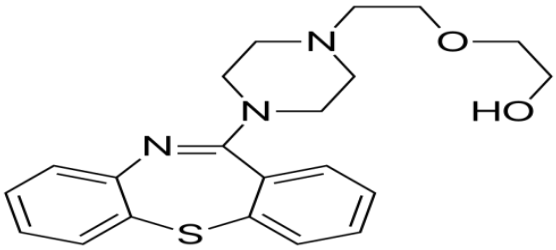
Quetiapine is licenced for use as an adjunct medication in MDD in the United States, the United Kingdom, and Australia.

Quetiapine drug information

Quetiapine, also known by its brand name Seroquel, is an atypical antipsychotic medicine that has shown effective in the treatment of schizophrenia, bipolar disorder, and major depressive disorder. Due to its sedative properties, it is often used as a sleep aid, however the benefits seem to not exceed the cons. It has to be ingested by mouth.

Drowsiness, constipation, weight gain, and dry mouth are typical adverse reactions. Besides these, tardive dyskinesia, neuroleptic malignant syndrome, seizures, extended erections, high blood sugar, and high blood pressure are also possible. It raises the chance of mortality in the elderly with dementia who take it. Ingesting throughout the last three months of pregnancy has been linked to postnatal movement disorders. Several receptors, including those for serotonin and dopamine, are thought to be blocked by quetiapine for it to have any effect at all.

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

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

Summarizing the results of a series of exploratory experiments is vital for planning an approach that would lead to partitioning under optimal conditions. The Hypersil BDS C18 (100 mm x 2.1 mm, 1.7 m) column was the most appropriate stationary phase because it produced symmetrical crests with high determination and a high degree of affectability. In a show of remarkable resolve, the flow velocity was held constant at 0.5 mL min-1. The wavelength of 210 nm was shown to be optimal for eliciting a response from the PDA locator in Quetiapine, demonstrating its sensitivity to external stimuli.

Using a slope programming approach, two different arrangements (Dimethylformamide and Acetonitrile at a stream rate of 0.5mL/min) were used as the portable phase for the distribution of Quetiapine. The column was maintained at a constant, ambient temperature.

Internal standard arrangement: Standard stock arrangement of working standard containing 100 micrograms per millilitre (g/mL) was prepared by weighing precisely approximately 10 mg of Testosterone working standard and exchanging it to a 100-ml volumetric carafe, adding 50 ml of portable phase, and sonicating to completely break it up, and then making up the required level with portable phase. It was then passed through a 0.20 micron layer channel while being ultrasonically handled for 10 minutes.

Quetiapine standard: 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

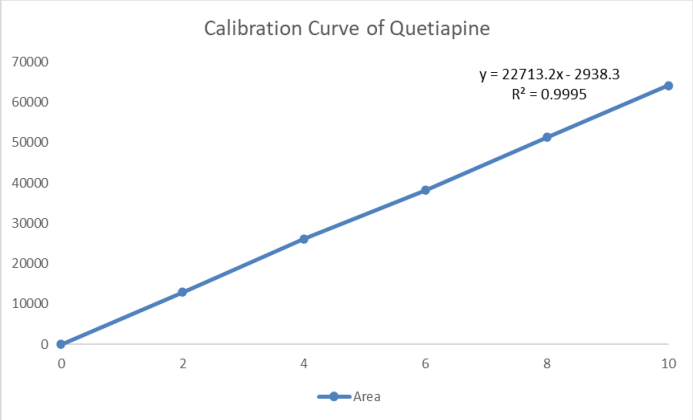
Parameters	**Quetiapine**
Retention time (min) ± % RSD	13.385 ± 0.07
Theoretical plates ± % RSD	6783.67 ± 0.50
Asymmetry ± % RSD	1.03 ± 0.02
Repeatability (% RSD)	0.09

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%

Linearity

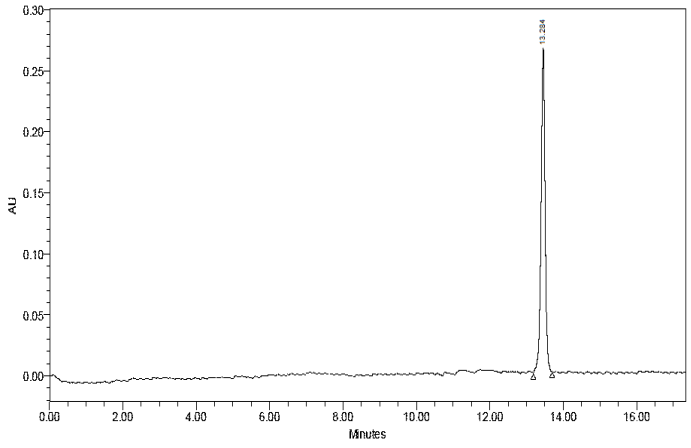
Quetiapine		
Linearity level	**Concentration in µg/mL**	**Area**
1	2 µg/mL	12931
2	4 µg/mL	26075
3	6 µg/mL	38189
4	8 µg/mL	51337
5	10 µg/mL	64183
Correlation co-efficient	0.9995	
Slope	2938.3	
Intercept	22713.2	



Ruggedness

Quetiapine			
Ruggedness			
Parameter	**Peak Area**	**% RSD**	**%LC**
Intraday precision	34396	0.09%	99.99%
	34459		99.81%
	34439		99.87%
Inter day precision	34395	0.1%	99.98%
	34452		99.83%
	34443		99.86%
Instrument:1 Acquity HPLC Waters, 2695H	34556	0.09%	99.53%
	34552		99.54%
	34605		99.39%
Instrument:2 Agilent Technologies, 1290	34558	0.1%	99.52%
	34556		99.53%
	34612		99.37%
Average			**99.68%**
Std.Dev			**0.2264**
%RSD			**0.23%**

Assay studies
Sample control



Evaluation of methods
Assay studies

- **Analysis of quetiapine**

Conditions	Sample amount (µg/ml)	Peak area	% claim	% Degradation
Sample control	04.15	34453	96.95%	-
Market	04.12	34218	96.29%	0.66%

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)

$$\%\ Assay = \frac{34453}{34859} \times \frac{04.27}{100} \times \frac{1}{25} \times \frac{100}{04.35} \times \frac{25}{1} \times \textbf{Error!} \times 99.80 = 96.95\%$$

CONCLUSION

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.

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