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UV SPECTROSCOPIC ESTIMATION OF BRIVARACETAM IN BULK DRUG AND FORMULATIONS

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ABSTRACT

Epilepsy is characterized by recurring, uncontrollable seizures and associated co-morbidities. Convulsion episodes are caused by aberrant brain activity that manifests as symptoms and indicators for a short time. A novel, uncomplicated, accurate, basic, exact, and reasonably priced ultraviolet (UV) spectrophotometric approach with an enhanced detection range was created for the current investigation. Following a review of the literature, we discovered that there was only one way for estimating brivaracetam, which motivated us to create further techniques utilizing a UV spectrophotometer. Brivaracetam's maximum absorbance was discovered at λmax 218 nm. With a correlation coefficient of 0.9998, brivaracetam was demonstrated to be linear using the UV spectroscopic technique over the concentration range of 10–50µg/ml.A statistical analysis of the process revealed results that fell within the acceptable bounds. Using the least squares approach, a linear regression equation with the following values was produced: y = 0.0150x + 0.0110. The process was demonstrated to be affordable and less time-consuming in relation to the results,as well as accurate, exact, reproducible,andeasytouse. The analytical approach was created and validated using all validation parameters in accordance with ICH guidelines (ICH Q2 (R1)) in order to satisfy requirements such as accuracy, precision, linearity, reproducibility, interday, precision, intraday precision, robustness, and the limit of detection and limit of quantitation being found to be within acceptable bounds. The analysis results were also statistically validated.

KEYWORDS: Brivaracetam, uv spectroscopy, validation, ICH Guidelines, Quantification.

1. INTRODUCTION

Brivaracetam is chemically known as 2-(2-oxo-4-propylpyrrolidin-1-yl).It is used for the treatment of the signs and symptoms of anti- epileptic agent.Brivaracetam is a second-generation antiepileptic drug (AED) designed to target and modulate synaptic vesicle protein 2A (SV2A), a key player in neurotransmitter release and seizure regulation. Developed as an analogue of levetiracetam, brivaracetam exhibits higher affinity for SV2A, potentially offering improved efficacy and tolerability in seizure management. Since its approval by regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), brivaracetam has been widely used as an adjunctive treatment for focal (partial-onset) seizures in both adults and pediatric patients.

Ultraviolet (UV) spectroscopy is a commonly used analytical method that provides numerous benefits, including ease of use, high sensitivity, and the ability to conduct non-destructive analyses. This technique is especially proficient in drug analysis because it can identify compounds featuring conjugated double bonds or chromophores. UV spectroscopy facilitates accurate quantification of pharmaceuticals in a variety of matrices, such as tablets, formulations, and biological specimens. Establishing and validating a dependable UV spectroscopic method for measuring Brivaracetam in both its pure and marketed forms is critically important.This investigation seeks to develop a reliable and sensitive UV method suitable for regular quality control and pharmacokinetic evaluation of Brivaracetam. The research will concentrate on refining the experimental parameters, validating the procedure, and confirming its accuracy, precision, linearity, and robustness, in accordance with regulatory requirements.

2. MATERIALS AND METHODS

Pharmaceutical grade of was kindly Brivaracetam gifted from Hetero Labs Limited, Hyderabad, Telangana. The brand of tablets used was Briviact and procured from Apollo Pharmacy, Jubliee hills, Hyderabad. All the solvents and chemicals used were of analytical reagent grade and procured from Quietens India pt. Ltd., and Lobe Chemist India Ltd.

Instruments

Kerron P5 Series Precision Electronic Balance, Model Bl -3003, T60 UV-Visible spectrophotometer with 1 cm matched quartz cells, Sonicator Sonica Ultrasonic cleaner model 2200Mh.

Method – simple uv- spectroscopy

Ultrasonic cleaner model 2200 MH. The solubility of Brivaracetam was determined in a variety of solvent ranging from non-polar to polar using essentially a method of Schefter and Higuchi. The drug was found to be freely soluble in Distilled water, Ethanol, Methanol, Acetone, Glacial Acetic acid (30% & 50%), 0.5 M NaOH, 1 M NaOH and Sparingly soluble in Glacial Acetic acid(10% & 20%), HCl(0.1M & 0.5 M) and Chloroform. Considering the economic factor and the drug were stable in Methanol for 3 h, Methanol was selected as the solvent for method.

Preparation of standard stock solution

10 mgBrivaracetam was accurately weighed and transferred into a 50 ml standard flask and dissolved with minimum quantity of Methanol and made up to 50 ml with more Methanol(100 µg /ml).

Selection of λ_{max} and stability studies

The standard stock solution was further diluted with Methanol to get 10 µg/ml concentration (1 ml to 100 ml). The solution was scanned between 200 and 400 nm usingMethanol as blank. From the spectrum obtained, 218 nm was selected as λ_{max} for the analysis of Brivaracetam. Stability studies were performed and Brivaracetam was found to be stable for 3 hrs

Calibration graph and linearity

In this method, the aliquots (0.5–2.5 ml) of standard stock solution of Brivaracetam were transferred into 100 ml standard flasks and made up to the mark with Methanol. The absorbance was measured at 218 nm against Methanol as blank. The sample solutions were found to be linear from 05-25 µ g/ml. The calibration curve was plotted between concentration and absorbance.

Quantification of formulations

Thirty tablets of formulation containing 5 mg of Brivaracetam were accurately weighed to find out the average weight and powdered. Transferred the powdered tablets equivalent to 50 mg of Brivaracetam into a 50 ml conical flask, extracted with Methanol for three times (3 x 10 ml), sonicated for 15 min and produced to 50 ml with Methanol using a standard flask. Half of the solution was filtered using Whatmann filter paper No. 41. From this clear solution, 5 ml was transferred to a 25 ml standard flask and produced to obtain 100 µg/ml solution with Methanol. The absorbance was measured at 218 nm using Methanol as blank. The amount of Brivaracetam present in each formulation was calculated from the slope and intercept of respective calibration curve.

Recovery studies

From each of the preanalyzed formulation, known quantities were taken (2.5 µg/ml) and the raw material solution was added in ascending amounts (2.5, 7.5, 12.5, 17.5 and 22.5 ml) to 100 ml standard flasks. The contents were mixed well, finally made up to the mark and filtered. The absorbance was measured at 218 nm using Methanol as blank and the amount of drug recovered from each formulation was calculated by the mathematical relation followed by Same.

Statistical Validation

The obtained results were treated for statistical validation parameters like Standard Deviation (SD) and Percentage Relative Standard Deviation (% RSD).

RESULTS AND DISCUSSION

The solubility profile of Brivaracetam was determined as per procedure followed by Schefter and Higuchi. Using various polar to nonpolar solvents and from the solubility studies the category of solvents for briviact was hereby confirmed as freely soluble in Methanol, Dist. Water, very soluble in 0.1 M Hydrochloric acid, Acetonitrile, Acetic acid, Chloroform, Ethanol.

Methanol was selected as solvent for simple UV-method because of its easy availability, cost factor and high stability. The proposed method for estimation of Brivaracetam in pure and in tablet dosage form were found to be simple and sensitive. The drug in Methanol shows λ_{max} at 218 nm, with linearity range of 05 – 25 µg/ml.

The optical parameters like Beer's law limits (10-50µg/ml), Sandel's sensitivity (0.01750), correlation coefficient (0.99998), slope (0.0150), intercept (0.0110), limit of detection (2.08), and limit of quantification (6.93) were calculated for Brivaracetam in Methanol and produced in Table 1. Quantification of Brivaracetam 3 from tablets dosage formwas performed and the amount present was determined by average of six replicate analysis and the amount in percentage purity is found to be 99.82 and shown in table 1s.

To evaluate the accuracy of the method and for knowing the interference from excipients recovery study was performed. The Recovery of Brivaracetam by UV- Spectroscopic method was found to be 99.88 and the results are shown in Table 3. The values of co-efficient of variance were satisfactorily low and recovery was close to 100 % indicating reproducibility of the methods. The excipients in the formulation did not interfere in the accurate estimation of Brivaracetam in tablet dosage form.

From the results, the UV-Spectroscopy method was found to be more precise. Since none of the spectroscopic method is reported for the estimation of Methanol in tablet dosage form, this developed method can be applied in industries for routine analysis of the Brivaracetam in tablet dosage form.

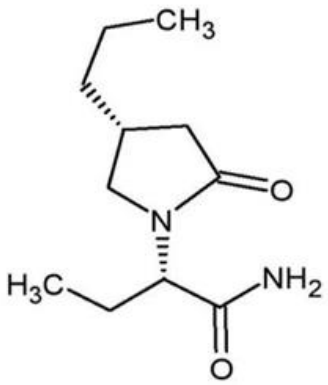

Fig. 1: Structure of Brivaracetam.

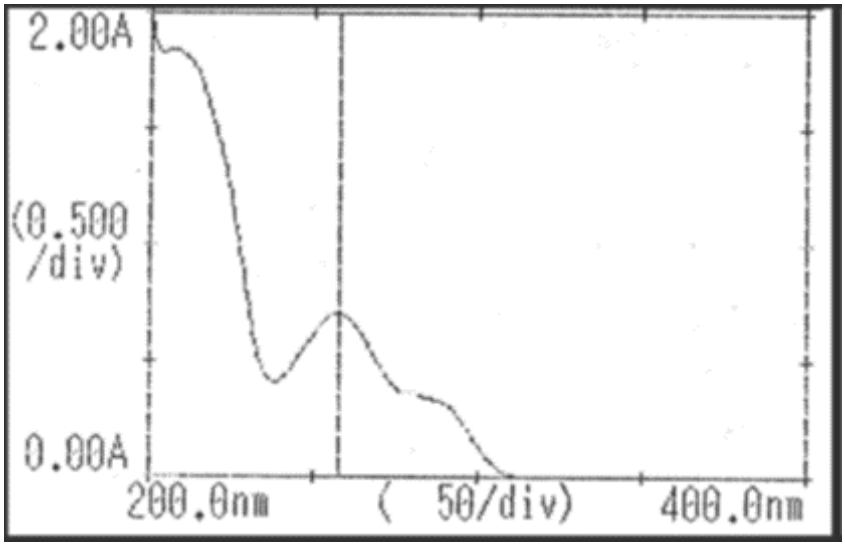

Fig. 2: UV Spectrum of Brivaracetam in Methanol (10µg/ml).

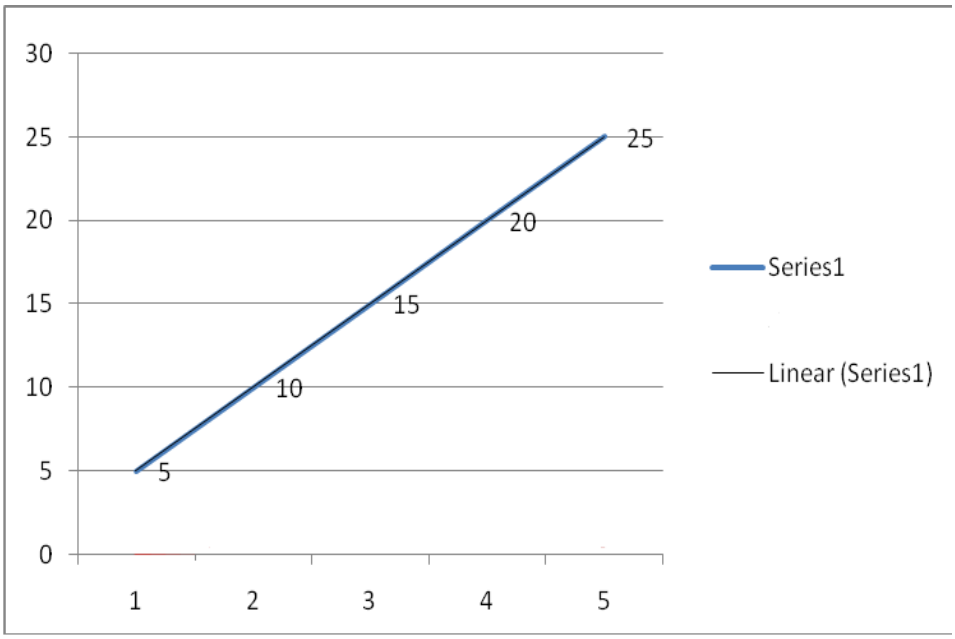

Fig. 3: Calibration Curve of Brivaracetam in Methanol (10µg/ml).

ABSORPTION VS CONCENTRATION

Table 1: Optical Characteristics of Brivaracetam.

Parameters	Method Values
λmax(nm)	218nm
Beer's law limit(µg/ml)	10 - 50
Sandell's sensitivity (µg/cm2/0.001 AU)	0.01750
Molar absorbtivity(L mol-1 cm-1)	0.928×10^3
Correlation Co-efficient (r)	0.9998
Regressionequation (Y= mx+c)	Y = 0.0150 X + 0.0110
Slope(m)	0.0150
Intercept(c)	0.0110

LOD(µg/ml)	2.08 µg/ml
Standard error of mean of regression line	0.2750

Table 2: Results of Analysis of Commercial Formulations.

S. No	Labelled Amount (mg/Tab)	Amount found (mg/Tab)	% obtained	Average %	S.D	%RSD	S.E
1	75	75.06	100.08	99.82	0.0801	1.04257	1.06874
2	75	74.71	99.61				
3	75	74.63	99.50				
4	75	74.93	99.90				
5	75	75.01	100.01				
6	75	75.02	100.03				

SD is standard deviation, % RSD percentage relative standard deviation

*Average of six determinations

Table 3: Results of Recovery Studies.

Name of drug	Recovery levels	Concentration (µg/ml)	Amount recovered	% Recovery with SD
Brivaracetam	80 %	30	30.002	100.02±0.80
	100 %	40	40.001	100.01±0.26
	120%	50	50.004	100.02±0.5

*Average of six determinations

Summary and Conclusion:

The proposed analytical methods are simple, reliable, rapid, sensitive, reproducible and accurate for the estimation of Brivaracetam.

The method adopted for our studies are

1. Simple UV-Spectroscopic method

The drug samples were analysed by UV spectroscopy using methanol as solvent and the average content of drug present in the formulation was found to be 99.82 mg (99.82%).

The above method does not suffer from any interference due to common excipients. Therefore, it was shown that the proposed method could be successfully applied to estimate commercial pharmaceutical products containing Brivaracetam Thus, the above studies and findings will enable the quantification of the drug for future investigation in the field of analytical chemistry.

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