International Journal of Pharmacognosy and Pharmaceutical Research
www.pharmacognosyjournals.com
Online ISSN: 2664-7176; Print ISSN: 2664-7168; Impact Factor: RJIF 5.42
Received: 30-11-2020; Accepted: 15-12-2020: Published: 29-12-2020
Volume 2; Issue 1; 2020; Page No. 20-23

Analytical techniques for the estimation of zolpidem in tablet dosage form by spectrophotometric method

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Abstract
For the determination of Zolpidem Tartarate in pure formulations and its pharmaceutical formulations, a simple UV-spectrophotometric method was developed. Zolpidem Tartarate exhibited maximum absorption at 244 nm in ethanol and obeyed linearity in the concentration range of 0.5-25 µg/ml. The method proposed was validated statistically. With good accuracy, all the proposed methods are simple, selective, reproducible, sensitive and precise. Some of the methods were proved to be superior to most of the reported methods. Many of these suggested prediction methods for chosen drugs, such as Zolpidem, have been successfully implemented either in bulk or in prescription formulations. The suggested methods can be used in bulk and prescription dosage formulations as alternative methods to the recorded ones for the routine determination of selected drugs in the sample.

Keywords: methanol, tablets, UV spectroscopy, zolpidem tartrate

Introduction
UV-visible spectrophotometric methods that fall in the 200-380 nm wavelength region and fluorimetric methods are very simple, inexpensive, and easy to estimate bulk-form drugs and their formulations. The drawbacks of certain analytical colorimetric or fluorimetric approaches lie in the chemical reaction on which the systems are based rather than the available instruments. Many of the reactions involve a certain drug's color or fluorescence are very selective or may be made selective by adding masking agents, regulating pH, using solvent extraction methods, changing oxidation states or previous elimination of intervening ingredients with the assistance of separate chromatographic ingredients [1, 2, 3]. Zolpidem tartrate (ZOL) is a hypnotic non-benzodiazepine in the imidazopyridine family and is available for oral administration in 5 mg and 10 mg strength tablets.
Chemically, it is: Bis [N, N-dimethyl-2-[6-methyl-2-(4-methylphenyl) imidazole[1,2-a]-3-yl]acetamide**]** **(**2R,3R)2,3 dihydroxybutanedioate. (Fig.1) The drug is official in British Pharmacopoeia. It is a white to off-white crystalline powder that Slightly soluble in water, sparingly soluble in methanol, practically insoluble in methylene chloride. ZOL modulates the alpha-subunit inside the macromolecular complex of the GABAA receptor chloride channel, known as the benzodiazepine receptor. ZOL binds preferentially to the alpha-1 receptor, unlike benzodiazepines, which interact non-selectively with all three alpha-receptor subtypes. Zolpidem is in a family of drugs known as sedative-hypnotics. According to the literature survey, it was found that few analytical methods were recorded for estimating Zolpidem Tartarate, such as UV-Visible analysis [4, 5, 6]. The aim of the approach proposed is to establish simple and precise methods for the determination of ZOL in pharmaceutical dosage forms using the UV-Spectrophotometry method. All of these findings have demonstrated the need for a fast and sensitive quality-control study of ZOL-containing pharmaceutical formulations. Since these methods are costly, we have tried to establish a more reliable, convenient and economical spectrophotometric approach with greater precision, specificity and sensitivity for the study of ZOL in bulk and dosage types.

Materials and Methods
ZOL was obtained as gift sample from Elite chemicals and all reagents were purchased from SD Chemicals Chennai. There was an analytical grade of all materials and reagents used.

Method Development
For the identification of Zolpidem Tartarate in pure form and its pharmaceutical formulation, a simple UV-Visible Spectrophotometric method was developed. ZOL demonstrated maximal ethanol absorbance at 244nm and obtained linearity in the 0.5 to 25 µg/ml concentration range. The method proposed was validated statistically.

Instrumentation
Analytical technologies ltd, T60 UV-Visible Spectrophotometric method was conducted using 1-cm quartz cells.

Selection of Solvent
Methanol was selected an ideal solvent for spectrophotometric analysis of ZOL.

Scanning and Determination of Maximum Wavelength (λmax)
Various drug solutions (0.5µg/ml and 25µg/ml) in Methanol were scanned using UV-Visible spectrophotometers within the 200-380nm wavelength region against Methanol as blank in order to determine the wavelengths of maximum absorption (λmax) of the drug. The resulting spectrum was presented in Fig 1 and the absorption curve showed characteristic absorption maximum at 244 nm for ZOL.

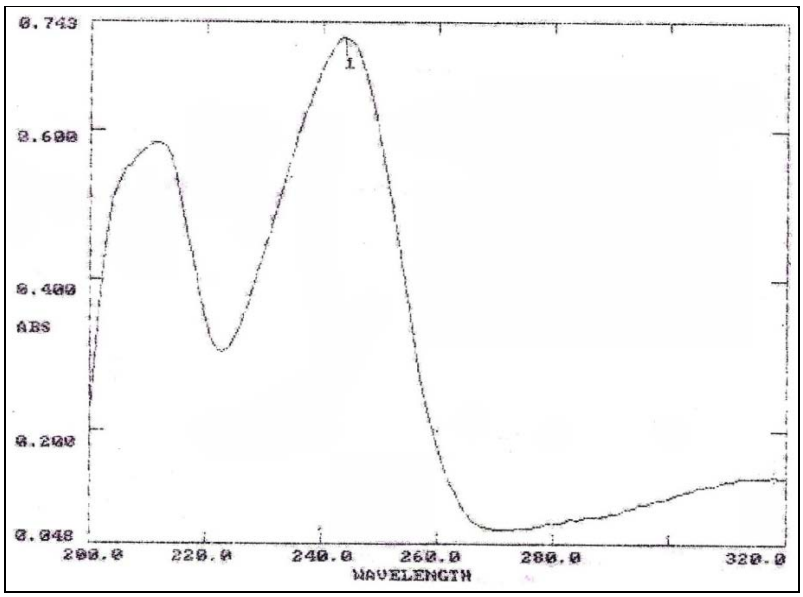

Fig 1: Absorption Spectrum of Zolpidem in Methanol

Preparation of Stock Solution

Standard stock solution of ZOL was prepared by dissolving 10mg of ZOL drug in 10ml of Methanol in 10ml of volumetric flask to get a concentration of 1mg/ml solutions.

Preparation of Working Standard Solutions and construction of standard graph

To achieve working quality solutions of 10ug/ml and 100ug/ml, the formulated stock solution was further diluted with Methanol. Different aliquots of ZOL were taken and diluted to 10 ml with Methanol to create Beer's law plot for ZOL to get the working normal solutions as shown in Table1. The absorbances of each solution were measured at lmax 244 nm against Methanol as blank. The results were shown in table1. The standard graph for ZOL was plotted by taking concentration of drug on x-axis and absorbance on y-axis and was shown in Fig 2. The drug has obeyed Beer's law in the concentration range of 0.5-25ug/ml [7].

Estimation of Zolpidem in commercial formulations

For analysis of commercial formulations, 20Tablets containing ZOL were taken and powdered. The powder equivalent to 0.010g of ZOL was taken in a 10ml volumetric flask, containing 7ml of Methanol and sonicated for 30 minutes. The volume was made up to 10ml with Methanol and filtered to get a solution of concentration 1000µg/ml. This was further diluted with Methanol to get a concentration within the linearity range and the absorbances were measured against the blank at 244nm.The results were shown in Table 3.

Table 1: Linearity table of Zolpidem (pure drug) in Methanol at 244nm

S. No	Concentration(ug/ml)	Absorption
1	0.5	0.047
2	2	0.18
3	5	0.465
4	10	0.932
5	15	0.365
6	20	0.823
7	25	2.263

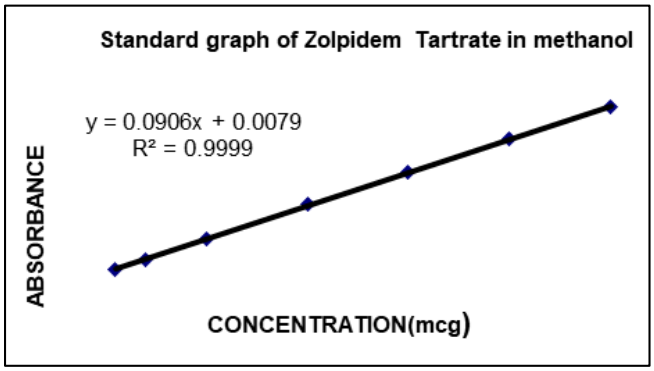

Fig 2: Linearity graph of Zolpidem Tartarate

Table 2: Optical characteristics of proposed method.

S. no	Parameter	Zolpidem Tartarate
1	lmax (nm)	244
2	Beer's Law limit (mg/ml)	0.5-25
3	Regression equation (Y)	0.090X+0.007
4	Slope (a)	0.090
5	Intercept (b)	0.007
6	% Range of error 95% confidence limits 99% confidence limits	0.0013 0.0018
7	Correlation co-efficient	0.999

Validation

Precision

The precision of the proposed method was ascertained by actual determination of six replicates of fixed concentration of the drug within the Beer's range and finding out the absorbance's by the proposed method [8]. From this absorbance's Mean, Standard deviations, % R.S. D were calculated. The readings were shown in Table 4.

Accuracy

Recovery experiments were performed to determine the accuracy of the proposed procedure by applying varying concentrations (80 %, 100 %and 120 %) of bulk samples of ZOL within the linearity range and adding 10mg/ml to the pre-analyzed concentration formulation [9]. From that % recovery values were calculated. The results were shown in Table 5.

Table 3: Amount of Zolpidem Tartarate in formulation by proposed method.

S. No	Formulation	Drug	Labeled amount (mg)	Observed amount	% Recovery
1	Nitrest-5	Zolpidem Tartrate	5	4.902±0.0040	98.046

Table 4: Precision data

S. No	Concentration (ug/ml)	Absorbance At 246nm
1	10	0.93
2	10	0.932
3	10	0.931
4	10	0.933
5	10	0.928
6	10	0.931
Mean		0.9308
S. D		0.0017
%R.S. D		0.184

Table 5: Accuracy data

80%						
S.No	Conc(bulk)	Conc(formln)	%Recovery	Mean	S. D	%R.S. D
1	8	10	98.6	98.62%	0.9712	0.098
2	8	10	98.73			
3	8	10	98.54			
100%						
4	10	10	98.12	98.14%	0.0929	0.094
5	10	10	98.07			
6	10	10	98.25			
120%						
7	12	10	99.24	99.17%	0.0763	0.076
8	12	10	99.09			
9	12	10	99.19			

Summary

Pharmaceutical research basically means that pharmaceuticals are analysed. Today, pharmaceutical research requires much more than an analysis of active pharmaceutical ingredients or a manufactured substance. The pharmaceutical industry is subject to heightened government and public stakeholder oversight to reduce costs and to reliably bring healthy, efficient drugs to the consumer that address unmet patient needs. In maintaining the origin, safety, effectiveness, purity, and consistency of a drug product, the pharmaceutical analyst plays a significant role [10]. The need for pharmaceutical analysis is primarily motivated by regulatory specifications. In general, the widely used pharmaceutical research tests include the development of compendia testing system, establishing criteria and evaluation of methods. One of the most interesting ways for scientists to take part in the quality process is by empirical research, which offers real evidence on the identification, substance and purity of drug products. With a great deal of commitment to global harmonization, new approaches are now being developed. As a consequence, it is possible to ensure that emerging goods have similar consistency and can be taken more easily to foreign markets.

Pharmaceutical research plays a pivotal role in the statutory approval, either by industry or by regulatory bodies, of medicines and their formulations. In industry, the divisions of quality assurance and quality management play a significant role in delivering a safe and reliable type of prescription or dose. The latest Good Manufacturing Practices and the recommendations of the Food Drug Administration (FDA) insist that sound analytical methods with greater specificity and reproducibility be followed. The sophistication of the problems encountered in pharmaceutical research is therefore critical for achieving the selectivity, speed, low cost, simplicity, specificity, sensitivity, accuracy and precision of drug estimation.

Conclusion

The method proposed was simple, sensitive and accurate with good precision and accuracy. The proposed approach is precise when calculating commercial formulations without intervention from excipients and other additives. This approach can also be used for the regular assessment of ZOL in bulk samples and pharmaceutical formulations.

Acknowledgement

The authors express their gratitude to the Management, Jeypore College of Pharmacy, Jeypore for providing their continuous support throughout the work. The authors are also grateful to Mr. Saswat Kumar Rath, Mr. Rama Krushna Gouda and Mr Sudhir Kumar Dash for their continuous encouragement and valuable inputs and cooperation while carrying out this study.

References

1. Kasekar M, Godiyal C, Jadhav R *et al*. Development and Validation of a Simple and Rapid HPLC Method for Determination of Itraconazole in Bulk and Marketed Formulation. Der Pharmacia Lettre. 2017; 9(10):36-43.
2. Chinmoy R, Chakrabarty J, Hitesh B *et al*. Development and Validation of a Stability Indicating Binary RP-UPLC Method for Determination of Itraconazole in Capsules dosage form. International Journal of Analytical and Bioanalytical Chemistry. 2012; 2(3):165-174.
3. Koteswara Rao M, Ramanjaneyulu K.V, Reehana SK *et al*. Method Development and Validation of Itraconazole by UV-Spectrophotometer. World Journal of Pharmaceutical Research. 2014; 3(10):777-787.
4. Parik K, Patel D, Dave JB, Dr. Patel CN *et al*. Development and Validation of Uv Spectrophotometric Method for Estimation of Itraconazole Bulk Drug and Pharmaceutical Formulation. International Journal of Drug Development & Research. 2011; 3(2):324-328.

5. Kirtimaya M, Aditya Prasanna K and Snigdha Rani B. Simultaneous Estimation of Sacubitril and Valsartan in Bulk and Pharmaceutical Dosage Form by Using RPHPLC. Research Journal of Pharmacy and Life Sciences, 2020; 1(2):25-32.
6. Kirtimaya M, Snigdha Rani B, Gowri Sankar CH, Sujit Kumar M. Development and Validation of Stability Indicating Assay Method (Siam) for Rabeprazole in Rabeprazole Sodium Delayed Release Tablets Using HPLC. Research Journal of Pharmacy and Life Sciences. 2020; 1(3):89-97.
7. Kirtimaya M, Snigdharani B, Sruti Ranjan M, Somesu M, Kiran Kumar BA. Validated Stability Indicating RP-HPLC Method Development for Platelet Aggregation Inhibitor Ticagrelor in Bulk and Tablet Formulation. Journal of Global Pharma Technology. 2019; 11(12):12-18.
8. Kirtimaya M, Saragi B, Kiran Kumar B. Simultaneous Estimation of Sertraline and Alprazolam in its Bulk and Tablet Dosage Form by RP-HPLC Method. Asian Pacific Journal of Pharmacy and Phytochemistry. 2016; 1(1):25-32.
9. Kirtimaya M, Kiran Kumar B, MuthuKumari M, Subrahmanyam B.S.S. New Analytical Method Development and Validation of Chlorpheniramine Maleate by Using Uv-Visible Spectrophotometry. Indo American Journal of Pharmaceutical Sciences. 2016; 3(7):767-772.
10. Kirtimaya M, Balamurugan K, Suresh R. Linagliptin: A Literature Review on Analytical and Bioanalytical Methods. International Journal of Pharmaceutical Quality Assurance. 2018; 9(3):225-230.