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Development of an Accurate, Specific and Precise Visible Spectrophotometric Method for Estimation of Rivastigmine in Bulk Drug and Its Formulation

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ABSTRACT

An accurate, specific and precise, visible spectrophotometric system was developed for estimation of Rivastigmine in bulk drug and its formulation. Rivastigmine is a cholinesterase inhibitor which is used for the treatment of mild to moderate memory related illnesses like Alzheimer's disease and dementia. The optimal circumstances for the analysis of rivastigmine were established. The maximum wavelength (λmax) was set up to be 621 nm. The linearity of the proposed system was set up within the range of 20- 60 µg/ ml. Estimation angles depicted a direct relationship between the absorbance and attention. Confirmation parameters were anatomized according to ICH guidelines. The LOQ and LOD were set up to be within the range. The proposed system was simple, sensitive, precise, accurate, quick and useful for routine analysis of Rivastigmine in bulk and capsule form.

Keywords: Rivastigmine, Visible spectrophotometry, Accuracy, Precision

1. INTRODUCTION

Rivastigmine is chemically (S)-3-[1-(dimethylamino)ethyl] phenyl N-ethyl-N-methylcarbamate is a drug for the treatment of different stages of alzheimer's disease and dementia. Rivastigmine is a cholinesterase inhibitor, an enzyme that breaks down acetylcholine. Acetylcholine is primary a neurotransmitter of cholinergic neuronal pathway projecting from basal forebrain to cerebral cortex and hippocampus, it assists in human memory, learning, attention, and cognitive processes[1, 2]. The chemical structure of Rivastigmine was shown in Figure 1. Literature survey reveals that a UV, HPLC and spectrofluorimetric method was developed for the determination of Rivastigmine[3, 4, 5]. But there was no reported method for the visible spectrophotometric studies of Rivastigmine by using UV-Visible double beam spectrophotometer. So the present work is to carry out the visible spectrophotometric studies. The method was examined according to the ICH guidelines. Visible spectrophotometric studies may help facilitate pharmaceutical development as well in areas such as formulation development, manufacturing, quality control, and quality assurance, in which knowledge of chemical behavior can be used to improve the standard of a drug product.

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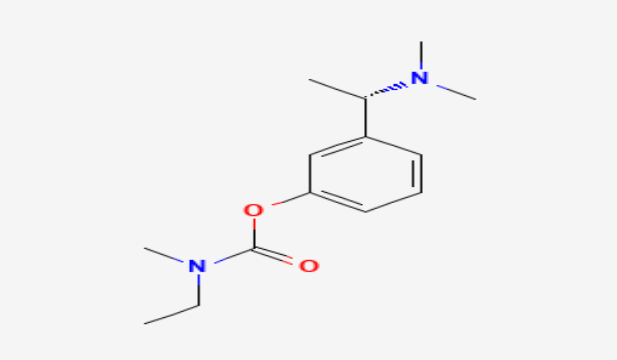

Figure 1: Structure of Rivastigmine.

2. MATERIALS AND METHODS

2.1 Instrument

Absorption spectral measurements were carried out with a UV – Visible spectrophotometer (Shimadzu Model 1700) using UV Probe software version 2 was employed with spectral bandwidth of 1 nm and wavelength precision to 0.3 nm (with automatic wavelength correction) with a pair of quartz cells, which are 5cm.

2.2 Chemicals

Rivastigmine API supplied by Dr. Reddy's Laboratories Pvt Ltd, India and used as such. Methanol used was from Qualigen fine chemicals Ltd, India. Double distillation was employed to generate water.

2.3 Selection of solvent

Solutions of rivastigmine was prepared in different solvents like water, methanol, ethanol, acetonitrile and UV spectrum of each were recorded by scanning between 400-800 nm. Better absorbance was observed for the drug when methanol is used as a solvent[6].

2.4 Preparation of standard solutions

Standard stock solutions of Rivastgmine were prepared by dissolving 10 mg of the drug in water and the volume was made up to 100ml in a standard flask. From the stock solution, concentrations ranging from 20-60 µg/ml was prepared for Rivastgmine and scanned in the visible region. Standard stock solutions of Rivastgmine were prepared by dissolving 10 mg of the drug in water and the volume was made up to 100 ml in a standard flask. From the stock solution, concentrations ranging from 20-60 µg/ml was prepared for Rivastgmine and scanned in the visible region.

2.5 Preparation of sample solution

Twenty tablets (Rivastgmine) were powdered and the average weight was calculated. A quantity equivalent to 10 mg of drug was dissolved in Methanol. Finally the volume was made up to get a working concentration of 60µg/ml of Rivastgmine. Absorbances were noted at 621 nm. The amounts of Rivastgmine were calculated as seen in Figure 2.

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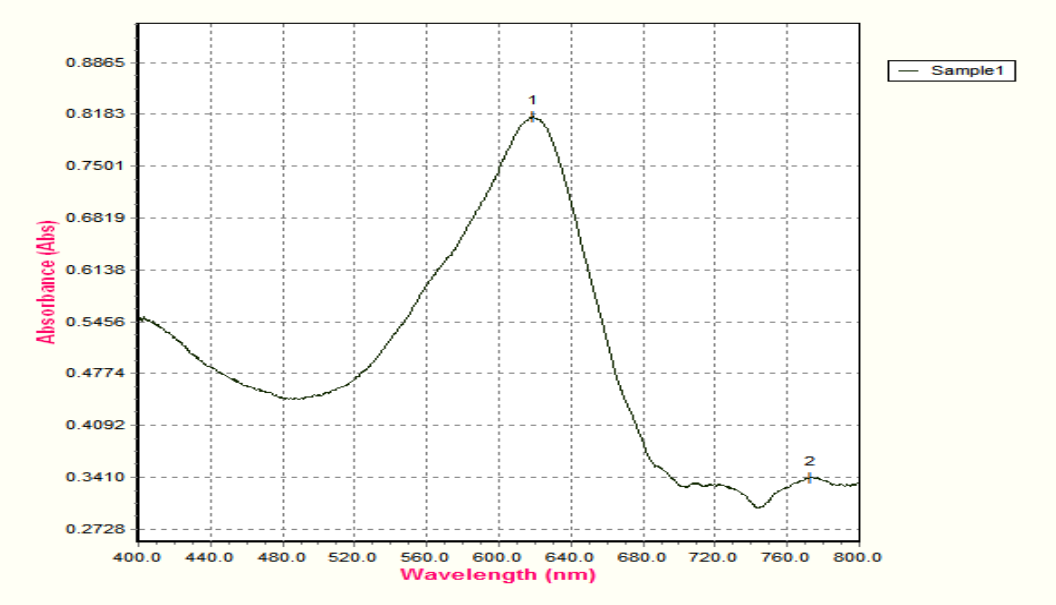

Figure 2: Spectrum of Rivastigmine

3. RESULTS AND DISCUSSION

3.1 Validation of the method

3.1.1 Linearity

Rivastigmine was found to be linear in a concentration range of 20-60 µg/ml. Calibration curves were plotted and the slope, intercept and correlation coefficient values were found to be 0.008, 0.007, and 0.998 respectively.

3.1.2 Precision

Precision studies were performed by preparing the standards six times and measuring absorbance of the drug at 621 nm. Reduced RSD values indicate that the method is precise[5].

3.1.3 Accuracy

Recovery studies were carried out to ascertain the reliability and suitability of this method. To an equivalent quantity of formulation powder (10 mg), a known quantity of standard Rivastigmine was added at 50%, 100%, and 150% level and the contents were re-analyzed by the proposed method and tabulated in Table 1,2.

Table 1: Recovery of Rivastigmine

Concentration of drug in pure analyzed sample	Drug solution added (µg/ml)	Recovered amount (mg)	% Recovery	Mean % recovery
50	5	4.86	98.81	98.6
100	10	9.88	99.08	
150	15	15.0	100	

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Table 2: Accuracy of Rivastigmine

Drug	Amount (mg/tab)		%Label Claim	% RSD
	Labelled	Found		
Rivastigmine	1.5	1.46	97.33	0.53

3.1.4 Assay for Rivastigmine

The proposed method was applied to analyze commercially available Rivastigmine tablets. Each tablet was having content of Rivastigmine equivalent to 1.5 mg. Twenty tablets were weighed and finely powdered. Amount equivalent to 10 µg/ml of the standard and sample solutions of Rivastigmine tablet were collected and the spectrum was recorded. The readings were taken. Amount was calculated in Table 3.

Table 3: Accuracy of Rivastigmine

Type of Assay	Lamda max	Absorbance
Standard	621	0.8005
Sample	621	0.8002

3.1.5 Limit of detection and Limit of quantification (LOD & LOQ)

Limit of detection and limit of quantification of rivastigmine demonstrates a reasonable standard precision, where unit of calibration is RSD (relative standard deviation) was found to be below 2%.

Table 4: LOD and LOQ of Rivastigmine

Parameter	Lamda max	Absorbance
LOQ	621	0.0723
LOD	621	0.1205

3.2 Discussions

Rivastigmine was freely soluble in Methanol. The drug has maximum absorbance at 621 nm. The optical characteristics of the drug were found to obey Beer's law at 20-60 µg/ml, and Correlation coefficient was determined to be 0.998. The drug sample was analyzed by Visible spectroscopy using methanol as solvent and the average content of drug present in the formulation was found to be 97.3%. The %RSD was found to be 0.53. Rivastigmine was tested and qualified for all validation parameters.

Conclusions

Spectroscopy is at present one of the most reliable tool of the analysis. The estimation of rivastigmine done by visible spectroscopic method was revealed to be simple, accurate, precise and linear. The method was found to be suitable and economical in routine laboratory analysis setting with high degree of accuracy and precision.

Acknowledgements

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Conflict of Interest Statement: All authors have nothing else to disclose.