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Determination of Saturated Solubility of Rasagiline Mesylate on Different Dissolution Medium Using Uv/Visible Spectrophotometer

Reethu Shree S*, J Adlin Jino Nesalin, Ganesh N S, Vineeth Chandy.

Department of Pharmaceutics, T. John College of Pharmacy, Bengaluru, Karnataka, India

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ABSTRACT

The formulation and development of the drug depend on the drug's solubility. The drug's solubility is one of the most crucial pre-formulation parameters. Solubility and permeability are also essential for the bioavailability of solid formulations like tablets and capsules. The aim of the study was to use a UV-visible spectrophotometer to examine the solubility of the drug in various pH environments. Buffers with a pH range of 1.2 to 7.4 and also distilled water were used for studying the solubility of drug. The results of this study confirmed that the solubility of Rasagiline Mesylate is pH-dependent.

KEYWORDS ; Saturated solubility, UV visible spectrophotometer, Rasagiline Mesylate and pH range.

INTRODUCTION

Solubility is very important parameter of preformulation studies. Solubility and permeability are the two important properties of Biopharmaceutical Classification System (BCS). The Biopharmaceutics Classification System (BCS) given by U.S. Food and Drug Administration determines the absorption of drug in intestine. As per this there are four classes of drugs; class I- drugs which are highly soluble and permeable, class II-drugs which have low solubility and high permeability, class III-It consists of less soluble and highly permeable drugs and class IV-d rugs which are very less soluble and permeation is also poor. Aqueous solubility effects on the bioavailability of the drug[1]. Solubility is important for a drug to achieve the desired concentration. Novel molecules with less solubility in water undergoes various problems while developing formulation as well as during generic drug development. Many drugs being weak acid or weak base are less soluble in water. The less solubility of drug results in poor absorption, variable bioavailabilty and is harmful to gastrointestinal mucosal tract. Dealing with drug dissolution problem is a big challenge for formulation scientist. Aim of the present study is to determine the saturation solubility of drug in different dissolution medium[2].

EXPERIMENTAL

Materials:

Hydrochloric acid, disodium hydrogen phosphate, sodium hydroxide and potassium dihydrogen phosphate were purchased from Qualigens Fine Chemicals., Mumbai, India. The distilled water was produced in our research laboratory with a distillation unit.

Determination of λ max of Rasagiline Mesylate in different dissolution medium

The UV Visible Spectrophotometer was used to scan the drug's maximum concentration in various dissolution mediums (such as distilled water, pH 1.2, pH 6.8 and pH 7.4 buffers). The stock solutions of Rasagiline Mesylate were made in each media for this study. Rasagiline Mesylate 10µg/ml concentration were prepared in different pH buffers. The solutions were scanned from 200-400nm by UV spectrophotometer and a spectrum were observed for absorption maxima.

Standard calibration curve of Rasagiline Mesylate in different medium

Standard curves of Rasagiline Mesylate was carried out in different dissolution medium such as distilled water, pH 1.2, pH 6.8 and pH 7.4. The stock solution of drug was made in every medium. For making stock solution, 100 mg of drug was taken in a volumetric flask and dissolved in 1 mL of methanol. Finally, dilution was done till the mark using particular solvent. Further the dilutions were made using the same dissolution medium to make different concentration solutions for standard curve. From the above solution 2, 4, 6, 8 and 10µg/ml were prepared and analyzed by UV spectrophotometer at λmax 271 nm. The graph of absorbance v/s concentration in µg/ml was plotted and r^2 value of this graph was calculated[3,4].

Saturated solubility study

Various buffers with pH ranges between 1.2, 6.8 and 7.4 and distilled water were used to measure the drug's saturation solubility. In a 100mL volumetric flask, 50mL of distilled water or a buffer with the required pH was added. To each volumetric flask, additional drug was poured and sealed with aluminum foil. In a water bath that was orbitally shaking, these volumetric flasks were fastened together. Throughout the entire investigation, the temperature was kept at around 37± 0.5°C by applying 50rpm of shaking for the duration of 48 hours. Syringe filters with pore sizes of 0.22 µm were then used to filter the final samples. After appropriate dilutions with the same solvent, the filtrates were collected, and the absorbance of the drug was examined using a UV-visible spectrophotometer (UV-1800, Shimadzu Corporation, Japan) at the pre-scanned λmax in that solvent. The concentration was then calculated from the absorbance using the drug's standard curve in each relevant solvent[5,6,7].

RESULTS AND DISCUSSION

Scanning of λmax of drug in different dissolution medium

The drug's scanned wavelengths (λmax) in various dissolving media were shown in Table No.1. The results demonstrate that the drug's wavelengths were identical in all dissolving mediums, demonstrating that the pH of the dissolution medium has no impact on the drug's wavelength.

Standard curve in different medium

The standard curves for several aquatic media are provided below, ranging from Figure No.1 to Figure No.4. In Table No.2, the standard curves for a particular medium's linear equation and co- efficient correlation (r2) values are listed. The findings demonstrated that for the drug in each dissolving media, good correlation coefficients were obtained. Since the analyte concentration and absorbance show a significant correlation, the method can be used for analysis.

Saturated solubility study

Figure No.5 displays the data for the saturated solubility analysis. The solubility investigations show that the solubility of drug is pH-dependent, with an increase in pH value the solubility increases. Here, the drug was shown to be least soluble in distilled water, which may be related to the substance's unionization. The drug's membrane permeability was enabled yet constrained by its unionized structure.

Table No.1: The λmax of the drug in different dissolution medium

SL.No	Solvent used for study	Scanned drug λmax (nm)
1	Distilled Water	271
2	0.1N HCl Buffer (pH 1.2)	271
3	Phosphate Buffer pH 6.8	271
4	Phosphate Buffer pH 7.4	271

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Table No.2: Linear equation and correlation coefficient values in different medium

SL.No	Solvent used for study	Linear equation (y = mx + c)	Correlation Coefficient (r2)
1	Distilled Water	0.0241x + 0.0076	0.9965
2	0.1 N HCl Buffer (pH 1.2)	0.019x + 0.009	0.9912
3	Phosphate Buffer pH 6.8	0.02x + 0.0101	0.9917
4	Phosphate Buffer pH 7.4	0.0258x + 0.0102	0.9915

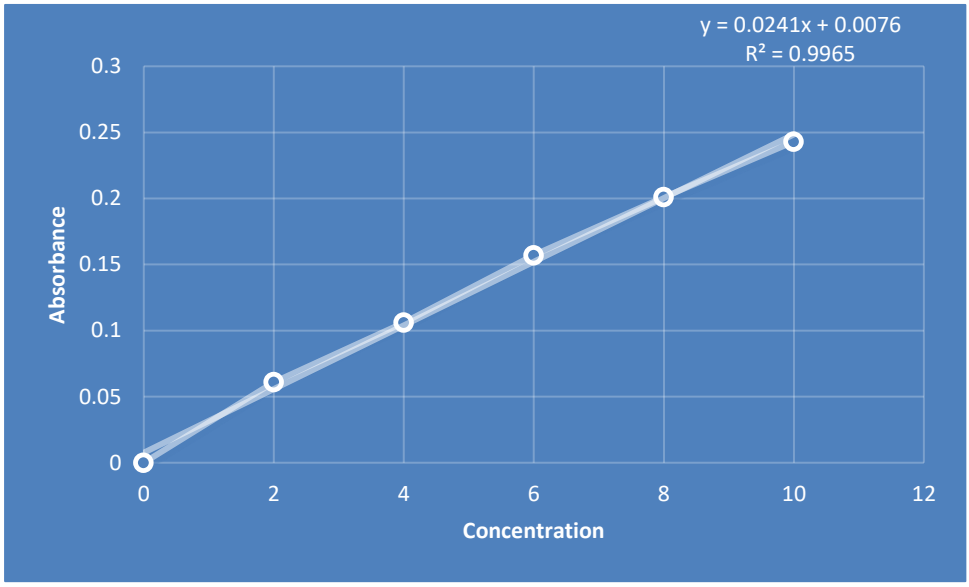

Figure No.1: Standard curve in distilled water

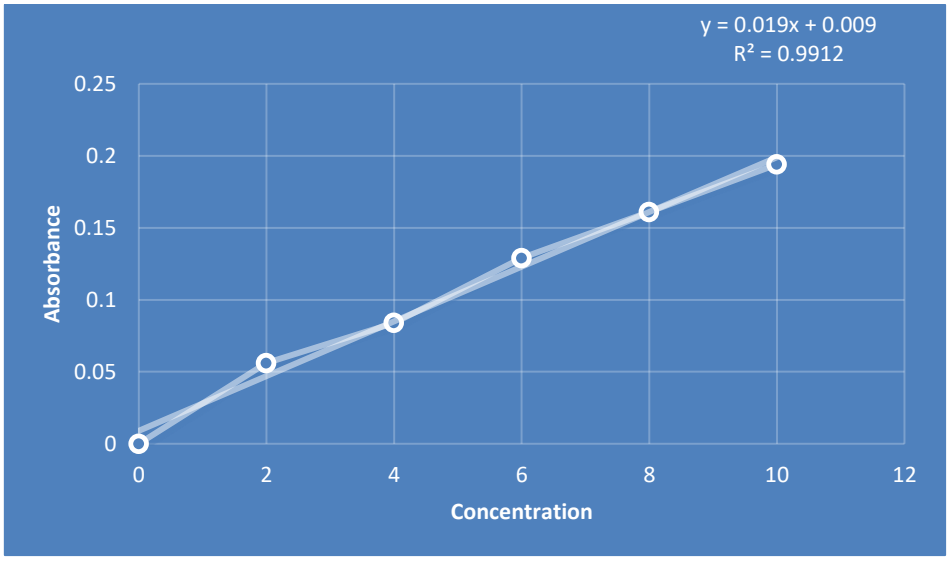

Figure No.2: Standard curve in pH 1.2

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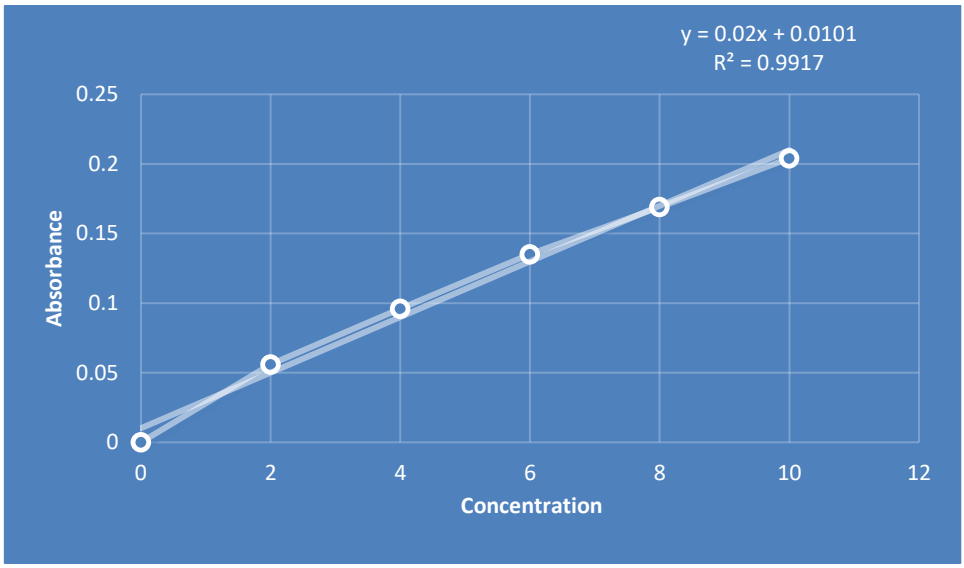

Figure No.3: Standard curve in pH 6.8

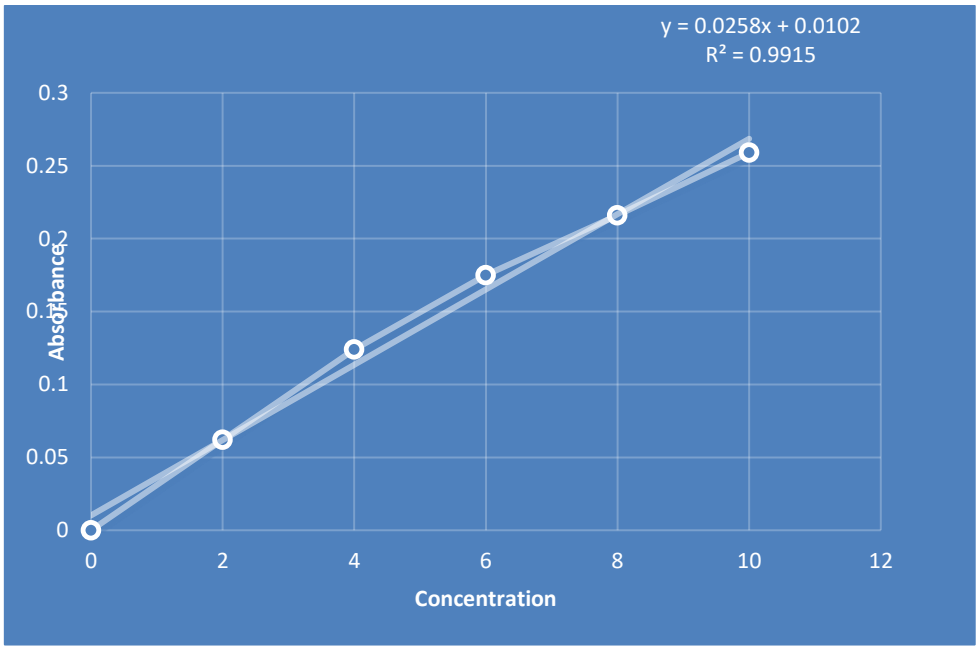

Figure No.4: Standard curve in pH 7.

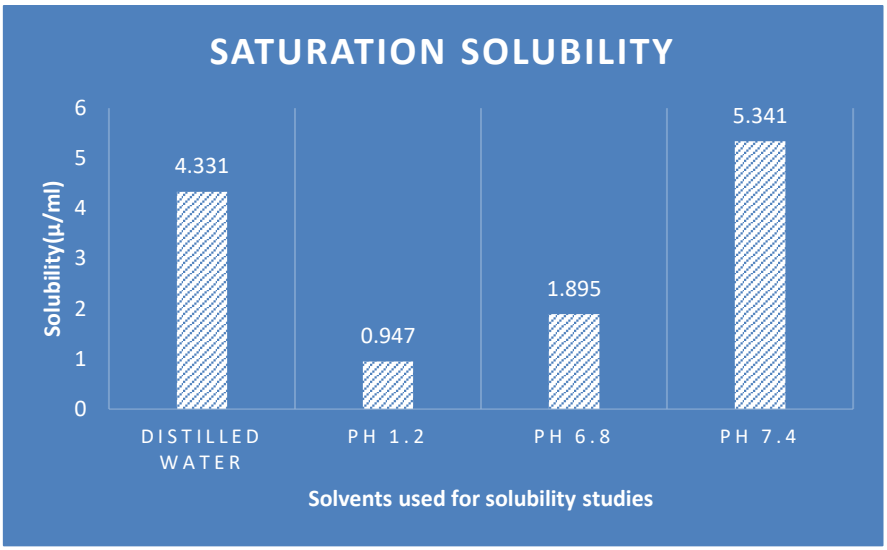

Figure No.5: Saturated solubility studies of Rasagiline Mesylate

CONCLUSION

The present research of saturated solubility study concludes that the low bioavailability of the drug is mainly due to low aqueous solubility. This study also suggests a need to improve the solubility of the drug in the acidic medium and distilled water.

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CONFLICT OF INTEREST : We declare that we have no conflict of interest.

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