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Research Article

Determination Of Saturated Solubility Of Cyclobenzaprine HCL Using UV Visible Spectrophotometer

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ABSTRACT

The capacity of a medicine to dissolve in water is an essential component of drug development since it influences the drug's bioavailability, which is the rate at which the drug is absorbed into the bloodstream. Evaluating the drug's solubility is one of the most crucial pre-formulation parameters. The study aimed to investigate the solubility of Cyclobenzaprine HCL, under different pH conditions using UV visible spectrophotometer. The pH is a measure of the acidity or alkalinity of a solution. It can significantly influence the solubility of a drug. The experimental approach utilized in this study provided a precise assessment of the impact of various pH conditions on the solubility of Cyclobenzaprine HCL. The findings clearly demonstrate that the solubility of Cyclobenzaprine HCL is pH-dependent. This means that alterations in the pH of the dissolution medium can substantially influence the drug's solubility. Buffers with pH range of 1.2, 6.8, 7.4 and distilled water were used for studying the solubility of drug. This significant observation carries particular relevance for pharmaceutical formulators. By understanding the pH-dependent solubility of Cyclobenzaprine HCL formulators can design formulations that optimize drug dissolution and bioavailability, ultimately enhancing therapeutic efficacy. The results of this study confirmed that the solubility of Cyclobenzaprine HCL is pH-dependent.

INTRODUCTION

Solubility, a fundamental property of a drug molecule, significantly influences its bioavailability and consequently, its therapeutic efficacy. As a key component of the Biopharmaceutical Classification System (BCS), solubility, in conjunction with permeability, provides a scientific framework for designing effective drug delivery systems. The Biopharmaceutical Classification System (BCS) categorizes drugs based on solubility and permeability. Class I drugs are highly soluble and permeable, while Class IV drugs have low

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solubility and permeability.1 Aqueous solubility, specifically, is a critical parameter that directly impacts the bioavailability of a drug. Its determination is often a pivotal step in the pre-formulation process, requiring extensive investigation. Understanding the solubility profile of a drug molecule is essential for optimizing its formulation and ensuring its effective absorption and distribution in the body.2 Drugs with low water solubility are often poorly absorbed from the gastrointestinal tract, leading to reduced bioavailability. This can result in inconsistent drug levels in the bloodstream and decreased therapeutic effectiveness. The absorption of poorly soluble drugs can be influenced by various factors, such as pH, food intake, and gastrointestinal motility. This variability can make it difficult to achieve and maintain consistent drug levels, leading to unpredictable therapeutic responses. Some poorly soluble drugs can irritate the gastrointestinal mucosa, leading to side effects such as nausea, vomiting, and diarrhoea. To address such challenges associated with low solubility, formulation scientists must carefully investigate the solubility properties of drug molecules.3,4 This involves studying the saturated solubility of the drug in various dissolution media to identify conditions that can show its maximum solubility and improve its bioavailability.

MATERIALS AND METHODS

Materials:

The Cyclobenzaprine HCL was purchased from Yarrow Chem Products., Mumbai, India. 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 λmax of Cyclobenzaprine HCL in Different dissolution medium

The study investigated the maximum concentration of Cyclobenzaprine HCL in various dissolution media using UV-visible spectrophotometry. Stock solutions of Cyclobenzaprine HCL were prepared in distilled water and buffers with different pH values (1.2, 6.8, and 7.4). Cyclobenzaprine HCL solutions with a concentration of 10 µg/ml were prepared in each pH buffer. The absorbance spectra of these solutions were scanned from 200-400 nm using UV-visible spectrophotometry to determine the wavelength of maximum absorption.5,6

Standard calibration curve of Cyclobenzaprine HCL in Different medium

The study investigated the solubility of Cyclobenzaprine HCl in various dissolution media by preparing standard curves using UV-visible spectrophotometry. Stock solutions of Cyclobenzaprine HCl were prepared in distilled water and buffers with different pH values (1.2, 6.8, and 7.4). To prepare the stock solutions, 100 mg of Cyclobenzaprine HCl was dissolved in 10 ml of methanol and the volume was adjusted to 100 ml with the appropriate pH buffer solution (1 mg/ml). These stock solutions were then further diluted with methanol to prepare solutions with concentrations of 2, 4, 6, 8, and 10 µg/ml. The absorbance of each solution was measured at λmax 290 nm using UV Visible Spectrophotometry. A calibration curve of absorbance versus concentration was plotted, and the r2 value (co-efficient of determination) was calculated to assess the linearity of the relationship.7

Saturated solubility study

The study determined the saturation solubility of a drug in various dissolution media, including distilled water and buffers with pH values ranging from 1.2 to 7.4. Excess drug was added to 50 mL of each medium in a 100 mL volumetric flask, which was then sealed and placed in an orbital shaking water bath. The flasks were shaken at 50 rpm for 24 hours at a temperature of 37 ± 0.5°C.

The final samples were filtered using syringe filters with a pore size of 0.22 µm. The filtrates were diluted with the same solvent, and their absorbance was measured using a UV-visible spectrophotometer at the pre-determined wavelength of maximum absorption (λ max) in that solvent. The concentration of the drug was calculated from the absorbance using the corresponding standard curve.8,9

RESULTS AND DISCUSSION

Scanning of λ max of drug in different dissolution medium

The drug's scanned wavelengths (λ max) 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, a good correlation co-efficient was obtained. Since the analyte concentration and absorbance showed 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 a decrease in pH value, the solubility increases. Here, the drug was shown to be least soluble in 0.1 N HCL (pH 1.2), which may be related to the substance's unionization. The drug's membrane permeability was enabled yet constrained by its unionized structure. The drug showed high solubility in phosphate buffer (pH 7.4) and this implies that, this buffer can be used as the highest considerable solvent for any sought of the analysis of the drug.

Table No.1 The λ max of the drug in different dissolution medium

Sl. No.	Solvent used for study	λ max of Drug (nm)
1.	Distilled Water	290
2.	0.1 N HCL pH (1.2)	290
3.	Phosphate buffer pH (6.8)	290
4.	Phosphate buffer pH (7.4)	290

Table No. 2 Linear equation and Correlation Co-efficient values in Different dissolution medium

Sl. No.	Solvent used for study	Linear equation (y = mx+c)	Correlation Co-efficient (r^2)
1.	Distilled Water	0.0217x + 0.009	0.9938
2.	0.1 N HCL pH (1.2)	0.0189x + 0.006	0.9847
3.	Phosphate buffer pH (6.8)	0.0233x + 0.009	0.9944
4.	Phosphate buffer pH (7.4)	0.0242x + 0.0085	0.9958

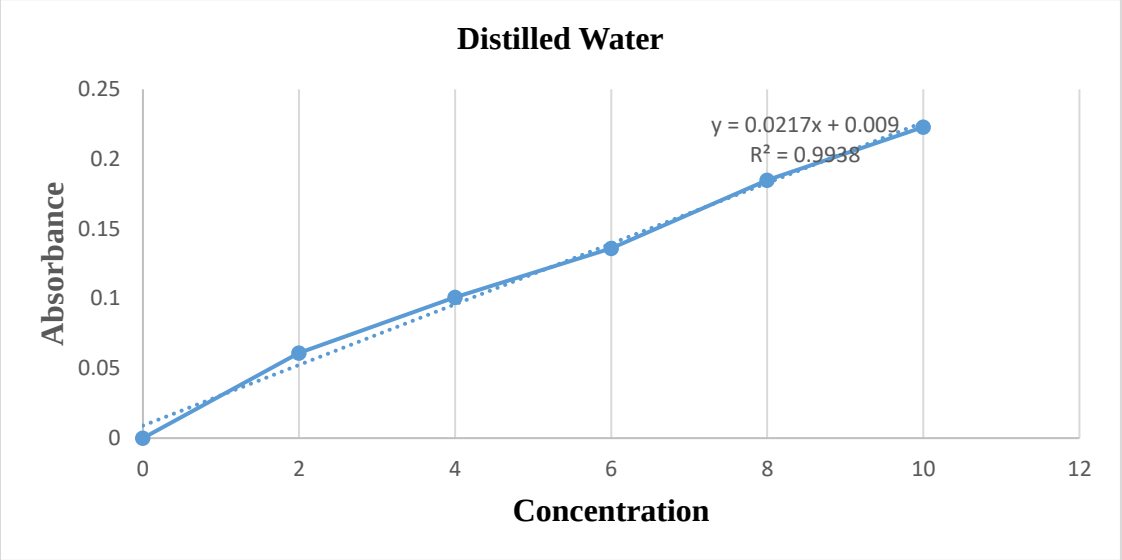

Figure No.1 Standard curve in distilled water

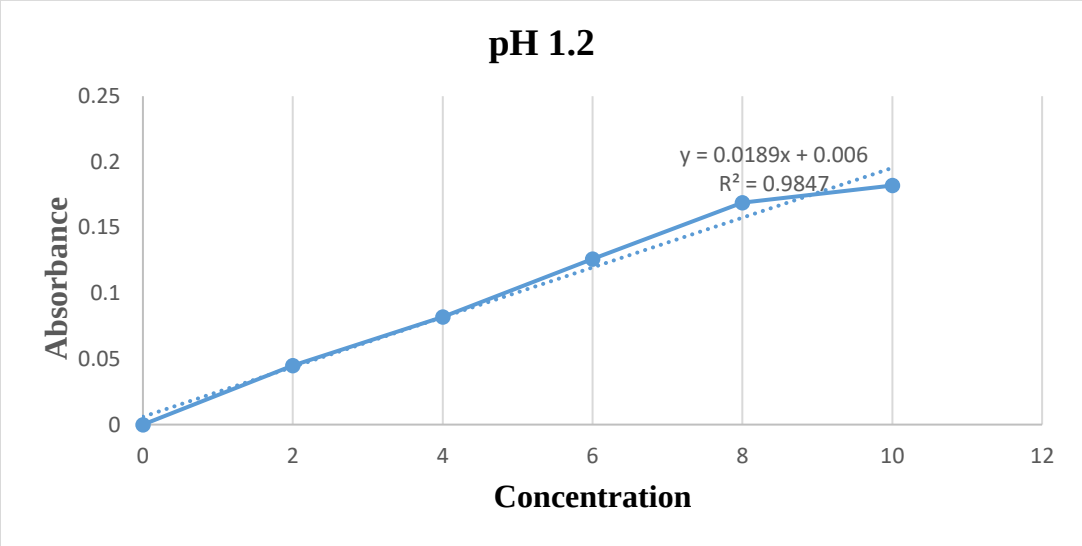

Figure No. 2 Standard curve in pH 1.2

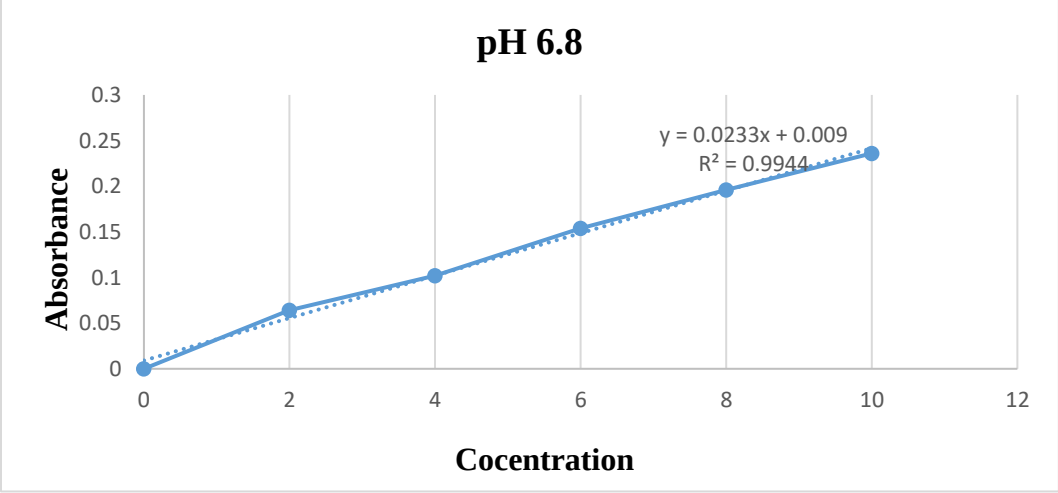

Figure No. 3 Standard curve in pH 6.8

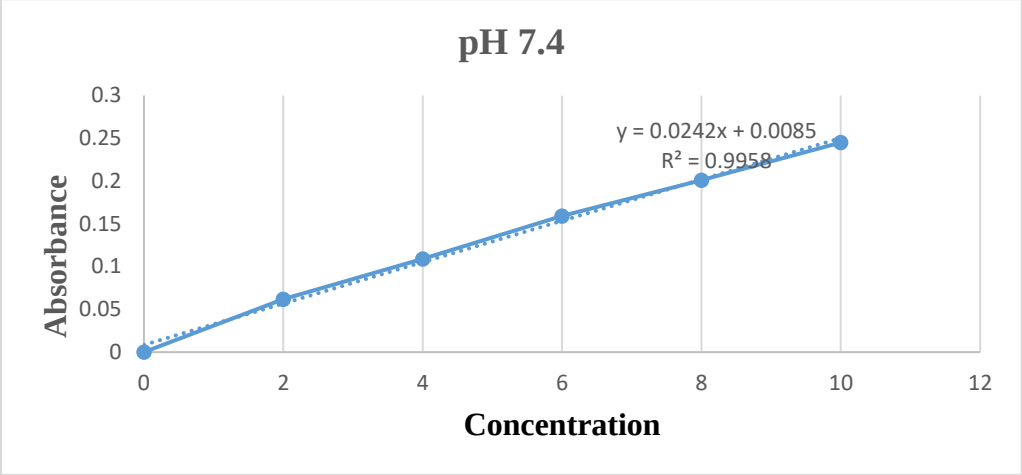

Figure No. 4 Standard curve in pH 7.4

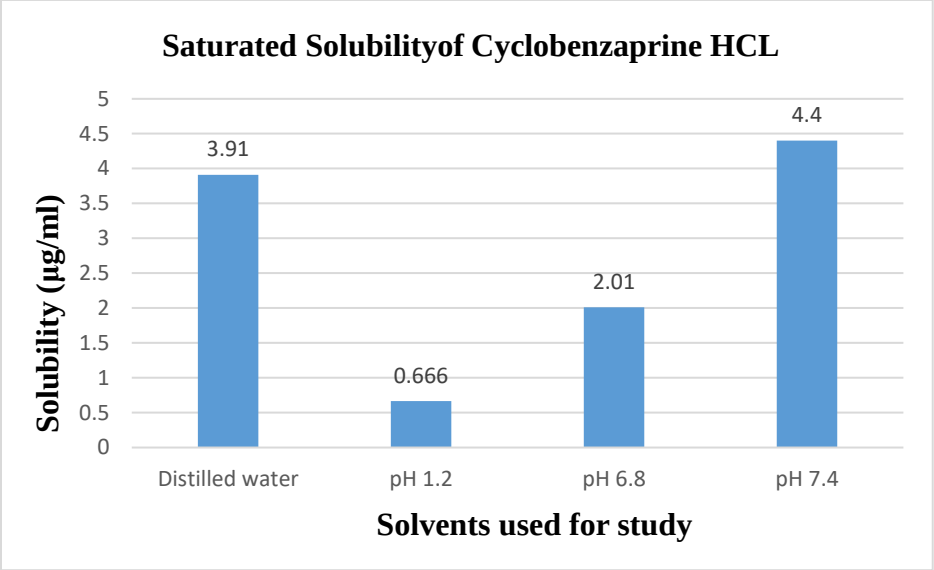

Figure No. 5 Saturated solubility study of Cyclobenzaprine HCL

CONCLUSION

The present research underscores the pH-dependent solubility of Cyclobenzaprine HCL. This means that the drug's solubility, and consequently its bioavailability, is significantly influenced by the acidity or alkalinity of the environment. Furthermore, the saturated solubility study reveals that the low bioavailability of Cyclobenzaprine HCL is primarily attributed to its poor acidic solubility. The study findings also emphasize the need to improve the solubility of Cyclobenzaprine HCL in acidic conditions.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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