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DETERMINATION OF SATURATED SOLUBILITY OF FENOFIBRATE ON DIFFERENT DISSOLUTION MEDIUM USING UV/VISIBLE SPECTROPHOTOMETER

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ABSTRACT

Drug formulation and development depend greatly on the drug's solubility. The most crucial pre-formulation parameter is determining the drug's solubility. For parenteral preparations, the drug molecules must be sufficiently soluble. In line with this, permeability and solubility both affect the bioavailability of solid formulations like tablets and capsules. The purpose of this study was to use a UV-visible spectrophotometer to examine the drug's solubility in various pH media. In the pH range of 1.2 to 7.4, the drug's solubility was investigated. This study has found that the solubility of fenofibrate is depending on pH.

KEYWORDS

Saturated Solubility, UV Visible Spectrophotometer, Fenofibrate and pH range

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INTRODUCTION

The majority of the novel medication candidates have inadequate bioavailability due to their poor water solubility[1]. Drugs with low solubility make up 40% of all newly produced medications, which is a global problem for the pharmaceutical industry[2]. A crucial pre-formulation study characteristic is solubility.

The Biopharmaceutical Classification System (BCS) bases its classification on two key characteristics: solubility and permeability. The U.S. Food and Drug Administration's Biopharmaceutics Classification System identifies the drug's intestinal absorption. According to this, there are four categories of drugs: class I, which

includes highly soluble and permeable drugs, class II, which includes low-soluble but highly permeable drugs, class III, which includes less soluble but highly permeable drugs, and class IV, which includes significantly less soluble drugs with poor permeation rates. The bioavailability of the medicine is impacted by its aqueous solubility. Drugs taken orally dissolve at first in the gastrointestinal environment.

The medicine is dissolved, and after passing through the intestinal barrier, it enters the bloodstream. According to the literature, water solubility and other non-optimal biopharmaceutical characteristics cause roughly 40% of therapeutic molecules to fall short of this procedure[3-5]. The purpose of the current investigation is to identify the drug's aqueous solubility in various dissolution mediums.

EXPERIMENTAL

Materials

The Fenofibrate was received as a gift sample. Disodium hydrogen phosphate sodium hydroxide, Potassium dihydrogen phosphate, and hydrochloric acid were purchased from Qualigens fine chemicals Mumbai, India. The distilled water was produced in our research laboratory with a distillation unit.

Scanning of λmax of the drug in different dissolution medium

The λmax of the drug in various dissolution mediums (like distilled water, pH 1.2, pH 6.8, pH 7.4) was scanned using a UV Visible Spectrophotometer. In this study, the stock solution of Fenofibrate was prepared in each medium. 100mg of the drug was taken in a 100mL volumetric flask and dissolved in 10mL of 5% tween 80. Then the final volume was made up to the mark with a suitable solvent and this is a stock solution. Further, the λmax of Fenofibrate in all solutions was scanned under spectrum mode in the wavelength range from 200-400nm and the peak table in all solutions was recorded.

The standard curve in a different medium

Standard curves of Fenofibrate have been carried out in different dissolution mediums (or solvents) such as distilled water, pH 1.2, pH 6.8, and pH 7.4.

1st Stock

100mg of Fenofibrate was accurately weighed into a 100ml volumetric flask and dissolved in a small quantity of each buffer. Volume was made up to100ml with buffer (1mg/ml or 1000µg/ml).

2nd Stock

1ml of the above solution was pipette into another 100ml volumetric flask. Volume was made upto 100ml with buffer (0.01mg/ml o r10µg/ml).

Pipette 2ml, 4ml, 6ml, 8ml, 10ml into 10ml into 10ml volumetric flasks respectively. Make up the volume with buffer solution to get 2µg/ml, 4µg/ml, 6µg/ml, 8µg/ml and 10µg/ml.

The absorbance of each concentration was measured at 286nm using buffer as blank. This was performed in triplicates and the average value was reported[6,7].

Saturated Solubility Study

The saturated solubility of the drug was determined in distilled water and various buffers from pH 1.2 to 7.4. The 50mL distilled water or buffer of the required pH was taken in a 100mL volumetric flask. An excess amount of drug was added to each volumetric flask and closed with Aluminum foil. These volumetric flasks were attached in an orbital shaking water bath. The shaking was carried out for 48 hours with a speed of 50rpm, and the temperature was maintained around 37 ± 0.5°C. Then the resulting samples were filtered using syringe filters with a pore size of 0.22µm. The filtrate was collected, and after suitable dilutions with the same solvent, the absorbance of the drug was analyzed with UV Visible Spectrophotometer (UV-1800, Shimadzu Corporation, Japan) at the prescanned λ max in a particular solvent. Then the absorbance was converted into concentration using the standard curve of a drug in each concerned solvent[8,9].

RESULTS AND DISCUSSION

Scanning of λmax of the drug in different dissolution medium the scanned wavelengths (λmax) of the drug in different dissolution mediums are given in Table No.1. As shown in the results, the wavelengths of the drug in all dissolution mediums are the same, which shows the pH of the dissolution medium doesn't affect the wavelength of the drug.

Standard curve in different medium

The standard curves in different aqueous medium are given below from Figure No.1 to Figure No.4. The linear equation and co-efficient correlation (r2) values of the standard curves in a different medium are given in Table No.2. The results showed that excellent correlation coefficients were obtained for the drug in all dissolution mediums. This demonstrates a significant correlation between analyte concentration and absorbance, and hence the method is suitable for analysis.

Saturated solubility study

The data for the saturated solubility study is shown in Figure No.5. The solubility studies indicate that the drug solubility is dependent on pH, where an increase in pH value increases the solubility of the drug. Here the drug is found to be least soluble in distilled water which might be due to the unionization of the drug. The unionized form of the drug enables the permeability of the drug through the membrane but limits the drug.

Table No.1: The scanned drug λ max values in different dissolution medium

S.No	The solvents used for the study	Scanned drug λmax (nm)
1	Distilled water	286nm
2	0.2N HCl Buffer (pH 1.2)	286nm
3	Phosphate Buffer pH 6.8	286nm
4	Phosphate Buffer pH 7.4	286nm

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

S.No	Solvents used for the study	Linear equation (y = mx + c)	Correlation Coefficient (r2)
1	Distilled water	0.0187x+0.0103	0.9874
2	0.2 N HCl Buffer (pH 1.2)	0.0185x+0.009	0.991
3	Phosphate Buffer pH 6.8	0.0226x+0.0071	0.9916
4	Phosphate Buffer pH 7.4	0.0242x+0.0099	0.9913

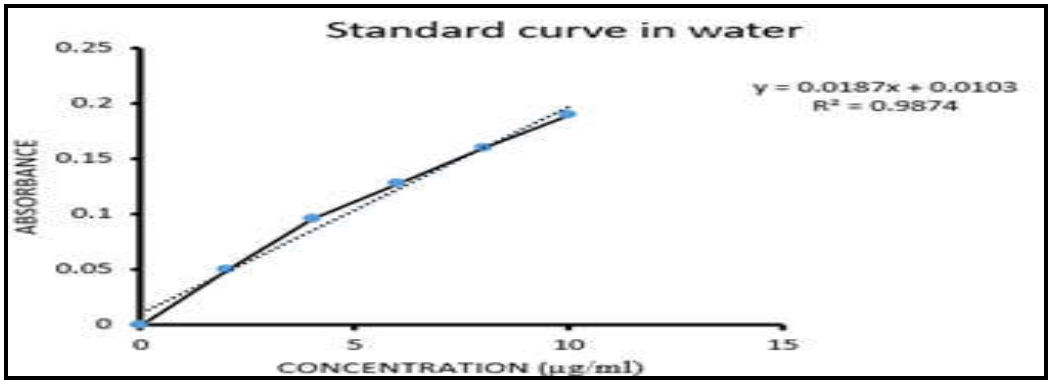

Figure No.1: Standard curve in distilled water

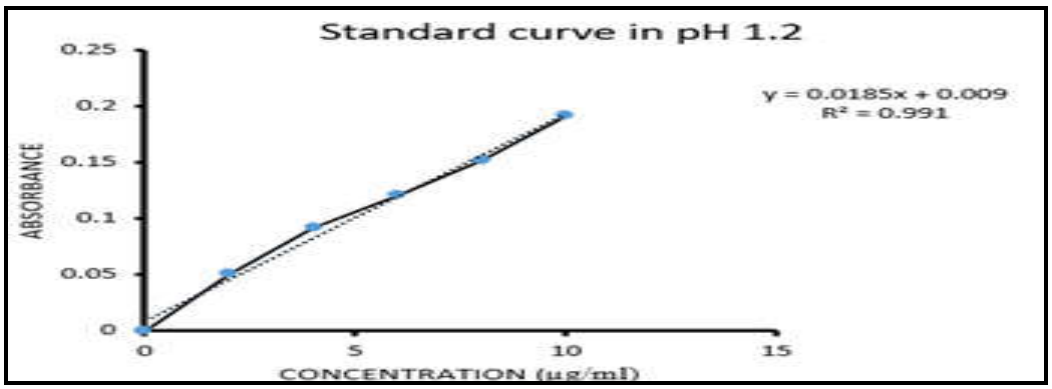

Figure No.2: Standard curve in pH1.2

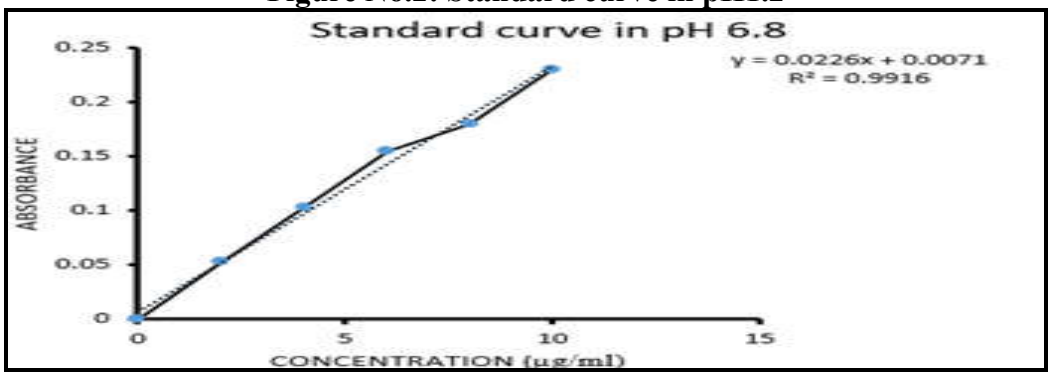

Figure No.3: Standard curve in pH 6.8

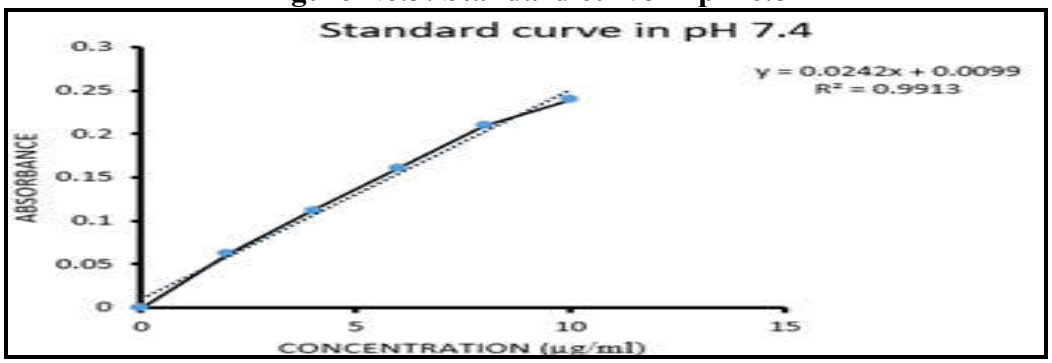

Figure No.4: Standard curve in pH 7.4

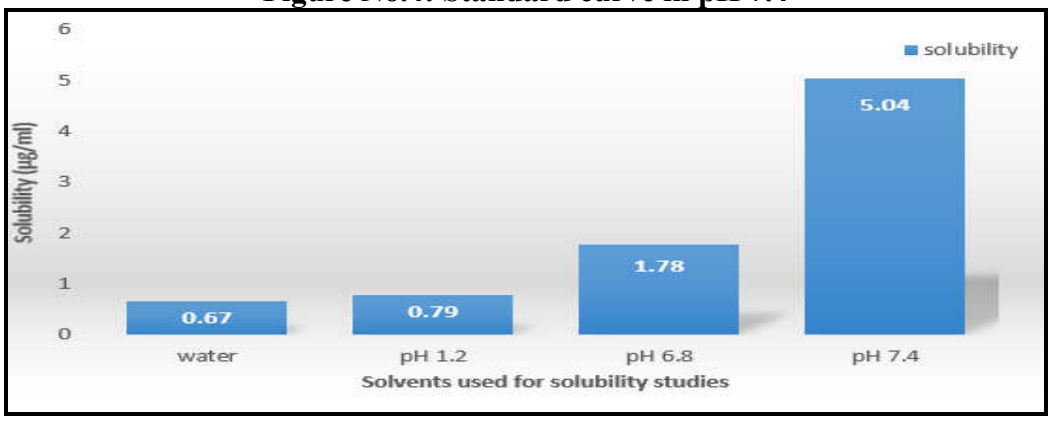

Figure No.5: Saturated solubility studies of fenofibrate

CONCLUSION

The present research study concludes that Fenofibrate has pH-dependent solubility, which means the drug has low bioavailability in the stomach. The 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 an 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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