Science Journal of Analytical Chemistry
2024, Vol. 12, No. 3, pp. 33-37
https://doi.org/10.11648/j.sjac.20241203.11

Research Article

Sustainable Spectrophotometric Quantification of Lansoprazole Through Mixed Hydrotropy Approach

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Abstract

Solubility is the property of a substance to dissolve in or form a homogeneous mixture with another substance. One of the most common problems associated with making a solution is poor solubility. There are many drugs that are sparingly soluble or insoluble in water, and lansoprazole is one of them. Aqueous solubility of lansoprazole is 0.05 mg/ml at room temperature. The current study aims to improve lansoprazole solubility using a mixed hydrotropy method. The purpose of the mixed hydrotropic solubilization approach is to increase the solubility of weakly water-soluble drugs in hydrotropic agent blends. To avoid the use of organic solvents, the mixed hydrotropy idea may be a good option. In this current research attempt, a novel method for spectrophotometric estimation of lansoprazole using a mixed solvent blend (containing 10% SC and 20% SB) as the solvent was developed. By observing the absorbances of the drug's standard solutions, the calibration curve for lansoprazole was drawn. The absorbances were measured at 275 nm compared to the corresponding reagent blanks. The percent label claims were found to be very near to 100, showing that the proposed approach is accurate. The suggested method estimates percent recoveries to be near 100 with significantly low percentage deviation and standard error values. As a result, the proposed process is simple, safe, and precise, and it does not require the use of harmful chemical solvents.

Keywords

Lansoprazole, Spectrophotometer, Hydrotropic Agents, Mixed Hydrotropy, Sodium Benzoate

1. Introduction

Solubility is the property of a substance to dissolve in or form a homogeneous mixture with another substance. One of the most common problems associated with making a solution is poor solubility. There are many drugs that are sparingly soluble or insoluble in water, lansoprazole is one of them. A poorly water soluble drug is not very soluble in water, which means that it will not be able to dissolve and it will stay on the surface of the water. Aqueous solubility of lansoprazole is 0.05 mg/ml at room temperature. The water solubility of insoluble and sparingly soluble drugs can be increased by a variety of methods, in which the use of organic solvents can be avoided [1-3]. These organic solvents' drawbacks include their high cost, volatility, pollution, and toxicity. If they get into the human body in any way, it is very harmful to them. The necessity to switch from organic to a cheap, environmentally friendly, and secure solvent for spectrophotometric analysis is therefore essential [4-6]. Concentrated aqueous solutions of sodium benzoate, sodium salicylate, urea, niacinamide, sodium citrate, and sodium acetate have been used to increase the water solubility of a

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Received: 30 August 2024; **Accepted:** 18 September 2024; **Published:** 18 November 2024

wide range of weakly water-soluble drugs [7].

The mixed hydrotropic concept is one technique for increasing the aqueous solubility of weakly water-soluble drugs [8-12]. To avoid the use of organic solvents, the mixed hydrotropic concept may be a suitable solution. As a result, the mixed hydrotropic concept has a broad application in the quantitative estimation of poorly water-soluble drugs [13-15]. Combinations of hydrotropic agents are necessary to increase the solubility of weakly water-soluble medicines using the mixed hydrotropic solubilization process [16]. The current research intends to improve lansoprazole solubility through the use of a mixed hydrotropy technique.

2. Material and Method

Lansoprazole drug was obtained as a gift sample from Lupin pharmaceuticals limited, India and lansoprazole tablets of two different companies (Cipla (30 mg) and Lupin (30 mg) were purchased from the local market of Indore. Analytical grade chemicals were used in this study.

2.1. Instrumentation

UV Visible spectrophotometer (Model 1800, Shimadzu) was used for spectrophotometric analysis.

2.2. Preliminary Solubility Studies

To assess the drug's solubility in distilled water and a mixed solvent blend (including 10% SC and 20% SB) at room temperature, a suitable amount of the drug was introduced to a 25 ml capacity vial containing distilled water and the mixed solvent blend. After settling the vial cap, the vial was mechanically shaken for 12 hours at room temperature in an orbital flask shaker. After resting for 24 hours, the solution was filtered through Whatman filter paper 41. The filtrate was adequately diluted with distilled water before measuring absorbance at 247 nm against reagent blanks. The solubility of lansoprazole (the drug) in distilled water and a hydrotropic solution is shown in Table 1.

Table 1. *Solubility of lansoprazole (drug) in distilled water and hydrotropic solution.*

Solvent	Absorbance	Solubility in mg/ml	Solubility improvement ratio
Distilled water	0.003	0.05	-
Blend solution (10% SC+ 20% SB solution)	0.125	5	5/0.05=100

2.3. Preparation of Calibration Curve

In a 10 ml volumetric flask, 10 mg of the lansoprazole standard drug were accurately weighed, along with 6 milliliters of blend. After the drug had completely dissolved, the flask underwent shaking to ensure complete dissolution before adding adequate blend to reach a total volume of 10 milliliters. By appropriately diluting this stock solution with distilled water, different standard solutions with concentrations of 10, 20, 30, and 40 ug/ml were created. At 247 nm, the absorbances of these solutions were measured in comparison to the corresponding reagent blank. The data for the calibration curve are shown in Table 2.

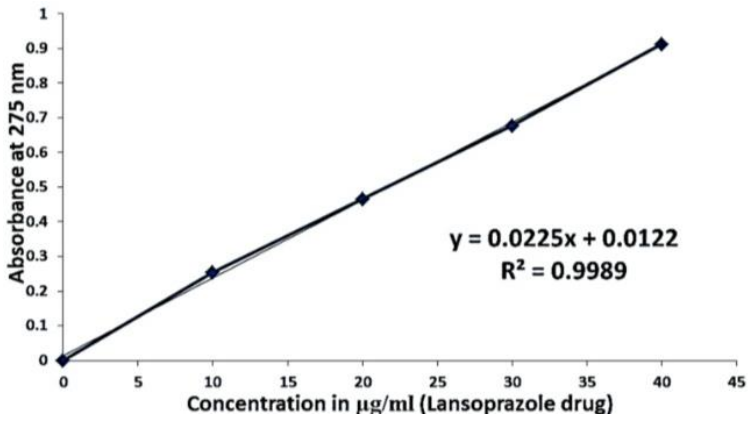

Figure 1. *Calibration curve of lansoprazole drug.*

Table 2. Data of calibration curve (Lansoprazole).

Serial dilution (ug/ml)	Absorbance
00	0.000
10	0.241
20	0.461
30	0.664
40	0.857

2.4. Proposed Method of Analysis

A tablet powder, consisting of 6 milliliters of blend solution and 10 milligrams of lansoprazole, filled a 10 milliliter volumetric flask. Upon shaking the flask vigorously for 10 minutes, the requisite amount of blend solution was introduced to achieve a final volume of 10 milliliters. The tablet excipients were removed through filtration using Whatman filter paper no. 41. After diluting 0.3 milliliters of the filtrate to 100 milliliters using distilled water, the absorbance at 247 nm was measured relative to the reagent blank. For tablet II, the same process was done. Table 3 presents the analysis' findings following calculation utilising the calibration curve. Three different analyses of each category were conducted.

Table 3. Analysis of lansoprazole tablet with statistical evaluation (n=3).

Tablet formulation	Label claim mg/tablet	Percent drug estimated (mean ± SD)	The percent coefficient of variation	Standard error
I Cipla pharma. Ltd.)	30	99.3 ± 0.363	0.365	0.210
II Lupin pharma. Ltd.	30	99.07 ± 0.358	0.361	0.208

2.5. Recovery Studies

The pre-analyzed tablet powder equivalent to 10 mg of standard Lansoprazole was added to for the recovery experiments (20 mg and 40 mg individually), and the drug content was assessed using the suggested method. Three different types of analyses were conducted. The analysis's findings are reported in Table 4.

Table 4. Statistically analysed findings from recovery studies (n=3).

Tablet formulation	The drug in pre-analyzed tablet powder (mg)	Amount of standard drug added (mg) (spiked)	Percent drug estimated (mean ± SD)	The percent coefficient of variation	Standard error
I (Cipla)	10	20	98.71 ±0.103	0.104	0.060
I (Cipla)	10	40	98.68 ±0.086	0.087	0.050
II (Lupin)	10	20	98.3 ±0.086	0.087	0.050
II (Lupin)	10	40	98.22 ±0.080	0.081	0.046

3. Results

At room temperature, lansoprazole was found to be 0.05 mg/ml soluble in distilled water, and it was 5 mg/ml soluble in a blend solution (Table 1). The data for the calibration curve are shown in Table 2. Table 3, a comprehensive overview of solubility and spectrophotometric analysis results for Lansoprazole tablets utilizing the mixed hydrotropy technique is provided. Mean percent estimations range from 99.07 to 99.3, coupled with consistently low values for standard deviation (0.358 to 0.363), percent coefficient of variation (0.361 to 0.365), and standard error (0.208 to 0.210).

Concluding in Table 4, the discussion encompasses mean

percent recoveries of Lansoprazole tablets, varying from 98.22 to 98.71. The proximity of these values to 100 further attests to the precision of the proposed spectrophotometric analysis method. Validation is underscored through the observation of consistently low statistical parameters, including standard deviation (0.080 to 0.103), percent coefficient of variation (0.087 to 0.104), and standard error (0.046 to 0.060).

4. Discussion

Hydrotropic solutions are currently in high demand because to their exceptional qualities, including their ease of availability, favourable recovery, lack of fire dangers, and eco-friendliness. The pharmaceutical industry can efficiently use mixed hydrotropic procedures. It can be used to avoid the use of organic solvents when spectrophotometrically estimating drugs that are poorly water-soluble from bulk drug samples.

5. Conclusion

It can be said that the Mixed hydrotropic approach can be employed in place of the more expensive and hazardous organic solvent. There is absolutely the further scope of a hydrotropic blend (containing 10% SC and 20% SB) as a hydrotropic solubilizing agent for the spectrophotometric analysis of different poorly water-soluble drugs precluding the use of organic solvents.

Abbreviations

SC	Sodium Citrate
SB	Sodium Benzoate

Conflicts of Interest

The authors declare no conflicts of interest.

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