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Solid as solvent- Novel spectrophotometric quantitative analysis of ornidazole tablets using solids (Eutectic liquid of phenol and lignocaine hydrochloride) as solubilizing agents (Mixed solvency concept)

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Abstract

The pollution and toxicity caused by most of the organic solvents is a big challenge. The researchers are doing much work to give eco-friendly solutions for this challenge. The present investigation is an attempt to show that solids can also be wisely used to act as solvent precluding the use of organic solvents. The main objective of the present study is to demonstrate the solvent action of solids. In the present study, a eutectic liquid (PL-41) obtained by triturating phenol crystals and lignocaine hydrochloride in 4:1 ratio on weight basis was employed to extract (dissolve) ornidazole drug from fine powder of its tablets. Distilled water was used for dilution to carry out spectrophotometric estimation at 319 nm without the help of organic solvent. The solubility of ornidazole in distilled water at room temperature was found to be 8.03mg/ml. The solubility of the same drug in PL-41 was more than 150 mg per ml (of PL-41). Proposed spectrophotometric analytical method is novel, rapid, free from toxicity of organic solvent, accurate and reproducible. Recovery studies and statistical data proved the accuracy, reproducibility and precision of the proposed method. The presence of tablet excipients, phenol and lignocaine hydrochloride did not interfere in the spectrophotometric estimation at 319 nm. Phenol does not interfere above 300 nm and lignocaine hydrochloride does not interfere above 310 nm.

Keywords: Mixed-solvency concept, ornidazole, phenol, lignocaine hydrochloride, spectrophotometric analysis, eutectic liquid.

Introduction

Maheshwari ^[1-5] has given a nice concept, known as mixed-solvency concept. By application of this concept, innumerable solvent systems can be developed. Maheshwari is of the opinion that each substance possesses solubilizing power. He has given several eco-friendly methods in the area of drug estimations and formulations precluding the use of toxic organic solvents. The solubility of a large number of poorly soluble drugs has been enhanced by mixed solvency concept ^[1-5]. The present research work also provides an eco-friendly method to estimate spectrophotometrically, the ornidazole drug in tablet formulations without the help of organic solvent.

The present investigation is an attempt to show that solids can also be wisely used to act as solvent precluding the use of organic solvents. The main objective of the present study is to demonstrate the solvent action of solids. In the present study, a eutectic liquid obtained by triturating phenol crystals and lignocaine hydrochloride in 4:1 ratio on weight basis was employed to extract (dissolve) ornidazole drug from fine powder of its tablets. Dilution was made with distilled water to carry out spectrophotometric estimation at 319 nm without the help of organic solvent. Proposed method is novel, economic, eco-friendly, rapid, free from toxicity of organic solvent, accurate and reproducible. Recovery studies and statistical data proved the accuracy, reproducibility and precision of the proposed method.

Materials and methods

Ornidazole bulk drug sample was a generous gift by M/S Shree Pharmaceuticals, Indore (India). Commercial tablets of ornidazole were procured from local market. Lignocaine hydrochloride was gifted by M/S Modern Laboratories. All other chemicals used were of analytical grade A Shimadzu-1700 UV visible spectrophotometer with 1 cm matched silica cells was used for spectrophotometric analysis.

Preparation of eutectic liquid - Phenol and lignocaine hydrochloride were triturated in 4:1 ratio on weight basis to obtain a eutectic liquid (PL-41)

Calibration curve- Accurately weighed 50 mg of ornidazole standard drug was transferred to a 500 ml volumetric flask. 10 ml of PL-41 was added and the flask was shaken to dissolve the drug. Then, about 400 ml of distilled water was added and the flask was shaken for 5 min to solubilize the contents. Then, the volume was made up to 500 ml with distilled water to get a stock solution of 100 µg/ml. The stock solution was suitably diluted with distilled water to prepare standard solutions of 5, 10, 15, 20 and 25 µg/ml. The absorbances of these standard solutions were noted at 319 nm against respective reagent blanks.

Preliminary solubility studies

The solubility of ornidazole was determined and was found to be 8.03 mg/ml in dilute water and 150 mg/ml in PL-41.

Proposed method of analysis

Twenty tablets of tablet formulation I were weighed and crushed to get a fine powder. Tablet powder equivalent to 50 mg ornidazole was transferred to a 500 ml volumetric flask. Then, 10 ml of PL-41 was transferred to it and the flask was

shaken vigorously for 10 min by hand shaking to extract (solubilize) the drug from the tablet powder. Then, about 400 ml distilled water was added and the flask was shaken for about 5 min for proper solubilization of phenol, lignocaine hydrochloride and drug in the distilled water. Then, sufficient distilled water was added to make up the volume up to 500 ml. Filtration was carried out through Whatmann filter paper # 41 to remove the insoluble tablet excipients. Then, 10 ml filtrate was diluted to 50 ml with distilled water and the absorbance was noted at 319 nm against the reagent blank. The drug content was calculated using the calibration curve. Same procedure was repeated for tablet formulation II. The results of analysis are reported in table 1.

Recovery studies

To perform the recovery studies, standard ornidazole drug was added (15 mg and 30 mg, separately) to the pre-analyzed tablet powder equivalent to 50 mg ornidazole and the drug content was determined by the proposed method. Results of analysis are reported in table 2 with statistical evaluation.

Table 1: Analysis data of ornidazole tablet formulations with statistical evaluation (n=3)

Tablet formulation	Label claim (mg/tablet)	Percent drug estimated (mean ± SD)	Percent coefficient of variation	Standard error
I	500	98.37 ± 0.732	0.744	0.423
II	500	99.86 ± 1.687	1.689	0.974

Table 2: Results of recovery studies with statistical evaluation (n=3)

Tablet formulation	Drug in pre-analyzed tablet powder (mg)	Amount of standard drug added (mg)	% Recovery estimated (mean ± SD)	Percent coefficient of variation	Standard error
I	50	15	100.33±0.786	0.783	0.454
I	50	30	99.08±1.068	1.078	0.617
II	50	15	100.89±1.607	1.593	0.928
II	50	30	98.92 ± 1.445	1.461	0.834

Results and discussion

The solubility of ornidazole in distilled water at room temperature was found to be 8.03 mg/ml. The solubility of ornidazole in PL-41 was more than 150 mg per ml (of PL-41). It is evident from table 1 that the percent drug estimated in tablet formulation I and II were 98.37 ± 0.732 and 99.86 ± 1.687 respectively. The values are very close to 100.0, indicating the accuracy of the proposed analytical method. Small values of statistical parameters viz. standard deviation, percent coefficient of variation and standard error (table 1) further validated the method. Further, table 2 shows that the range of percent recoveries varied from 98.92 ± 1.445 to 100.33 ± 0.786 which are again very close to 100.0, indicating the accuracy of the proposed method. Proposed analytical technique is further supported by significantly small values of statistical parameters viz. standard deviation, percent coefficient of variation and standard error (table 2).

Conclusion

In the present study, a eutectic liquid obtained by triturating phenol crystals and lignocaine hydrochloride in 4:1 ratio on weight basis was employed to extract (dissolve) ornidazole drug from fine powder of its tablets. Dilution was made with distilled water to carry out spectrophotometric estimation at 319 nm without the help of organic solvent. Proposed method is novel, rapid, free from toxicity of organic solvent, accurate and reproducible. Recovery studies and statistical data proved the accuracy, reproducibility and precision of the proposed method. The presence of tablet excipients, phenol and

lignocaine hydrochloride did not interfere in the spectrophotometric estimation at 319 nm. Phenol does not interfere above 300 nm and lignocaine hydrochloride does not interfere above 310 nm.

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