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Solid as solvent: Novel spectrophotometric analytical technique for quantitative analysis of tinidazole tablets using solids (eutectic liquid of phenol and metformin hydrochloride) as solubilizing agents (mixed solvency concept)

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Abstract
The main objective of the present study is to demonstrate the solvent action of solid. In the present study, a eutectic liquid (PMHCl 41) obtained by triturating phenol crystals and metformin hydrochloride in 4:1 ratio on weight basis was employed to extract (dissolve) tinidazole drug from fine powder of its tablets. Distilled water was used for dilution to carry out spectrophotometric estimation at 318 nm without the help of organic solvent. The solubility of tinidazole in distilled water at room temperature was found to be 5.38 mg/ml. The solubility of the same drug in PMHCl 41 was more than 150 mg per ml (of PMHCl 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 metformin hydrochloride did not interfere in the spectrophotometric estimation at 318 nm. Phenol and metformin hydrochloride do not interfere above 300 nm.

Keywords: Mixed-solvency concept, tinidazole, phenol, metformin hydrochloride, spectrophotometric analysis, eutectic liquid.

1. Introduction
Majority of drugs show the problem of poor solubility, whether in the case of their analytical estimations or in the field of liquid dosage forms in the form of solutions. Commonly used organic solvents for spectrophotometric analysis of water insoluble drugs include methanol, ethanol, chloroform, benzene, dichloromethane, dimethyl formamide, actonitrile, ethyl acetate, toluene, carbon tetrachloride, acetone, hexane etc. The main drawbacks of organic solvents include high cost, toxicity and pollution. They should be replaced by other eco-friendly alternative sources. The pollution and toxicity caused by most of the organic solvents is a big challenge.Maheshwari[1-5] has given a nice concept, known as mixed-solvency concept. 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.
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 metformin hydrochloride in 4:1 ratio on weight basis was employed to extract (dissolve) tinidazole drug from fine powder of its tablets. Dilution was made with distilled water to carry out spectrophotometric estimation at 318 nm without the help of organic solvent.

2. Materials and methods
Tinidazole drug sample was a generous gift by M/S Alkem Laboratories Ltd, Mumbai (India).Metformin Hydrochloride was a generous gift by M/S IPCA Laboratories, Ratlam (M.P.). Commercial tablets of tinidazole were procured from local market. 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 Metformin Hydrochloride were triturated in 4:1 ratio on weight basis to obtain a eutectic liquid (PMHCl 41).

Calibration curve- Accurately weighed 50 mg of tinidazole standard drug was transferred to a 500 ml volumetric flask. Ten ml of PMHCl 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 10, 20, 30, and 40 µg/ml. The absorbances of these standard solutions were noted at 318 nm against respective reagent blanks.

Preliminary solubility studies

The solubility of tinidazole and PMHCl 41 was determined and was found to be more than 150 mg/ml

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 tinidazole was transferred to a 500 ml volumetric flask. Then, 10 ml of PMHCl 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, metformin 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 of the filtrate was noted at 318 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 tinidazole drug was added (15 mg and 30 mg , separately) to the pre-analyzed tablet powder equivalent to 50 mg tinidazole 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 piroxicam 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	300	98.17 ± 1.449	1.476	0.837
II	300	99.87 ± 1.761	1.763	1.017

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	99.17±1.172	1.175	0.677
I	50	30	100.84±1.665	1.651	0.961
II	50	15	100.99±1.148	1.137	0.663
II	50	30	101.38±0.887	0.875	0.512

3. Results and discussion

The solubility of tinidazole in distilled water at room temperature was found to be 5.38 mg/ml. The solubility of tinidazole in PMHCl 41 was more than 150 mg per ml (of PMHCl 41).

It is evident from table 1 that the percent drug estimated in tablet formulation I and II were 98.17±1.449 and 99.87±1.761, 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 99.17±1.172 to 101.38±0.887 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).

4. Conclusion

In the present study, a eutectic liquid obtained by triturating phenol crystals and metformin hydrochloride in 4:1 ratio on weight basis was employed to extract (dissolve) tinidzole drug from fine powder of its tablets. Dilution was made with distilled water to carry out spectrophotometric estimation at 318 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 metformin hydrochloride did not interfere in the spectrophotometric estimation at 318 nm. Phenol and metformin hydrochloride do not interfere above 300 nm.

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