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"Solid as solvent"- Novel spectrophotometric analysis of Satranidazole tablets using solids (Eutectic Mixture of Phenol and Metformin 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. Using mixed solvency concept, innumerable solvent systems can be developed based on an assumption that each substance possesses solubilizing power which can be further explored to develop eco-friendly methods in the area of drug estimation and formulation precluding the use of any toxic organic solvents. In present study we used eutectic mixture of phenol and metformin hydrochloride (PMHCl 41) which is obtained by vigorous trituration of crystals of phenol and metformin hydrochloride (in 4:1 ratio) employed to extract (dissolve) Satranidazole from fine tablet triturate powder. Distilled water is used for dilution to carry out spectrophotometric analysis at 320nm without using any types of organic solvents. The solubility of Satranidazole in distilled water at room temperature was found to be 6.41mg/ml while the solubility of Satranidazole in PMHCl 41 was more than 150mg/ml (of PMHCl 41). The accuracy, reproducibility and precision of the method were confirmed by continuous recovery studies and statistical data. The presence of excipients, eutectic mixture PMHCl 41 did not interfere in spectrophotometric analysis at 320nm. Phenol and metformin hydrochloride PMHCL 41 does not interfere above 300nm.

Keywords: Mixed Solvency Concept, Satranidazole, Phenol, Metformin Hydrochloride, Spectrophotometric Analysis, Eutectic Liquid.

1. Introduction
The present study 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. The poor water solubility is the major issue for most of the existing and upcoming pharmaceutical product. All substance present on the earth posses solubilizing power, each substance shall show solubilizing power for some solutes and non solubilizing power for other. Present study describes the application of solvent character of eutectic liquid consisting of phenol and Metformin hydrochloride in 4:1 ratio (PMHCL 41) on the weight basis for spectrophotometric estimation of Satranidazole tablets. Solubility of Satranidazole in distilled water is 6.41mg/ml at room temperature. In the present investigation, PMHCL was utilized to extract out (dissolve) the drug from powder of tablets. Distilled water was used for dilution purpose. Absorbance was noted at 320 nm against reagent blank for determination of drug content. 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. The presence of tablet excipients, phenol and metformin did not interfere in the spectrophotometric estimation of Satranidazole at 320 nm. Phenol and metformin hydrochloride do not interfere above 300 nm in spectrophotometric analysis.

2. Materials and Methods
Satranidazole bulk drug sample was a generous gift by Alkem Laboratories Limited Mumbai. All other chemicals used were of analytical grade. Commercial tablets of Satranidazole were produced from local market. A Shimadzu-1700 UV visible spectrophotometer with 1cm matched silica cells was used for spectrophotometric analysis.

Preparation of Eutectic Liquid
Phenol and metformin hydrochloride were triturated in (4:1) ratio of their respective weight quantity and prepared the eutectic liquid (PMHCL 41).

Preparation of Calibration Curve

Accurately weighed 50 mg of Satranidazole standard drug was transferred to a 500ml volumetric flask and 10ml of PMHCL 41 was added to it. The flask was shaken to solubilize the drug. Then, about 400ml distilled water was added and the flask was shaken for 5min to solubilize the contents. The volume was made up to the mark with distilled water. This stock solution (100µg/ml) was suitably diluted with distilled water to obtain standard solutions of 10, 20, 30, 40 and 50µg/ml. The absorbances of these standard solutions were noted at 320 nm against respective reagent blanks to obtain the calibration curve.

Proposed Method of Analysis

To carry out spectrophotometric analysis, twenty tablets of tablet formulation I were weighed and crushed to get a fine powder. Tablet powder equivalent to 50 mg Satranidazole was transferred to a 500 ml volumetric flask. Then, 10 ml of PMHCL 41 was transferred to it and the flask was briskly shaken for 10 minutes to extract the drug from tablet powder. Then, 400 ml distilled water was added and the flask was shaken for 5 minutes to homogenize the contents. The volume was made up to the mark with sufficient distilled water. Filtration was carried out through Whatmann filter paper #41 to remove the tablet excipients. Ten ml of the filtrate was diluted to 50 ml with distilled water. Then, the absorbance of the filtrate was noted at 320 nm against reagent blank. Using the calibration curve, the drug content was calculated. Same procedure was repeated for tablet formulation II. The results of analysis were reported as in table 1.

Recovery Studies

The recovery studies were performed in which standard Satranidazole drug was added to the pre-analyzed tablet powder equivalent to 50 mg Satranidazole and drug content was determined by the proposed method. Results of analysis were reported as in table 2 with statistical evaluation.

Table 1: Analysis data of Satranidazole 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	98.72 ± 1.229	1.245	0.710
II	300	99.64 ± 0.871	0.874	0.503

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	100.79 ± 1.739	1.725	1.004
I	50	30	100.14 ± 1.207	1.205	0.697
II	50	15	99.04 ± 1.555	1.570	0.898
II	50	30	99.17 ± 0.882	0.889	0.509

3. Results and Discussion

The solubility of metronidazole in distilled water at room temperature was found to be 6.41 mg/ml. The solubility of metronidazole in PMHCl 41 was more than 150 mg/gm of PMHCl 41.

It is evident from table 1 that the percent drug estimated in tablet formulation I and II were 98.72±1.229 and 99.64±0.871, 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 further validated the method. Further, table 2 shows that the range of percent recoveries varied from 99.04±1.555 to 100.79±1.739 which are again very close to 100.0, indicating the accuracy of the proposed method which is further supported by significantly small values of statistical parameters viz. standard deviation, percent coefficient of variation and standard error.

4. Conclusion

The proposed method is new, simple, environment friendly, accurate and reproducible. The proposed method can be successfully employed in the routine analysis of Satranidazole tablets. Phenol does not interfere above 300 nm. Obtained accuracy of the proposed analytical method is also indicative of the proof that the solids possess solvent character.

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