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“SOLID AS SOLVENT”- NOVEL SPECTROPHOTOMETRIC ANALYSIS OF PIROXICAM TABLETS USING PHENOL AS SOLVENT

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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. Maheshwari 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 present research work also provides an eco-friendly method to estimate spectrophotometrically, a poorly water-soluble drug, piroxicam 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 solid. In the present investigation melted phenol was employed as solubilizing substance to extract out the drug to estimate piroxicam tablets spectrophotometrically at 358 nm. Phenol does not interfere in spectrophotometric analysis above 300 nm. 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 and phenol did not interfere in the spectrophotometric estimation at 358 nm.

Keywords - Mixed-solvency concept, piroxicam, phenol, spectrophotometric analysis.

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, acetonitrile, ethyl acetate, toluene, carbon tetrachloride, acetone, hexane etc. The main drawbacks of organic solvents include high cost, toxicity and pollution. Organic solvents have innumerable adverse effects caused by single exposure like dermatitis, headache, drowsiness, nausea, eye irritation and long term exposure causes serious effects such as neurological disorders, chronic renal failure, liver damage, necrosis, mutagenesis disorder. They should be replaced by other ecofriendly alternative sources. 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. Maheshwari¹⁻⁶ 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 ecofriendly 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 concept¹⁻²⁸. The present research work also provides an eco-friendly method to estimate spectrophotometrically, the piroxicam 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 investigation melted phenol was employed as solubilizing substance to extract out the drug to estimate piroxicam tablets spectrophotometrically at 358 nm. Phenol does not interfere in spectrophotometric analysis above 300 nm. 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 and phenol did not interfere in the estimation at 358 nm.

MATERIALS AND METHODS

Piroxicam bulk drug sample was a generous gift by M/S Shree Pharmaceuticals, Indore (India). Commercial tablets of piroxicam (Piroxits DT of Intas Pharmaceuticals Limited, Ahmedabad and Nesprex-DT of Nestor Pharmaceuticals Limited, Goa) were procured from the 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.

Calibration curve- 50 mg of piroxicam standard drug was transferred to a 500 ml volumetric flask. Phenol (10 g) was added and the flask was heated on a water bath (50-60°C) to melt the phenol. After that, the flask was shaken to dissolve the drug. After complete dissolution, about 400 ml distilled water (at 50-60°C) was poured in the volumetric flask and the contents were shaken for about 5 min to give a clear solution. Then, the flask was allowed to cool to room temperature and sufficient distilled water was added to make up the volume (500 ml).

From this stock solution (100 µg/ml), standard solutions containing 5, 10, 15 20 and 25 µg/ml were prepared by suitable dilution with distilled water. The absorbances of these solutions were noted at 358 nm against respective reagent blanks.

Preliminary solubility studies

To determine the solubility of the drug in distilled water at room temperature, sufficient excess amount of the drug was added to a 25 ml capacity vial containing distilled water. After putting the vial cap and applying the aluminium seal, the vial was shaken mechanically for 12 hours at room temperature (27±1°C) in an orbital flask shaker (Khera Instrument Pvt. Ltd., India). The solution was allowed to equilibrate for 24 hours undisturbed and then filtration was done through Whatmann filter paper # 41. The filtrate was appropriately diluted with distilled water to measure the absorbance at 358 nm. In order to determine the approximate solubility of drug in melted phenol, 1 g phenol was transferred to a 10 ml volumetric flask. The weight of the stoppered volumetric flask (initial weight) was noted. Then, the flask was heated on the water bath to melt the phenol (at 50-60°C). About 5 mg of drug was added and the flask was shaken to solubilize the drug. As soon as a clear solution was obtained, again about 5 mg of drug was added and the flask was shaken to solubilize the drug to get a clear solution. Same

process was repeated till the melted phenol (at 50-60°C) was saturated with drug. Again, the weight of volumetric flask was noted (final weight). Difference in these two weights (initial and final) gave the approximate amount of drug which saturates (nearly) one gram of melted phenol (50-60°C).

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 piroxicam was transferred to a 500 ml volumetric flask and 10 g phenol was added. The flask was heated on a water bath (50-60°C) to melt the phenol. Then, the flask was shaken vigorously for 10 min by hand shaking to extract (solubilize) the drug from the tablet powder. Then, 400 ml distilled water (at 50-60°C) was added and the flask was again shaken for 5 min by hand to solubilize phenol and drug in water. The flask was allowed to cool to room temperature and sufficient distilled water was added to make up the volume (500 ml). Filtration was carried out through Whatmann filter paper # 41 to remove the tablet excipients. Ten ml filtrate was diluted to 50 ml with distilled water and the absorbance was noted at 358 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 piroxicam drug was added (15 mg and 30 mg, separately) to the pre-analyzed tablet powder equivalent to 50 mg piroxicam 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)

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

RESULTS AND DISCUSSION

The solubility of piroxicam in distilled water at room temperature was found to be 0.401 mg/ml. The solubility of piroxicam in melted phenol was more than 460 mg per gm of melted phenol.

It is evident from table 1, that the percent drug estimated in tablet formulation I and II were 98.91 ± 0.883 and 99.76 ± 1.388 , 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 98.93 ± 1.661 to 100.91 ± 1.374 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

The proposed method is new, simple, environment friendly, accurate and reproducible. The proposed method can be successfully employed in the routine analysis of piroxicam tablets. Melted phenol can also be tried with other water insoluble drugs which are estimated above 300 nm. Phenol does not interfere above 300 nm.

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