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Novel Spectrophotometric Analysis of Piroxicam Tablets Using Ibuprofen Sodium as Hydrotropic Solubilizing Agents

R. K. Maheshwari[1*], Sita Prasad[1], P. Pandey[2], G. Wanare[1]

[1]*Department of Pharmacy, S. G. S. I. T. S., 23 Park Road, Indore, 452 003, India*
[2]*Swami Vivekanand College of Pharmacy, Khandwa Road, Indore, 452 003, India*

ABSTRACT
The term hydrotropy has been used to designate the increase in solubility in water of various substances due to the presence of large amount of additives. Concentrated aqueous hydrotropic solutions of sodium benzoate, urea, nicotinamide, sodium salicylate, sodium ascorbate and sodium glycinate have been observed to enhance the aqueous solubility of many poorly water-soluble drugs. In the present investigation hydrotropic solubilization technique has been employed to solubilize the poorly water-soluble NSAID, piroxicam. Determination of solubilities of the drug in 1.5 M ibuprofen sodium hydrotropic solution and distilled water was carried out at 28±1°C. There was more than 50-fold enhancement in aqueous solubility of piroxicam with 1.5 M ibuprofen sodium (as compared to aqueous solubility). Therefore, it was thought worthwhile to solubilize the poorly water-soluble piroxicam from fine powder of its tablets to carryout spectrophotometric analysis at 358 nm. Ibuprofen sodium does not show any absorbance above 300 nm. Beer's law was obeyed in the concentration range of 5-35 µg/ml. Tablets containing piroxicam have been analyzed successfully. Recovery studies and statistical data proved the accuracy, reproducibility and the precision of the proposed method. Based on the same principle a large number of drugs having λmax above 300 nm can be estimated by 1.5 M ibuprofen sodium (inexpensive hydrotropic agent). Thus, hydrotropic solutions can be used in place of organic solvents (which are pollutants, toxic and give error due to volatility).

Keywords: Piroxicam, Ibuprofen sodium, Spectrophotometry, Hydrotropy.

INTRODUCTION

Hydrotropy is the term used to describe the increase in the solubility of a solute by the addition of fairly high concentrations of alkali metal salts of various organic acids. However, the term has been used in the literature [1-3] to designate non-micelle-forming substances, either liquids or solids, organic or inorganic, capable of solubilizing insoluble compounds. Concentrated solutions of sodium benzoate, sodium salicylate, urea, nicotinamide, sodium glycinate and sodium ascorbate have been employed to enhance the aqueous solubilities of a large number of drugs. [4-25]

UV/Vis absorption spectrophotometric method for the estimation of poorly water-soluble drug piroxicam in pharmaceutical formulations has been developed. Aqueous solubility of the selected drug was enhanced to a great extent (more than 50 fold) in 1.5 M ibuprofen sodium. The primary objective of the present investigation was to employ the hydrotropic solutions to extract the drug from their dosage forms precluding the use of costlier organic solvents.

***Corresponding author: Dr. R. K. Maheshwari,**
Department of Pharmacy, S. G. S. I. T. S., 23 Park Road, Indore, 452 003, India; **E-mail:** prajapati.sp@gmail.com

The selected λ-max for piroxicam was 358 nm.
Ibuprofen sodium does not show any absorbance above 300 nm and therefore no interference in the estimation was observed. The results of analysis have been validated statistically and by recovery studies. Proposed method is new, simple, economic, accurate, safe and precise.

MATERIALS AND METHOD

A Shimadzu UV/Vis recording spectrophotometer (Model-UV160A) with 1 cm matched silica cells was employed for spectrophotometric analysis. Piroxicam was obtained from M/s. Alkem Laboratories Limited, Mumbai as gift sample. The tablet formulations used were obtained directly from market as Piroxitas-DT tablet (Intas Pharmaceutical Ltd, Ahmedabad) and Nesprex-DT tablets (Nestor Pharmaceutical Ltd, Goa). All other chemicals used were of analytical grade.

In order to prepare calibration curve, 50 mg of piroxicam bulk drug was accurately weighed and transferred to a 25 ml volumetric flask. Twenty ml of 1.5 M ibuprofen solution was added and the flask was shaken to solubilize the drug. After complete dissolution of drug, sufficient distilled water was used to make up the volume. Then, 2.0 ml of this solution

was diluted to 100 ml with distilled water to give a solution containing 40µg/ml. This stock solution was further diluted with distilled water to get different standard solutions containing 5, 10, 15, 20, 25, 30 and 35 µg/ml of drug. Absorbance values of these solutions were noted at 358 nm against their respective reagent blanks.

Solubility of drug was determined at 28±1°C. An excess amount of drug was added to screw capped 30 ml glass vials containing distilled water and 1.5 M ibuprofen sodium solution .The vials were shaken mechanically for 12 h at 28±1°C in a mechanical shaker. These solutions were allowed to equilibrate for next 24 h and then centrifuged for 5 min at 2000 rpm. The supernatant of each vial was filtered through Whatman filter paper No. 41. Filtrates were diluted suitably with distilled water and analyzed spectrophotometrically against corresponding reagent blank.

In analysis of piroxicam in tablets by the proposed method, tablet powder equivalent to 50 mg piroxicam was transferred to a 25 ml volumetric flask containing 20 ml of 1.5 M ibuprofen sodium solubilizing agent. Flask was shaken for about 10 minutes to solubilize the drug present in tablet powder and volume was made up to the mark with distilled water. After filtration through Whatman filter paper No. 41, the filtrate was appropriately diluted with distilled water and absorbance was noted at 358 nm against reagent blank. Using the calibration curve, the drug content was computed in (Table I). Recovery studies were performed by spiking the preanalyzed tablet powder with piroxicam bulk drug sample at two levels and determining the drug content by the proposed method. Each type of analysis was performed three times.

For recovery studies, tablet powder (formulation I) equivalent to 50 mg drug was taken in a 25 ml volumetric flask. In this flask 10 mg of pure drug (spiked drug) was transferred and 20 ml of 1.5 M ibuprofen sodium solution was added and the flask was shaken for about 10 min. Then, volume was made up to the mark with distilled water and filtered through Whatman filter paper No. 41. The solution was diluted appropriately with distilled water and analyzed for drug content against reagent blank (Table II). Similar treatment was done for 20 mg spiked drug in case of formulation I. similar recovery studies were performed for formulation II. The results of analysis of recovery studies are presented in Table II.

RESULTS AND DISCUSSION

Results of solubility studies indicated that enhancement in aqueous solubility of piroxicam in 1.5 M ibuprofen sodium solution as compared to solubility in distilled water was more than 50 fold.

From Table I, it is evident that there is good agreement between the amounts estimated and those claimed by the manufacturers. The mean Percent label claims 98.38 and 99.88 (Table I) are very close to 100 with low values of standard deviation, % coefficient of variation and standard error which confirms the accuracy of the proposed method. Accuracy, reproducibility and precision of the proposed method were further confirmed by the mean percent recovery values (99.84 to 101.38), which were close to 100 with low values of standard deviation, % coefficient of variation and standard error (Table II).

From this study, it is obvious that there was no interference of ibuprofen sodium in the estimation of piroxicam (λ-max– 358 nm). Ibuprofen sodium does not absorb above 300 nm. Because of these reasons it can be concluded that a large number of poorly water-soluble drugs having λ-max above 300 nm may be tried for estimation by the proposed method provided that their preliminary solubility studies are conducted to observe the enhancement effect on solubility. Ibuprofen sodium solution is cheaper than most of the organic solvents and can thus substitute expensive organic solvents. Drawbacks of organic solvents include toxicity, error due to volatility, pollution and cost. Thus, 1.5 M ibuprofen sodium solution may be better substitute for organic solvents. By proper choice of hydrotropic agents, the use of organic solvents in analysis may be discouraged to a large extent.

Table I: Analysis data of tablet formulations with statistical evaluation

Tablet Formulation	Label Claim (mg/Tablet)	%Label Claim Estimated* (Mean±S.D.)	% Coeff. of Variation	Standard Error
I	20	98.38±0.770	0.782	0.444
II	20	99.88±0.909	0.910	0.525

Formulation I: Piroxitas-DT 20 mg tablets, (Intas Pharmaceutical Ltd, Ahmedabad)
Formulation II: Nesprex-DT 20 mg tablets, (Nestor Pharmaceutical Ltd, Goa)
***** Mean (n = 3)

TABLE II: RESULTS OF RECOVERY STUDIES OF TABLET FORMULATIONS WITH STATISTICAL EVALUATION

Tablet Formulation	Drug Present in Preanalyzed Tablet Powder (mg)	Amount of Drug Added (Spiked) (mg)	% Recovery Estimated* (Mean±S.D.)	% Coeff. of Variation	Standard Error
I	50	10	101.38±1.197	1.181	0.691
	50	20	100.59±0.802	0.797	0.463
II	50	10	99.84±1.336	1.338	0.771
	50	20	100.93±1.559	1.545	0.900

Formulation I: Piroxitas-DT 20 mg tablets, (Intas Pharmaceutical Ltd, Ahmedabad)
Formulation II: Nesprex-DT 20 mg tablets, (Nestor Pharmaceutical Ltd, Goa)
* Mean (n = 3)

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