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Original Article

Mixed Solvency Approach for Spectrophotometric Analysis of Diclofenac Sodium Tablets

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ABSTRACT

Present experimentation was aimed to prevail over the solubility problems coupled with diclofenac sodium tablets for spectrophotometric investigation (selected λ_{max}, 276 nm). A selected blend of mixture of polyethylene glycol 300, 400, 6000 and 10% urea each was employed considering the additives not to interfere with the analysis. The data obtained from proposed method (selected blend) was very secure to those obtained from standard method (as per I.P. method). The solubility of diclofenac sodium was improved by 14 folds compared to distilled water and the results of analysis were validated statistically as well as by recovery studies. On other hand percent label claimed and percent recovery estimated were close to cent percent with having negligible standard deviation and standard error.

Keywords: Mixed solvency, spectrophotometric analysis, diclofenac sodium, solubility studies.

INTRODUCTION

In the world of chemistry, majority of the newly developed drug molecules or synthesized chemical entities are lipid soluble (lipophilic) in nature. There is a problem of lower aqueous solubility associated with these molecules[1]. To overcome the solubility issue of such molecule and its application in spectrophotometric analysis is the major approach and finding of this experiment.

Some authors have already applied the concept of hydrotropic solubilization for quantitative estimation of large number of drug molecules[2]. Hydrotropy, co-solvency and use of water soluble solutes are some methods to increase the aqueous solubility of weakly soluble drugs. The concept of mixed solvency demonstrates synergistic effect on solubilization phenomena. The methods of hydrotropy and mixed

solvency are widely applicable for the titrimetric as well as spectrophotometric estimation of variety of drug molecules. Simultaneously the concepts of mixed solvency approach also bypass the use of organic solvents and toxic influences associated with them for the development of dosage form. A mixture of solubilizers taken in small concentration each with least toxicity level can be utilized to significantly increase the solubility of poor soluble drug molecules[3-6].

The concept of hydrotropy is useful improve the aqueous solubility various drugs due to presence of large amount of additives. In this method hydrotropic solution of urea, nicotinomide, sodium benzoate, sodium salicylate, sodium acetate and sodium citrate was observed to be most useful in enhancing the aqueous solubility by manifolds[7-10].

Maheshwari et. al. (2006), gave the concept that all the substances (whether solid, liquid or gas) can have the solubilizing power and can enhance solubility of weakly soluble drugs. He has experimentally studied the poorly soluble drug (salicylic acid) and enhanced aqueous solubility by using solution containing hydrotropic agents i.e. urea and sodium citrate, co-solvents i.e. glycerin, propylene glycol, PEG 300 and 400; and water soluble solids i.e. PEG 4000 and 6000 individually[11-12].

The primary objective of the present study is to employ the concept of mixed solvency so as to extort the drug (diclofenac sodium) from dosage form (tablets) for spectrophotometric analysis and to evade the exercise of costly organic solvents.

MATERIALS AND METHOD

Diclofenac sodium (drug) was obtained as gift sample from M/S Pharmaceuticals; Indore (MP, India) while diclofenac sodium tablets has been purchased from local market. Chemicals used in the experiment were of analytical grade. Spectrophotometric analysis was done in matched spectrophotometer cells (4 cm X 1 cm silica cells) using Schimadzu UV-visible spectrophotometer (Model-UV 160A).

Calibration curve

100 mg of diclofenac sodium was accurately weighed and solubilized with mixed blend (10 ml) of PEG-300, 400, 6000 and urea each 10% (w/v) in a volumetric flask of 100 ml. Distilled water was added to make up the volume. The stock was further diluted with distilled water to get various dilutions containing 15, 30, 45, 60, 75 and 90 µg/ml of drug and the absorbance's were recorded at 276 nm against corresponding reagents blank.

Preliminary solubility studies

Solubility of diclofenac sodium in said blend was found improved by more than 14 folds as compared to

that in distilled water.

Analysis of diclofenac sodium tablets by proposed method (Table 1)

20 tablets of diclofenac sodium (formula-I and II) were weighed and powdered. Powder equivalent to 100 mg of diclofenac sodium was taken in a 100 ml volumetric flask. 10 ml of blend of solubilizing agents was added. The flask was shaken briskly for 10 minutes to solubilize the drug and volume was made up to the mark with distilled water. After filtration (Whatmann#41), the filtrate was properly diluted with distilled water. Spectrophotometric estimation was done against reagent blank to calculate the drug content.

Table 1: Results of Analysis of Commercial Tablet Formulation with Statistical Evaluation

Tablet Formulation	Label Claim/ Tablet (mg)	Method of Estimation	Percent Label Estimated (Means±SD)	Percent Coefficient of Variation	Standard Error
I	100	IP Method	99.32±0.777	0.782	0.449
I	100	Proposed Method	100.82±1.277	1.267	0.737
II	50	IP Method	101.19±1.386	1.370	0.800
II	50	Proposed Method	100.13±0.808	0.807	0.467

Recovery study (Table 2)

20-40 mg of pure diclofenac sodium was added to pre analyzed tablet powder (equivalent to 100 mg of pure diclofenac sodium). The method of analysis was similar using 8.0 M urea solution and % recovery was calculated.

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

Tablet Formulation	Amount (mg) of Drug Present in Pre-analyzed Tablets	Pure Diclofenac Sodium Added (mg)	% Recovery Estimated (Mean ±SD)	% Coefficient of Variation	Standard Error
I	100	20	101.28±1.931	1.907	1.115
I	100	40	99.46±1.131	1.137	0.653
II	100	20	100.53±1.558	1.550	0.900
II	100	40	99.72±0.645	0.647	0.372

RESULTS AND DISCUSSION

From the solubility study it was revealed that diclofenac sodium was 14 folds more soluble in mixed blend of solubilizing agent as compared to its solubility in distilled water. It is evident from the values of mean percent of drug (diclofenac sodium) estimated by proposed spectroscopic method for formulation I and II i.e. 100.82±1.277 and 100.13±0.808 respectively. On the other hand mean percent of drug estimated by Indian Pharmacopoeial method for formulation I and II was 99.32±0.777 and 101.19±1.386 respectively. The accuracy of proposed method was indicated by such values as these values are close to 100 as shown in the tables. Similarly the value of standard deviation, percent coefficient of variation and standard error were satisfactorily lower and thus validate the proposed method.

CONCLUSION

The proposed method of analysis was concluded to be simple, accurate and reproducible. It can also be employed for routinely analysis of diclofenac sodium in tablet formulation. This concept of using blend of different solubilizers can be applied in different field of analysis.

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