



NEW TITRIMETRIC ESTIMATION OF ACECLOFENAC TABLETS USING MIXED-HYDROTROPY

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ABSTRACT

The Present investigation illustrates the application of mixed hydrotropy. Miraculous synergistic effect on enhancement in solubility of poorly water soluble drug was observed by mixing two hydrotropic agents. The enhancement of solubility of drug aceclofenac was more than 700 fold in (22.5% urea + 22.5% sodium citrate) solution as compared to solubility in distilled water. This proved a synergistic enhancement in solubility of a poorly water soluble drug due to mixed hydrotropy. Mixed hydrotropic solution was employed to solubilize a poorly water soluble drug, aceclofenac, from fine powder of its tablets to carry out titrimetric estimation precluding the use of organic solvents. The tablet containing aceclofenac were analyzed. Recovery studies and statistical data proved accuracy, reproducibility and precision of the proposed method. The presence of hydrotropic agents (urea and sodium citrate) did not interfere in the analysis.

Keywords: Mixed-hydrotropy, Aceclofenac, Urea, Sodium citrate, 700 fold enhancement in solubility.

INTRODUCTION

The term hydrotropy used to designate the increase in solubility of various poorly water soluble compounds, due to presence of large amount of additives. Concentrated aqueous hydrotropic solution of Sodium benzoate, sodium salicylate, urea, niacinamide, sodium acetate and sodium citrate has been employed to enhance the aqueous solubilities of poorly water soluble drugs. Various organic solvents like methanol, chloroform, ethanol and dimethyl formamide are widely used to conduct their titrimetric analysis. Draw backs of organic solvents includes their higher cost, toxicities and pollution. There was more than 700 folds enhancement in the aqueous solubility of aceclofenac (a poorly water soluble drug) in urea- sodium citrate solution (an inexpensive hydrotropic agent) as compared to its aqueous solubility. Therefore it was thought worthwhile to solubilize the poorly water soluble aceclofenac in water, from fine powder of its tablets with the help of solution to carry out its titrimetric analysis. This found more cost effective and safe. Chemically aceclofenac is 2-[(2, 6 dichloro phenyl) amino] benzene acetic acid carboxymethyl ester.^{1, 2, 4}

MATERIALS AND METHODS

Analysis of aceclofenac tablets by proposed method

About 300 mg aceclofenac tablet powder was accurately weighed and transferred to a conical flask 20ml of blend (22.5% urea + 22.5% sod. Citrate) was added and the flask was shaken vigorously for 10 min to solubilize the drug sample. Sodium hydroxide solution (0.1M) employed for titration using few drops of phenolphthalein solution as indicator. Blank determination was performed for necessary correction to determine the drug content. This

procedure was performed thrice (n=3) and the results are presented in table -1.^{1, 3, 4}

Recovery studies

To perform recovery studies, aceclofenac pure drug was added (60mg and 120mg separately) to tablet powder equivalent to 300mg aceclofenac and drug content was determined by the proposed method.¹⁻³

RESULTS

The percent label claims were 101.25±0.871 and 99.974 ± 1.141 (table-1) in case of proposed method. Percent label claim very close to 100 and values of standard deviation, percent coefficient of variation and standard error were satisfactorily low therefore this indicate the accuracy of proposed method.

Accuracy, reproducibility and precision of the proposed method were further confirmed by percent recovery values. The percent recovery values ranges from 98.66±0.992 to 100.24±0.938 (table-2) in cases of proposed methods employing blend solution of urea and sodium citrate. Percent recovery values were close to 100 with low values of standard deviation, percent coefficient of variation and standard error. Therefore these indicate the accuracy of proposed method and validate the method.

DISCUSSION

By proper choice of hydrotropic agent, the use of organic solvents in analysis may be discouraged to a large extent. Hydrotropic agents did not interfere in the proposed method. This method can be successfully employed in the routine analysis of aceclofenac in tablet dosage form. Mixed hydrotropy may find wide use in development of aqueous formulation of poorly water soluble drug in future.^{4, 6}



Table 1: Results of titrimetric analysis of aceclofenac tablets using mixed hydrotrophy (n=3)

Tablet formulation	Label claim per tablet (mg)	% Label claim estimated (mean \pm SD)	% Coefficient of variation	Standard Error
I	100	101.25 \pm 0.871	0.860	0.503
II	100	99.974 \pm 1.141	1.144	0.659

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

Tablet formulation	Drug present in Preanalyzed tablet powder (mg)	Pure drug added (spiked)	% Recovery estimated mean \pm SD	% Coefficient of variation	Standard Error
I	300	60	99.38 \pm 1.861	1.873	1.074
I	300	120	100.24 \pm 0.938	0.936	0.542
II	300	60	99.08 \pm 1.283	1.295	0.741
II	300	120	98.66 \pm 0.992	1.005	0.573

CONCLUSION

It may be concluded that the proposed method of analysis is new, rapid, simple, cost effective, environment friendly, safe, accurate and reproducible. So it can be use as a standard method for analysis of tablet aceclofenac.^{2, 4,5}

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