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SHORT COMMUNICATION

# APPLICATION OF MIXED-HYDROTROPY IN TITRIMETRIC ANALYSIS OF ACECLOFENAC BULK DRUG SAMPLE

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**The present investigation includes the enhancement of solubility of aceclofenac by more than 1155 fold in (20% *N,N*-dimethyl urea + 20% sodium citrate) solution as compared to solubility in distilled water, utilizing the concept of mixed-hydrotropy. Mixed hydrotropic solution was employed to solubilize a poorly water-soluble drug - aceclofenac, in bulk to carry out titrimetric estimation precluding the use of organic solvents which are toxic, eco-pollutant and costlier. Statistical data proved the accuracy, reproducibility and the precision of the proposed method. The proposed method of analysis is new, rapid, simple, cost-effective, eco-friendly, safe, accurate and reproducible. The presence of hydrotropic agents (*N,N*-dimethyl urea and sodium citrate) did not interfere in the titrimetric analysis.**

**Key words:** Mixed-hydrotropy, Aceclofenac, Titrimetry, *N,N*-dimethylurea, Sodium citrate.

## INTRODUCTION

Hydrotropes are a class of chemical compounds that cause several fold increase in the solubility of sparingly soluble solute under normal condition. Ibuprofen, flurbiprofen (Maheshwari *et al* 2007), nalidixic acid, norfloxacin, tinidazole, metronidazole (Maheshwari *et al* 2006a), paracetamol (Maheashwari *et al* 2006b), naproxen, cefixime, benzoic acid, ornidazole (Maheshwari *et al* 2010a; 2010b; 2010c; 2010d), hydrochlorthiazide (Jain *et al* 2010), ketoprofen (Nair and Rajput, 2010), aspirin (Maheshwari *et al* 2005), indomethacin (Etman and Nada, 1999), atorvastatin (Jadhav *et al* 2010) and nifedipine (Jain *et al* 1988) are analyzed by the use of hydrotropic solubilization technique.

There was tremendous increase in solubility of aceclofenac (a poorly water-soluble drug) in a mixed hydrotropic solution containing 20% *N,N*-dimethylurea and 20% sodium citrate. For the titrimetric analysis of poorly water-soluble drugs, various organic solvents like acetone, chloroform, *N,N*-dimethylformamide, ethanol, methanol have been employed. Drawbacks of organic solvents include their toxicity, higher costs and pollution. To preclude the use of organic solvent, a mixed hydrotropic solution of *N,N*-dimethylurea and sodium citrate was used for the estimation of aceclofenac bulk drug. This phenomenon overcomes the drawbacks of organic solvent including higher cost, toxicity, pollution and error in analysis due to the volatility.

## MATERIALS AND METHODS

### *Instrument*

Aceclofenac was a generous gift by Aristo Pharmaceuticals Ltd., Mandideep (India). All chemicals used were of analytical grade.

### *Methods*

*Analysis of aceclofenac bulk drug sample by British Pharmacopoeial method (BP, 2007)*

Accurately weighed 300 mg of aceclofenac bulk drug sample was dissolved in 40 ml of methanol and titrated with 0.1 M NaOH solution, determining the end point potentiometrically.



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*Analysis of aceclofenac bulk drug sample by proposed method*

About 300 mg aceclofenac bulk drug sample was accurately weighed and transferred to a 100 ml conical flask. 20 ml of blend (20% *N,N*-dimethylurea + 20% sodium citrate) was added and the flask was shaken vigorously for about 10 min to solubilize the drug sample. Sodium hydroxide solution (0.1 M) was employed for titration using few drops of phenolphthalein solution as indicator. Blank determination was performed for necessary correction to determine the drug content (**Table 1**). Whole procedure was performed thrice (n=3).

**Table 1.** Results of titrimetric analysis of aceclofenac tablets using mixed hydrotropy (n=3)

| Amount of bulk drug analyzed (mg) | Method of analysis | Percent drug estimated (mean ±SD) | Percent coefficient of variation | Standard error |
|---|---|---|---|---|
| 300 | B.P. method | 99.11± 1.647 | 1.662 | 0.951 |
| 300 | Proposed method | 98.73 ± 0.661 | 0.700 | 0.382 |

## RESULT AND DISCUSSION

Results of solubility studies of aceclofenac revealed that enhancement in solubility in a mixed hydrotropic solution containing 20% *N,N*-dimethyl urea and 20% sodium citrate was more than 1155 fold as compared to its solubility in distilled water. It is evident from results that the mean percent of aceclofenac estimated in drug sample was 99.11±1.647 and 98.73±0.661 by the British Pharmacopoeial and proposed titrimetric methods, respectively. The percent estimated by British Pharmacopoeial and proposed titrimetric methods are very close to each other and very near to 100.0, indicating the accuracy of the proposed method of analysis. Low values of standard deviation, percent coefficient of variation and standard error further validated the proposed titrimetric method.

## CONCLUSION

The proposed method is new, simple, environment friendly, accurate and reproducible. Decided advantage is that organic solvent is precluded but not at the expense of accuracy. The proposed method can be successfully employed in the routine analysis of aceclofenac in bulk drug sample. Mixed hydrotropy may find wide use in development of aqueous formulations of poorly water-soluble drugs in future.

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