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NOTE

Application of Hydrotropic Solubilization in the Analysis of Aceclofenac Drug

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In the present investigation, 2.0 M sodium benzoate solution was employed as hydrotropic solubilizing agent to solubilize poorly water-soluble drug, aceclofenac, for its titrimetric analysis. Proposed method is new, simple, environmentally friendly, accurate and reproducible. Accuracy, reproducibility and precision of the proposed method was validated statistically.

Key Words: Hydrotropy, Aceclofenac, Sodium benzoate.

The term "hydrotropy" has been used to designate the increase in solubility of various substances due to the presence of large amount of additives. Various hydrotropic agents have been used to enhance the aqueous solubility of a large number of drugs[1-13]. Maheshwari[1] has analyzed cefixime (a poorly water-soluble drug) in tablet dosage forms using urea (8.0 M), sodium acetate (4.0 M) and sodium citrate (1.25 M) as hydrotropic solubilizing agents. Maheshwari[2] analyzed frusemide (a poorly water-soluble drug) by titrimetric analysis using hydrotropic solution of sodium benzoate (2.0 M). The same author[3] has developed titrimetric methods to analyze ketoprofen and salicylic acid. Hydrotropic solutions of sodium benzoate (2.0 M), sodium salicylate (2.0 M) and sodium acetate (2.0 M) were employed for ketoprofen. Hydrotropic solutions of urea (8.0 M), sodium citrate (1.25 M) and sodium benzoate (2.0 M) were employed in the estimation of salicylic acid. Maheshwari *et al.*[4] used hydrotropic solution of sodium benzoate (2.0 M) as solubilizing agent to analyze a poorly water-soluble drug, ofloxacin, by spectrophotometric estimation. Maheshwari[5] has also developed a spectrophotometric method to analyze ketoprofen in tablet dosage form using hydrotropic solution of sodium acetate (4.0 M).

There was tremendous increase in the solubility of aceclofenac (a widely used non-steroidal anti-inflammatory agent) in 2.0 M sodium benzoate solution. Therefore, it was thought worthwhile to solubilize the drug with the help of sodium benzoate solution (2.0 M) to carryout the titrations. Chemically, aceclofenac is 2-[2,6-dichlorophenyl) amino] benzeneacetic acid carboxymethyl ester.

All chemicals and solvents used were of analytical grade. Aceclofenac was obtained as gift sample from Aristo Pharmaceuticals Limited, Mandideep.

Preliminary solubility studies of aceclofenac

Solubility of aceclofenac was determined in distilled water and 2.0 M sodium benzoate solution at 28 ± 1°C. There was more than 1000 fold enhancement in the solubility of drug in 2.0 M sodium benzoate solution, as compared to the solubility in distilled water.

Analysis of aceclofenac bulk drug sample by British Pharmacopoeial method[14]

Accurately weighed (0.3 g) aceclofenac bulk drug sample was dissolved in 40 mL methanol. Using a potentiometer, the volume of 0.1 M sodium hydroxide consumed by the drug was determined and the drug content was noted in Table-1.

Analysis of aceclofenac bulk drug sample by the proposed method

Accurately weighed (0.3 g) aceclofenac bulk drug sample was solubilized in 25 mL of 2.0 M sodium benzoate solution in a conical flask by shaking for about 5 min and titrated with 0.1 M sodium hydroxide solution using phenolphthalein as indicator. Blank determination was carried out to make necessary correction and the amount of aceclofenac was computed (Table-1).

TABLE-1
ANALYSIS DATA OF ACECLOFENAC BULK DRUG WITH STATISTICAL EVALUATION

	1	2	3	4	5	Mean	Standard deviation (± S.D.)	Per cent coeff. of variation	Standard error
Aceclofenac drug sample (mg)	300	300	300	300	300	—	—	—	—
Amount found by B.P. 2002 method (mg)	302.1	300.7	298.7	301.3	298.8	300.3	1.831	0.610	0.819
Amount found by proposed method (mg)	298.3	301.1	297.5	301.7	297.8	299.3	1.968	0.658	0.880

As evident from Table-1, the amounts of aceclofenac estimated in bulk drug sample by the method of British Pharmacopoeia (2002) and the proposed method are 300.3 ± 1.831 and 299.3 ± 1.968, respectively. The results of analysis by the proposed method are very close to the results of analysis by standard method (British Pharmacopoeal method). This confirms the accuracy of the proposed method. Validation of the proposed method is further confirmed statistically by low values of standard deviation, per cent coefficient of variation and standard error (Table-1).

Conclusions

It may be concluded that the proposed method of analysis is new, simple,

cost-effective, environmentally friendly, safe, accurate and reproducible. Decided advantage is that the organic solvent is precluded but not at the expense of accuracy. Definitely there is further scope of 2.0 M sodium benzoate as solubilizing agent for the titrimetric analysis of other poorly water-soluble drugs. The proposed method can be successfully employed in the routine analysis of aceclofenac in the bulk drug sample.

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