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NOTE

Application of Hydrotropic Solubilization Technique for Quantitative Determination of Aspirin

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In the present investigation, 10 M urea solution has been employed to solubilize a poorly water-soluble drug, aspirin for its titrimetric analysis in tablets. Results of analysis by proposed methods were very comparable with those of a standard, British Pharmacopoeial method. Results of analysis have been validated statistically. The proposed method is quicker than pharmacopoeial method, new, rapid, simple, accurate and reproducible.

Key Words: Hydrotropy, Determination, Aspirin, Urea.

Concentrated aqueous solutions of several hydrotropic agents *viz.*, sodium salicylate, sodium benzoate, sodium citrate, sodium acetate, urea and niacinamide have been employed to enhance the aqueous solubilities of poorly water-soluble drugs[1-15]. Using hydrotropic solubilization technique, Maheshwari has analyzed poorly water soluble drugs *e.g.*, salicylic acid[1], ketoprofen[1], frusemide[2], cefixime[3], tinidazole[4] and aceclofenac[5]. Maheshwari *et al.* have used the same technique for quantitative estimations of metronidazole[6], norfloxacin[6], hydrochlorthiazide[7], cephalexin[8] and ofloxacin[9]. Several organic solvents like chloroform, methanol, dimethyl formamide and ethanol have been employed for solubilization of poorly water-soluble drugs to conduct their titrimetric analysis. Drawbacks of organic solvents include their higher costs, toxicities and pollution. There was more than 6 times enhancement in the aqueous solubility of aspirin (a poorly water-soluble drug) in 10 M urea solution as compared to its aqueous solubility. Therefore, it was thought worthwhile to employ 10 M urea solution to solubilize aspirin for its titrimetric analysis. Back titration method of Pharmacopoeia[16] is time consuming. Proposed method is rapid and involves direct titration, according to Fig. 1.

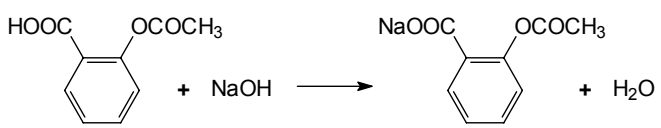

Fig. 1. Equation showing the reaction involved in the proposed method

All chemicals and solvents used were of analytical grade. Aspirin bulk sample was obtained as gift sample from Shree Pharmaceuticals, Indore. Tablets of aspirin were procured from local market.

Preliminary solubility study of aspirin: Solubility of aspirin bulk sample was determined in distilled water and 10 M urea solution at room temperature. There was more than 6 fold enhancement in solubility in 10 M urea solution as compared to water solubility.

Analysis of commercial tablets of aspirin by proposed method: 20 Tablets of aspirin were weighed and finely powdered. Tablet powder equivalent to about 500 mg of aspirin (as per label claim) was taken in a conical flask. 60 mL of 10 M urea solution was added and the flask was shaken for about 5 min to solubilize aspirin from tablet powder and titrated with 0.5 M NaOH using phenolphthalein solution as indicator. Necessary correction was made by conducting blank determination and amount of aspirin was calculated (Table-1). (Each mL of 0.5 M NaOH is equivalent to 90.08 mg of aspirin).

Analysis of commercial tablets of aspirin by British Pharmacopoeial method[16]: Tablet powder equivalent to 0.5 g aspirin was boiled gently for 10 min with 30 mL of 0.5 M sodium hydroxide. Excess of alkali was titrated with 0.5 M hydrochloric acid using phenol red solution as indicator. Operation was repeated without substance being examined. The difference between the titration represented the amount of alkali required. Aspirin content was thus determined (Table-1) (each mL of 0.5 M NaOH is equivalent to 45.04 mg of aspirin).

TABLE-1
RESULTS OF ANALYSIS OF ASPIRIN TABLETS WITH STATISTICAL EVALUATION

Tablet formulation	Label claim per tablet (mg)	Method of analysis	Per cent label claim estimated* (mean ± SD)	CV (%)	Standard error
I	150	Proposed method	101.74 ± 1.005	0.988	0.580
	150	B.P. method	100.32 ± 2.333	2.361	1.347
II	75	Proposed method	98.81 ± 1.534	1.552	0.884
	75	B.P. method	99.53 ± 0.901	0.905	0.520

*Average of three determinations.

Recovery studies on commercial aspirin tablets by proposed method: Recovery studies were performed by adding pure drug in preanalyzed tablet powder and determining the drug content by proposed method. The results are presented in Table-2.

Solubility of aspirin was determined in 10 M urea solution and distilled water at room temperature. Solubility studies indicated that there was more than 6 fold enhancement in solubility in 10 M urea solution as compared to water solubility. This hydrotropic solubilization phenomenon was utilized to perform titrimetric analysis (direct titration).

Table-1 shows that mean per cent label claims for formulation-I were 101.74 and 100.32 % by the proposed method and British Pharmacopoeial methods, respectively. Similarly, mean per cent label claims for formulation-II were 98.81 and 99.53 % by the proposed method and British Pharmacopoeial methods, respectively. The mean per cent values are close to 100 and the results of analysis by the proposed method compares very well with the results obtained by a standard method (British Pharmacopoeia method) indicating the accuracy of the proposed method. Accuracy, reproducibility and precision of the proposed method are confirmed by low values of standard deviation, % coefficient of variation and standard error (Table-1).

Validation of the proposed method is further confirmed by mean percent recovery values (98.85 to 101.61 %) which are close to 100 with significantly low values of standard deviation, per cent coefficient of variation and standard error (Table-2).

TABLE-2
RECOVERY STUDIES FOR SPIKED CONCENTRATION OF ASPIRIN ADDED TO THE PREANALYSED TABLET POWDER (USING PROPOSED METHOD)

Tablet formulation	Amount of Aspirin in preanalyzed tablet powder taken (mg)	Pure aspirin added (spiked) (mg)	Percent recovery estimated* (mean ± S.D.)	Percent coefficient of variation	Standard error
I	500	50	101.61 ± 1.111	1.093	0.641
	500	100	100.96 ± 1.742	1.725	1.006
II	500	50	99.69 ± 0.905	0.908	0.522
	500	100	98.85 ± 1.522	1.540	0.879

*Average of three determinations.

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