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NOTE

Quantitative Estimation of Aspirin Using Hydrotropic Solubilization Technique

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In the present study, 2 M sodium salicylate 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 comparable with those of standard British Pharmacopoeial method. Results of analysis have been validated statistically. The proposed method is quicker than Pharmacopoeial method with its novelity, simplicity, accuracy and reproducibility.

Key Words: Hydrotropy, Aspirin, Sodium salicylate, Titrimetry.

Therapeutic effectiveness of a drug depends upon the bioavailability and ultimately upon the solubility of drug molecules. Solubility is one of the important parameter. A variety of solubilization techniques are available including pH adjustment, cosolvency, surfactant addition, hydrotropy and complexation. 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 solubility of poorly water-soluble drugs[1-8]. Using hydrotropic solubilization technique, Maheshwari *et al.* have analyzed poorly water-soluble drugs from different pharmacological categories[1-6]. Several organic solvents have been employed for solubilization of poorly water-soluble drugs to conduct their titrimetric analysis. Drawbacks of which include their higher costs, toxicities and pollution.

There was more than 8 times enhancement in the aqueous solubility of aspirin (a poorly water-soluble drug) in 2 M sodium salicylate solution as compared to its aqueous solubility. Therefore, it was thought worthwhile to employ 2 M sodium salicylate solution to solubilize aspirin for its titrimetric analysis. Back titration method of Pharmacopoeia[9] is time consuming while proposed method is rapid and involves direct titration.

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 2 M sodium salicylate solution at room temperature. There was more than 8 fold enhancement in solubility in 2 M sodium salicylate solution as compared to water solubility.

Analysis of commercial tablets of aspirin by proposed method: Twenty 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. Fifty mL of 2 M sodium salicylate solution was added and the flask was shaken for *ca*. 5 min to solubilize aspirin from tablet powder and titrated with 0.5 M sodium hydroxide 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 sodium hydroxide is equivalent to 90.08 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)	Per cent coefficient of variation	Standard error
I	150	Proposed method	98.44±0.941	0.956	0.543
	150	B.P. method	99.56±1.229	1.234	0.709
II	75	Proposed method	99.31±1.773	1.785	1.024
	75	B.P. method	98.71±1.308	1.325	0.755

*Average of three determinations.

Analysis of commercial tablets of aspirin by British Pharmacopoeial method[9]. 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 HCl 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).

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

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

Tablet formulation	Amount of Aspirin in pre-analyzed tablet powder taken (mg)	Pure aspirin added (spiked) (mg)	Per cent recovery estimated* (mean ± SD)	Per cent coefficient of variation	Standard error
I	500	50	99.38±1.227	1.235	0.708
	500	100	102.49±0.831	0.811	0.480
II	500	50	100.66±1.870	1.858	1.080
	500	100	99.08±2.225	2.276	1.302

*Average of three determinations.

Solubility of aspirin was determined in 2 M sodium salicylate solution and distilled water at room temperature. Solubility studies indicated that there was more than 8 fold enhancement in solubility in 2 M sodium salicylate 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 98.44 and 99.56 % by the proposed method and British Pharmacopoeial methods, respectively. Similarly, mean per cent label claims for formulation-II were 99.31 and 98.71 % by the proposed method and British Pharmacopoeial methods, respectively. The mean percent values are close to 100 and the results of analysis by the proposed method compare 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 (99.08 to 102.49 %) which are close to 100 with significantly low values of standard deviation, per cent coefficient of variation and standard error (Table-2).

Conclusion

Thus, it is concluded that the proposed method is new, simple, rapid, accurate and precise. In future, attempts can be made to solubilize other water insoluble drugs in concentrated solutions of hydrotropic agents to carry out titrations precluding the use of costlier, unsafe, pollution causing organic solvents.

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