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QUANTITATIVE ESTIMATION OF ASPIRIN IN TABLETS AND BULK SAMPLE USING METFORMIN HYDROCHLORIDE AS HYDROTROPIC AGENT

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ABSTRACT

Concentrated aqueous solutions of a large number of hydrotropic agents viz. sodium benzoate, sodium salicylate, niacinamide, urea , sodium citrate and sodium acetate have been employed to enhance the aqueous solubilities of poorly water-soluble drugs. Various organic solvents like methanol, chloroform, dimethyl formamide and ethanol have been employed for solubilization of poorly water-soluble drugs to conduct their titrimetric analyses. Drawbacks of organic solvents include their higher costs, toxicities and pollution. There was more than 15 times enhancement in the aqueous solubility of aspirin (a poorly water-soluble drug) in 1.5 M metformin hydrochloride solution (an inexpensive antidiabetic drug, used here as hydrotropic agent) as compared to its aqueous solubility. Therefore, it was thought worthwhile to employ 1.5 M metformin hydrochloride solution to solubilize aspirin for its titrimetric analysis. Back titration methods of Pharmacopoeia are time consuming. Proposed method is rapid and involves direct titration.

Key words: Aspirin,Metformin, Hydrotropy,Titrimetry

INTRODUCTION

Concentrated aqueous solutions of a large number of hydrotropic agents viz. sodium benzoate, sodium salicylate, niacinamide, urea , sodium citrate and sodium acetate have been employed to enhance the aqueous solubilities of poorly water-soluble drugs.[1-13]

Various organic solvents like methanol, chloroform, dimethyl formamide and ethanol have been employed for solubilization of poorly water-soluble drugs to conduct their titrimetric analyses. Drawbacks of organic solvents include their higher costs, toxicities and pollution. There was more than 15 times enhancement in the aqueous solubility of aspirin (a poorly water-soluble drug) in 1.5 M metformin hydrochloride solution (an inexpensive antidiabetic drug, used here as hydrotropic agent) as compared to its aqueous solubility. Therefore, it was thought worthwhile to employ 1.5 M metformin hydrochloride solution to solubilize aspirin for its titrimetric analysis. Back titration methods of Pharmacopoeia are time consuming. Proposed method is rapid and involves direct titration.

Solubility of aspirin bulk sample was determined in distilled water and 1.5 M metformin hydrochloride solution at room temperature. There was more than 15 fold enhancement in solubility of aspirin in 1.5 M metformin hydrochloride solution as compared to water solubility.

EXPERIMENTAL

Analysis of aspirin bulk sample by proposed method

Aspirin bulk sample (0.5g) was accurately weighed and solubilized in 50 ml of 1.5 M

metformin hydrochloride solution in a conical flask by shaking. This solution was titrated with 0.5 M sodium hydroxide using phenolphthalein solution as indicator. Necessary correction was done by conducting blank determination (using 50 ml of 1.5 M metformin hydrochloride solution) and amount of aspirin was calculated. (Each ml of 0.5 M sodium hydroxide is equivalent to 90.08 mg of aspirin).

Analysis of aspirin bulk sample by British Pharmacopoeial method (2002)[14]

Aspirin bulk sample (1.000 g) was weighed and dissolved in 10 ml of alcohol in the conical flask. Fifty ml of 0.5 M sodium hydroxide was added and allowed to stand for 1 h. Titration was done with 0.5 M hydrochloric acid using phenolphthalein solution as indicator. Blank titration was carried out to calculate aspirin content. (Each ml of 0.5 M sodium hydroxide is equivalent to 45.04 mg of aspirin).

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 was taken in a conical flask. Fifty ml of 1.5 M metformin hydrochloride solution was added and the flask was shaken for about 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. Recovery studies were performed by adding pure drug in preanalyzed tablet powder at two levels and determining the drug content by proposed method. (Each ml of 0.5 M sodium hydroxide is equivalent to 90.08 mg of aspirin).

Analysis of commercial tablets of aspirin by British Pharmacopoeial method (2002)[15]

Tablet powder equivalent to 0.5 g aspirin was boiled 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 titrations represented the amount of alkali required. Aspirin content was thus determined. (Each ml of 0.5 M sodium hydroxide is equivalent to 45.04 mg of aspirin).

RESULTS AND DISCUSSION

The values of mean percent drug estimated in the bulk drug sample of aspirin by the proposed and BP method were 98.44 and 98.77, respectively. The values are very comparable and close to 100 indicating the accuracy of the proposed method. In case of tablets, the values of mean percent drug estimated by the proposed method were 101.35 (formulation-1) and 98.57 (formulation-2) while the values of mean percent drug estimated by the proposed method were 99.83 (formulation-1) and 99.03 (formulation-2). These values are very comparable and close to 100 indicating the accuracy of the proposed method. The values of the mean percent recoveries by the proposed method ranged from 98.71 to 101.55 which are very close to 100 which further confirm the accuracy of the proposed method. The low values of standard deviation, % coefficient of

variation and standard error validated the method.

Table 1: Results of Tritimetric Analysis of Aspirin Bulk Drug Sample (N=3)

Method of analysis	Percent drug estimated (Mean ± S.D.)	Percent coefficient of variation	Standard error
Proposed method	98.44±1.661	1.687	0.959
B.P. method	98.77±0.811	0.821	0.468

Table 2: Results of commercial tablets with statistical evaluation (n=3)

Tablet formulation	Method of analysis	Percent label claim estimated (Mean ± S.D.)	Coefficient variation	Standard error
I	Proposed method	101.35±2.330	2.299	1.345
	B.P. Method	99.03±0.922		
			0.924	0.532
II	Proposed method	98.57±0.455	0.441	0.251
	B.P. Method	98.57±0.455		
		99.03±0.997	1.007	0.576

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

Tablet formulation	Amount of drug added in preanalysed tablet powder	Pure drug added (spiked drug)	% recovery estimated	% Coefficient of variation	Standard error
I	1000	100	100.73±2.228	2.212	1.286
II	1000	150	101.55±1.777	1.750	1.260
III	1000	100	98.71±1.220	1.236	0.704
IV	1000	150	99.58±0.994	0.998	0.574

CONCLUSION

Thus, it may be concluded that the proposed method of analysis is new, rapid, simple, cost-effective, environmentally friendly, safe, accurate and reproducible. By proper choice of hydrotropic agents, the use of organic solvents in analysis may be discouraged to a large extent. Hydrotropic agent did not interference in the proposed method. The bulk sample and tablets of aspirin can be analyzed by the proposed method in routine practice.

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