RESEARCH ARTICLE

Novel method for spectrophotometric analysis of hydrochlorothiazide tablets using niacinamide as hydrotropic solubilizing agent

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In the present investigation, 2 M niacinamide (an inexpensive drug) solution was employed as hydrotropic solubilizing agent to solubilize poorly water-soluble drug hydrochlorothiazide for its spectrophotometric analysis. The proposed method is new, simple, environmentally friendly, accurate, and reproducible. Accuracy, reproducibility, and precision of the proposed method were validated statistically.

Key words: *Hydrochlorothiazide, hydrotropy, niacinamide, spectrophotometry*

INTRODUCTION

The term "hydrotopy" has been used to designate the increase in solubility of various substances due to the presence of large amounts of additives. Various hydrotropic agents have been used to enhance the aqueous solubility of a large number of drugs.[1-16] Maheshwari and his associates have analyzed a large number of poorly water-soluble drugs by titrimetric and spectrophotometric analysis.[1-14]

Since niacinamide does not absorb above 300 nm and there was more than 43-fold enhancement in solubility of hydrochlorothiazide in 2 M niacinamide solution, it was thought worthwhile to use this hydrotropic solution to extract the drug from fine powder of tablets to carry out spectrophotometric estimation. Chemically, hydrochlorothiazide is 6-chloro-3, 4-dihydro-2*H*-1,2, 4- benzothiadiazine-7-sulphonamide 1,1-dioxide.

All chemicals and solvents used were of analytical grade. Niacinamide was obtained as a gift sample from M/s Alkem Laboratories Ltd., Mumbai; and hydrochlorthiazide was obtained as a gift sample from M/s Ranbaxy Laboratories Ltd., Dewas; and hydrochlorthiazide tablets were purchased from the local market.

Calibration curve

Accurately weighed 100 mg of hydrochlorothiazide was solubilized by 20 mL of 2 M niacinamide solution in a 25-mL volumetric flask, and distilled water was added to make up the volume. This stock solution was further diluted with distilled water to get various dilutions containing 20, 40, 60, 80, 120, 140, 160, and 180 μg/mL of drug. Absorbances were noted at 317 nm against corresponding reagent blanks.

Preliminary solubility studies of hydrochlorothiazide

Solubility of hydrochlorothiazide was determined in distilled water and 2 M niacinamide solution at 28°C ± 1°C. There was more than 43-fold enhancement in the solubility of drug in 2 M niacinamide solution, as compared to the solubility in distilled water.

Analysis of hydrochlorothiazide tablets by the proposed method

Twenty tablets of hydrochlorothiazide (formulation-I and -II) were weighed and finely powdered. Powder equivalent to 100 mg of hydrochlorothiazide was taken in a 25-mL volumetric flask. Twenty milliliters of 2 M niacinamide solution was added, and the flask was shaken properly for 10 min to solubilize the drug; and the volume was made up to the mark with distilled water. After filtration through a Whatman filter paper no. 41, the filtrate was appropriately diluted with distilled water for spectrophotometric estimation against reagent blank to calculate the drug content [Table 1].

Recovery studies

Recovery studies taking 15 mg and 30 mg of pure drug as spiked drug, together with preanalyzed tablet powder (equivalent to 100 mg drug), were performed using the same proposed method of analysis. The

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Table 1: Analysis data of hydrochlorothiazide tablet formulations with statistical evaluation

Tablet formulation	Label claim (mg/tablet)	Percent drug estimated* (Mean ± S.D.)	Percent coefficient of variation	Standard error
I	12.5	97.91 ± 0.734	0.750	0.224
II	25	98.46 ± 0.887	0.901	0.512

*n = 3

Table 2: Result of recovery studies of tablet formulations with statistical evaluation

Tablet formulation	Drug present in preanalyzed tablet powder (mg)	Spiked drug added (mg)	Percent recovery estimated* (Mean ± S.D.)	Percent coefficient of variation	Standard error
I	100	15	99.37 ± 1.213	1.041	0.443
	100	30	100.56 ± 2.031	1.304	0.403
II	100	15	98.88 ± 0.909	1.002	0.646
	100	30	99.30 ± 1.522	1.331	0.772

*n=3

percent recoveries estimated are presented in Table 2.

RESULTS AND DISCUSSION

The mean percent drug estimated was 97.91 and 98.46 for formulation-I and formulation-II respectively. These values are close to 100, indicating the accuracy of the proposed analytical method. Standard deviation for formulation-I and formulation-II was found to be 0.734 and 0.887 respectively. Percent coefficient of variation and standard error in formulation-I were found to be 0.750 and 0.424 respectively. Percent coefficient of variation and standard error in formulation-II were found to be 0.901 and 0.512 respectively. The low values of these statistical parameters validated the method. The values of mean percent recoveries for formulation-I and formulation-II ranged from 98.88 to 100.56, which are again close to 100. This fact, together with satisfactorily low values of statistical parameters, further validated the method.

CONCLUSION

Thus, it may be concluded that the proposed method is new, simple, eco-friendly (precluding the use of organic solvents), precise, and cost-effective. Niacinamide does not show absorbance above 300 nm (wavelength). Therefore, a large number of poorly water-soluble drugs having λ_{max} above 300 nm may be tried for estimation by this method, provided their solubilities are enhanced sufficiently by niacinamide solution.

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