

NOTE

**Spectrophotometric Analysis of Hydrochlorothiazide
Tablets using Chlorpheniramine Maleate as
Hydrotropic Solubilizing Agent**

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In present work, hydrotropic solution of chlorpheniramine maleate (20 % w/v) was employed to solubilize hydrochlorothiazide (a poorly water-soluble drug) from fine powder of its tablets, to carry out spectrophotometric analysis at 317 nm. Beer's law was obeyed in the concentration range of 30-180 mcg/mL. Recovery studies and statistical data proved the accuracy, reproducibility and the precision of the proposed method. Presence of chlorpheniramine maleate and commonly used tablet excipients did not interfere in the analysis.

Key Words: Spectrophotometry, Hydrotropy, Hydrochlorothiazide, Chlorpheniramine maleate.

Concentrated aqueous solutions of a large number of hydrotropic agents have been utilized to enhance the aqueous solubility of many poorly water-soluble drugs¹⁻¹⁶. Maheshwari¹⁻⁶ has analyzed a large number of poorly water-soluble drugs quantitatively using a wide range of hydrotropic agents.

Hydrochlorothiazide is a widely used diuretic drug. There was more than 40 fold enhancement in the solubility of hydrochlorothiazide in hydrotropic solution of chlorpheniramine maleate (20 % w/v) as compared to its solubility in distilled water. Therefore, it was thought worthwhile to extract out the hydrochlorothiazide from the fine powder of its tablets with hydrotropic solution to carry out spectrophotometric analysis at 317 nm.

Shimadzu UV/Vis recording spectrophotometer (model UV-160 A) with 1 cm matched silica cells was employed. Hydrochlorothiazide bulk drug sample was a generous gift by M/s Ranbaxy Laboratories Limited; Dewas. Commercial tablets were purchased from local market. Other chemicals were of analytical grade.

The solubility of hydrochlorothiazide was determined in distilled water and 20 % chlorpheniramine maleate solution at 27 ± 1 °C. Enhancement in solubility was more than 40 fold in 20 % chlorpheniramine maleate solution with respect to its water solubility.

In order to obtain calibration curve, 50 mg hydrochlorothiazide was accurately weighed and transferred to a 50 mL volumetric flask and solubilized with 20 mL of 20 % w/v chlorpheniramine maleate solution by shaking. After complete solubilization, the volume was made up to the mark with distilled water to obtain various dilutions containing 30, 60, 90, 120, 150 and 180 mcg/mL of the drug. The absorbances of these solutions were noted at maximum at about 317 nm against respective reagent blank to obtain calibration curve.

20 Tablets of hydrochlorothiazide (formulation 1 and 2) were weighed and ground to a fine powder, tablet powder equivalent to 50 mg of drug was transferred to a 50 mL volumetric flask containing 20 mL of chlorpheniramine maleate solution. The blank was shaken for about 10 minutes to solubilize the drug and then volume was made up to 50.0 mL with distilled water. After filtration through Whatmann filter paper no. 41, the filtrate was appropriately diluted with distilled water and absorbance was noted at 317 nm against the reagent blank. Drug contents of tablets were computed using the calibration curve and values were reported in Table-1. To evaluate the validity and reproducibility of the proposed method, recovery studies were performed by adding a known amount of bulk drug sample to the pre-analyzed tablet powder at two levels (15 and 30 mg) and analyzing them by the same proposed method. The total amount of the drug was determined and the amount of added drug was found by the difference. The results of recovery studies were presented in Table-2. Each type of analysis was done in triplicate.

The values of mean percent label claim estimated by the proposed method (Table-1) were found to be 98.77 and 99.22 for formulation 1 and 2, respectively. These values are very close to 100 indicating the accuracy of the proposed method. Satisfactorily low values of statistical parameters *viz.* standard deviation, % coefficient of variation and standard error (Table-1) further validated the method. The values of mean percent recoveries (Table-2) ranged between 99.51 to 101.36, which are again close to 100. This, together with the low values of statistical parameters (Table-2) further validated the accuracy and reproducibility of the proposed method. Presence of chlorpheniramine maleate and tablet adjuvants did not interfere in the method. There is further scope of chlorpheniramine maleate in UV estimation of poorly water-soluble drugs having λ_{max} above 300 nm (provided there is sufficient enhancement in the solubility in 20 % w/v chlorpheniramine maleate solution).

TABLE-1
ANALYSIS DATA OF TABLET FORMULATIONS WITH
STATISTICAL EVALUATION (n = 3)

Tablet formulation	Label claim (mg/tablet)	% Label claim estimated (mean \pm SD)	% Coefficient of variation	Standard error
I	12.5	98.77 \pm 0.992	1.004	0.573
II	25.0	99.22 \pm 1.364	1.375	0.788

TABLE-2
RESULTS OF RECOVERY STUDIES OF TABLET FORMULATIONS
WITH STATISTICAL EVALUATION (n = 3)

Tablet formulation	Drug in pre-analysed tablet powder (mg)	Drug added (spiked) mg	% Recovery estimated (mean \pm SD)	% Coefficient of variation	Standard error
I	50	15	100.84 \pm 1.660	1.646	0.958
I	50	30	99.08 \pm 2.018	2.037	1.165
II	50	15	101.36 \pm 1.821	1.797	1.051
II	50	30	99.51 \pm 0.844	0.848	0.487

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