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Preparation and Chemical analysis of Hydrochlorothiazide Tablets Using Lignocaine Hydrochloride as Hydrotropic Agent

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There was more that 50-fold enhancement in aqueous solubility of hydrochlorothiazide in 1 M lignocaine hydrochloride solution as compared to the solubility in distilled water. Therefore 1 M lignocaine hydrochloride solution was employed to extract out the drug from fine powder of the tablets of hydrochlorothiazide to carry out spectrophotometric estimation at 317 nm (Selected Wavelength). The hydrotropic agent and the additives used in the manufacture of tablets did not interfere in the analysis. Statistical data proved the accuracy, reproducibility and precision of proposed method.

Key Word: Hydrotropy, Hydrochlorothiazide, Lignocaine hydrochloride, Spectrophotometry.

Increasing the aqueous solubility of insoluble and slightly soluble drug is of major importance. In hydrotropic solubilization phenomenon, addition of larger amount of a second solute results in and increase in the aqueous solubility of another solute. Concentrated aqueous hydrotropic solutions of sodium benzoate, urea, nicotinamide, sodium salicylate, sodium gluconate and sodium glycinate have been observed to enhance the aqueous solubility of many poorly water-soluble drugs[1-11].

Maheshwari *et al.*[1-7] have developed new analytical methods based on the hydrotropic solubilization phenomenon for quantitative estimation of poorly water soluble drugs frusemide, cefixime, ketoprofen. Salicylic acid, tinidazole, aceclofenac, ofloxacin, metronidazole, nalidixic acid, tinidazole, norfloxacin and cephalexin.

There was considerable increase in the solubility of hydrochlorothiazide in 1 M lignocaine hydrochloride solution. Thus, it was thought worthwhile to solubilize the poorly water-soluble hydrochlorothiazide from fine power of its talets by 1 M lignocaine hydrochloride solution to carry out spectrophotometric estimation precluding the use of organic solvent.

Hydrochlorothiazide and lignocaine hydrochloride were gifted by Dexo chemical Lab ankeshwar Gujrat. Commericial tablets of hydrochlorothiazide were procured from market. All chemicals used were of analytical grade. A shimadzu UV-visible recordingspectrophotometer (model-UV 160 A) with 1 cm matched silica cells was used for spectrophotometric analysis.

Preparation of calibration curve:- 50mg of hydrochlorothiazide bulk drug was solubilized with 10 mL of 1 M lignocaine hydrochloride solution and then diluted to 50 mL with distilled water to obtain stock solution (1000 µg/mL). The Stock solution was diluted with distilled water to obtain various dilutions (30, 60, 90, 120, 150 µg/mL). A linear relationship was observed over the range of 30 to 150 µg/mL of hydrochlorothiazide (λ_{max} 317 nm), after measuring their absorbance's at 317 nm against respective reagent blanks.

Preliminary solubility studies of drug:- Solubility of hydrochlorothiazide was determined in distilled water and 1 M lignocaine hydrochloride solution at room temperature. Enhancement In the solubility of hydrochlorothiazide in 1 M lignocaine hydrochloride solution was more than 50-fold as compared to solubility in distilled water.

Analysis of hydrochlorothiazide tablets using 1 M lignocaine hydrochloride solution:- Twenty tablets of hydrochlorothiazide (formulation-I) were weighted and ground to fine powder. An accurately weighed powder sample equivalent to 50 mg of hydrochlorothiazide was transferred to a 100 mL volumetric flask containing 10 mL of 1 M lignocaine hydrochloride solution. The flask was shaken for about 10 min (to solubilize the drug) and then volume was made up to the mark with distilled water. The solution was filtered through whatmann filter paper No.-41. The filtrate wa diluted sufficiently with distilled water and analyzed o UV spectrophotometer against reagent blank. Drug content of tablet formulation was then calculated (Table-1). Same procedure was followed for formulation-II.

(3)

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

Tablet Formulation	Label claim (mg/tablet)	% Label claim estimated (mean ± SD)	% Coefficient of variation	Standard error
I	12.5	100.73 ± 1.888	1.874	1.090
II	25.0	98.91 ± 1.033	1.044	0.596

Recovery studies: To evaluate the validity and reproducibility of the proposed method, recovery experiments were carried out. For recovery studies 15 and 30 mg of hydrochlorothiazide pure drug was added to the pre-analyzed tablet powder equivalent to 100 mg hydrochlorothiazide. Procedure of analysis was same using 1 M lignocaine hydrochloride solution. Per cent recoveries were calculated and reported in Table-2.

Result of solubility determination studies indicated that enhancement in aqueous solubility of hydrochlorothiazide in 1 M lignocaine hydrochloride solution was more than 50-fold as compared to solubility in distilled water. It is evident from Table-1 that the mean per cent label claims estimated were 100.73 and 98.91 for formulation I and formulation II, respectively. The mean per cent lebal claims are very close to 100 with low values of standard deviation, per cent coefficient of variation and standard error showing the accuracy of the proposed method.

TABLE-2

RECOVERY STUDIES FOR SPIKED CONCENTRATION OF DRUG ADDED TO PREANALYZED TABLET POWDER WITH STATISTCAL EVALUATION (n=3)

Tablet formulation	Drug present in tablet powder taken (mg)	Drug added (spiked) (mg)	% Recovery estimated (mean ± SD)	% Coefficient of Variation	Standard error
I	50	15	98.71 ± 1.330	1.447	0768
I	50	30	100.41 ± 0.933	0.929	0.539
II	50	15	101.05 ± 1.819	1.800	1.050
II	50	30	99.62 ± 0.663	0.665	0.383

(4)

Accuracy, reproducibility and precision of proposed methods were further confirmed by per cent recovery values. As evident from Table-2, the mean per cent recovery values ranged from 98.21 to 101.05. the values are very close to 100, indicating the accuracy of the proposed method. The values of standard deviation, % coefficient variation and standard error were satisfactorily low which further validated the method.

It is thus concluded that the proposed method is new, simple, cost-effective, accurate, safe, eco-friendly ad precise and can be successfully employed in the routine analysis of hydrochlorothiazide tablets. Lignocaine hydrochloride doest not interfere in the spectrophotometric estimation above 275 nm. Thus, other poorly water-soluble drugs can be checked for their solubility's in this hydrotropic solution. If they have good solubility's in lignocaine hydrochloride solution, they can be easily estimated excluding the use of organic solvents provided their λ_{max} Value is above 275 nm.

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