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SPECTROPHOTOMETIC ANALYSIS OF GATIFLOXACIN TABLETS USING MIXED HYDROTROPHY

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ABSTRACT

A new, simple, safe, accurate and reproducible spectrophotometric analytical method was developed for the quantitative estimation of gatifloxacin in solid dosage form by mixed hydrotropic agents. The enhancement of solubility of drug gatifloxacin was more than 15 fold in mixed hydrotropic solution (20% N,N dimethyl urea and 20% sodium citrate solution) as compared to solubility in distilled water. Therefore, it was thought worthwhile to solubilize this poorly water soluble drug from fine powder of its tablets by this novel mixed hydrotropic solubilization technique and then carryout its spectrophotometric estimation at 333 nm (20% N,N dimethyl urea and 20% sodium citrate being non-interfering in the estimation). The results of the analysis were validated statistically and by recovery studies & its follows Beer's law in concentration range of 10-60 mcg/ml. The percent label claims and percent recoveries estimated were close to 100 with low values of standard deviation, percent coefficient of variation and standard error. Thus, the method was accurate providing additional advantage of being cost effective and environment friendly.

INTRODUCTION: The drug (gatifloxacin) analysis is much difficult when it is analyze by the conventional method, using organic solvents. This method is expansive and hazardous due to use of combustible solvents. To over come this problem a new method is developed for simple and safe analysis of drug (gatifloxacin). Which is called as hydrotropic solublization method.

Hydrotropy is another type of cosolvency and all water-soluble substances whether liquids, solids, or gases may act as solubilizers for poorly water-soluble drugs. In the present investigation, aqueous solution of 20% N, N dimethyl urea & 20% sodium citrate was employed as solubilizing agents to solubilize the poorly water-soluble drug gatifloxacin from fine powder of its tablet dosage form for spectrophotometric determination in ultraviolet region [1]. Gatifloxacin exhibits maximum absorbance at 333 nm and follows Beer's law in concentration range of 10-60 mcg/ml. Results of analysis were validated statistically and by recovery studies.

MATERIAL AND METHODS:

Drug used in the experiment: the drug used was purchased from market.

Chemicals: chemicals (N, N dimethyl urea, sodium citrate) were collected from COP IPS Academy, Indore, India.

Preliminary Solubility Studies: The solubility of gatifloxacin was determined in distilled water and mixed hydrotropic solution (20% N, N-dimethylurea solution & 20% sodium citrate solution). The enhancement in solubility of gatifloxin in hydrotropic solution was found to be more than 15 folds as compared to distilled water [1, 2].

Calibration curve: The standard stock solution (1000 mcg/ml) of gatifloxin was prepared by solubilizing, accurately weighed 100 mg gatifloxin in 50 ml volumetric with 20 ml of 20% N,N dimethylurea & 20% sodium citrate solution and further diluting with distilled water up to the mark with distilled water. The stock solution was further diluted with distilled water to obtain various dilutions. Standard solutions of 10, 20, 30, 40, 50 and 60 mcg/ml of drug were used to plot the calibration curve by taking the absorbance at 333 nm against corresponding reagent blanks. A linear relationship was obtained [1, 2].

Proposed method for analysis of gatifloxacin: An accurately weighed powder sample equivalent to 100 mg of gatifloxacin was transferred to a 50 ml volumetric flask containing 20 ml of mixed hydrotropic solution (20% N, N-dimethylurea solution & 20% sodium citrate solution). Drug content of tablet I and II were then calculated [3, 4].

Recovery studies: The preliminary solubility showed the progress of the proposed method by increasing the solubility of poorly water soluble drug gatifloxacin in 20% N, N dimethyl urea & 20% sodium citrate by more than 15 folds. Therefore, hydrotropic solution is used to extract the drug from fine powder of tablet formulation. Table No. I reflect the percentage of label in the proposed method using 20% N, N dimethyl urea & 20% sodium citrate solution as 99.41±1.424 and 98.89±1.666, which is very close to 100 indicating the accuracy of proposed method.

The accuracy, precision and reproducibility of proposed methods further confirmed by percentage recovery studies. The method is further validated by low values of standard error, percentage coefficient of variation and standard deviation. Table No. 2 indicated the percentage recovery ranged from 99.37±1.077 to 101.22±0.888, in case of 20% N,N dimethyl urea & 20% Sodium citrate which is very close to 100 indicates the accuracy of the proposed method [4, 5, 6].

RESULTS: The preliminary solubility study shows the efficiency of the method. After the experiment the accurately calculated figure 99.41 ± 1.424 and 98.89 ± 1.666 (**table 1**) shows that result is very near to 100 which is indicating accuracy of the proposed method.

The accuracy of proposed methods further confirmed by percentage recovery studies percentage recovery ranged from 99.37±1.077 to 101.22±0.888 (**table 2**) in case of 20% N,N dimethyl urea & 20% Sodium citrate which is very close to 100 indicates the accuracy of the proposed method.

TABLE 1: RESULTS OF ANALYSIS OF GATIFLOXACINE TABLET FORMULATIONS WITH STATISTICAL EVALUATION (n=3)

Tablet formulation	Label claim per tablet	%Label claim estimated (mean ± standard deviation)	% Coefficient of variation	Standard error
I	400	99.41 ± 1.424	1.432	0.822
II	400	98.89 ± 1.666	1.684	0.972

TABLE 2: RECOVERY STUDIES WITH STATISTICAL EVALUATION (n=3)

Tablet formulation	Amount of drug in preanalyzed tablet powder (mg)	Gatifloxacin pure drug added (mg)	% Recovery estimated (mean ± standard deviation)	% Coefficient of variation	Standard error
I	100	20	101.22 ± 0.888	0.877	0.513
I	100	40	100.34 ± 1.820	1.814	1.051
II	100	20	99.37 ± 1.077	1.083	0.622
II	100	40	100.52 ± 1.229	1.223	0.710

DISCUSSION: This method is very useful in the estimation of the drug which is insoluble in the distilled water, and majorly analyzed in the organic solvent. As we know the hydrotropic solvent does not interfere in the result of spectrophotometric analysis above 288 nm so the drug gatifloxacin can be easily analyzed in

UV, because the gatifloxacin is estimated in the 333 nm range**.** This method is very simple and effective and gives the accurate results [4, 6].

CONCLUSION: It is concluded that the proposed method is new, simple, cost-effective, accurate, safe and precise and can be successfully employed in the routine analysis of gatifloxacin in tablet. There is good scope for other poorly water-soluble drugs which may be tried to get solubilized by suitable hydrotropic agents to carry out their spectrophotometric analysis precluding the use of costlier and unsafe organic solvents.

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