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UTILIZATION OF MIXED-SOLVENCY TECHNIQUE IN SPECTROPHOTOMETRIC ANALYSIS OF CEFIXIME TRIHYDRATE TABLETS

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ABSTRACT

A novel, economic, eco-friendly, accurate and reproducible method was developed for quantitative analysis of cefixime trihydrate tablets. In present investigation, aqueous blend containing 5% each of sodium citrate, glycerine, PEG300, PEG400, urea and 10% PEG 4000 was used for solubilisation of poorly water soluble drug, cefixime trihydrate, to carry out spectrophotometric analysis. As per statement of Maheshwari (Mixed Solvency concept), each substance (gas, liquid, solid) possesses solubilizing power. The solubility of cefixime trihydrate increased to more than 120 fold as compared to water solubility. Calibration curve of cefixime trihydrate was plotted by noting absorbances of standard solutions (5, 10, 15, 20 and 25 µg/ml) of cefixime trihydrate which were made by diluting stock solution of cefixime trihydrate. The absorbances were noted at 288 nm against respective reagent blanks. No interference of solubilizers was seen above 245 nm. The percentage drug content in two types of marketed tablets was found close to 100 (99.19±1.238 and 100.85±1.821) indicating the accuracy of the proposed method. Recovery studies confirmed accuracy and precision of proposed method. Percentage recoveries estimated by the proposed method ranged from 97.62±1.723 to 99.58±1.073, which are very close to 100. Low values of standard deviation, percentage coefficient of variation and standard error further validated the proposed methods.

Keywords: Mixed solvency, PEG300, PEG400, PEG4000, Urea, Sodium citrate, Glycerin, UV spectroscopy, Cefixime trihydrate.

INTRODUCTION

Various organic solvents like ethanol, methanol, dimethylformamide, acetonitrile ethylacetate, toluene, chloroform, benzene, dichloromethane, carbon tetrachloride, acetone, hexane etc. have been employed for spectrophotometric estimation of poorly water-soluble drugs. Drawbacks of organic solvents include higher cost, toxicity and pollution. Organic solvents have innumerous adverse effects caused by single exposure like dermatitis, headache, drowsiness, nausea, eye irritation and long term exposure causes serious effects such as neurological disorders, chronic renal failure, liver damage, necrosis, mutagenesis disorder. They should be replaced by other eco-friendly alternative sources.

The present research work describes the application of concept of "Mixed solvency" for spectro photometric estimation of poorly water soluble drug, cefixime trihydrate, using aqueous blend containing 5% each of sodium citrate, glycerine, PEG300, PEG400, urea and 10% PEG 4000 (Blend MS) as solubilizing agent. As per the statement of Maheshwari (Mixed solvency concept), each substance (gas, liquid or solid) possesses solubilizing power. As per the statement of Maheshwari [1-3], each substance present on our planet has got solubilizing power. By combining the excipients in solution, additive solvent actions and synergistic solvent actions can be obtained. The problem of toxicity issue due to high concentration of a solvent can be solved in this manner. The solubility of a large number of poorly soluble drugs has been enhanced by mixed solvency concept [4-21].

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MATERIALS AND METHOD

Cefixime trihydrate bulk drug sample was a generous gift by M/S Alkem Laboratories Limited, Mumbai, (India). All other chemicals used were of analytical grade. Commercial tablets of cefixime trihydrate were procured from the local market.

A Shimadzu-1700 UV visible spectrophotometer with 1 cm matched silica cells was used for spectrophotometric analysis.

Prepration of calibration curve

50 mg of cefixime trihydrate was accurately weighed and dissolved with the help of 10 ml of Blend MS in a 50 ml volumetric flask. Sufficient distilled water was added to make up the volume to 50 ml to obtain a stock solution of 1000 µg/ml. Using this stock solution, standard solutions of 5, 10, 15, 20 and 25 µg/ml were prepared. Then, the absorbances of five standard solutions were recorded at 288 nm against respective reagent blanks to obtain the calibration curve.

Solubility studies

To determine the solubility of the drug in distilled water and the blend MS at room temperature, sufficient excess amount of the drug was added to 25 ml capacity vials containing distilled water and the blend MS. Vial caps and aluminium seals were applied on the vials and the vials were shaken mechanically for 12 hours at room temperature in an orbital flask shaker (Khera Instrument Pvt. Ltd., India). These systems were allowed to equilibrate for 24 hours undisturbed and then filtered through Whatmann filter paper # 41. The filtrates were appropriately diluted with distilled water to measure the absorbance at 288 nm.

Proposed method of analysis for tablet formulation

Twenty tablets were weighed and crushed to obtain a fine powder. Tablet powder equivalent to 50 mg of cefixime trihydrate was transferred to a 50 ml volumetric and 10 ml of the blend MS was added and the flask was shaken for 10 minutes briskly to solubilise the drug. Then, the volume was made up to 50 ml with distilled water. After filtration through Whatmann filter paper # 41to remove tablet excipients the filtrate was sufficiently diluted with distilled water and the absorbance was noted at 288 nm against reagent blank. The drug content was determined using calibration curve.

Recovery studies

Recovery studies taking 10 mg and 20 mg of pure drug as spiked drug together with preanalysed tablet powder (equivalent to 50 mg) were performed using the same proposed method.

Table 1. Analysis of commercial tablets of cefixime trihydrate with statistical evaluation (n=3)

Tablet formulation	Label claim per tablet (mg)	% Label claim estimated (mean ± SD)	% Coefficient of variation	Standard error
I	100	99.19±1.238	1.248	0.715
II	200	100.85±1.821	1.806	1.051

Table 2. Results of recovery studies with statistical evaluation (n=3)

Tablet Formulation	Drug present in preanalyzed tablet powder taken (mg)	Pure drug added (spiked) (mg)	% Recovery estimated (mean ± SD)	Per cent coefficient of variation	Standard error
I	50	10	97.62±1.723	1.765	0.995
	50	20	99.58±1.073	1.078	0.620
II	50	10	97.85±1.616	1.652	0.933
	50	20	98.75±1.446	1.464	0.835

RESULTS AND DISCUSSION

There was significant enhancement in solubility in blend MS (more than 120 fold as compared to solubility in distilled water).The percent label claim were found very close to 100 (99.19±1.238 and 100.85±1.821) indicating accuracy of the proposed method. Percent recoveries estimated by the proposed methods are close to 100 (97.62±1.723 to 99.58±1.073) with low values of standard deviation, percent coefficient of variation and standard error which further validated the proposed method.

CONCLUSION

It may be concluded that the proposed method is simple, safe and precise. The proposed method can be successfully employed in the routine analysis of cefixime trihydrate tablets. The mixed solvency concept can be tried in place of costlier and toxic organic solvents.

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