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Spectrophotometric analysis of poorly water soluble drug (nimesulide) using mixed hydrotropy concept

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1.0 Introduction

Increasing the aqueous solubility of Insoluble and slightly soluble drugs has been done by various methods to avoid the usage of organic solvents. Poor solubility is one of the most difficult problems of maximum drugs [1-3]. Drug analysis of pure or final product also important. The drawback of these organic solvents includes high cost, volatility, pollution and toxicity. Organic solvents are harmful if swallowed, inhaled or absorbed through the skin. also, as per I.C.H guideline Q3 CR3 (impurities guideline for residual solvents), these solvents come under the category of Class 2 solvent i.e solvents which are in limited use. So, there is an urgent need to replace organic solvent with safe eco-friendly, cost-effective solvent for spectrophotometric analysis [4-5]. Concentrated aqueous solutions of sodium benzoate, sodium salicylate, urea, niacinamide, sodium citrate, and sodium acetate have been employed to enhance the aqueous solubilities of a large number of poorly wate soluble drugs [6].

Mixed hydrotropy concept is one of the methods to enhance the aqueous solubility of poorly water soluble drugs [7-9]. Mixed hydrotropy concept may be a proper choice to preclude the use of organic solvents. So there is a broad scope for mixed hydrotropy concept in quantitative estimation of poorly water soluble drugs[10-12]. Mixed hydrotropic solubilization technique is to increase the solubility of poorly water-soluble drugs in the blends of hydrotropic agents [13]. The present research work provides an ecofriendly method to estimate spectrophotometrically, the Nimesulide drug in tablet formulations without the help of organic solvent.

2.0 Material and method

Nimesulide drug was obtained as a gift sample from Schon pharmaceutical Ltd. Indore and nimesulide tablets of two different companies (Dr. Reddys and Combitic global) were purchased from the local market of Indore. All other chemicals used were of analytical grade.

2.1 Instrumentation

UV Visible spectrophotometer (Model 1800, Shimadzu) was used for spectrophotometric analysis.

2.2 Preliminary solubility studies

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To determine the solubility of the drug in distilled water and mixed solvent blend (containing 25% Sodium citrate and 30% phenol) at room temperature sufficient excess amount of the drug was added to a 25 ml capacity vial containing distilled water and the mixed solvent blend. After putting the vial cap and applying the aluminum seal, the vial was shaken mechanically for 12 hours at room temperature in an orbital flask shaker. The solution was allowed to equilibrate for 24 hours undisturbed and then filtration was done through Whatmann filter paper 41. The filtrate was appropriately diluted with distilled water to measure the absorbance at 390 nm against reagent blanks.

2.3 Preparation of calibration curve of drug (nimesulide)

Accurately weighed 50 mg of nimesulide standard drug and 8 ml blend A were transferred to a 10 ml volumetric flask. Complete dissolution of the drug was performed by shaking the flask after complete dissolution, sufficient blend A was added to make up the volume up to 10 ml. From this stock solution, various standard solutions of concentration 10, 20, 30, and 40 µg/ml were prepared by suitable dilution with distilled water. The absorbances of these solutions were noted at 390 nm against respective reagent blank.

Data of calibration curve

S.no.	Concentration (µg/ml)	Absorbance
1	00	0.000
2	10	0.360
3	20	0.678
4	30	1.083
5	40	1.440

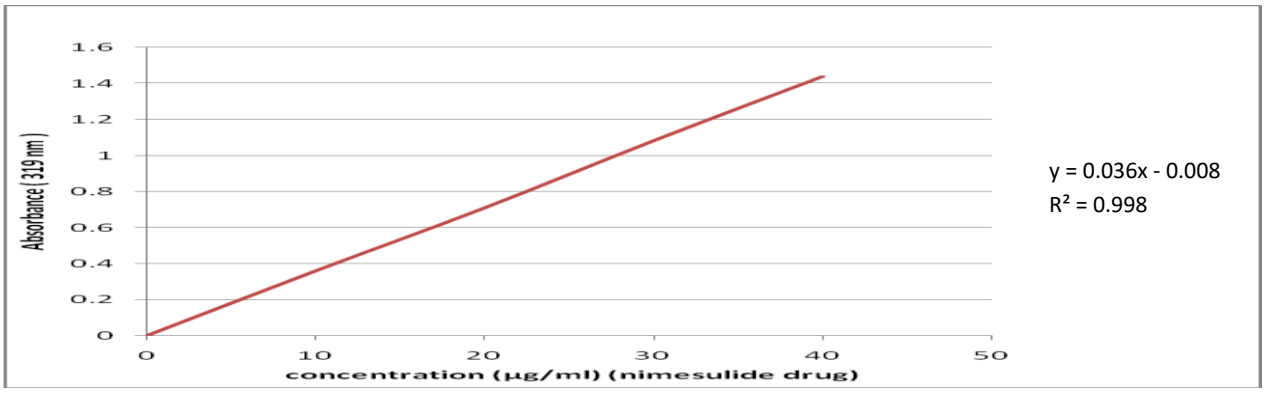

Fig.- Calibration curve of nimesulide

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2.4 Proposed method of analysis

Tablet powder equivalent to 50 mg nimesulide and 8ml of blend solution were transferred to a 10 ml volumetric flask. The flask was shaken vigorously for 10 min and sufficient blend solution was added to make up the volume up to 10 ml. Filtration was carried out through Whatman filter paper no. 41 to remove the tablet excipients. 0.6 ml filtrate was diluted to 100 ml with distilled water and the absorbance was noted at 390 nm against the reagent blank. Same procedure was repeated for tablet II. The results of analysis are reported in table I after calculation using the calibration curve. All types of analysis were repeated thrice.

Table I

Tablet formulation	Label claim mg/tablet	Percent drug estimated (mean ± SD)	Percent coefficient of variation	Standard error
I (Dr. Reddys)	100	102.61± 0.669	0.651	0.375
II (Combitic global)	100	102.10± 0.461	0.451	0.260

2.5 Recovery studies

To perform the recovery studies, standard nimesulide drug was added (20 mg and 40 mg separately) to the pre-analyzed tablet powder equivalent to 50 mg nimesulide and the drug content was determined by the proposed method. All types of analysis were repeated thrice. The results of analysis are reported in table II.

Table -II Results of recovery studies with statistical analysis (n=3)

Tablet formulation	Drug in pre analyzed tablet powder (mg)	Amount of standard drug added (mg) (spiked)	Percent drug estimated (mean ± SD)	Percent coefficient of variation	Standard error
I (Dr. Reddys)	50	20	102.83±0.442	0.429	0.247
I (Dr. Reddys)	50	40	102.57±0.444	0.432	0.249
II (Combitic global)	50	20	103.63±0.155	0.149	0.086
II (Combitic global)	50	40	102.24±0.508	0.496	0.286

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3.0 Results and Discussion

The solubility of nimesulide in distilled water at room temperature was found to be 0.017 mg/ml and the solubility of nimesulide in blend solution was 20 mg/ml of blend. Table I denotes that the mean percent estimations of nimesulide tablets determined by spectrophotometric analysis using mixed hydrotropic solubilization technique (by use of sodium citrate and phenol solution) ranged from 102.10 (formulation II) to 102.61 (formulation I). Observed values of mean percent estimation are very close to 100, indicating the accuracy of the proposed method. Low values of standard deviation (0.461 to 0.669), percent coefficient of variation (0.451 to 0.651) and standard error (0.260 to 0.375) validated the proposed method of analysis.

Table II show that mean percent recoveries estimated using the proposed method ranged from 102.24 to 103.63, which are again very close to 100, indicating the accuracy of the proposed method. Validation of the proposed analysis method is confirmed by satisfactorily low values of statistical parameters viz., standard deviation (0.155 to 0.508), percent coefficient of variation (0.149 to 0.496) and standard error (0.086 to 0.286).

Currently hydrotropic solutions possess high industrial demand due to their unique features such as easy availability, good recovery, absence of fire hazards and eco-friendly nature. Mixed hydrotropic technique can be effectively employed in the pharmaceutical field. It can be used for spectrophotometric estimation of poorly water soluble drugs from their bulk drug samples precluding the use of organic solvents providing simple, economic, eco-friendly, safe and accurate analytical method.

4.0 Conclusion

It can be concluded that Mixed hydrotropic technique can be used to replace the use of organic solvent which are more costly and hazardous to our environment. There is definitely further scope of hydrotropic blend containing 25% sodium citrate and 30% phenol as a hydrotropic solubilizing agent for the spectrophotometric analysis of other poorly water soluble drugs precluding the use of organic solvents.

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