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Ecofriendly Analytical Method for Quantitative Estimation of Mefenamic Acid Using Hydrotropic Solubilizing Agents

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ABSTRACT

To investigate an eco-friendly method to enhance the solubility of Mefenamic acid. The present investigation was to employ these hydrotropic solutions to extract the drugs from their dosage forms, precluding the use of costlier and harmful organic solvents. Methodology: Mefenamic acid was analyzed by using UV Visible spectrophotometer (Model 3000+, lab India) and its solubility (poorly water-soluble drug) measured by mixed solvency method. Urea: Sodium benzoate solution was used as a hydrotropic solubilizing agent. Findings: The solubility of the Mefenamic acid drug in water was very low at about 0.01 mg/ml and the solubility of Mefenamic acid in the 20% Urea+20%Sodium benzoate solution was 2.94 mg/ml. The value of percentage estimation obtained was from (96.0 to 98.0). This value is obtained near to 100% hence; we can say that the proposed method is correct. Novelty: Mixed solvency concept can be utilized for spectrophotometric estimation of poorly water-soluble drugs from their bulk drug samples to avoid the use of organic solvents that provide a new, economical, environmentally friendly, safe, and reliable analytical method.

INTRODUCTION

Mefenamic acid is a nonsteroidal anti-inflammatory drug (NSAID) that has analgesic, anti-inflammatory, and antipyretic actions. It is used for the relief of mild to moderate pain. It is also indicated for the treatment of rheumatoid arthritis [1], primary Dysmenorrheal [2], and periodontitis [3]. The official method for the assay of the pure drug and tablets is titrimetry using sodium hydroxide as the titrant and phenol red as the indicator [4]. The visible spectrophotometric methods are the instrumental methods of choice commonly used in industrial laboratories because of their simplicity, selectivity, and sensitivity. In the literature, only a few spectrophotometric methods have been reported for the determination of mefenamic acid combined with paracetamol in pharmaceutical formulations [5–8]. However, most of these methods involve complicated procedures, which require several manipulation steps. To the best of my knowledge, no single visible spectrophotometric method has been reported for the individual determination of mefenamic acid in pharmaceutical formulations. By using hydrotropic solubilizing technique, therefore, the need for a fast, low-cost, and selective method is obvious, especially for the routine quality control analysis of pharmaceutical products containing mefenamic acid. The proposed method here was successfully applied to the determination of mefenamic acid in bulk pharmaceuticals, tablets, The results obtained by the proposed method were in excellent agreement with those given by the official method [4], proving that the method is a reliable alternative for the analysis of mefenamic acid in pure form and in pharmaceutical preparations.

EXPERIMENTAL

Instrument: Spectrophotometric measurements were performed using LAB-INDIA; UV-VIS spectrophotometer 3000+ with matched quartz cell is used in this analysis. All of the absorbance measurements were carried out at 25 ± 5°C.

Materials, reagents, and solutions. All chemicals used were of analytical reagent grade. For the preparation of solutions and samples, double-distilled water and calibrated Pyrex glassware were used throughout. Mefenamic acid obtained from Airish Pharma,hyd.

Preparation of standard solution: (stock) Standard drug solution of mefenamic acid was prepared by dissolving 50mg of mefenamicacid in 100ml of 20% urea + 20% sodium benzoate solution. In volumetric flask to give stock solution (500µg/ml). 10ml of stock

solution was withdrawn and further diluted with 100ml distilled water. In volumetric flask to give stock solution of 50µg/ml concentration.

Preparation of sample solution: Ten tablets purchased from local market and weighed accurately and grounded to fine powder. An accurately weighed quantity of tablet powder equivalent to 50mg of Mefenamic Acid into 100mlvolumetric flask. The contents in the flask was dissolved with minimum amount of hydrotropic solvent solution, sonicated for 15min, and then diluted to 100ml with solvent solution. The resultant was filtered with Whatmann filter paper. Suitable concentration of the sample was transferredinto10ml volumetric flask and diluted with distilled water (2ml in 100ml) was added and the absorbance was noted at 300nm against reagent blank.

Selection of wavelength (ƛ max): Standard solution of Mefenamic acid concentration 15µg/ml were prepared and scanned in the UV region i.e., 200-400nm to detect the maximum wavelength the spectrum was recorded and its wavelength showed at 300nm.

Validation:

Linearity: The stock solution of Mefenamic Acid in Urea+sodium benzoate (20:20) (stock-A) suitably diluted with water. From stock A varying concentrations of 5µg/ml 10µg/ml, 15µg/ml, 20µg/ml,25µg/ml, were taken in 6 different 10ml volumetric flasks were prepared and scanned at selected wave length 300nm and the absorbance were plotted against concentration. From the graph it was found that the Beer's law limit lies between 5-25 µg/ml for Mefenamic Acid in U+B(20:20). The regression analysis was carried out for calibration graph to find out correlation coefficient(r), intercept and slope of the regression line.

Precision:

Repeatability Studies: Repeatability is given by inter-day and intra-day precision. Intra-day precision was determined by analyzing, the six sets of selected concentration of drug in the same day. Inter-day precision was determined by analyzing the drug for three days in a week.

Accuracy:

Accuracy: Specificity of the proposed method was performed by conducting recovery studies. Recovery studies were carried out by mixing a known quantity of standard drug in three levels to pre-analyzed sample solution and the contents were re-analyzed by the proposed method and the percentage was calculated by using the formula.

ASSAY:

Preparation of sample solution: Ten tablets were prepared in house and weighed accurately and grounded to fine powder. An accurately weighed quantity of powder equivalent to 100mg of Mefenamic acid into100ml volumetric flasks. The contents in the flask was dissolved with minimum amount of solvent solution, sonicated for 15min, and then diluted to 100ml with solvent solution. The resultant was filtered with Whatmann filter paper No: 1. Suitable concentration of the sample was transferred into 10ml volumetric solutions and hydrotropic solvent was added and the concentration of each component was obtained by analysis of the spectral data of sample solution using the absorbance of sample. The amount in the formulation was calculated.

RESULTS AND DISCUSSION:

Table 1: MFA SOLUBILITY IN DIFFERENT CONCENTRATIONS OF HYDROTROPES

S.No	Hydrotropic Agents	Saturation Solubility of MFA (mg/ml)				Solubility enhancement ratio(Time or Fold)			
		10%	20%	30%	40%	10%	20%	30%	40%
1	Urea	0.724	1.140	1.501	2.190	15.73	24.7	32.63	47.60
2	Sodium Acetate	0.142	1.057	1.636	3.123	3.08	22.9	35.5	67.89
3	Sodium Benzoate	1.223	4.462	11.91	22.792	26.58	97	258.9	495.4
4	Sodium Citrate	0.140	0.392	0.723	1.502	3.04	8.52	15.71	32.65
5	Urea + Sodium Benzoate (20%+20%)	2.94				294			

Highest solubility was obtained in 40% sodium benzoate and solution. Then, in order to decrease the concentration of sodium benzoate, with combinations of Urea in 20:20 ratios were tried to determine enhancement in solubility, so that total concentration of hydrotropic agents was always 40% w/v, with fixed ratio of 20:20.

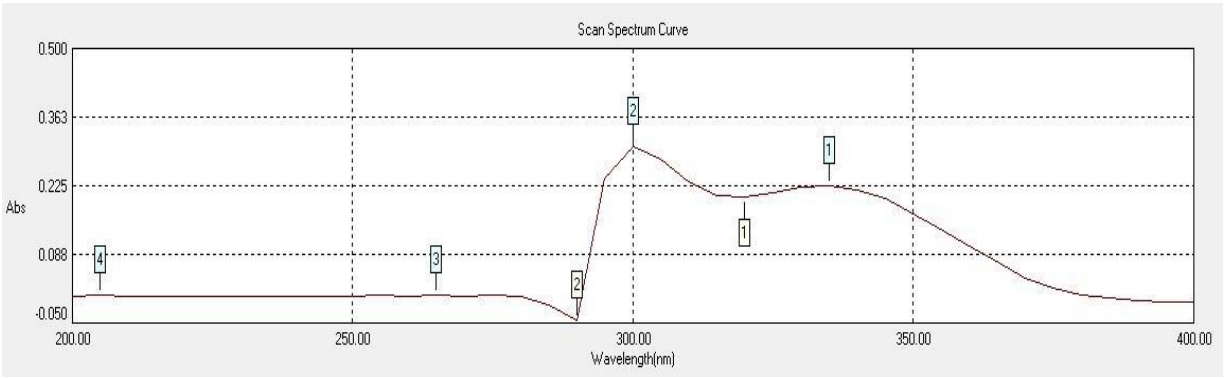

Figure no 1: Spectrum of the MFA in Hydrotropic blend

Table 2: Linearity Studies

S.NO	Concentration(µg/ml)	Absorbance
1	5	0.138
2	10	0.293
3	15	0.479
4	20	0.648
5	25	0.826

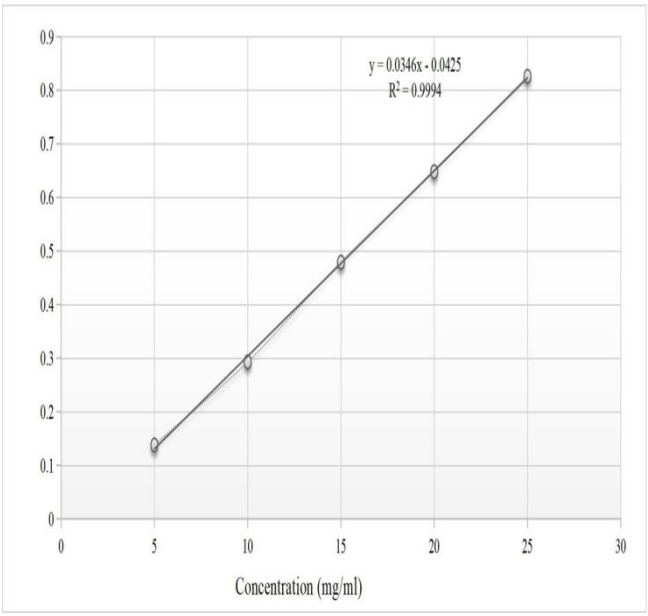

Figure no 2: Calibration curve of Mefenamic Acid

Table 3: Study of Precision

S.NO	Amount taken (µg/ml)	Amount found (µg/ml)	
		Inter-day	Intra-day
1	15	15.4	15.03
2.	15	15.1	15.06
3.	15	15.2	14.97
4.	15	15.1	14.73
5.	15	15.3	15.20
6.	15	15.1	15.20
MEAN	---	101.2%	100.2%
SD	---	0.05	0.035
%RSD	---	0.32	0.23

Table 4: Study of Accuracy

Sno	% Level	Amount added (µg/ml)	Amount recovered (µg/ml)	%recovered	Avg recovered	limit
1	50	7.5	7.2	96 .0	96.4	80-120
		7.5	7.2	96 .0		
		7.5	7.3	97.3		
2	100	15	14.7	98.0	98.2	80-120
		15	14.8	98.6		
		15	14.7	98.0		
3	150	22.5	22.3	99.1	98.7	80-120
		22.5	22.2	98.6		
		22.5	22.2	98.6		

Table 5: Assay of Marketed Formulation

S.no	drug	Lable claim (mg/tab)	Test conc. (µg/ml)	Amount found (µg/ml)	%Assay	%RSD
1	MEFENAMIC ACID (meftal P)	100mg	10	9.8	98.0%	0.55
2			10	9.6	96.0%	
3			10	9.7	97.0%	

CONCLUSION

Different methods have been used for the enhancement of the solubility of poorly water soluble drugs It may be assumed that it's possible to use the mixed solvency technique to replace the use of an organic solvents that is more expensive and harmful for our atmosphere.

The solubility enhancement for mefenamic acid in the hydrotropic solution was found to be more than 294 times as compared to the distilled water. The result concluded that the developed Spectrophotometric method for the detection of Mefenamic acid in bulk and formulation using urea +S.B (20:20%) used as hydrotropic agents reliable, accurate, precise and ecofriendly.

The method can be successfully utilized in the routine analysis of Mefenamic acid in bulk and dosage formulations for the Spectrophotometric study of other poorly water soluble drugs avoiding the use of organic solvents, There is a further scope of (Urea+S.B) solution as hydrotropic solubilising agent.

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