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New Spectrophotometric Method for the Estimation of Naproxen in Tablets using *N, N*- di methyl urea as Hydrotropic Agent

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ABSTRACT

A novel, safe and sensitive method of spectrophotometric estimation in ultraviolet region has been developed using 7.5 M *N, N*- di methyl urea solution as hydrotropic agent for the quantitative determination of Naproxen, a poorly water-soluble drug in tablet dosage form. Naproxen shows maximum absorbance at 272 nm. Beer's law was obeyed in the concentration range of 10 to 60 µg/ml, N, N- di methyl urea does not absorb above 260 nm. Commonly used tablet excipients and *N, N*- di methyl urea did not interfere in spectrophotometric estimation. Results of the analysis were validated statistically and by recovery studies. Using 7.5 M *N, N*- di methyl urea solution for analysis of two different tablet formulations of Naproxen , 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.

KEYWORDS: Naproxen, hydrotropy, *N, N*- di methyl urea, spectrophotometry.

1. INTRODUCTION

The term “hydrotropy” has been used to designate the increase in solubility of various substances in water, due to the presence of large amounts of additives. Various hydrotropic agents have been used to enhance the aqueous solubility of a large number of drugs[1-12] several chromatographic methods are reported for estimation of drugs using hydrotropic agents from pharmaceutical formulations[1-15], yet not any method for the estimation of Naproxen using hydrotropic agents.

Since *N, N*- di methyl urea does not absorb above 260 nm and there was more than 68 fold enhancement in solubility of Naproxen in 7.5 M, *N, N*- di methyl urea solution, it was through worthwhile to use this hydrotropic solution to extract the drug from fine powder of tablets to carryout spectrophotometric estimation. Chemically Naproxen is (*S*)-2-(6-methoxynaphthalen-2-yl) propanoic acid is a widely used as nonsteroidal anti-inflammatory drug (NSAID).

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2. MATERIALS AND METHODS

N, N- di methyl urea was obtained from C.D.H. Pvt. Ltd. and Naproxen was obtained as a gift sample from Piramal Healthcare and Naproxen tablets were purchased from the local market. All chemicals and solvents used were of analytical grade.

2.1 Calibration curve

Accurately weighed 50 mg of Naproxen was solubilized by 40 ml of 7.5 M *N, N*- di methyl urea solution in a 100 ml volumetric flask, and distilled water was added to make up the volume. This stock solution was further diluted with distilled water to get various dilutions containing 10, 20, and 30, 40, 50 and 60 µg/ml of drug. Absorbance was noted at 272 nm against corresponding reagent blank.

2.2 Preliminary solubility studies of Naproxen

Solubility of Naproxen was determined in distilled water and 7.5 M *N, N*- di methyl urea solution at 28 ± 1^0C. There was more than 68 fold enhancement in solubility of Naproxen in 7.5 M, *N, N*- di methyl urea solution, as compared to solubility in distilled water.

2.3 Analysis of Naproxen tablets by the proposed method

Analysis of tablet formulation of Naproxen by the proposed method was done by a method in which two different marketed tablet formulations of Naproxen were used. Twenty tablets of Naproxen from formulation 1 (Gatri 400 mg, Piramal Healthcare) were weighed and ground to a fine powder. An accurately weighed powder sample equivalent to 50 mg of Naproxen was transferred to a 100 ml of volumetric flask containing 40 ml of 7.5 M *N, N*- di methyl urea solution. The flask was shaken for about 5 min to solubilize the drug and the volume was made up to mark with distilled water. The solution was filtered through Whatmann filter paper No 41. The filtrate was diluted appropriately with distilled water and was analyzed on UV spectrophotometer against reagent blank. Drug content of tablet formulation was then calculated (Table No 1). Tablet formulation 2 (Gatiquine, 400 mg, Aristo Pharma Ltd.) was treated in the same way.

2.4 Recovery studies

Recovery studies taking 15mg and 30mg of pure drug as spiked drug, together with preanalysed tablet powder (equivalent to 50 mg drug), were performed using the same proposed method of analysis. The percentage recoveries estimated are presented in Table No 2.

Table No 1: Analysis data of Naproxen tablet formulations with statistical evaluation (*n=3)

Tablet Formulation	Label Claim Mg/tablets	Percentage drug estimated* (mean±S.D)	Percentage Coefficient of variation	Standard error
I	250	98.82±1.449	1.466	0.837
II	750	99.57±1.894	1.902	1.094

Table No 2: Result of recovery studies of tablet formulations with statistical evaluation (*n=3).

Tablet Formulation	Drug present in preanalysed tablet powder	Spiked drug added (mg)	Percentage Recovery estimated* (mean± S.D)	%age Coeff. of variation	Standard error
I	50 mg	15	100.81±1.401	1.390	0.809
I	50 mg	30	99.22±1.610	1.623	0.930
II	50 mg	15	98.91 ± 1.076	1.088	0.621
II	50 mg	30	99.15 ± 1.267	1.278	0.732

3. RESULTS AND DISCUSSION

The mean percentage drug estimated was 99.82 and 99.57 for formulation I and II respectively. These values are close to 100, indicating the accuracy of proposed analytical method. Standard deviation for formulation I and II was found to be 1.449 and 1.894 respectively. Percent coefficient of variation and standard error in formulation I was found to be 1.466 and 0.837 respectively. Percent coefficient of variation and standard error in formulation II were found to be 1.902 and 1.094 respectively. The low values of these statistical parameters validated the method. The values of mean percentage recoveries for formulation I and II range from 99.15 to 100.81, which are again close to 100. This fact together with satisfactorily low values of statistical parameters further validated the method.

4. CONCLUSION

Thus, it may be concluded that the proposed method is new, simple, eco-friendly (precluding the use of organic solvent), precise and cost effective. *N, N*- di methyl urea does not absorb above 260 nm (wavelength). Therefore a large number of poorly

water soluble drugs having λmax above 260 nm may be tried for the estimation by this method, provided their solubilities are enhanced sufficiently by *N*, *N*- di methyl urea solution.

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