ISSN 0976 – 3333

Available Online at www.ijpba.info

International Journal of Pharmaceutical & Biological Archives 2011; 2(5):1479-1480

ORIGINAL RESEARCH ARTICLE

Analytical Application of Hydrotropic Solubilization in Spectrophotometric Determination of Naproxen in Tablet Dosage Form

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Received 24 Jul 2011; Revised 19 Oct 2011; Accepted 24 Oct 2011

ABSTRACT

A new, simple, safe, accurate and reproducible spectrophotometric analytical method was developed for the quantitative estimation of naproxen in solid dosage form by the novel application of hydrotropic solubilization. The enhancement of solubility of naproxen drug was more than 65 fold in hydrotropic solution (7.5M N,N-dimethyl urea 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 hydrotropic solubilization technique and then carry out its spectrophotometric estimation at 317 nm (N,N-Dimethyl urea does not interfere above 260nm). The results of the analysis were validated statistically and by recovery studies. 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.

Key words: Hydrotropic solubilization technique, Analysis of naproxen, Naproxan.

INTRODUCTION

Various organic solvents like methanol, chloroform, ethanol and dimethyl formamide (which are very costly, toxic and unsafe) are widely used to conduct the spectrophotometric analysis. The primary objective of this study was to preclude the use of organic solvent and to employ hydrotropic solutions of hydrotropic agents like N,N-dimethyl urea solution (which is an economic agent) for the spectrophotometric analysis of naproxen in solid dosage form.

It was thought worthwhile to employ hydrotropic solution (7.5M N,N-dimethyl urea solution) to solubilize naproxen for its spectrophotometric analysis as there was more than 65 folds enhancement in the aqueous solubility of naproxen (a poorly water soluble drug) in hydrotropic solution (an inexpensive hydrotropic agent) as compared to its aqueous solubility.

EXPERIMENTAL METHODS

1. **Preliminary solubility study of naproxen:** The solubility of naproxen was determined in distilled water and hydrotropic solution (7.5M N,N-dimethylurea solution) . Enhancement in solubility of naproxen in hydrotropic solution was more than 65 fold as compared to the aqueous solubility.
2. **Calibration curve:** Shimadzu UV/Visible recording spectrophotometer (model-uv-160-A) was used for analysis. Naproxen bulk drug sample (50 mg) was accurately weighed and transferred in a 100 ml volumetric flask and hydrotropic solution (40ml of 7.5M N,N-dimethyl urea solution) was added. The drug was solubilized by shaking and volume was made up to the mark with distilled water. The stock solution was diluted with distilled water to obtain various dilutions. Standard solutions of 40,80,120,160,200,240 µg/ml of drug were used to plot the calibration curve by noting the absorbances at 317 nm against corresponding reagent blanks.
3. **Proposed method for analysis of naproxen:** An accurately weighed powder sample equivalent to 50 mg of naproxen was transferred to a 50 ml volumetric flask containing hydrotropic solution (40ml of 7.5M N,N-dimethyl urea solution).The flask was shaken for about 10 min to solubilize the drug and then volume was made up to the mark with distilled water. The solution was filtered through Whatman filter paper #41. The filtrate was diluted appropriately with distilled water and analyzed on uv/visible spectrophotometer

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against reagent blank. Drug content of tablet I and II were then calculated.

4. **Recovery studies:** To study the accuracy, precision and reproducibility of the proposed method, recovery studies were carried out. In recovery studies pre-analyzed tablet powder equivalent to 50 mg was taken and 15 and 30 mg of naproxen bulk drug were added to it at two different levels. Percent recoveries were calculated. Each type of analysis was performed three times. Results of analysis were validated statistically.

RESULTS AND DISCUSSIONS

The mean percent drug estimated was 101.32 and 99.51for 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 0.885 and 1.229 respectively. Percent coefficient of variation and standard error in formulation I and II was 0.873and1.235 respectively. The low values of these statistical parameters validated the method. The values for mean percent recoveries for formulation I and II ranged from 99.21 to 100.49, which is again close to 100. This fact together with low values of statistical parameters (Table 2), proved the accuracy of the proposed method.

Table 1: Results of analysis of marketed tablets of naproxen with statistical evaluation (n=3)

Tablet Formulation	Label claim per tablet(mg)	Percent drug estimated mean+-standard deviation	% Coefficient of variation	Standard error
1	250	101.32±0.885	0.873	0.511
2	750	99.51±1.229	1.235	0.710

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

Tablet formulation	Drug present in pre analyzed tablet powder(mg)	Pure drug added(mg)	Percent recovery estimated mean ±SD	% Coefficient of variation	Standard error
1	50	15	99.21±1.629	1.642	0.941
2	50	30	100.77±0.924	0.917	0.533
3	50	15	101.02±1.546	1.530	0.893
4	50	30	100.49±1.333	1.327	0.770

CONCLUSION

Thus it may be concluded that the proposed method is new, simple, validated, eco-friendly, precise and cost effective. So the prescribed method can be used to estimate naproxen tablets.

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