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A Simple UV Spectroscopic Method for the Determination of Naproxen in Bulk and Tablets

B. Famida*, S. Muneer, B. Mohammed Ishaq, Hindustan Abdul Ahad, T. Nuzhath

PG Department of Pharmaceutical Analysis, Balaji College of pharmacy, Ananthapuramu, Andhra Pradesh, India

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Abstract

A simple, economic, accurate UV method was developed for the estimation of Naproxen (NPR) in bulk and tablet dosage form. Water was used as a diluent to dissolve NPR. The drug mixture was sonicated for 3mins for the enhanced solubility. The absorptions were observed at 262.0 nm, which was selected for the further analysis of NPR in bulk and its tablet dosage forms. The proposed method was validated according to ICH guidelines. The method showed high sensitivity with linearity range from 5 to 30 µg/ml (r2=0.9991) at 262.0 nm. The limit of detection (LOD) was found to be 0.67 and the limit of quantization (LOQ) was determined as the lowest concentration was found to be 2.24. The reports expressed that the proposed method was found to be simple, precise, accurate and rapid for the estimation of NPR in bulk and tablet dosage form using UV spectroscopy.

Keywords: Naproxen, Distilled water, UV spectroscopy, ICH guidelines

Contents

***Corresponding author**
B. Famida
PG Department of Pharmaceutical Analysis,
Balaji College of Pharmacy,
Ananthapuramu, Andhra Pradesh, India
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1. Introduction

Naproxen (NPR), chemically known as 2-(6-methodynaphthalen-2-y1) Propanoic acid [1]. It is used in the treatment of Inflammations, rheumatoid arthritis, musculoskeletal disorders and gout [2]. Naproxen is a non-steroidal anti-inflammatory drug (NSAID) commonly used for the reduction of moderate to severe pain, fever, inflammation and stiffness. It works by inhibiting both the COX-1 and COX-2 enzymes.*Naproxen*is extensively *metabolized* in the liver to 6-0-desmethyl*naproxen*. The corresponding half-lives of both *naproxen's metabolites* and conjugates. From the literature survey, it was found that NPR estimated by analytical methods such as Spectrophotometric and HPLC methods have been reported for the estimation of naproxen in tablet formulation [3-7], API [8], plasma [9,10], urine [11] and intestinal perfusion samples [12]. Hence, the aim of this study was to

develop and validate a simple UV method, to quantify NPR in pure form and pharmaceutical formulation (tablets). The proposed method was validated according to ICH guidelines [13]. The validated method was applied to the analysis of tablets containing naproxen (250 mg).

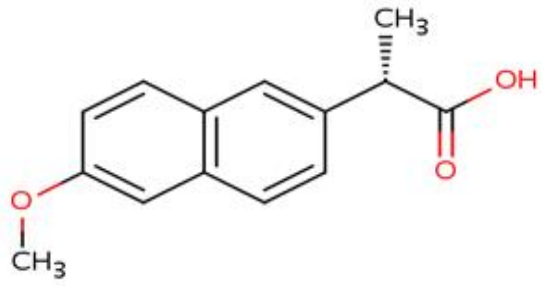

Figure 1: Chemical structure of NPR

2. Materials and Methods

Instruments and reagents

An analytically pure sample of NPR was procured as gift sample from MSN laboratories (Hyderabad, India). Distilled water was used as solvent for dilution. Distilled water was prepared in house. A PG Instruments T-60 UV/VIS spectrophotometer was used with 1 cm matched quartz cell. Tablet formulation [Naprosyn RPG Life sciences, India] was procured from a local pharmacy with labeled amount 250 mg per tablet.

Preparation of working standard drug solution

The standard NPR (50 mg) was weighed accurately and transferred to volumetric flask (50 ml). It was dissolved properly and diluted up to the mark with diluent to obtain final concentration of 1000 µg/ml. 15µg/ml solution was prepared from the stock solution which was used as working standard.

Analysis of marketed formulations

For the estimation of Naproxen in tablets formulations, 20 tablets were weighed and triturate to fine powder. Tablet powder equivalent to 50 mg of NPR was weighed and transfer into 50 ml volumetric flask than dissolved in diluent. It was kept for sonication for 3 min; this was filtered through Whatman filter paper No. 41 and then final dilution was made with diluent to get the final stock solution of 1000 µg/ml. From this stock solution, various dilutions of the sample solution were prepared and analyzed.

Validation: Method validation was performed in terms of specificity and selectivity, precision and accuracy, linearity, LOD & LOQ.

Linearity and range

Calibration standards of NPR, covering the range 5-30 µg/ml were prepared with the suitable dilution made from NPR stock solution. The calibration curves were obtained by plotting the intensity of absorbance against of concentration of NPR. The slope and intercept of the calibration line were determined by linear regression using the least squares method.

Specificity and selectivity

The interference from endogenous compounds was investigated by the analysis of tablets of various concentrations.

Precision

The intra& inter-day precision was evaluated by analyzing six sample solutions (n = 6), at the final concentration of analyses (30 µg/ml) of NPR. The NPR concentrations were determined and the relative standard deviations (RSD) were calculated.

Accuracy: NPR reference standards were accurately weighed and added to a mixture of the tablets excipients, at three different concentration levels (7.5, 15 and 30µg/ml of ritonavir). At each level, samples were prepared in triplicate and the recovery percentage was determined.

Detection and quantitation limits

Limit of detection LOD and limit of quantification LOQ were calculated by using the standard deviation from the precision and the slope of linearity.

3. Results and Discussion

NPR has the zero order absorbance spectra maxima (figure 2 and 3) at 262.0 nm. The polynomial regression data for the calibration plots showed good linear relationship in the concentration range of 5-30µg/ml with correlation coefficient (r^2) was found to be higher than 0.9991 and the linearity curve was shown in figure 4. Recovery studies were carried out at three different levels i.e. 50 %, 100 %, and 150 % by adding the pure drug to the previously analysed tablet powder sample. Percentage recovery for Naproxen was determined by all the methods and they were found to be under acceptance criteria which are 99 % to 101 %according to ICH guidelines [13]. The results of accuracy were in table 2. The percentage recovery value indicates noninterference from excipients used in

formulation. The precision was carried out as described in method and the results were presented in table 1. The values obtained in the repeatability (precision) shows that there is no significant difference in the precision values; hence the developed method can be used to analyze the NPR in tablet formulation. The mean assay of the precision value is 100%. The LOD determined as the amount drug was found to be 0.67 µg/ml and the LOQ was determined as the lowest concentration was found to be 2.24 µg/ml in formulation. The summary of all the optical characterizes were shown in table 2.

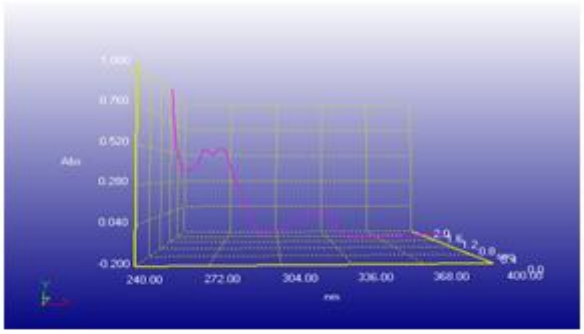

Figure 3: λ max (3-D view) curve of NPR

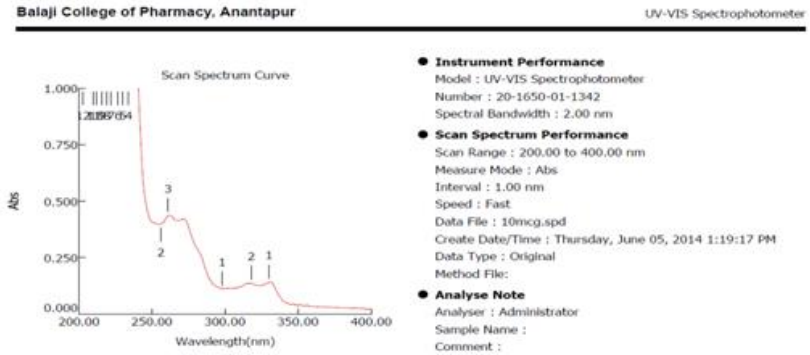

Figure 3: λ max curve of NPR

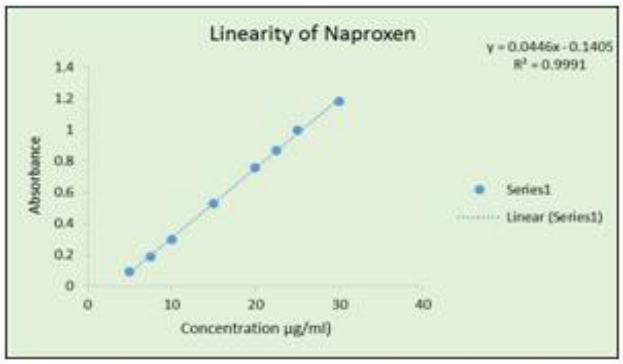

Figure 4: Linearity curve of NPR

Table1: Results of Precision

Sample No.	**Sample Abs - 1**	**% Assay - 1**
1	0.521	100.5
2	0.537	102.42
3	0.526	102.03
4	0.521	99.92
5	0.532	101.46
6	0.529	101.27
Average Assay:		100.27
STD		0.931
% RSD		**0.920**

Table 2: Summary of Optical characteristics and Other Parameters

S No.	Parameters	Results
1	Absorption Maxima (nm)	262
2	Beer's-Lambert's range (µg/ml)	5-30
3	Regression equation (y)*	Y = 0.0446x - 0.1405
4	Slope (b)	0.0446
5	Intercept (a)	-0.1405
6	Correlation coefficient (r^2)	0.9991
7	Sandell's sensitivity ($\mu g/cm^2$-0.001absorbance units)	0.02857
8	Intraday precision (% RSD)**	1.13
9	Interday precision (% RSD)**	1.37
10	Accuracy (% mean recovery)	98.86
11	Limit of detection (µg / ml)	0.67
12	Limit of quantification (µg / ml)	2.24
13	Assay of tablets (%Purity)	100.25

*y = a + bx; when x is the concentration in mg/ml and y is absorbance unit.
**Average of six determinations.

4. Conclusion

The most striking features of the method was its simplicity and rapidity, non- requiring consuming sample preparations such as extraction of solvents, heating, degassing which are needed for HPLC or other procedures. It can be concluded that the proposed methods was fully validated and found to be simple, sensitive, accurate, precise, reproducible, rugged and robust and relatively inexpensive. So, the developed method can be easily applied for the routine Quality Control analysis of NPR in pharmaceutical preparations.

5. Acknowledgement

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