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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF NAPROXEN SODIUM BY UV SPECTROSCOPY

M.K. CHAITANYA PRASAD[1], B.DINESH[2], B. DIVYA SRI[2], K. SRIKANTH[2], M. TANU SRI[2], V. BHAGYA SUDHA[2]
[1]Associate Professor, Department of Pharmaceutical Analysis, St .Ann's college of Pharmacy, Chirala.
[2]Department of Pharmaceutical Analysis, St. Ann'S college of Pharmacy, Chirala.

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***Corresponding author**
M.K. Chaitanya Prasad

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Abstract
This study focuses on the development and validation by a UV spectrophotometric method for the estimation of Naproxen in bulk and tablet formulation. Naproxen is a Nonsteroidal Anti-Inflammatory Drug (NSAIDs) .It is mostly used to treat pain or inflammation caused by condition such as arthritis, gout, tendinitis or menstrual cramps. Naproxen is available in isolated dose with various similar anti-inflammatory drug, i.e.; Esomeprazole, Pantoprazole, Paracetamol, Ranitidine, Sumatriptan and Ibuprofen. The analytical method was optimized using a ratio of two solvents to ensure accuracy and reproducibility. Validation of the API (Active Pharmaceutical Ingredient) was performed in accordance with ICH (International Council for Harmonization) guidelines, evaluating key parameters such as specificity, linearity, precision, accuracy and robustness. The method demonstrated a high degree of reliability for routine quality control analysis. Additionally, the assay of Naproxen tablets using the developed method exhibited consistent and precise results, confirming its suitability for pharmaceutical applications. This validated method offers a simple, cost-effective, and efficient approach for the quantitative analysis of Naproxen.

Keywords: *Naproxen, UV Spectrophotometry, Method Validation, Pharmaceutical Analysis, Tablet Formulation, ICH Guidelines.*

INTRODUCTION
Pharmaceutical analysis serves as the backbone of ensuring drug safety, efficacy, and consistency. It encompasses the evaluation of chemical substances, whether isolated compounds or complex mixtures, across various dosage forms. With components derived from both natural and synthetic sources, pharmaceutical analysis plays a fundamental role in modern medicine and its applications. Analytical chemistry [1]. particularly spectrophotometric methods, provides powerful tools for assessing pharmaceutical formulations. These techniques are categorized into two primary approaches: qualitative analysis, which identifies chemical constituents, and quantitative analysis which measures their concentration. Both methods are indispensable in pharmaceutical development and quality control. Naproxen is a nonsteroidal anti-inflammatory drug (NSAID). It works by reducing [2-4].

TableNo1: Drug Profile [5-6]

S.No	Parameters	Naproxen
1.	Molecular formula	C14H14O3.
2.	Synonyms	Naproxen,Naprosyn.
3.	Molecular weight	230.26 g/mol.
4.	Category	Analgesic agents; Nonsteroidal Anti-Inflammatory Agent.
5.	Solubility	Slightly soluble in ether; soluble in methanol, chloroform, Dimethyl formamide (DMF).
6.	Mechanism of Action	Exerts its clinical effects by blocking COX-1 and COX-

		2enzymes leading to decreased prostaglandin synthesis.
7.	Uses	Headache,muscle aches, Tendonitis, Dental pain and menstrual cramps. It also reduces pain and swelling.
8.	Adverse effects	Indigestion, heartburn, stomach pain, swelling or ringing in ears.
9.	Interaction	Should not use naproxen if you have a history of allergic reactions to aspirin and /or analgesics or other related NSAIDs.

MATERIALS AND METHODS

Materials

Shimadzu UV-160 and UV-1800 UV/VIS Spectrophotometer were used with 1 cm matches quartz cell, CP224S analytical balance (Sartorius) and ultra-sonic cleaner (Fisher scientific FB15061) were used. Micropipette of Variable volume 10-1000 eppitte single channel) and Digital balance (Mettler Toledo XP 105). Naproxen (Ezo life sciences) (CAS 22204-53-1) was supplied by Sigma Aldrich. Naprosyn® USP gel (RPG Life sciences, India) was purchased from local market. All other chemicals and solvents used were of HPLC grade [7].

Preparation of stock solution

Standard stock solution of naproxen were prepared by dissolving accurately weighed 100 mg of naproxen in methanol in a 100 mL volumetric flask to give a concentration of 1000 µg/mL.From this, 10 mL of the solution was transferred to a 100 mL volumetric flask and made up the volume with methanol to give a concentration of 100 µg/mL which is the standard stock solution [8].

Determination of maximum wavelength (λmax) [9]

The samples were scanned in UV spectrophotometer from a range of 200-400 nm against methanol as blank and the wavelength corresponding to maximum absorbance in methanol were determined

Preparation of standard calibration curve [10]

For the preparation of standard calibration curve, concentration of 10-60 µg/mL were prepared by pipetting out 1.0, 2.0, 3.0, 4.0, 5.0 and 6.0 mL from the 100 µg/mL solution into a 10 mL volumetric flask and made up the volume with methanol. The absorbance of each solution was measured at maximum wavelength.

Validation [11-12]

Validation can be defined as (ICH) establish documented evidence, which provides a high degree of assurance that a specific activity will consistently produce a desired result or product meeting its predetermined specifications and quality characteristics. The method were validated for several parameters like linearity, accuracy, precision, ruggedness, robustness, Limit of detection (LOD), Limit of quantification (LOQ) according to ICH guidelines

RESULTS

Determination of maximum wavelength (λ max)

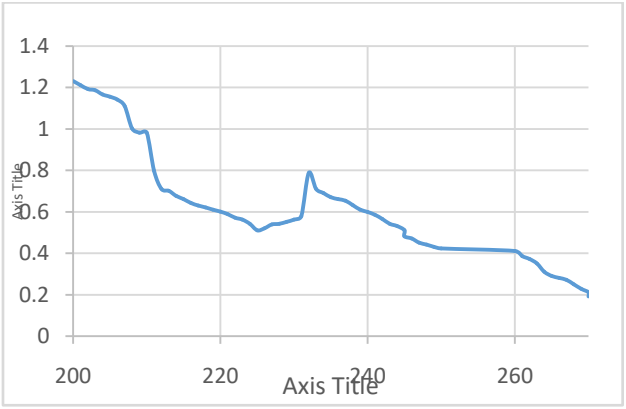

Figure 1: UV Spectrum of Spectrum of 232nm of Naproxen

Linearity

A calibration curve was plotted using concentration (on x-axis) against absorbance at 252 nm (on y-axis) from the graph linearity regression co-efficient y-intercept was calculated.

Table 2: Linearity studies of Naproxen in Bulk form

Concentration [µg/ml]	Absorbance [nm]
10	**0.228**
15	**0.354**
20	**0.579**
25	**0.789**
30	**0.945**

Table 3: Linearity studies of Naproxen in Tablet Dosage Form

Concentration [µg/ml]	Absorbance [nm]
10	0.228
15	0.354
20	0.579
25	0.789
30	0.945

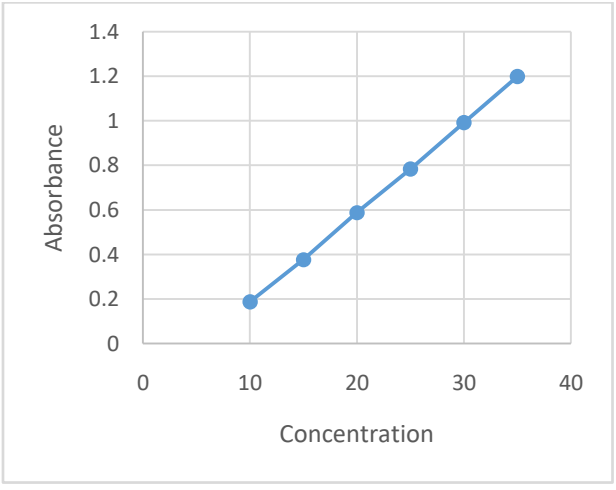

Figure 4: Linearity studies of Naproxen in Bulk form

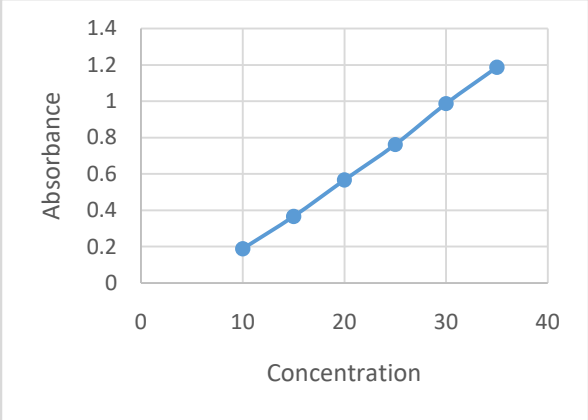

Figure 5: Linearity studies of Naproxen in Tablet Dosage Form

The linearity regression co-efficient was more than 0.99 and hence the method was said to obey Beer's law and there is a linear and proportional relationship exists between concentration and absorbance.

Accuracy

The accuracy of the method was demonstrated by recovery experiment performed at three different levels, i.e., 75%, 100%, and 125%., 3 different solutions of same concentration i.e., 11.25 µg/ml, 15 µg/ml and 18.75 µg/ml were prepared and analyzed on a day and the absorbance was noted. According to ICH guidelines the % RSD value should not exceeded upto 2%.

The formula for calculating the %RSD is

%RSD = SD/Mean x 100

Table 4: Accuracy studies of Naproxen in Bulk form

S. No	Concentration (µg/ml)	Samples	Absorbance at 232 nm	Statistical Analysis
1	75%	15	0.365	Mean = 0.4093314 S.D = 0.0015275 %RSD = 0.3737
		15	0.366	
		15	0.365	
2	100%	20	0.564	Mean = 0.564333 S.D = 0.000577 %RSD = 0.102307
		20	0.565	
		20	0.564	
3	125%	25	0.763	Mean = 0.762333 S.D = 0.00057735 %RSD = 0.75735
		25	0.762	
		25	0.762	

Table 5: Accuracy studies of Naproxen in Tablet Dosage form

S. No	Concentration (µg/ml)	Samples	Absorbance at 232 nm	Statistical Analysis
1	75%	11.25	0.366	Mean = 0.366667 S.D = 0.0005773 %RSD = 0.157459
		11.25	0.367	
		11.25	0.367	
2	100%	15	0.567	Mean =0.567667 S.D = 0.000577 %RSD = 0.101706
		15	0.568	
		15	0.568	
3	125%	18.75	0.768	Mean = 0.767667 S.D = 0.000577 %RSD = 0.075208
		18.75	0.767	
		18.75	0.768	

Precision

From the above prepared standard stock solution, 10 ml of the solution was diluted to 100 ml using methanol to get a concentration of 100 µg/ml. From the above solution 6 ml of solutions were pipetted out into 6 different 100 ml volumetric flasks and the volume was made with methanol to get the final concentrations of 15 µg/ml. The calculated percentage relative standard deviation (% RSD) of the results was used to evaluate the method precision. According to ICH guidelines, the %RSD should not be exceeded up to 2%.

Table 6: Precision studies of Naproxen in Bulk Form

S. No	Samples (µg/ml)	Absorbance at 232 nm	Statistical Analysis
1	20	0.577	Mean = 0.571333 S.D =0.005887841 % RSD = 1.030544
2	20	0.576	
3	20	0.577	
4	20	0.565	
5	20	0.566	
6	20	0.567	

Table 7: Precision studies of Naproxen in Tablet Dosage form

S. No	Samples (µg/ml)	Absorbance at 232 nm	Statistical Analysis
1	20	0.579	Mean = 0.580333
2	20	0.579	

3	20	0.580	S.D = 0.00121106 % RSD = 0.208684
4	20	0.581	
5	20	0.581	
6	20	0.582	

DISCUSSION

The Method was developed and validated as pre ICH Guidelines. The Method was validated in terms of linearity precision and accuracy. Detection wavelength was selected at 232nm. Linearity in Responses was observed on 10-30µg/ml. The precision results showed a % RSD was calculated at each level clearance indicating that the method was precise enough for the analysis of naproxen. The accuracy of the method was checked by recovery was studied.

CONCLUSION

The developed method can be concluded to be simple, accurate, reliable and economical. The proposed method is specific without and interference of excipients and hence can be used for the routine analysis of Naproxen bulk and in tablet dosageform as per ICH guidelines.

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CONFLICT OF INTEREST

Not declared

INFORMED CONSENT AND ETHICAL STATEMENT

Not applicable

AUTHOR CONTRIBUTIONS

All authors are contributed equally.

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