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DEVELOPMENT AND VALIDATION OF NEW ANALYTICAL METHOD ON NAPROXEN SODIUM BY USING AUC SPECTROSCOPIC METHOD

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ABSTRACT

A novel simple, accurate and precise area under curve (AUC) spectroscopic method was developed and validated for the estimation of naproxen sodium in bulk forms has an absorption maximum at 225-235 nm in The linearity was found to be in the concentration range of 1-3µg/ml and the correlation coefficient was found to be 0.9999 and it has showed good linearity, reproducibility, precision in this concentration range. The regression equation was found to be y = 0.248x + 0.0012. The percent recovery values were found to be within 97.9-100.5% showed that the method was accurate. The LOD and LOQ were found to be 0.06 and 0.2 µg/ml, respectively. The % RSD values were less than 2. The method has been validated according to ICH guideline for linearity, accuracy, precision, robustness, ruggedness, limit of detection and limit of quantitation.

KEYWORDS: Naproxen sodium AUC spectroscopy method, water linearity, precision, reproducibility and accuracy.

INTRODUCTION

Naproxen sodium, a Non steroidal anti-inflammatory drug (NSAID) used to treat pain, menstrual cramps, inflammatory diseases such as rheumatoid arthritis, and fever. It is taken by mouth. It is available in immediate and delayed release formulations. Onset of effects is within an hour and last for up to twelve hours.[1-2]

Common side effects include dizziness, headache, bruising, allergic reactions, heartburn, and stomach pain. Severe side effects include an increased risk of heart disease, stroke, gastrointestinal bleeding, and stomach ulcers. The heart disease risk may be lower than with other NSAIDs. It is not recommended in people with kidney problems. Use is not recommended in the third trimester of pregnancy.[3-6]

Naproxen is a nonselective COX inhibitor. It is in the propionic acid class of medications. As an NSAID, naproxen appears to exert its anti-inflammatory action by reducing the production of inflammatory mediators called prostaglandins. It is metabolized by the liver to inactive metabolites.

Naproxen was patented in 1967, and approved for medical use in the United States in 1976, where it is available over the counter and as a generic medication. In the United Kingdom, it cost about £0.15 per dose in 2017. In the United States, the wholesale cost per dose is less than US$0.10 as of 2018. In 2016, it was the 68th most prescribed medication in the United States, with more than 11 million prescriptions. [7-14]

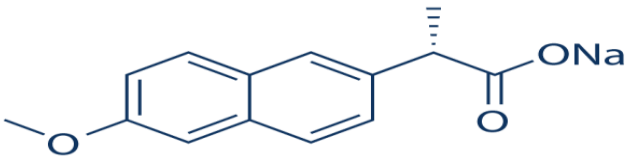

Fig. 1: Chemical structure of naproxen sodium.

MATERIAL AND METHOD

Instrument

UV-visible double beam spectrophotometer, SHIMADZU (model UV-1800) with UV probe software. All weights were taken on analytical balance.

Chemicals: Naproxen sodium drug was obtained as a gift sample from INM research private limited.

Solvent: Water.

Selection of analytical wavelength

Appropriate dilutions were prepared for drug from the standard stock solution and the solution was scanned in the wavelength range of 200-400 nm. The absorption spectra thus

obtained were derivatized from AUC spectroscopic method. It shows maximum absorbance at 225-235 nm was shown in fig.2.

Preparation of standard stock solution

Accurately weigh 100mg of naproxen sodium was transferred into 100 ml volumetric flask and diluted with purified water up to the mark. From this pipette out 10ml in to 100ml volumetric flask and diluted with water up to mark, from this solution pipette out 1, 1.5, 0.2, 2.5. And 3.ml into 10ml individual volumetric flask and add water up to the mark, this gives 1, 1.5, 2, 2.5, and 3.µg/ml concentrations.

Method validation

The method is validated according to the ICH guidelines.[15-19]

RESULT AND DISCUSSION

Method: Area under curve spectroscopic method

Linearity

The working standard solution was diluted serially with water to obtain the range of 1-3µg/ml. A calibration curve for naproxen sodium was obtained by measuring the absorbance at the λmax of 225-235nm and absorbance values are shown in table.1 and calibration graph were presented in fig.3. statistical parameters like slope, intercept, coefficient of correlation, and sandell's sensitivity were determined and presented in table.2.

Precision

Precision of the method was studied as intra-day inter-day precision. Intra –day precision was determined by analysing the 1, 1.5, 2, 2.5, and 3.µg/ml concentration for three times in same day. Inter-day precision was determined by analysing the same concentration of solution daily for three days. Precision results are shown in table.3.

Accuracy

To assess the accuracy of the proposed method, recovery studies were carried out at the different level i.e, 50%, 100%, and 150%. In which the formulation concentration was kept constant and varied pure drug concentration. Accuracy results were shown in table.4.

Ruggedness

Ruggedness was determined between different analysts. The value of % RSD was found to be less than 2 were shown in table.5.

Limit of detection and limit quantitation

The LOD and LOQ of the present method were calculated based on standard deviation of these response and slope of linear curve. LOD and LOQ values of naproxen sodium were found to be 0.06µg/ml and 0.2µg/ml.

Table 1: Result of calibration curve at 225-235nm AUC spectroscopy method.

SL NO	Concentration in µg/ml	Absorbance ±Standard Deviation*
1	0	0
2	1	0.251±0.001
3	1.5	0.371±0.0032
4	2	0.498±0.0046
5	2.5	0.626±0.00045
6	3	0.741±0.0032

*Average of six determinations.

Table 2: Regression parameter for naproxen sodium by AUC spectroscopy method.

Regression parameter	Results
Range(µg/ml)	1-3
λ_{max}(nm)	225-235
Regression Equation	y = 0.248x + 0.0012
Slope(b)	0.248
Intercept(a)	0.0012
Correlation Coefficient(r^2)	0.9999
Sandell's equation	0.004
Limit of detection(µg/ml)	0.06
Limit of quantification(µg/ml)	0.2

Table 4: Determination of precision results for naproxen sodium at 225-235nm by AUC spectroscopy method.

Concentration (µg/ml)	Intra-day Absorbance ±Standard Deviation*	%RSD**	Inter-day Absorbance ±Standard Deviation*	%RSD**
1	0.245±0.004	1.6	0.245.±0.003	1.2
1.5	0.362±0.002	0.5	0.363±0.0030	0.8
2	0.491±0.0020	0.4	0.493±0.0025	0.5
2.5	0.623±0.0025	0.4	0.625±0.0025	0.3
3	0.733±0.0032	0.4	0.736±0.0051	0.6

*Average of six determination, **percentage relative standard deviation.

Table 4: Determination of Accuracy results for naproxen sodium at 225-235nm by AUC spectroscopy method.

Spiked Level	Amount of Sample (µg/ml)	Amount of Standard (µg/ml)	Amount recovered	%Recovery ±Standard Deviation*	% RSD
50	1	0.5	1.47	97.9º C±0.8544	0.8
100	1	1	2.0	99.9ºC ± 0.7023	0.7
150	1	1.5	2.53	101.5ºC ± 0.984	0.9

*Average of three determinations.

Table 5: Determination of Ruggedness results for naproxen sodium at 225-235nm by AUC spectroscopy method.

Analysts	Analyst 1	Analyst 2
Mean absorbance	0.491	0.494
Standard deviation*	0.0020	0.0035
%RSD**	0.4	0.6

***Average of three determination, **percentage relative standard deviation.

Figures

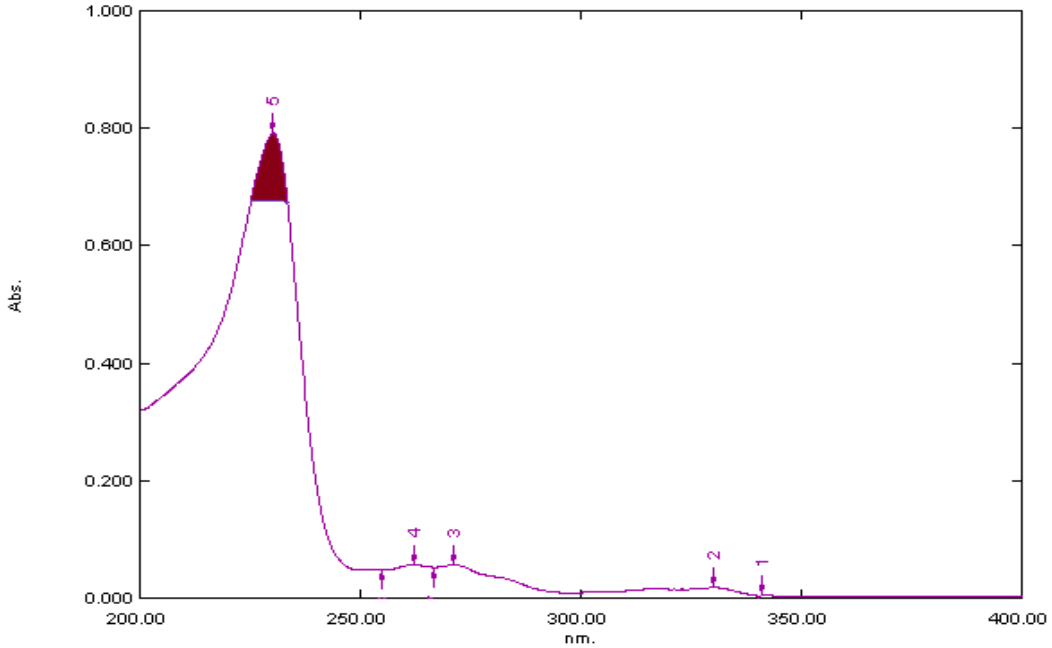

Fig. 2: Zero order spectrum of naproxen sodium at 225-235nm.

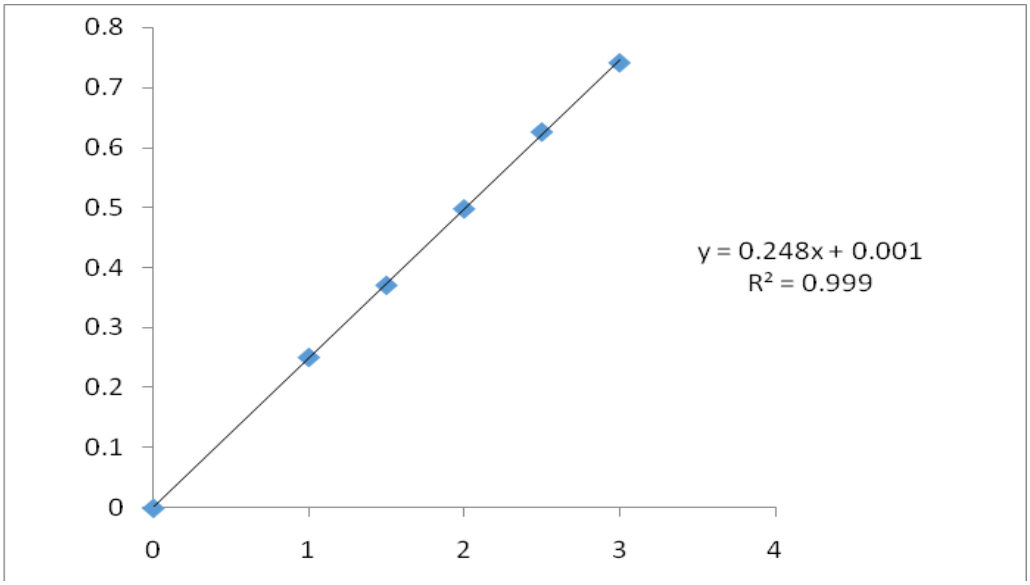

Fig. 3: Calibration curve of naproxen sodium.

CONCLUSION

From the above study it can be concluded that all validation parameters (precision, accuracy, linearity, LOQ, LOD, Ruggedness) met the predetermined acceptance criteria as mentioned in ICH guidelines. The developed spectrophotometric method is simple, rapid, accurate, and precise of naproxen sodium.

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