WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 13, Issue 14, 372-377. Review Article ISSN 2277–7105

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF NAPROXEN USING HPLC

Shah Alam, Prem Prasad and Sanjay Kumar Kushwaha*

Bhavdiya Institute of Pharmaceutical Science and Research Sewar Sohawal Ayodhya (UP).

Article Received on
24 May 2024,

Revised on 14 June 2024,
Accepted on 04 July 2024

DOI: 10.20959/wjpr202414-33183

***Corresponding Author**
Sanjay Kumar Kushwaha
Bhavdiya Institute of Pharmaceutical Science and Research Sewar Sohawal Ayodhya (UP).

ABSTRACT

The nonsteroidal anti-inflammatory medicine (NSAID) is called naproxen. It is mostly used to alleviate pain or inflammation brought on by conditions including ankylosing spondylitis, tendonitis, gout, arthritis, or menstrual cramps. Naproxen comes in separate dosage forms with other comparable anti-inflammatory medications such as ibuprofen, pentoprazole, esomeprazole, ranitidine, sumatriptan and ibuprofen. For the quantification of naproxen in pharmaceutical dosage forms, a straightforward, sensitive, and accurate reversed phase high performance liquid chromatography (RP-HPLC) approach has been devised. Sodium hydroxide was used to modify the pH of dibasic sodium phosphate buffer (Na2HPO4), which was used as the mobile phase in the method's developmenA siand acetonitrile in a ratio of 70:30 (v/v) was placed at room temperature over a C-18 column (250 x 4.6 mm, 5µm, Phenomenex Inc.). The UV detector at 225 nm was used to track the column cleaning process, and the flow rate was set at 0.7 ml/min. The fine, perceptive, and accurate. Naproxen had a retention time of 4.8 ± 0.1 minutes. The recovery was found to be >97%, indicating that the methodology is accurate. The newly developed method's inter-day and intra-day precision fell below the maximum permissible level (RSD% < 2.0) as per ICH, USP, and FDA recommendations. .. The technique produced a linear response with a 0.9991 correlation coefficient (r2). As a result, the technique was discovered to be precise, repeatable, sensitive, and time-efficient, and it can be effectively used for routine analysis of naproxen in pharmaceutical formulas.

KEYWORDS: HPLC validation, and naproxen.

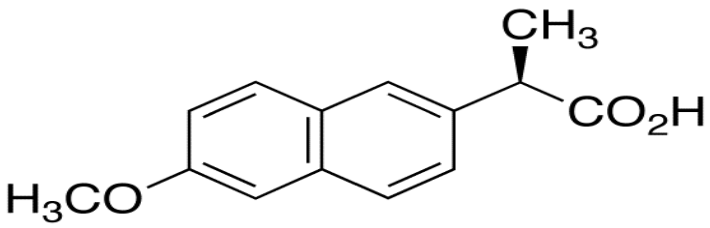
INTRODUCTION

Chemically, naproxen is propanoic acid, or (+)-(S)-2-(6-methoxynaphthalen-2-yl) (Figure 1). It belongs to the NSAID family of 2-arylpropionic acid. The analgesic, anti-inflammatory, and antipyretic effects of naproxen are believed to be mediated through inhibition of prostaglandin synthetase, which reduces the amount of prostaglandins that are synthesised from arachidonic acid. Through the suppression of platelet thromboxane A2, naproxen also prevents platelet.

Aggregation. Patients with ankylosing spondylitis, osteoarthritis, rheumatoid arthritis, bursitis, tendinitis, and acute gout are also treated with naproxen. According to Brunton et al. (2005), it is similar to aspirin and indomethacin in that it controls disease activity while having fewer, milder adverse effects. A review of the literature indicated several analytical techniques for its examination, including UV, LC-MS, HPTLC, and HPLC.

Gondalia and Dharamsi (2010); Shubhangi et al. (2010); Palavai et al. (2011); Haque et al. (2011); Mohideen et al. (2011); Sujana et al. (2012); Pakhuri et al. (2012). Still, There are restrictions on each of these techniques. The majority of the accessible techniques are pricy and complicated. Thus, it would be ideal to design a straightforward and adapted HPLC method for naproxen estimation.

The current study's objectives were to create an easy-to-use and quick RP-HPLC method for measuring naproxen in pharmaceutical preparations and to validate it in accordance with ICH and FDA (Food and Drug). The invention of an RP-HPLC method that is straightforward, fast, accurate, precise, and selective for determining Related Substances of Naproxen in pharmaceutical dosage forms is the subject of the current work.



Chemical structure of naproxen

MATERIALS AND METHODS

Reagent and Chemicals: Aarti Drugs Ltd., Mumbai, India, furnished the working standard of naproxen, which was acquired from Drug International Ltd., Dhaka, Bangladesh. The

buffer, HPLC-grade acetonitrile, and the marketed formulations (tablets each containing 500 mg of naproxen) were bought from the local market.

Instrumentaion: The analysis was conducted using a Shimadzu-UFLC Prominence High Performance Liquid Chromatography system, which was outfitted with an auto sampler (Model: SIL 20AC HT) and a UV-visible detector (Model: SPD 20A). The software LC-solutions was used to record the data.

HPLC

- HPLC stands for high performance liquid chromatography.
- HPLC is a powerful tool in analysis, it yields high performance and high speed compared to traditional columns chromatography because of the forcibly pumped mobile phase
- HPLC chromatographic technique that can separate a mixture of compounds.
- It is used biochemistry and analytical chemistry to identify, quantify and purty of individual component of mixture.
- **Chromatography:** Physical method in which separation of components takes place between two phases a stationary phase and mobile phase.
- **Stationary phase:** The substance on which adsorption of the analyte (The substance to be separated during chromatography) takes place. It can be solid, a gel, or a solid liquid combination
- **Mobile phase:** Solvent which carries the analyte (a liquid or gel).

Method validation

Specificity: To make sure that the excipients included in the pharmaceutical product were not interfering, the specificity of the LC method was assessed. By injecting the excipients and naproxen standard solution, the specificity was investigated.

Linearity: It evaluate the analytical procedure and has the ability to obtain a response with should be directly proportional to concentration of analyte in the given sample.

Five solutions were made, each with a concentration of 10, 20, 30, 40, and 50 µg/ml. Subsequently, the auto-sampler was used to inject 20 µl of each solution, and three repeats of the analyses were conducted while monitoring at 225 nm. Plotting the average peak areas versus the corresponding concentration was done. By calculating coefficient of correlation

and intercept values using calibration curves, the linearity of the suggested approach was assessed.

Range: It is define as the interval between the upper and lower concentration of the analyte in the given sample.

It is used to demonstrate that result can be obtained with in specified limit. Generally it is expressed as % / ppm and ranges from 80-120% / PPM.

Accuracy: The procedure's accuracy is measured by how closely the result produced by the method matches the actual value. The percent recovery (R%) of the analyte recovered by the assay is used to express accuracy. The accuracy of the suggested approach was assessed by performing successive analyses (n = 2) with the proposed method for two different concentrations (11 and 23 µg/ml) of standard naproxen solutions. Therefore, every metric (such as Recovery, Recovery%, Error, and Error%) fell within the predicted range of 95–105% Recovery.

Precision: The assay's precision was evaluated in terms of its repeatability and reproducibility. When an analytical method is used repeatedly to multiple samplings, the precision of the method is defined as the degree of agreement among individual test findings. It was illustrated by investigations of fluctuation within and between days. In the accuracy studies, standard solutions were run three times in a row and three times a day The response factor's percentage of relative standard deviation (%RSD) was computed. The created approach was found to be accurate since the precision studies'%RSD values were less than 2%, in accordance with the recommendations of the ICH. The formula [RSD (%) = (Standard deviation/Mean) x 100%] was used to check it. In the present Using a standard naproxen solution at a single concentration of 5 µg/ml, 15 µg/ml, and 25 µg/ml, the precision of the method development and validation methodology was ascertained.

L.O.D: It is the lowest amount of analyte that can be detected but can not be quantified.

L.O.Q: It is lowest amount of analyte that can be quantified is a sample.

Robustness: It is the ability of analytical procedure to remain unaffected by the small but deliberate variation int the method parameters Like- PH, mobile phase, temperature, instrument, and the Solution.

Sample preparation

Naproxen-containing pharmaceutical dosage forms and a range of medication formulations were among the samples submitted for analysis. Sample preparation was done before analysis in order to extract naproxen from the matrix and eliminate any possible interfering chemicals. To guarantee the precise quantification of naproxen, methods including liquid-liquid extraction (LLE), solid-phase extraction (SPE), or dilution were used.

CONCLUSION

The established RP-HPLC method can be utilised for ordinary bulk naproxen analysis as well as medicinal formulations because it is straightforward, sensitive, precise, and accurate.

ACKNOWLEDGEMENT

I am ecstatic to have finished this summary with the help of my director, Mr. Sanjay Kumar Kushwaha (Professor), and MR. Prem Prasad (Associated Professor), Department of Pharmaceutical Chemistry. I want to thank him for talking about the issue and watching over us all the time.

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