WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
SJIF Impact Factor 6.647
Volume 7, Issue 2, 790-796 Research Article ISSN 2278 – 4357

METHOD DEVELOPMENT AND VALIDATION OF NAPROXEN SODIUM IN PHARMACEUTICAL TABLET DOSAGE FORM BY RP-HPLC

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Article Received on
27 November 2017,
Revised on 18 Dec. 2017,
Accepted on 07 Jan. 2018
DOI: 10.20959/wjpps20182-10823

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ABSTRACT

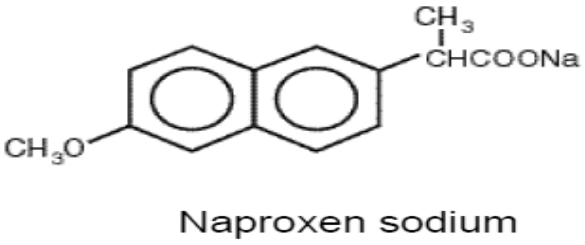
A simple, sensitive, precise and accurate method was developed and validated for naproxen sodium in pharmaceutical tablet dosage form. The method was developed using the mobile phase comprising of methanol and water in the ratio 60:40 (v/v) over C_{18} column (150 x 4.6 mm, 5µm, Waters Inc.). The flow rate was at 1.0 ml/min and UV detection was performed at 238 nm. The retention time was at 2.26 min of a total run time of 10 min. The method showed linear response with correlation coefficient (r^2) value of 0.9983. The method was validated for accuracy, precision, specificity, and robustness, limit of detection and limit of quantitation, in accordance with ICH guidelines. The wide linearity range, sensitivity, accuracy and simple mobile phase showed that the method is suitable for routine analysis of Naproxen sodium in pharmaceutical dosage forms with high precision and accuracy.

KEYWORDS: Naproxen sodium, Validation, RP-HPLC.

INTRODUCTION

Naproxen sodium chemically is (+)-(*S*)-2-(6-methoxy naphthalen-2-yl) propanoic acid sodium (Figure1) is a non-steroidal anti-inflammatory agent with analgesic and antipyretic properties.[1] Both the acid and its sodium salt are used in the treatment of rheumatoid arthritis and other rheumatic or musculoskeletal disorders, dysmenorrhoea, and acute gout, in tablet formulations.[1] It works by blocking body's production of certain natural substances that cause inflammation. Literature survey revealed a few analytical methods like UV[2-3], UPLC[4] and RP-HPLC[5-12] for its analysis, but however these are complex and expensive.

The aim of the present study was to develop a simple, precise, accurate RP-HPLC method using a simple mobile phase combination for analysis of naproxen sodium in pharmaceutical tablet dosage forms and to validate that method according to ICH guidelines.[13]



Naproxen sodium

Figure 1: Structure of Naproxen sodium.

MATERIALS

Naproxen working standard was provided by pharma tech laboratories, ameerpet, telangana, India. All chemicals were of analytical standard. The pharmaceutical tablet dosage form used in this study was naprosynwith a label claim of Naproxen 200mg and were purchased from local pharmacy. High quality HPLC grade milli-Qwater was used.

1. Chromatographic Conditions

Analytical reverse phase C_{18} (Symmetry column, 4.6 x 150mm, 5 µm, Waters Inc.) was equilibrated with the mobile phase consisting of methanol, water in the ratio of 60: 40% (v/v). The flow rate was maintained at 1 ml /min. Eluent were monitored with UV detector at 238 nm and the injection volume was 10µl. Total run time was kept 10 min.

2. Preparation of Stock Solution

Accurately 10 mg of Naproxen sodium was weighed and transferedinto a 10ml clean dry volumetric flask add about 7 ml of mobile phase and sonicate to dissolve it completely and make volume up to the mark with the same solvent.Further pipette 0.3ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with mobile phase.

RESULTS AND DISCUSSION

1. Method development and optimization of chromatographic conditions

a. Linearity

The linearity of an analytical procedure is its ability (within a given range Table 1) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample (figure 2).

Table 1: Regression equation parameters.

Parameter	Naproxen sodium
Linearity Range(µg/ml)	10-50
Correltioncoeffecient	0.99
Slope	504768
Y-intercept	419233

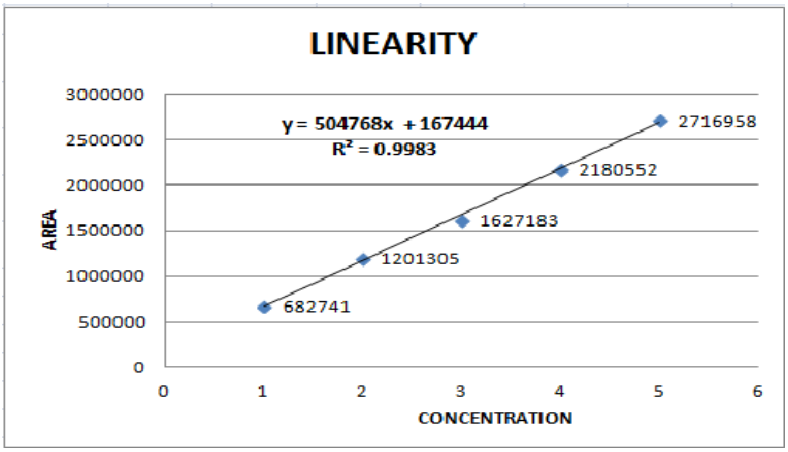


Figure 2: Linearity curve of Naproxen sodium.

Table 2: System Suitability Results.

Parameter	Naproxen sodium
Retention Time (min)	2.26
Theoretical plates	2804.8
Tailing Factor	1.5
Resolution	0.18
% RSD of peak area	0.069
% RSD of retention time	0.16%

b. System Suitability

A standard solution was injected. Peak area responses for five replicate injections of standard solution were recorded and system suitability parameters including retention time, peak area, relative standard deviation, tailing factor, USP theoretical plates were observed **(**Table 2).

c. Specificity

Specificity is the ability to assess unequivocally the target pathogen or analyte in the presence of components which may be expected to be present.

d. Limit of Detection (LOD)

The lowest amount of analyte in sample that can be detected, but not necessarily quantified was determined by comparison of measured signal with 0.02 µg/ml of Naproxen sodium standard solutions with those of blank (mobile phase).

e. Limit of Quantitation (LOQ)

The lowest amount of analyte in the sample that can be determined with acceptable precision and accuracy was determined by the comparison of measured signal with 0.05 µg/ml of Naproxen sodium.

f. Accuracy

The accuracy of the analysis was evaluated by determined of recovery at three different Concentrations equivalent to 50%, 100% and 150% of the amount pre analysed dosage form and average recoveries were calculated (table 3).

Table 3: Accuracy result at 50%, 100% and 150%.

%Concentration (at specification Level)	Area	Amount taken (mg)	Amount recovered(mg)	% Recovery	Mean Recovery
50%	823686.2	5.0	5.0	100.1%	99.5%
100%	1634793	10	9.93	99.3%	
150%	2451939	15.0	14.9	99.3%	

g. Precision

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the homogeneous sample under the prescribed conditions.

a. System precision

The system precision of the test method was performed by injecting 5 replicate standard preparations injections (table 4).

Table 4: System precision study.

Injection	Area
Injection-1	1631295
Injection-2	1630511
Injection-3	1636464
Injection-4	1628557
Injection-5	1635684
Average	1632502.2
Standard Deviation	3420.4
%RSD	0.2%

b. Intermediate Precision/Ruggedness

To evaluate the intermediate precision (also known as Ruggedness) of the method, precision was performed on different day by using different make column of same dimensions (table 5).

a. Robustness

The robustness is a measure of method capacity to remain unaffected by small, deliberate variations in method parameters and provides an indication of method reliability during normal use.

Table 5: Intermediate precision/ Ruggedness.

Injection	Area
Injection-1	1639701
Injection-2	1645897
Injection-3	1640705
Injection-4	1637036
Injection-5	1638609
Average	1640389.4
Standard Deviation	3365.9
%RSD	0.2

b. Effect of flow rate

Robustness of assay method was carried out with variation of flow rate. Standard preparation was prepared and performed analysis as per test method and evaluated the system suitability parameters (table 6).

Table 6: Effect of Flow Rate.

S.No.	Flow Rate (ml/min)	System Suitability Results	
		USP Plate Count	USP Tailing
1	0.8	3353.0	1.5
2	1	2804.8	1.5
3	1.2	2384.0	1.4

c. Effect of Organic Solvent

Robustness of assay method was carried out with variation of Organic Solvent. Standard preparation was prepared and performed analysis as per test method and evaluated the system suitability parameters (table 7).

Table 7: Effect of Organic Solvent.

S.No.	Change in Organic Composition in the Mobile Phase	System Suitability Results	
		USP Plate Count	USP Tailing
1	10% less	2396.0	1.3
2	*Actual	2804.8	1.5
3	10% more	2218.0	1.4

CONCLUSION

Thus, the study concluded that the RP-HPLC method developed was very much suit for routine analysis. Naproxen sodium in tablet formulations and future planning to use this method for estimation Naproxen sodium in clinical trials.

ACKNOWLEDGEMENT

The authors are thankful to Pharma Tech Laboratories, Hyderabad, India and C.L. Baid Metha College of pharmacy, Chennai for all the facilities provided to complete our work.

REFERENCES

1. www.drugbank.com/naproxen.
2. Sunil Singh, Surabhi Sharma, Ajit Kumar Yadav, HemendraGautam. (Simultaneous estimation of naproxen and domperidone using U.V spectrophotometry in tablet dosage form). Bulletin of Pharmaceutical Research., 2013; 3(2): 66-70.
3. Muhammad Hashim Zuberi, Urooj Haroon, Yasmin bibi, Talat Mehmood, Iffat Mehmood. (Optimization of Quantitative Analysis of Naproxin Sodium Using UV Spectrophotometry in Different Solvent Mediums). American Journal of Analytical Chemistry., 2014; 5: 211-214.
4. Kanaka Parvathi K, Vijaya Nagarjan, Shantha Arcot. (Method development and validation for Simultaneous assessment of paracetamol and Naproxen in mixed tablet dosage form by RP-UPLC). World journal of pharmacy and pharmaceutical sciences., 2014; 3(3): 1973-1980.
5. Pakhuri Mehta, Chandra Shekhar Sharma, Deepak Nikam, Ranawat MS. (Development and Validation of Related Substances Method by HPLC for Analysis of Naproxen in Naproxen Tablet Formulations). International Journal of Pharmaceutical Sciences and Drug Research., 2012; 4: 63-69.
6. Akiful Haque S, Hasan Amrohi, Mahesh Nasare, Prashanth Kumar K, Pradeep kumar T, Nivedita G, Prakash V Diwan. (Analytical Method Development and Validation for

theEstimation of Naproxen Using RP-HPLC). IOSR Journal of Pharmacy., 2012; 2(4): 19-24.

7. Anton Smith A, Jasim K, VaraprasadK. (Development and Validation of a Stability-Indicating RP-HPLC Method for Analysis of Naproxen Sodium). International Journal of Chemtech Applications., 2013; 2(4): 40-50.
8. Saleha Tanjin, Farhana Islam, Md. Zakir Sultan, Asma Rahman, Sharmin Reza Chowdhury, Tasnuva Sharmin, Mohammad A. Rashid. (Development and Validation of a Simple RP-HPLC Method for Determination of Naproxen in Pharmaceutical Dosage Forms. Bangladesh Pharmaceutical Journal., 2013; 16(2): 137-141.
9. Vasanth Kumar Kunithala, Uma Rani Rondla, VaruniKollu, DivyajaChatharaju, Sateesh Kumar Vemula. (New RP-HPLC Technique Development and Validation ofEffective and Economical Tool for Quantitative Estimation ofNaproxen in Dosage Forms). Journal of Natural Sciences Research., 2015; 5(7): 85-92.
10. Mohideen S, Shivakanth M, Suresh Kumar P, Navaneetha Krishnan S, Surendranath Y, Satyanarayana T. (Development and validation of analytical method for naproxen and Pantoprazole in capsule dosage form). Pelagia Research Library., 2011; 2(6): 114-121.
11. Palavai Sripal Reddy, Shakil Sait, Gururaj Vasudevmurthya, Badri Vishwanatha, Vure Prasada, Jayapal Reddy S.(Stability indicating simultaneous estimation of assay method for naproxen and esomeprazole in pharmaceutical formulations by RP-HPLC). Der Pharma Chemica., 2011; 3(6): 553-564.
12. Chandra Sekhar E, Senthil Kumar R, Ravi Sankar M, Prasanthi P. (Simultaneous Estimation of Naproxen Sodium and Domperidone Maleate in Bulk and Pharmaceutical Dosage Form by Modified RP-HPLC Method). International journal of pharmaceutical and chemical sciences., 2012; 1(4): 1615-1623.
13. International Conference on Harmonisation (ICH), 2005. Harmonised Tripartite Guideline: Validation of Analytical Procedures: Methodology (Q2B)., 2005.