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Analytical Method Development and Validation for Simultaneous Estimation of Naproxen and Esomeprazole in Pharmaceutical Dosage Forms

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Introduction: An accurate, specific and precise reverse phase UV spectrophotometric method was developed for the simultaneous estimation of Naproxen and Esomeprazole in tablet dosage form. Naproxen and Esomeprazole tablets were used to relieve the spondylitis, osteoarthritis and rheumatoid arthritis in adults' juvenile idiopathic arthritis in children.
Methods: Simple and accurate UV spectroscopic method was developed using Naproxen and Esomeprazole tablet and results were tabulated.
Results and Discussion: The optimum conditions were established for the analysis of the drug. The maximum wavelength of Naproxen (λmax) was found to be 231nm and for Esomeprazole was 301nm respectively. The linearity of the method developed was in the range 10-50 µg/ml for Naproxen and 30-70 µg/ml for Esomeprazole. Calibration curves for Naproxen and Esomeprazole showed a linear relationship among the absorbance and concentration. The line equation observed for Naproxen is Y= 0.0374X + 0.0805 with r^2 of 0.9936 and for Esomeprazole drug was 0.0377 X+0.0576 with R^2 of 0.9962 . Validation parameters were performed as per ICH guidelines for all validation parameters like linearity, accuracy, precision, LOD and LOQ. The results of LOD and LOQ were found to be within the range.
Conclusion: The proposed method for Naproxen and Esomeprazole was simple, yet sensitive and precise for repeated analysis of Naproxen and esomeprazole in bulk and tablet formulations.

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Keywords: UV spectrophotometric; naproxen; esomeprazole.

1. INTRODUCTION

"Naproxen is an NSAID used to treat rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, tendinitis, bursitis, acute gout, primary dysmenorrhea, and mild to moderate pain" [1]. "**Esomeprazole** exerts its stomach acid-suppressing effects by preventing the final step in gastric acid production by covalently binding to sulfhydryl groups of cysteines found on the (H+, K+)-ATPase enzyme at the secretory surface of gastric parietal cells" [2-6]. "**Naproxen** blocks arachidonate binding to competitively inhibit both cyclooxygenase (COX) isoenzymes, COX-1 and COX-2, resulting in analgesic and anti – inflammatory effects. The aim of the present study was to develop simple, sensitive, precise, accurate, quick UV spectroscopic method for estimation of Naproxen and esomeprazole in bulk and tablet dosage forms.This method is simple tobe used for routine analysis in laboratories" [7-10].

2. MATERIALS AND METHODS

2.1 Apparatus

UV double beam spectrophotometer (ELICO) with quartz cells(1CM) were used for all analysis. AR grade methanol and distilled water were used.

2.2 Commercial Formulation

Naproxen and Esomeprazole Tablets were available in the market as VIMOVO .The sample were properly checked for the manufacturing license number, batch number, production, expiry date and store properly [11,12].

2.3 Procedure

2.3.1 Selection of solvent

Solutions of Naproxen and Esomeprazole were prepared using different solvents like chloroform, acetonitrile, buffers, methanol and ultra violet spectrum of each were recorded by scanning between UV range. Better absorbances could be observed for both the drugs when Methanol is selected as solvent [13,14].

2.4 Validation of the Method

Linearity of Naproxen was seen in the range of 10-50µg/ml. The absorbance of Naproxen solutions were recorded at wavelengths 231 and 301 nm for simultaneous estimation. Linearity graphs were recorded using concentration Vs absorbance at wavelength 231 nm and 301nm. The slope, intercept and correlation coefficient values for Naproxen at 231 is found to be 0.0374, 0.0805 and 0.9936 respectively. At wavelength 301nm the slope, intercept and correlation coefficient values are 0.0377, 0.0576 and 0.9962.

3. RESULTS AND DISCUSSION

Esomeprazole is linear at 30-70µg/ml. The absorbance values were observed at 231 and 301nm. Linearity is observed at wavelength 231 nm with slope as 0.080, intercept as 0.001 and correlation coefficient values as 0.999. At wavelength 301 nm the slope was 0.005, intercept as 0.006 and correlation coefficient values was 0.999.

3.1 Precision

Precision studies were performed ad low RSD values indicate that the method is precise. The values are shown in Tables 3 and 4.

3.2 Recovery Studies

In order to ensure the suitability and reliability of proposed method, recovery studies were carried out. To an equivalent quantity of formulation powder (10mg), a known quantity of standard Naproxen sodium and Esomeprazole were added at 80%' 100%and 120% level and the contents analysed by the proposed method. The % recovery and %RSD were calculated as shown in Table 5.

Table 1. Naproxen (Linearity data) at 231nm and 301 nm

S.NO	Concentration(µg/ml)	Absorbance 231nm	Absorbance 301nm
1	10	0.5035	0.5044
2	20	0.9012	0.8232
3	30	1.2151	1.1680
4	40	1.5432	1.5830
5	50	1.9325	1.9234

Table 2. Esomeprazole at 231nm and 301 nm

S. No	Concentration(µg/ml)	Absorbance at 231nm	Absorbance at301nm
1	10	0.6894	0.6754
2	20	0.9231	0.9454
3	30	1.1157	1.1344
4	40	1.3880	1.4054
5	50	1.6230	1.6770

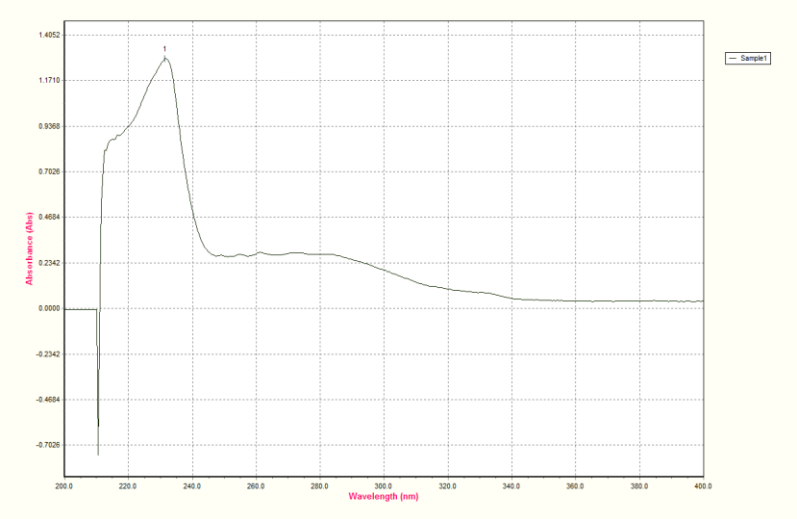

Fig. 1. Naproxen sodium

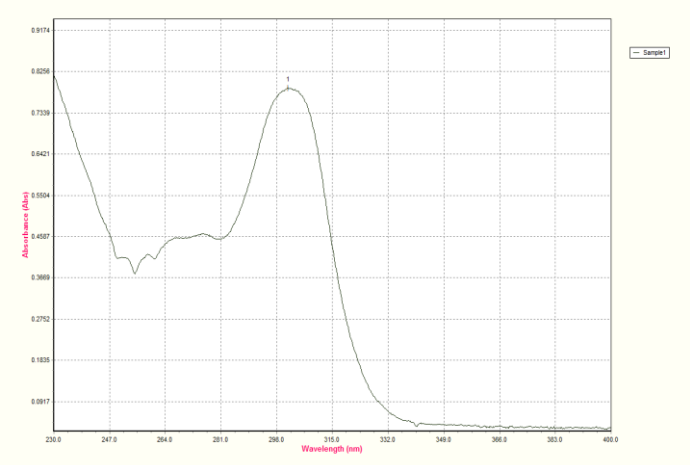

Fig. 2. Esomeprazole

Table 3. Intra day precision studies

Concentration	Absorbance		%RSD	
	Naproxen	Esomeprazole		
	231nm	301nm	231nm	301nm
10ug/ml	1.2753	0.8067	0.51%	0.53%
	1.2770	0.0878		
	1.2780	0.8179		
	1.2798	0.079		

Table 4. Inter day Precision studies

Concentration	Absorbance		%RSD	
	Naproxen	Esomeprazole	231 nm	301 nm
	231nm	301 nm	1.65%	1.56%
10ug/ml	1.2603	0.7970		
	1.2655	0.8023		
	1.2660	0.8125		
	1.2680	0.8127		
	1.2635	0.8036		

Table 5. Recovery studies

Level	%Recovery		%RSD
	Naproxen	Esomeprazole	
80%	103%	99.56%	0.18%
100%	101%	102.5%	0.99%
120%	99.28%	100.2%	0.80%

Table 6. Analysis of naproxen and esomeprazole formulation

Drug	Amount (mg/tab)		% label claim	% RSD*
	Labeled	Found		
Naproxen	375mg	369.6mg	98.66%	0.95%
Esomeprazole	20mg	19.6mg	98.4%	0.80%

**RSD of three observations*

3.3 Analysis of Formulation

3.3.1 Preparation of standard solutions

Standard Naproxen solution was prepared by mixing 10 mg of the drug in methanol and making volume to get the desired concentration. Dilutions ranging from 10-50 µg/ml was prepared for Naproxen. Further 10mg of drug is dissolved in solvent methanol and volume prepared to makeup 10ml. Similarly stock solution from 30-70ug/ml was prepared for Esomeprazole and scanned between 200-400nm.

3.3.2 Preparation of sample solution

Twenty tablets were crushed and powdered in mortal pesser and the average weight was determined. A quantity equivalent to 40 mg of powdereddrug was taken and mixed with Methanol.Working concentration of 10µg/ml was prepared and absorbance was noted at 231nm and 301nm.

4. CONCLUSION

In the present investigation a precise ,sensitive and accurate UV Spectroscopic method was developed for the quantitative estimation of Naproxen and Esomeprazole in bulk drug and pharmaceutical dosage forms.. The results expressed were promising.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Douglas A, Skoog F. James holler & stanley r. crouch. instrumental analysis, India edition. 2007;13-14.

2. Gurdeep R Chatwal, Sham K Anand. Instrumental methods of chemical analysis (Analytical Chemistry). 2.566-2.567.
3. Ahuja S, Dong MW. Handbook of Pharmaceutical Analysis by HPLC. 1st edition, Academic Press Publisher.UK; 2005.
4. Satinder Ahuja, Neil Jespersen. Modern Instrumental Analysis 47 (Comprehensive Analytical Chemistry). 47;7-8.
5. Willard HH, Merrit LL, Dean JA, Settle FA. Instrumental methods of analysis, CBS Publishers and Distributors, New Delhi, 6th edition. 1986;1-15.
6. Douglas A. Skoog, F. James Holler, Timothy A. Nieman. Principles of instrumental analysis, Saunders Golden Sun burst Series, Philadelphia, 2nd edition. 1980;725-760.
7. David G Watson. Pharmaceutical analysis, a text book for pharmacy students and pharmaceutical chemists, Harcourt Publishers Limited, 2nd Edition. 1999;221-232, 267-311.
8. Snyder LR, Kirkland JJ, Joseph LG. Practical HPLC method development, wiley inter science, New York, 2nd Edition. 1997;1-56, 234-289,685-712.
9. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, 4th edition. C.B.S. Publications, Pg. No.53-62.
10. Catherine Datto, Richard Hellmund, Mohd Kashif Siddiqui. Efficacy and tolerability of naproxen/esomeprazole magnesium tablets compared with non-specific NSAIDs and COX-2 inhibitors: a systematic review and network analyses, Open Access Rheumatology: Research and Review. 2013;(5):1–19.
11. Dominick J Angiolillo, Steven M Weisman. Clinical pharmacology and cardiovascular safety of naproxen. American Journal of cardiovascular drugs. 2017;17(2): 97–107.
12. Thomas J Johnson, Dennis D Hedge. Esomeprazole: A clinical review. American Journal of Health-System Pharmacy. 2002; 59(14):1333–1339.
13. Mingxing HOU,[1] Haiqing HU,[2,*] Chunlu JIN,[2] and Xuemei YU. Efficacy and safety of esomeprazole for the treatment of reflux symptoms in patients with gastroesophageal reflux disease: A systematic review and meta-analysis. Iranian journal of public. 2020;49(12): 2264–2274.
14. Olivier Terrier, Sebastien Dilly, Andres Pizzorno, Dominika Chalupska. Antiviral properties of the NSAID drug naproxen targeting the nucleoprotein of SARS-CoV-2 Coronavirus, Molecules, 2021;26(9): 2593.

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