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Research article

Development and validation of RP-HPLC method for simultaneous estimation of Naproxen and Esomeprazole in pharmaceutical dosage form

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Abstract

The objective of the study was to develop a simple, accurate, precise RP-HPLC method for the determination of Esomeprazole and Naproxen using mobile phase (A mixture of Acetonitrile and Methanol in the ratio of 60:40 was considered to be the optimal composition of solvent) as the solvent. The proposed method was involves the measurement of retention time at selected analytical wavelength 260.0 nm was selected as the analytical wavelength. The retention time of Esomeprazole and Naproxen was found to be 3.425 and 4.352. The linearity of the proposed method was in the range of r = 0.9999 for Esomeprazole and r = 0.9999 for Naproxen. The method was statistically validated for its linearity, accuracy and precision of the formulation.

Key words: Esomeprazole, Naproxen, RP-HPLC method.

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1. Introduction

The drug analysis plays an important role in the development, manufacture and therapeutic use of drug. Standard analytical procedure for newer drugs or formulation may not be available in pharmacopoeias, it is essential for the develop a newer analytical methods which are accurate, precise, specific, linear, simple and rapid. Many studies have been reported for the determination of Esomeprazole and Naproxen in Pharmaceutical formulations.

Naproxen is chemically designed as (2S)-2-(6-methoxynaphthalen-2-yl) propanoic acid Naproxen is used as Anti inflammatory and analgesic drug and Esomeprazole is a chemically bis (5-methoxy-2-[(S)-[(4-methoxy-3, 5-dimethyl -2-pyridinyl) methyl] sulfinyl]-1H-benzimidazol-1-yl) a compound that inhibits gastric acid secretion.

Esomeprazole is cost effective in the treatment of gastric esophageal reflux diseases.

Drug Profile
Esomeprazole
Structure

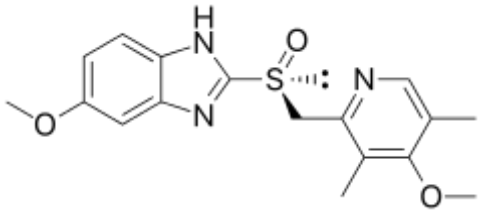

Figure 1. Esomeprazole

Naproxen
Structure

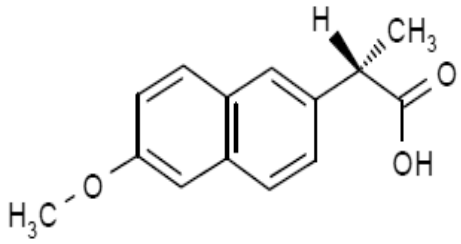

Figure 2. Naproxen

2. Materials and Methods

Chemicals and reagents: The working standards of Esomeprazole and Naproxen were gifted from Pharma Tech labs, Hyderabad. Acetonitrile and Methanol (HPLC grade) were obtained from E. Merck Ltd Mumbai, India.

Instrument used: A Shimadzu VP series, pH meter Adwa – AD 1020.

Preparation of standard solution: Esomeprazole 100 mg and 100mg Naproxen were weighed separately and transferred in two different volumetric flasks. Both the drugs were dissolved in 50 ml of mobile phase by ultra-sonication and then volume was made up to the mark with mobile phase to obtain final concentration of 1000 µg/ml of each component.

Preparation of Mobile phase: Mobile phase was prepared by mixing 600 ml of the HPLC grade Acetonitrile with 400 ml of the HPLC grade and Methanol, filtered through 0.4 µm membrane filter paper and ultrasonicated for 20 min for mobile phase preparation.

Chromatographic condition: In the mobile phase containing Methanol and Acetonitrile whose ratio was 40:60 was selected as the optimum composition of mobile phase. The flow rate was set to 1.0 ml/min and UV detection was carried out at 260 nm.

Preparation of calibration curves: Dilutions prepared separately and 20 µl of each was injected into the HPLC system and their chromatograms were recorded. Peak areas were recorded for all the peaks and a standard calibration curve of area under the curve against concentration was plotted.

Selection of analytical concentration: The standard solution pipetted out into a series of 10 ml vol. flasks. The volume was made up to the mark with the mobile phase and the concentration range, ranging from 4-20µg/ml Naproxen and 10-50µg/ml of Esomeprazole respectively.

Analysis of tablet formulation: Twenty tablets of average weight of Esomeprazole and Naproxen weighed. The tablets were then crushed to fine powder and powder equivalent to 100 mg of Esomeprazole and 40 mg of Naproxen was weighed and transferred to 100 ml vol. flask (mobile phase). The contents were ultrasonicated for 20 minutes.

Method validation: The proposed method has been extensively validated in terms of

specificity, accuracy, precision, linearity, LOD, LOQ, robustness, and system suitability. The accuracy was expressed in terms of percent recovery of the known amount of the standard drugs added to the known amount of the pharmaceutical dosage forms. The precision (%RSD) was expressed with respect to the repeatability. After validation, the developed methods have been applied to pharmaceutical dosage form.

3. Results and discussion

The present study is of simultaneous estimation of Esomeprazole and Naproxen by RP- HPLC method of pharmaceutical dosage form. The linearity of the proposed method was established by least square regression analysis of the calibration curve and the constructed calibration curves were linear and concentration range of 10-50 µg/ml for Esomeprazole (r = 0.9999) and 4-20 µg/ml Naproxen (r = 0.9999).

The robustness was evaluated by analyzing the samples by varying few parameters like wavelength and flow rate. The validation results obtained confirm the suitability of the proposed RP-HPLC method for simple, accurate and precise analysis of Esomeprazole and Naproxen in pharmaceutical preparations.

Table 1. Validation, parameters of Esomeprazole and Naproxen.

Parameters	Esomeprazole	Naproxen
Linear range (µg/ml)	10-50	4-20
Slope	49585	10114
Regression coefficient (r^2)	0.9999	0.9999
Limit of Detection (LOD)(µg/ml)	0.0386	0.1171
Limit of Quantification (LOQ) (µg/ml)	0.0216	0.0656
Retention time (min)	3.425	4.352
Tailing factor	1.269	1.283

Conclusion

In this present study, an attempt was made to develop an analytical method for the simultaneous estimation of Esomeprazole and Naproxen in tablet dosage form, which is simple and fast. The method gives good resolution between the compounds with a short analysis time. The method was validated to simple, accurate and precise. So the developed method can be used conveniently for analysis of esomeprazole and naproxen in pharmaceutical dosage forms.

Therefore, it was concluded that the proposed method could be used for routine analysis of Esomeprazole and Naproxen in its tablet dosage form.

References

1. Skoog D.A., Holler F.J., Nieman T.A.: Principles of Instrumental Analysis 5th edition, 2005; 733-738.
2. Beckett HA and Stenlake BJ: Practical Pharmaceutical chemistry. CBS Publishers. New Delhi; 4th edition 2003; 168-9.
3. British Pharmacopoeia: Convention Inc., Rockville, 2008.Vol.I; 965-966.

4. Sharma BK: Instrumental methods of chemical analysis. Goel Publishers; Meerut, 3rd edition 2005; 861-76.
5. Gennaro, A.R., Remington. The science and practice of pharmacy, 28th edition, Luppincott, Williams and Wilkins, Baltimore, Maryland, USA, 2000; 534 - 549.
6. Ghulam A. Shabir: HPLC Method Development and Validation for Pharmaceutical Analysis 2004; 25-27.
7. International Conference on Harmonization : ICH Q 2 (R1) Validation of Analytical Procedure, Text and Methodology 1995.
8. British Pharmacopoeia, Stationary office on behalf of Medicine and Healthcare Products Regulatory agency, London UK 13th Edn 2007; (1):373.
9. The United State Pharmacopoeia. United States Pharmacopoeial Convention Inc. Washington DC, 31st Ed, 2008, Vol. III 2760.
10. Yerragunta V, Patil P, V. Anusha, T. Kumara Swamy, D. Suman, T. Samhitha: Pyrimidine and Its Biological Activity: A Review. Pharma Tutor 2013; 1(2):39-44.
11. Chandrakant sojitra and Sadhana rajput: development and validation of rp-hplc methods for simultaneous estimationof naproxen and esomeprazole magnesium trihydrate in combined pharmaceutical formulation. International Journal of Pharmacy and Pharmaceutical Sciences 2012; 4(3):533-537.
12. Akiful haque, S.Hasan Amrohi, Mahesh Nasare, Prashanth Kumar. K, Pradeep Kumar.T, Nivedita. G and Prakash V Diwan: analytical method development and validation for the estimation of naproxen using rp-hplc. IOSR Journal Of Pharmacy 2012; 4(2):19-24.
13. Validation of analytical procedure: methodology Q2B, ICH Harmonized Tripartite Guidelines 1996; 1-8.