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Research Article

DEVELOPMENT AND VALIDATION OF REVERSED-PHASE HIGH PERFORMANCE LIQUID CHROMATOGRAPHIC METHOD FOR SIMULTANIOUS ESTIMATION OF SUMATRIPTAN SUCCINATE AND NAPROXEN SODIUM IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A simple reversed-phase liquid chromatographic method was developed and validated for determination of sumatriptan succinate (SUMA) and naproxen sodium (NAP) in tablet dosage form. The analysis was performed at ambient temperature on a reversed-phase C18 column with detection at 277 nm. The mobile phase consisting of ACN: Water (60:40) and 0.05% v/v trifluro acetic acid was added in water at a constant flow rate of 1.0 ml/min. The method was validated for accuracy, precision, linearity and specificity. The linearity was found to be in the range of 05-80 ppm. The % recoveries were found between the ranges of 98.0% to 102.0% to the labeled value. The proposed method was successfully applied for the routine quantitative analysis of tablets containing SUMA and NAP.

Keywords: Sumatriptan succinate, Naproxen sodium, HPLC.

INTRODUCTION

Sumatriptan succinate (Fig. 1) is chemically 3-[2-(dimethylamino) ethyl]-N-methyl-indole-5-methanesulfonamide succinate. Sumatriptan succinate is official in British pharmacopoeia [1], European Pharmacopoeia [2] and United States Pharmacopoeia [3]. It is a selective 5-hydroxytryptamine receptor subtype agonist and used as anti migraine drug. SUMA is a selective agonist of vascular serotonin ((5-hydroxytryptamine; 5-HT) type 1-like receptors, likely the 5-HT1D and 5-HT1B subtypes [4].

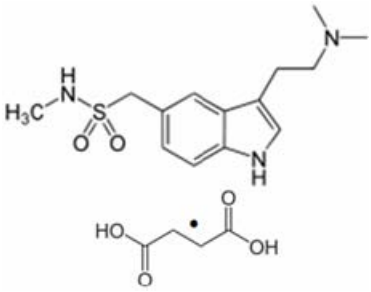

Fig. 1: Sumatriptan succinate

A literature survey regarding quantitative analysis of SUMA revealed that attempts were made to develop analytical methods for SUMA in combination with ergotamine tartrate by HPLC [5] sumatriptan by HPTLC [6] and visible spectrophotometry [7].

Naproxen sodium is (Fig. 2) is chemically (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid, sodium salt. NAP is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic properties. Both the acid and its sodium salt are used in the treatment of rheumatoid arthritis and other rheumatic or musculoskeletal disorders [8].

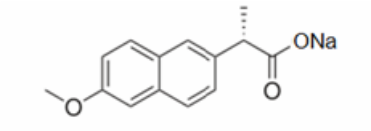

Fig. 2: Naproxen sodium

A literature survey regarding quantitative analysis of NAP revealed that attempts were made to develop analytical methods for NAP in combination with other drugs or single by HPLC [9-11] and capillary electrophoresis [12].

In this study, reversed-phase high performance liquid chromatographic method has been developed for determination of SUMA and NAP in bulk as well as commercial tablet dosage forms. The results obtained were validated according to the ICH guidelines.

MATERIALS AND METHODS

Chromatographic conditions

The HPLC system consisted of a Young Lin 9101 vaccum degasser, a Young Lin 9001 quaternary pump and a Young Lin 9160 PDA detector (Seoul, South Korea). An YL-clarity chromatography data system was used to record and evaluate the data collected during and following chromatographic analysis. The chromatographic separation was achieved on a Purospher® 5µm, 250mm X 4.6mm column.

The mobile phase consisting of ACN: Water (60:40) and 0.05% v/v trifluro acetic acid was added in water, pumped at a constant flow rate of 1.0 ml/min. The eluent was monitored using PDA detector at a wavelength of 277 nm.

The column was maintained at room temperature and injection volume of 20µl was used. The mobile phase was filtered through 0.45µm Chrom Tech Nylon-66 filter to use.

Ultra sonic cleaner (Life care equipment pvt. Ltd.)

Reagents

Sumatriptan succinate was kindly provided as gift sample by Astron Pharmaceuticals, Ahmedabad.

Naproxen sodium was kindly provided by Zydus research centre, Ahmedabad.

Commercially available Suminat 50 tablets were purchased from local market, India.

Acetonitrile (ACN) and water [HPLC grade] were purchased from the Merck [India].

Preparation of standard solution and calibration graphs

The stock solutions of SUMA and NAP were prepared by dissolving accurately weighed 25 mg of each drugs, transferred to 25 ml volumetric flask, dissolved and made up to the volume using mobile phase. Then appropriate dilutions were made to adjust the final concentration 5, 10, 20, 40, 80 ppm. The results of calibration curve and system suitability parameters are shown in table 1.

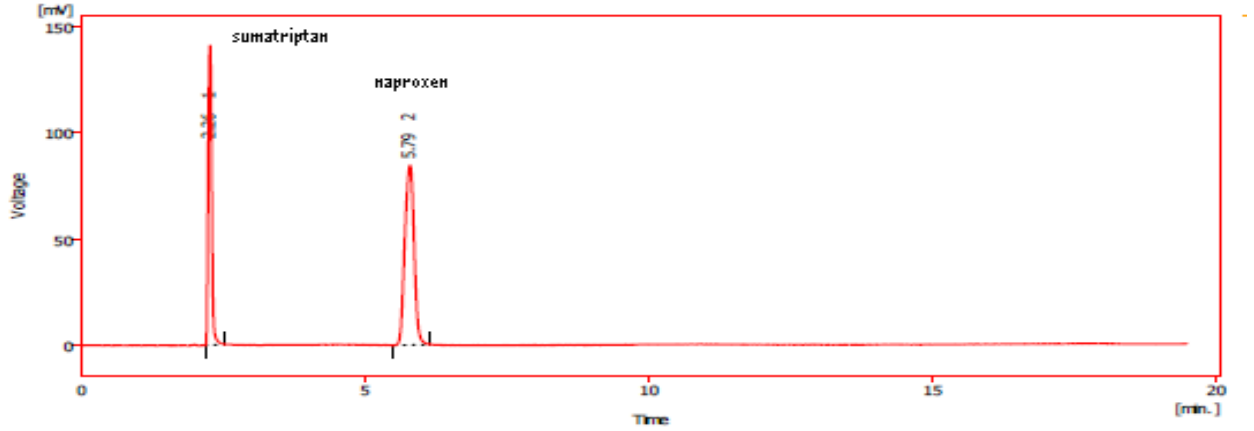

Fig. 3: Chromatogram of Sumatriptan succinate and Naproxen sodium (40 ppm)

Table 1: Data from standard curve of SUM and NAP by RP-HPLC method

Parameters	SUMA	NAP
Linear Range (µg/ml)	5-80 µg/ml	5-80 µg/ml
Slope	13.782	21.382
Intercept	48.503	90.243
Linear equation	y = 13.782x +48.503	y = 21.382x +90.243
R^2 value	0.9994	0.9995
Retention time	2.26	5.79
Tailing factor	1.21	0.91
Theoretical plate	9341	4051

Preparation of sample solution

For the estimation of drugs in Suminat plus tablets, twenty tablets were accurately weighed, crushed and powdered in a glass mortar. The tablet powder equivalent to 50 mg for SUMA and 275 mg for NAP was transferred accurately to a 100 ml volumetric flask and diluted to volume with mobile phase. The solution was further diluted to obtain concentration of 5 ppm of SUMA and 27.5 ppm of NAP. The results are shown in table 2.

Table 2: Application of the proposed method to the pharmaceutical dosage forms

Assay	Amount Labeled (ppm)	Amount found (ppm)	% Amount found S.D. (n=3)
Sumatriptan succinate	5.0	4.97	99.40 ± 1.31
Naproxen sodium	27.5	27.56	100.21± 0.92

Method validation [13]

The developed method was validated for parameters like accuracy, precision, linearity and range, LOD, LOQ, ruggedness and specificity etc, according to the ICH guidelines. The data for which are presented in the table 3.

Accuracy

Accuracy was determined by adding the three different quantities [Low, Medium, and High] of the standard sample to the sample solution containing the concentration of 5 µg/ml of SUMA and 27.5µg/ml of NAP.

Repetability

Repeatability was determined on 6 replicate of each concentration of the standard solution.

Precision

Precision was determined by performing Intra day and Inter day determination concentration on three different concentrations.

Limit of Detection and Limit of Quantification

The limit of Detection (LOD) and limit of Quantification (LOQ) were determined according to the ICH guidelines.

Where detection limit DL = $\frac{3.3\sigma}{S}$ and quantitation limit QL = $\frac{10\sigma}{S}$

Where σ = standard deviation of y-intercepts of regression lines

S = the slope of the calibration curve

Table 3: Summary of Validation Parameter

Validation parameter	SUMA	NAP
Recovery (%)	98.56-101.50	98.88-100.16
Repeatability (RSD, n=6)	0.7359-1.6592	0.6360-1.3267
Precision range (CV)		

Intra-day (n=3)	0.7816-1.0721	0.4629-1.1258
Inter-day (n=3)	1.0279-1.7662	0.9720-0.1857
Limit of detection (µg/ml)	0.67	0.25
Limit of quantification (µg/ml)	2.03	0.77

RESULTS AND DISCUSSIONS

The reversed-phase LC method described in this paper was developed for determination of SUMA and NAP in tablet dosage form. The method was validated according to ICH guidelines.

The linearity of the peak response versus concentration were studied from 5 to 80 µg/ml. The representative linear equation were y = 13.782x +48.503 and y = 21.382x +90.243, the correlation coefficient (r) were 0.9994 and 0.9995 for SUMA and NAP respectively.

Recovery study was performed and found in range of 98.56-101.50 and 98.88-100.16, the repeatability is usually expressed as the %RSD and it was found to be 0.7359-1.6592 and 0.6360-1.3267 for SUMA and NAP respectively.

An economic, simple and rapid RP-LC method has been developed for determination of SUMA and NAP in tablet dosage forms. The proposed method is simple, accurate and precise for the quantification in tablet dosage form as well as bulk drugs for routine analysis.

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