RESEARCH ARTICLE

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DEVELOPMENT AND VALIDATION OF SPECTROPHOTOMETRIC METHOD FOR SIMULTANEOUS ESTIMATION OF SUMATRIPTAN SUCCINATE AND NAPROXEN SODIUM IN PHARMACEUTICAL DOSAGE FORM

Sagar D. Solanki[*1], Dr. Paresh U. Patel[2], Dr. Bhanu bhai N. Suhagiya[3]
[*1]K.B.Raval College of Pharmacy, Sertha- 382324, Gandhinagar, Gujarat, India.
[2]S.K.Patel College of Pharmacy, Kherva- 382711, Gujarat, India.
[3]L.M.College of Pharmacy, Ahmedabad- 380009, Gujarat, India.

ABSTRACT

A simple UV-Visible Spectrophotometric method was developed for the simultaneous determination of Sumatriptan succinate (SUMA) and Naproxen sodium (NAP) in tablet dosage form. The First order derivative method was developed. In this method the zero crossing point of SUMA was selected at 329.8 nm and for NAP was 297.6 nm. The method was validated for accuracy, precision, linearity and specificity. The linearity was found to be in the range of 3-18 ppm for both the drugs. The % recoveries were found in the range of 98.0% to 102.0% of the labeled value for both SUMA and NAP. The proposed method was successfully applied for the routine quantitative analysis of tablets containing SUMA and NAP.

Key words: Sumatriptan succinate, Naproxen sodium, UV-Visible Spectrophotometric method

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*Corresponding author.
K.B.Raval College of Pharmacy, Sertha- 382324, Gandhinagar, Gujarat, India.

E-mail address: sagarrx@yahoo.co.in

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INTRODUCTION

Sumatriptan succinate (SUMA) is chemically 3-[2-(dimethylamino) ethyl]-N-methyl-indole-5-methanesulfonamide succinate (Fig:1).

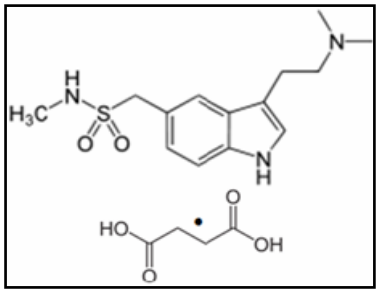

Figure 1 Sumatriptan succinate

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 antimigraine 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].

Naproxen sodium is (NAP) is chemically (S)-6-methoxy -α- methyl-2- naphthaleneacetic acid, sodium salt. (Fig 2). 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 [5].

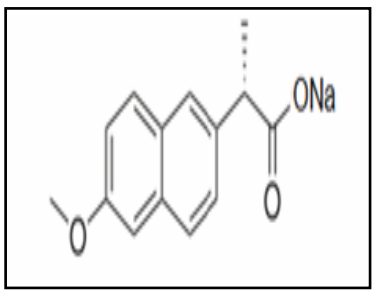

Figure 2 Naproxen sodium

A literature survey regarding quantitative analysis of these drugs revealed that attempts were made to develop analytical methods for SUMA by HPLC[6,7], HPTLC[8], visible spectrophotometry[9] and for NAP in combination with other drugs or single by HPLC [10-12], capillary electrophorsis[13].

In this study, UV-Visible Spectrophotometric method has been developed for determination of Sumatriptan succinate and Naproxen sodium and applied to commercial tablet dosage forms. The results obtained were validated according to the ICH guidelines.

MATERIALS AND METHODS

Materials

Shimadzu UV-1800 UV-VIS Spectrophotometer was used with 1 cm matches quartz cell, Analytical balance (Shimadzu-AUX220) Ultra sonic cleaner (Life Care Equipment Pvt. Ltd.) Sumatriptan succinate was kindly provided by Astron Pharmaceuticals, Ahmedabad. Naproxen sodium was kindly provided by Zydus research centre, Ahmedabad. Commercially available Suminat plus tablets (containing 50 mg SUMA and 275 mg NAP) were obtained from Unimed Technologies Ltd., India. Methanol of analytical reagent grade was purchased from Merck (India).

Methods

First order derivative spectroscopy method [14,15]: The stock solutions of SUMA and NAP were prepared separately by dissolving accurately weighed 25 mg of the drug, transferred to 25 ml volumetric flask, dissolved and made up to the volume by using methanol as solvent. Then appropriate dilutions were made to adjust the final concentration 3, 6, 9, 12, 15, 18 ppm for both the drugs. Each solution of SUM and NAP were scanned in the wavelength range of 400 to 200 nm to obtain overlain spectra then it was converted to first order derivative spectra (Fig 3). In this method, 297.6 nm was selected for the determination of SUMA, which is the zero crossing point of NAP and 329.8 nm, the zero crossing point of SUMA, was selected for the determination of NAP.

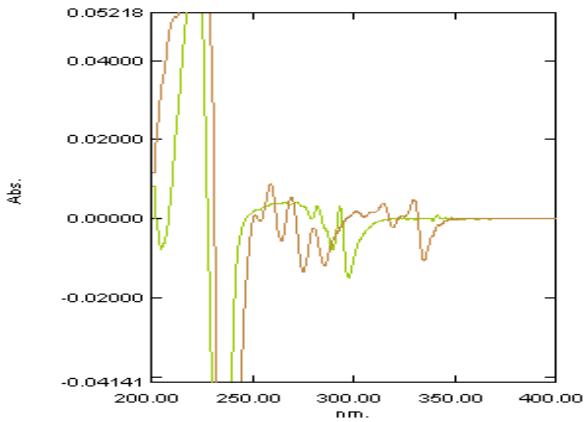

Figure 3 First derivative overlain spectra of SUMA and NAP

Preparation of sample solution: For the estimation of drugs in Suminat plus tablets, 10 tablets were accurately weighed, crushed and powdered in a glass mortar. The tablet powder equivalent to 50 mg SUMA and 275 mg NAP was transferred accurately to a 50 ml volumetric flask and diluted to volume with methanol. The solution was further diluted to obtain concentration of 3 ppm and 16.5 ppm of SUMA and NAP respectively.

Method validation[16]: The developed methods were validated for parameters like accuracy, precision, linearity and specificity etc, according to the ICH guidelines. The data for which were presented in the Tables 1 to 3.

Assay: The developed methods after validation were applied to the estimation of SUMA and NAP

in tablet dosage forms available commercially. The results of the study were presented in Table-3.

Table 1 Data from standard curve of SUMA and NAP

No.	Parameters	Sumatriptan succinate	Naproxen sodium
1	Linear Range (μg/ml)	3-18 μg/ml	3-18 μg/ml
2	Slope	-0.0019	0.0006
3	Intercept	0.0014	-0.0003
4	R^2 value	0.9909	0.9976

Table 2 Validation parameters for Sumatriptan succinate and Naproxen sodium

Sr. No.	Validation parameter	Sumatriptan succinate	Naproxen sodium
1	Recovery (%)	98.50-101.66	99.90-101.74
2	Repeatability (RSD, n=6)	(-1.10186)-(-1.83613)	1.23184-1.80993
3	Precision Range(CV)		
	Intra-day (n=3)	(-0.58546)-(-1.55027)	0.78988-1.00495
	Inter-day (n=3)	(-1.61542)-(-1.87848)	1.26956-1.84621
4	Limit of Detection (μg/ml)	0.31	0.24
5	Limit of Quantification (μg/ml)	0.94	0.74

Table 3 Assay results of Market formulation

Sr No	Assay	Actual concentration (μg/ml)	Percentage (%)
1	Sumatriptan succinate	3.0	101.33
2	Naproxen sodium	16.5	98.96

RESULTS

The First order derivative method described in this paper was developed for simultaneous determination of SUMA and NAP in tablet dosage form. The method was validated according to ICH guidelines.

The wavelengths selected for analysis were 329.8 nm for SUMA and for NAP 297.6. The linearity of the absorbance versus concentration was studied from 3 to 18 μg/ml for both drugs (Table-1). Recovery study was found in range of 98.50%-101.66% for SUMA and 99.90%-101.74% for NAP. The precision is usually expressed as the %RSD and it was found to be (-1.10186)-(-1.83613) for SUMA and 1.23184-1.80993 for NAP. The Inter-day and intra-day precision were (-1.61542)-(-1.87848) and (-0.58546)-(-1.55027) respectively for SUMA and Inter-day and intra-day precision 1.26956-1.84621 and 0.78988-1.00495 for NAP repectively (Table-2). Actual concentration of SUMA and NAP in tablet dosage form was 3 μg/ml and 16.5 μg/ml respectively (Table 3).

CONCLUSION

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

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