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Development and validation of spectrophotometric method for simultaneous estimation of Sumatriptan and Naproxen sodium in tablet dosage form

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ABSTRACT

Sumatriptan and Naproxen sodium in combined dosage form is used for the treatment of Migraine. Two new simple UV spectrophotometric methods have been developed and validated for the simultaneous determination of Sumatriptan (SUM) and Naproxen sodium (NAP) in their combined dosage forms. First method is Q Absorption Ratio Method using two wavelengths, 272 nm (λ_{max} of NAP) and 284 nm (Isoabsorptive point). The second method is the First order derivative technique. In this method the zero crossing point of Naproxen sodium was selected at 298 nm and for Sumatriptan it was 335 nm. The solvent used was methanol in both the above mentioned methods. The linearity range for Q Absorption Ratio was 10- 90 µg/mL and for derivative method it was 20-190 µg/mL. All methods were validated statistically and recovery studies were carried out. All methods were found to be accurate, precise and reproducible. These methods were applied to the assay of the drugs in marketed formulation, which were found in the range of 98.0% to 102.0% of the labeled value for both Sumatriptan and Naproxen sodium. Hence, the methods herein described can be successfully applied in quality control of combined pharmaceutical dosage forms.

Key words: Sumatriptan, Naproxen sodium, UV-Spectrophotometric.

INTRODUCTION

Sumatriptan 1-[3-(2-dimethylaminoethyl)-1H-indol-5-yl]-N-methyl-methane sulfonamide is a triptan drug including a sulfonamide group for the treatment of migrane headaches[1]. Naproxen sodium is (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid, sodium salt. Naproxen has analgesic and antipyretic properties. Literature survey reveals few analytical methods for

estimation of naproxen sodium with other drug combinations like psuedoephedrine hydrochloride by HPLC. [2]

A detailed survey of analytical literature reveal that there is no UV spectrophotometric study on Sumatriptan and Naproxen sodium in combined dosage form in pharmaceutical preparations. In this study, UV spectrophotometric method has been developed for determination of Sumatriptan and Naproxen sodium and applied to commercial tablet dosage forms. The results obtained were validated as per the ICH guidelines.

MATERIALS AND METHODS

Spectral runs were made on a Perkin Elmer UV-Visible spectrophotometer, model- Lambda - 25 was employed with spectral bandwidth of 0.5 nm and wavelength accuracy of ± 0.3 nm with automatic wavelength corrections with a pair of 10 mm quartz cells. Glassware's used in each procedure were rinsed thoroughly with double distilled water and methanol, dried in hot air oven.

Sumatriptan reference standard and Naproxen sodium reference standard were kindly provided by NATCO Pharma. Ltd. Hyderabad. The pharmaceutical preparations of combination of Sumatriptan and naproxen sodium that is SUMINAT PLUS (Unimed Technologies Ltd. India.) were obtained from local market. Methanol of analytical reagent grade was purchased by Loba Chemie (India).

Q Absorption Ratio Method [3-5]

This method is applicable to the drugs that obey Beer's law at all wavelengths and the ratio of absorbance's at any two wavelengths is a constant value, independent of concentration or path length. The solutions of 10 µg/mL each of SUM and NAP were scanned in the wavelength range of 400 to 200 nm to obtain overlain spectra (figure-2). Two wavelengths, 284 nm (Isoabsorptive point) and 272 nm (λ_{max} of NAP) were selected for the formation of Q-absorbance equation. The calibration curves were determined in the concentration range of 10-90 µg/mL and 10-60 µg/mL, for SUM and NAP drugs respectively. The absorptivity co-efficient of each drug at both the wavelengths were determined. The concentration of individual components, C_{NAP} and C_{SUM} may be calculated using the following equations.

$C_{NAP} = (Q_m – Q_{SUM} / Q_{NAP} – Q_{SUM}) * A_1/ax_1$ …….. (1)
$C_{SUM} = (Q_m – Q_{NAP} / Q_{NAP} – Q_{SUM}) * A_1/ay_1$ …….. (2)
$Q_m = A_2 / A_1$……..(3)
$Q_{NAP} = ax_2 / ax_1$ & $QSUM = ay_2/ay_1$……..…….. (4)

where, A_1 and A_2 are absorbance of sample solution at Isoabsorptive point (284 nm) and λ_{max} of NAP (272 nm) respectively; ax_1 and ax_2 are the absorptivities of NAP at 284 and 272 nm respectively and ay_1 and ay_2 are the absorptivities of SUM at the two wavelengths respectively.

Preparation of test solution

Weigh and powder 20 tablets. Weigh accurately a quantity of the powder equivalent to about 50 mg of Sumatriptan and 275 mg of Naproxen sodium into 100 mL volumetric flask and diluted to 100 mL with methanol. This solution is sonicated for 20 minutes. The solution was filtered

through whatman filter paper no. 41. Transfer 1 mL of solution into 50 mL volumetric flask and dilute to the mark with methanol to get a final concentration 10 µg/mL of Sumatriptan and 55 µg/mL of Naproxen sodium.

First derivative spectroscopy method [3-5]
First derivative spectroscopy on the basis of zero-crossing measurements involves measurement of the absolute value of the total derivative spectrum at an abscissa value corresponding to the zero-crossing wavelength of the derivative spectrum of another component. The solutions of 20 µg/mL each of SUM and NAP were scanned in the wavelength range of 400 to 200 nm to obtain overlain spectra. In this method, 298 nm was selected for the determination of SUM, which is the zero crossing point of NAP and 335 nm, the zero crossing point of SUM, was selected for the determination of NAP. First-derivative technique (D_1) traced with $\Delta\lambda$= 2 nm was used to resolve the spectral overlapping. The calibration curves were checked for linearity and linear behavior was observed in the concentration range of 20-190 µg/mL, for each of the drugs.

Preparation of test solution
Weigh and powder 20 tablets. Weigh accurately a quantity of the powder equivalent to about 50 mg of Sumatriptan and 275 mg of Naproxen sodium into 100 mL volumetric flask and diluted to 100 mL with methanol. This solution is sonicated for 20 minutes. The solution was filtered through whatman filter paper no. 41. Transfer 1 mL of solution into 25 mL volumetric flask and dilute to the mark with methanol to get a final concentration 20 µg/mL of Sumatriptan and 110 µg/mL of Naproxen sodium.

Method validation [6]
All the methods were validated as per ICH guidelines for parameters like Linearity, Accuracy and Precision. The accuracy studies were carried out at different concentrations by spiking a known concentration of standard drug to the pre-analyzed sample and contents were reanalyzed by the developed method. Precision was studied by analyzing six replicates of sample solutions. Intraday and interday precision was determined in a similar manner on the next day using a different instrument.

RESULTS AND DISCUSSION

Q - Absorption ratio Method
As shown in figure-1, the overlain spectra of both drugs (20 µg/mL of each drug) show a reproducible Isoabsorptive point at 284 nm. Thus estimation of drugs by Q-absorbance ratio equation method was carried out at 284 nm (Isoabsorptive point) and 272 nm (λ_{max} of NAP). The standard solutions of SUM and NAP were prepared to determine the absorptivity values of the subject analyte at the two selected wavelengths. The method showed good linearity in the concentration range of 10-90 µg/mL and 10-60 µg/mL, for SUM and NAP drugs. The absorptivity values of SUM were found to be 128.1 and 108.0 at the wavelengths of 284 nm and 272 nm respectively and similarly the absorptivity values of NAP were found to be 130.75 and 247.0 at the wavelengths of 284 nm and 272 nm respectively.

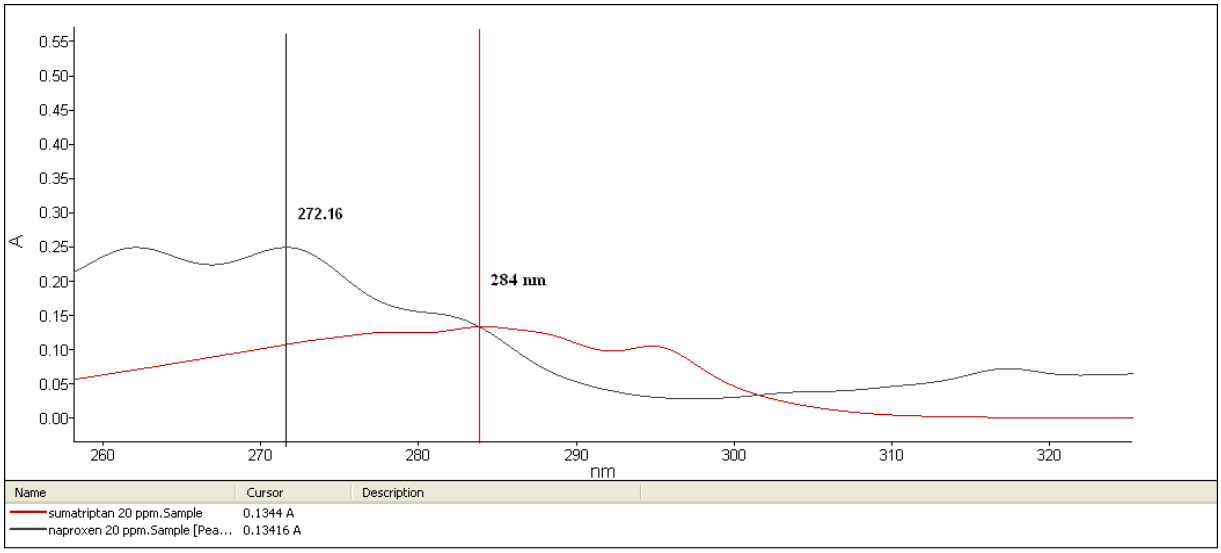

Fig. 1: Overlain spectra of 10 µg/mL of SUM and NAP

First derivative spectroscopy method

In this method, the absorption spectra of standard solutions of SUM and NAP were recorded in the range of 200 nm to 400 nm. The 1st derivative spectra, obtained were traced with smoothing at Δλ=2 nm for determining zero cross points for both the drugs as shown in figure-2. It was found that the 1st derivative spectrum of NAP crosses zero point at 298 nm and that of SUM crosses zero point at 335 nm. The amplitudes at 298 nm were plotted against the respective concentrations of SUM and the amplitudes at 335 nm were plotted against the respective concentrations of NAP. The method showed good linearity in the range of 20-190 µg/mL for both the drugs.

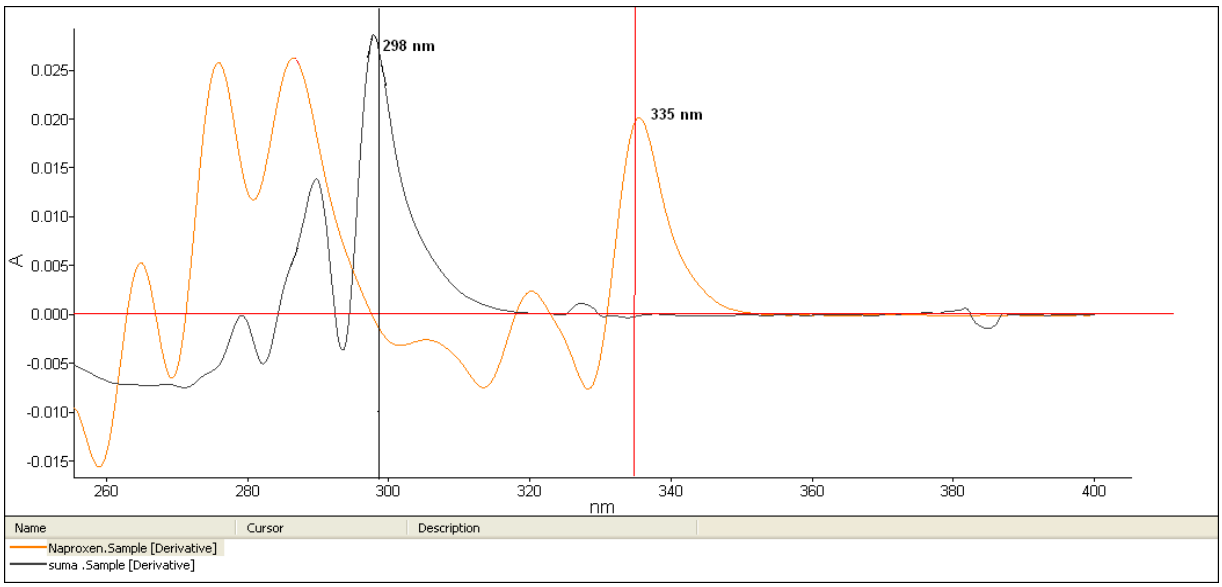

Fig. 2: First derivative overlain spectra of SUM and NAP

Method validation:

The developed methods were validated for parameters like linearity, precision and accuracy. The data for which are presented in the tables -1 to 3. The low value of R.S.D. value indicates that all the methods are precise and accurate.

Table I: Data showing linearity of developed methods

Methods	**Q- Absorption ratio method**		**First derivative spectroscopy method**	
Parameters	**SUM**	**NAP**	**SUM (at 298 nm)**	**NAP (at 335 nm)**
Linearity range	10-90 µg /mL	10-60 µg /mL	20-190 µg /mL	20-190 µg /mL
Slope	0.013 at 272nm	0.0157 at 272 nm	0.0011	0.0006
	0.0128 at 284 nm	0.0134 at 284 nm		
Intercept	0.0088 at 272 nm	-0.0157 at 272 nm	0.0013	0.0009
	0.0015 at 284 nm	- 0.0082 at 284 nm		
Correlation coefficient	0.9991 at 272 nm	0.9967 at 272 nm	0.9994	0.9997
	0.9994 at 284 nm	0.9971 at 284 nm		

Table II: Data showing precision of the developed method

Methods	**Q- Absorption ratio method**		**First derivative spectroscopy method**	
Parameters	SUM	NAP	SUM	NAP
Intraday Precision (% Assay) [a]	99.8	99.0	100.3	99.6
Intraday Precision (% RSD) [b]	0.54	0.59	0.81	0.62
Interday Precision (% Assay) [a]	99.2	99.5	101.4	100.5
Interday Precision (% RSD) [b]	0.32	0.75	0.26	0.65

a- Average of six determinations, b- Estimated on six determinations

Table III: Data showing recovery of the developed methods

Parameters	**% Accuracy**	**SUM µg/mL**	**NAP µg/ mL**	**STD SUM added µg /mL**	**STD NAP added µg /mL**	**SUM found µg /mL**	**NAP found µg /mL**	**%SUM recovered**	**%NAP recovered**
Methods									
Q– Absorption ratio method	80	10	55	08	44	17.83	98.39	99.08	99.39
	100	10	55	10	55	19.75	110.0	99.88	100.00
	120	10	55	12	66	21.64	132.17	98.38	101.12
First derivative spectroscopy	80	20	55	16	44	35.92	99.43	99.50	100.97
	100	20	55	20	55	39.91	111.06	99.54	101.93
	120	20	55	24	66	43.97	121.55	99.88	100.84

Table IV: Results of analysis of tablet dosage forms containing SUM and NAP

	Q- Absorption method		First derivative spectroscopy	
Parameters	SUM	NAP	SUM	NAP
% Assay *	100.6	100.8	101.78	101.12
% RSD	0.35	0.48	0.21	0.65

** Average of six determinations*

Application of methods to Tablet dosage form

The developed methods after validation were applied to the estimation of SUM and NAP in tablet dosage forms available commercially. The results of the study are presented in table-4.

CONCLUSION

In the present work, two methods namely Q-absorption ratio method and first derivative spectroscopy method were developed for the simultaneous spectroscopic estimation of SUM and NAP in commercially available tablet dosage forms. Methanol was used as the solvent since both the drugs exhibit good solubility in it and no interference due to excipients of the tablet formulation were observed. The methods evaluated were found to be accurate, precise and reproducible. The methods described can be successfully applied in quality control of combined pharmaceutical dosage forms.

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