



SPECTROPHOTOMETRIC SIMULTANEOUS ESTIMATION OF SUMATRIPTAN SUCCINATE AND NAPROXEN SODIUM IN TABLET DOSAGE FORMS

GONDALIA RP*1, DHARAMSI AP²

¹ Pioneer Pharmacy Degree College, vadodara - 390019, Gujarat, India, ²Atmiya Institute Of Pharmacy, Yogidham Gurukul, Kalawad Road, Rajkot-360005, Gujarat, India Email: rp_gondalia@yahoo.co.in

ABSTRACT

A binary mixture of Naproxen sodium and Sumatriptan succinate was determined by UV spectroscopic methods. The method involved determination of NAP and SUMA using the first derivative spectrophotometry at 241.0 and 236.0 nm over the concentration ranges of 0.5-3.5 µg/ml for both. The methods were successively applied to pharmaceutical formulation because no Spectroscopic interferences from the tablet excipients were found. The suitability of these methods for the quantitative determination of the compounds was proved by validation.

Key words: Naproxen Sodium, Sumatriptan succinate, First derivative spectrophotometry.

INTRODUCTION

Naproxen (NAP)¹ is chemically 2-Naphthaleneacetic acid, 6-methoxy-methyl-, (s)-(+)-(s)-6- Methoxy-, -methyl-2-phthaleneacetic acid. Naproxen is a non-steroidal anti-inflammatory drug (NSAID) commonly used for the reduction of moderate to severe pain, fever, inflammation and stiffness. It works by inhibiting both the COX-1 and COX-2 enzymes. Like other NSAIDs, naproxen is capable of producing disturbances in the gastrointestinal tract. Sumatriptan succinate is a selective 5-hydroxytryptan₁ receptor subtype agonist. Sumatriptan succinate²⁻³ is chemically designated as 3-[2-(dimethylamino)ethyl]-N-methyl-indole-5-methanesulfonamide succinate (1:1).

Sumatriptan succinate is official in European Pharmacopoeia and United State Pharmacopoeia suggests chromatographic method for sumatriptan succinate in bulk and tablet formulation. Several analytical techniques like HPLC⁴⁻⁵ and LS-MS⁶⁻¹⁰ have been reported for sumatriptan succinate in combination with other drugs.

MATERIALS AND METHODS

Instrument

A Shimadzu UV-1800 UV/VIS Spectrophotometer was used with 1 cm matches quartz cell, CP224S analytical balance (Sartorius) and ultra sonic cleaner (Frontline FS 4) were used.

Materials

Gift samples of SUMA and NAP were procured from Sun Pharmaceutical Ltds., Vadodara (Gujarat). Tablets containing both drugs were purchased from local pharmacy. Solvent used: Water

Method

For simultaneous equation method, SUMA (10mg) and NAP (10mg) were accurately weighed and transferred to two separate 100 ml volumetric flask, dissolved in Water solvent to obtained stock solution of 100 µg/ml each. The stock solutions of both the drugs were further diluted separately with solvent to obtain 10µg/ml solution each and scanned in spectrum mode from 400-200nm. The overlain spectra of both the drug obtained (Fig No.1) to determine the λ_{max}. From the stock solution, working standard solution of drugs were prepared by appropriate dilution and were scanned in the entire U.V. range. Two wavelengths selected for the method are 241.0 nm and 236.0 nm that are absorption maximas NAP and SUMA, respectively in Distilled water. A series dilution were prepared of standard solutions SUMA and NAP 0.5-3.5 µg/ml, both. The absorptivity coefficients of SUMA within concentration range of 0.5-3.5 µg/ml and NAP within concentration range of 0.5-3.5 µg/ml were determined at 236.0 and 241.0 nm by calibration curve.

Preparation of sample solution

For the estimation of drugs in the commercial formulations, ten tablets containing 85 mg of SUMA and 500 mg of NAP were weighed and average weight was calculated. The tablets were crushed and powdered in glass mortar. Powder from the mixed contents of 20 tablets, equivalent to 12 mg SUMA and 2 mg NAP, was transferred accurately to a 50 ml volumetric flask and diluted to volume with water. The solution was diluted to the same concentrations of working standard solutions and treated according to the linearity for the Simultaneous equation method.

RESULTS AND DISCUSSION

The methods discussed in the present work provide a convenient and accurate way for simultaneous analysis of SUMA and NAP. In first derivative spectrophotometry, wavelengths selected for analysis were 241.0 nm for NAP and 236.0 nm for SUMA. Linearity was observed in the concentration range of 0.5-3.5 µg/ml for SUMA and NAP, both.

The proposed methods have been applied to assay SUMA and NAP in tablets without any interference from the additives (Table 1). The validity of the suggested procedures was further assessed by applying the standard addition techniques (Table 2). The results of assay validation of the proposed methods show that they are accurate and precise according to the RSD values of intra and interday determinations (Table 3).

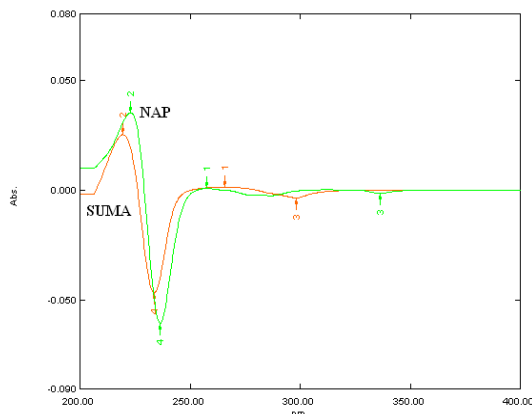


Fig. 1: Derivative spectra of NAP and SUMA

Table 1: Assay results for tablets using the proposed methods

Formulation	Proposed methods	Mix.	Amount of drug added (mg)		Amount of drug found (mg)		% Amount found (n ^a =3) ± SD ^b	
			SUMA	NAP	SUMA	NAP	SUMA	NAP
Tablets	First derivative	1	2	2	2.29	1.9	101.1±0.56	99.5±0.23
	spectrophotometry	2	2	2	2.36	1.8	100.5±0.98	98.4±0.69

^a n is number of determinations, ^b SD is a Standard deviation, SUMA is Sumatriptan succinate, NAP is Naproxen sodium

Table 2: Application of the standard addition technique to the analysis of suma and nap in tablets by the proposed methods

Proposed methods	Amount of drug taken (µg/ml)		Amount of drug added (µg/ml)		Amount of drug found (µg/ml)		% Recovery (n ^a =3) ± SD ^b	
	SUMA	NAP	SUMA	NAP	SUMA	NAP	SUMA	NAP
Simultaneous	2	2	1	1	2.94	2.89	99.14±0.54	98.16±1.09
Equation Method	2	2	2	2	3.98	4.02	99.75±0.67	100.25±1.03
	2	2	3	3	5.12	4.98	100.3±0.12	99.8±0.45

^a n is number of determinations, ^b SD is a Standard deviation

Table 3: Summary of validation parameters for the proposed methods

Proposed Methods	Drug	Parameters			
		LOD ^a (µg/ml)	LOQ ^b (µg/ml)	Interday (n = 3) (RSD ^c , %)	Intraday (n ^d = 3) (RSD ^c , %)
Simultaneous Equation Method	SUMA	0.18	0.5	0.23-0.61	0.10-1.16
	NAP	0.16	0.5	0.24-0.58	0.19-0.31

^a LOD is Limit of detection, ^b LOQ is Limit of quantification, ^c RSD is Relative standard deviation, ^d n is number of determination

CONCLUSION

The proposed procedures can be applied for the simultaneous determination of SUMA and NAP. Moreover, the methods are rapid, sensitive, accurate, precise and can be used in routine analysis.

ACKNOWLEDGEMENT

The authors are thankful to Pioneer Pharmacy Degree College, Vadodara for providing facilities to carry out the work.

REFERENCES

1. The United States Pharmacopoeia, 31st Revision. US Pharmacopoeial convention. Inc. Rockville, MD. 2008, Vol.3 p. 3310, 2762.
2. European Pharmacopoeia 6th Edition, 2008, Vol.2, p. 3005.
3. María J Nozal, José L Bernal, L Toribio, María T Martín, Francisco J Diez J Pharm Biomed Anal. 2002; 30(2):285-91.
4. Ge Z, Tessier, E Neirinck, L Zhu Z. Journal of chromatography B. 2004; 806(2):299-303.
5. Karthick Vishwanathan, Michael G. Bartlett, James T. Stewart * Rapid Communication in mass spectrom . 2000; 14(3):168-172.
6. X Xu, M G Bartlett, J T Stewart J Pharm Biomed Anal. 2001; 26 (3): 367-77.
7. K Vishwanathan, M G Bartlett, J T Stewart. Rapid Communication Mass Spectrom. 2000; 14 (3):168-72.
8. K N Cheng, M J Redrup, A Barrow, P N Williams J Pharm Biomed Anal. 1998; 17(3):399-408.
9. Boulton, David W, Duncan, Glenn F, Vachharajani, Nimish N. Biomedical Chromatography. 2003; 17 (1): 48-52.
10. Amin M, Sepp W. J Chromatography. 1976; 118(2):225-32.
11. Ali S. Moubarak, Edgar L. Piper, Zelpha B. Johnson and Miroslav Flioger J. Agric. Food Chem., 1996; 44 (1):146-148.
12. Charles R. Brownell, Gerald K. Shiu and Abraham Croitoru. Journal of food and drug analysis. 1998; 6(1):405-412.