

DEVELOPMENT AND VALIDATION OF NEW ANALYTICAL METHODS FOR  
SIMULTANEOUS ESTIMATION OF SUMATRIPTAN AND NAPROXEN IN A  
PHARMACEUTICAL DOSAGE FORM BY RP-HPLCDr. Atthapu Thirupathaiah<sup>\*1</sup>, Dr. Madireddy Mamata<sup>2</sup>, Dr. Fathima Nausheen Usman<sup>3</sup><sup>1</sup>Assistant Professor, Dept. of Pharmaceutical Chemistry (5Yr IPC course) and University College of Pharmaceutical Science (Dept. of Pharmaceutics Biotechnology), Mahatma Gandhi University, Nalgonda, Telangana, India.<sup>2</sup>Associate Professor and HOD, Department of Pharmaceutical Analysis, Trinity College of Pharmaceutical Sciences, Peddapalli, Bandarikunta, Telangana, India.<sup>3</sup>Registered Pharmacist, Karnataka State Pharmacy Council, India.**\*Corresponding Author: Dr. Atthapu Thirupathaiah**Assistant Professor, Dept. of Pharmaceutical chemistry (5Yr IPC course) and University College of Pharmaceutical Science (Dept. of Pharmaceutics Biotechnology), Mahatma Gandhi University, Nalgonda, Telangana, India. DOI: <https://doi.org/10.5281/zenodo.20443969>**How to cite this Article:** Dr. Atthapu Thirupathaiah<sup>\*1</sup>, Dr. Madireddy Mamata<sup>2</sup>, Dr. Fathima Nausheen Usman<sup>3</sup>. (2026). Development And Validation of New Analytical Methods For Simultaneous Estimation of Sumatriptan and Naproxen In A Pharmaceutical Dosage Form By Rp-Hplc. European Journal of Pharmaceutical and Medical Research, 13(6), 291–295. This work is licensed under Creative Commons Attribution 4.0 International license.

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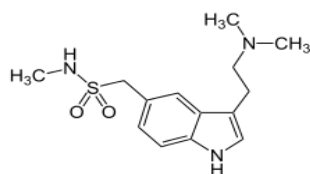
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**ABSTRACT**

High performance liquid chromatography is at present one of the most sophisticated tool of the analysis. The estimation of Sumatriptan and Naproxen was done by RP-HPLC. The Phosphate buffer was  $p^H$  3.0 and the mobile phase was optimized with consists of Methanol: Phosphate buffer mixed in the ratio of 70:30 % v/ v. Inertsil C<sub>18</sub> column C18 (4.6 x 150mm, 5 $\mu$ m) or equivalent chemically bonded to porous silica particles was used as stationary phase. The detection was carried out using UV detector at 265 nm. The solutions were chromatographed at a constant flow rate of 0.8 ml/min. the linearity range of Sumatriptan and Naproxen were found to be from 100-500  $\mu$ g/ml of Sumatriptan and 1-5 $\mu$ g/ml of Naproxen. Linear regression coefficient was not more than 0.999. The values of % RSD are less than 2% indicating accuracy and precision of the method. The percentage recovery varies from 98-102% of Sumatriptan and Naproxen. LOD and LOQ were found to be within limit. The results obtained on the validation parameters met ICH and USP requirements .it inferred the method found to be simple, accurate, precise and linear. The method was found to be having suitable application in routine laboratory analysis with high degree of accuracy and precision.

**KEYWORDS:** Methanol: Phosphate buffer, Inertsil C<sub>18</sub> column, Sumatriptan and Naproxen.

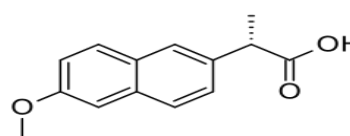
Sumatriptan, sold under the brand name Imitrex among others, is a medication used to treat migraine headaches and cluster headaches. It is taken by mouth, in the nose, or by injection under the skin.



Sumatriptan

Naproxen, sold under the brand name Aleve or Apranax among others, is a nonsteroidal anti-inflammatory

drug used to treat pain, menstrual cramps, inflammatory diseases such as rheumatoid arthritis, gout and fever. It is taken orally. It is available in immediate and delayed release formulations.



Naproxen

**MATERIALS AND METHOD****Instrumentation**

System Alliance Waters 2690 separation module, Pump Analytical HPLC isocratic pump, Detector Photo diode

array detector, Software Empower 2 software, Column Agilent (250×4.6mm, 5 $\mu$ ) C-18 RP-column, Sonicator Analytical Technologies Limited- Ultrasonic cleaner. U.V double beam spectrophotometer LABINDIA, UV 3000<sup>+</sup>pH meter, Weighing machine.

### Chemicals

Sumatriptan and Naproxen, Potassium dihydrogen orthophosphate, Water and Methanol for HPLC, Acetonitrile for HPLC, Ortho phosphoric Acid.

### Chromatogram for (Optimised)

Column : Inertsil C18 (4.6 x 250mm, 5 $\mu$ m)  
 Buffer pH : 3.0.  
 Mobile phase : 30% buffer 70% Methanol  
 Flow rate : 1.0ml per min  
 Wavelength : 265 nm  
 Temperature : ambient.  
 Run time : 10min.

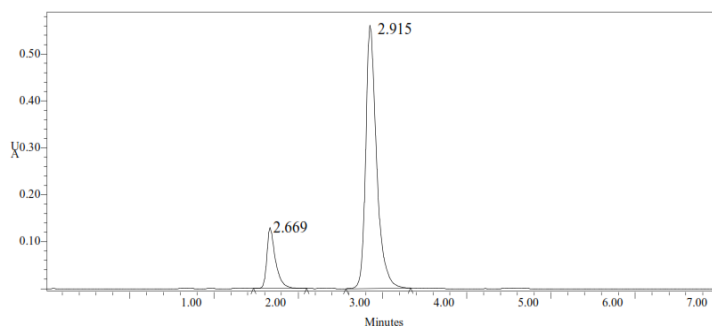


Fig. 1: Chromatogram of Trail-5.

### METHOD VALIDATION

- System Suitability
- Linearity
- Specificity
- Precision
- Intermediate Precision
- Accuracy
- Limit of Detection and Limit of Quantification
- Robustness

### RESULTS AND DISCUSSION

#### System suitability

Table 1: Results of system suitability parameters for Sumatriptan and Naproxen.

S.No	Name	Retention Time(min)	Area ( $\mu$ V sec)	Height ( $\mu$ V)	USP Resolution	USP Tailing	USP Plate Count
1	Sumatriptan	2.5	124505	213642		1.2	4673.4
2	Naproxen	3.9	1308495	154566	6.0	1.3	6090.3

#### Precision

Table 2: Results of method precision for Sumatriptan.

Injection	Area
Injection-1	1302729
Injection-2	1302947
Injection-3	1303236
Injection-4	1303977
Injection-5	1309759
Average	1304529.8
Standard Deviation	2961.1
%RSD	0.2

Table 3: Results of Method Precision for Naproxen.

Injection	Area
Injection-1	123149
Injection-2	123766
Injection-3	124271
Injection-4	124691
Injection-5	124956
Average	124162.7
Standard Deviation	725.6
%RSD	0.6

**Intermediate Precession (Ruggedness)****Table 4: Results of Intermediate precision for Sumatriptan.**

Injection	Area
Injection-1	1300148
Injection-2	1304520
Injection-3	1305937
Injection-4	1306476
Injection-5	130871
Average	1305070.2
Standard Deviation	3061.8
%RSD	0.2

**Table 5: Results of Intermediate precision for Naproxen.**

Injection	Area
Injection-1	122487
Injection-2	122626
Injection-3	122632
Injection-4	122702
Injection-5	122962
Average	122681.8
Standard Deviation	174.8
%RSD	0.1

**Accuracy****Table 6: Accuracy (recovery) data for Sumatriptan.**

%Concentration (at specification Level)	Area	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	656659.5	5.0	5.036	100.7%	99.84%
100%	1304258	10.0	10.003	100.0%	
150%	1854608	14.4	14.224	98.780%	

**Table 7: Accuracy (recovery) data for Naproxen.**

%Concentration (at specification Level)	Area	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	65800	5.3	5.34	100.8%	100.51%
100%	124353	10	10.10	100.01%	
150%	177940	14.2	14.45	99.68%	

**Linearity****Table 8: Area of different concentration of Sumatriptan.**

S.No.	Linearity Level	Concentration	Area
1	I	100ppm	668934
2	II	200ppm	956781
3	III	300ppm	1313873
4	IV	400ppm	1563458
5	V	500ppm	1867084
Correlation Coefficient			0.999

**Table 9: Area of different concentration of Naproxen.**

S.No	Linearity Level	Concentration	Area
1	I	1ppm	66510
2	II	2ppm	94701
3	III	3ppm	124802
4	IV	4ppm	152731
5	V	5ppm	179732
Correlation Coefficient			0.999

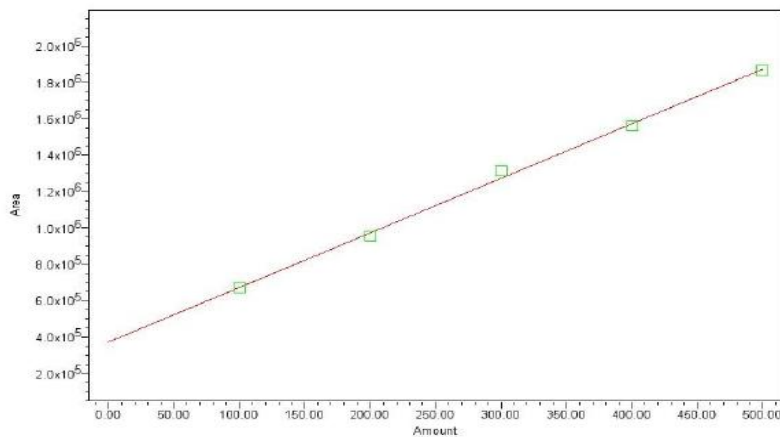


Figure 2: Calibration graph for Sumatriptan.

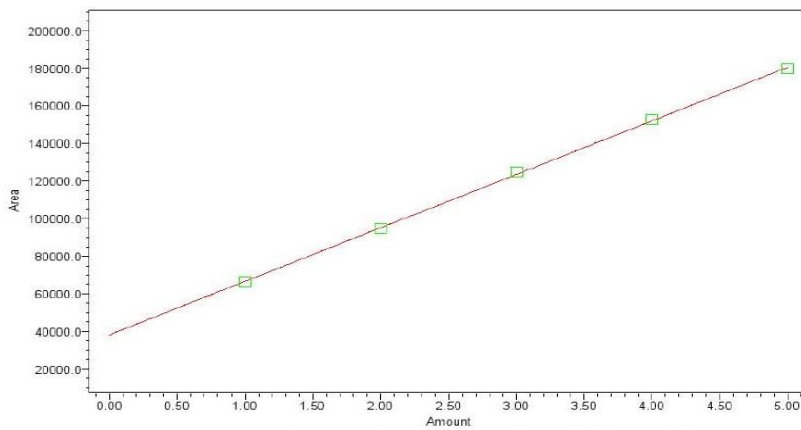


Figure 3: Calibration graph for Naproxen.

Table 10: Analytical Performance Parameters of Sumatriptan and Naproxen.

Parameters	Sumatriptan	Naloxone
Slope (m)	66574	12529
Intercept (c)	53592	50245
Correlation coefficient (R <sup>2</sup> )	0.999	0.999

**Limit Of Detection**

Table-11 Results of LOD.

Drug name	Baseline noise(μV)	Signal obtained (μV)	S/N ratio
Sumatriptan	52	152	2.9
Naproxen	52	156	3

**Limit Of Quantification**

Table no-12 Results of LOQ.

Drug name	Baseline noise(μV)	Signal obtained (μV)	S/N ratio
Sumatriptan	52	522	10.03
Naproxen	52	524	10.1

**Robustness**

Table-13 Flow Rate (ml/min) data for Sumatriptan.

S. No	Flow Rate (ml/min)	System Suitability Results	
		USP Plate Count	USP Tailing
1	0.6	5339.9	1.4
2	0.8	4673.4	1.3
3	1.0	5216.0	1.4

**Table 14: Flow rate (ml/min) data for Naproxen.**

S. No	Flow Rate (ml/min)	System Suitability Results	
		USP Plate Count	USP Tailing
1	0.8	7063.3	1.3
2	1.0	6090.3	1.2
3	1.2	6998.0	1.3

**Table 15: Change in Organic Composition in the Mobile Phase for Sumatriptan.**

S.No	Change in Organic Composition in the Mobile Phase	System Suitability Results	
		USP Plate Count	USP Tailing
1	10% less	4508.4	1.3
2	*Actual	4673.4	1.4
3	10% more	4318.1	1.3

**Table 16: Change in Organic Composition in the Mobile Phase for Naproxen.**

S.No	Change in Organic Composition in the Mobile Phase	System Suitability Results	
		USP Plate Count	USP Tailing
1	10% less	6387.7	1.2
2	*Actual	6090.3	1.2
3	10% more	6232.5	1.2

**SUMMARY AND CONCLUSION**

High performance liquid chromatography is at present one of the most sophisticated tool of the analysis. The estimation of Sumatriptan and Naproxen was done by RP-HPLC. The Phosphate buffer was  $p^H$  3.0 and the mobile phase was optimized with consists of Methanol: Phosphate buffer mixed in the ratio of 70:30 % v/ v. Inertsil C<sub>18</sub> column C18 (4.6 x 150mm, 5 $\mu$ m) or equivalent chemically bonded to porous silica particles was used as stationary phase.

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