

## Development and Validation of Reversed-Phase High Performance Liquid Chromatographic Method for Estimation of Sumatriptan Succinate In Pharmaceutical Dosage Form

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### Abstract

A simple liquid chromatographic method was developed and validated for determination of sumatriptan succinate (SUMA) in tablet dosage form. The analysis is performed at ambient temperature on a reversed-phase C18 column with detection at 232 nm. The mobile phase consisting of ACN : Water (18:82) and 0.05% v/v trifluoro 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 10-50 ppm. The % recovery was found between the range of 98.0% to 102.0% of the labeled value. The proposed method was successfully applied for the routine quantitative analysis of tablets containing SUMA.

### Key words:

Sumatriptan succinate, HPLC.

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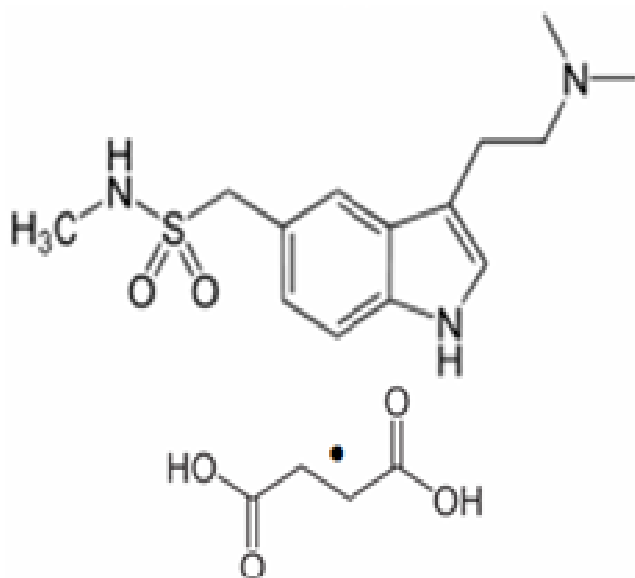
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**Introduction** Sumatriptan succinate (SUMA) is chemically 3-[2-(dimethylamino)ethyl]-N-methyl-

indole-5-methanesulfonamide succinate (Figure :1). Sumatriptan succinate is official in British pharmacopoeia<sup>[1]</sup>, European Pharmacopoeia <sup>[2]</sup> and United States Pharmacopoeia <sup>[3]</sup>. 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-HT<sub>1D</sub> and 5-HT<sub>1B</sub> subtypes<sup>[4]</sup>.



**Figure 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 <sup>[5]</sup> sumatriptan by HPTLC<sup>[6]</sup> and visible spectrophotometry<sup>[7]</sup>. The aim of our investigation was to develop and validate an LC method for the determination of SUMA in pharmaceutical dosage forms.

In this study, reversed-phase high performance liquid chromatographic method has been developed for determination of Sumatriptan succinate and applied to commercial tablet dosage forms. The results obtained were validated according to the ICH guidelines.

## 2. MATERIALS AND METHODS

### 2.1. Chromatographic conditions

The HPLC system consisted of a Young Lin 9101 vacuum 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.

The mobile phase consisting of ACN : Water (18:82) and 0.05% v/v trifluoro 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 232 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.)

### 2.2 Reagents

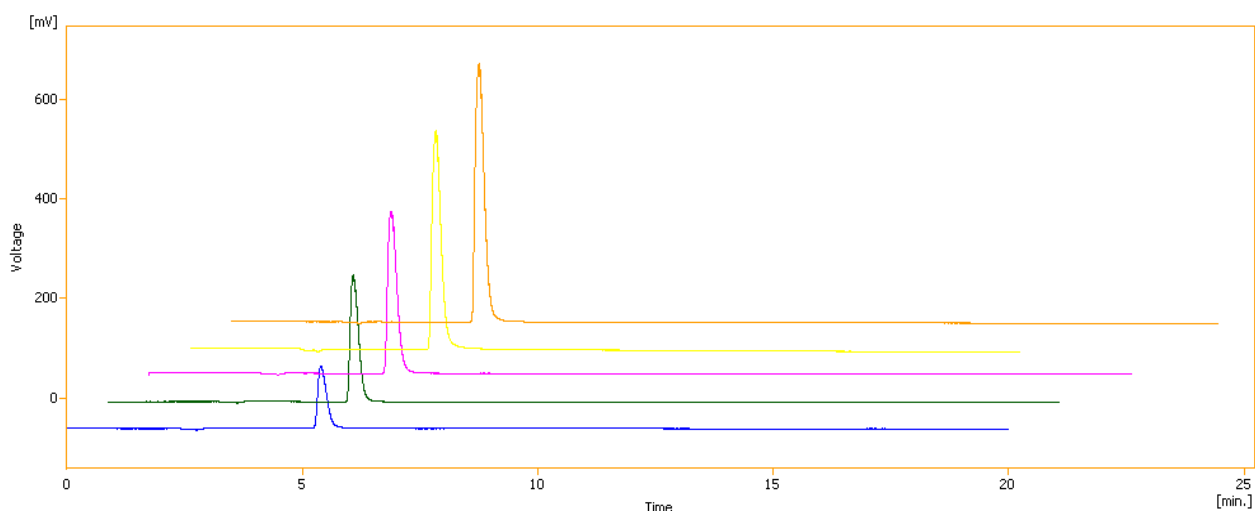
Sumatriptan succinate was kindly provided as gift sample by Astron Pharmaceuticals, Ahmedabad.

Commercially available Suminat 50 tablets (Sun pharmaceutical) were purchased from local market, India.

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

### 2.3 Preparation of standard solution and calibration graphs

The stock solutions of SUMA was prepared by dissolving accurately weighed 25 mg of the drug, transferred to 25 ml volumetric flask, dissolved and made up to the volume by using water (HPLC grade). Then appropriate dilutions were made to adjust the final concentration 10, 20, 30, 40, 50 ppm. The results of calibration curve are shown in table 1.



**Figure 2.** Chromatogram of Sumatriptan succinate

**Table 1.** Data from standard curve of SUMA by RP-HPLC method

S. no.	Parameters	SUMA
1	Linear Range (µg/ml)	10-50 µg/ml
2	Retention time (min)	5.20
3	Slope	130.87
4	Intercept	418.7
5	Linear equation	$y = 130.87x + 418.7$
6	R <sup>2</sup> value	0.9974

#### 2.4. Preparation of sample solution

For the estimation of drugs in Suminat 50 tablets, twenty tablets were accurately weighed, crushed and powdered in a glass mortar. The tablet powder equivalent to 50 mg SUMA was transferred accurately to a 50 ml volumetric flask and diluted to volume with water (HPLC grade). The solution was further diluted to obtain concentration of 40 ppm and the results are shown in table 2.

**Table 2.** Assay Results of Market Formulation

S. no.	Formulations	Actual concentration (µg/ml)	%SU MA
1	Suminat 50 (Sunpharmaceutical)	40(µg/ml)	101.92 %

#### 2.5 Method validation [8]

The developed methods were 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.

##### 2.5.1 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 10 µg/ml. The results are shown in table 3.

##### 2.5.2 Repetability

Repeatability was determined on 6 replicate of each concentration of the standard solution. The results are shown in table 3.

##### 2.5.3 Precision

Precision was determined by performing Intra day and Inter day determination concentration on three different concentration as shown in table 3.

##### 2.5.4 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  $DL = 3.3\sigma$  and quantitation limit  $QL = 10\sigma$  S S

Where  $\sigma$  = standard deviation of y-intercepts of regression lines

S = the slope of the calibration curve

The result is shown in table 3.

### 2.5.5 Ruggedness

The ruggedness of the method was determined by carrying out the experiment on different instruments. The %RSD values with two different instruments were 0.70-1.05 and 0.63-1.44 respectively.

**Table 3.** Summary of Validation Parameter

S. no.	Parameters	Sumatriptan
1	Recovery (%)	98.55 - 101.86
2	Repeatability (RSD, n=6)	0.7025- 1.1928
3	<b>Precision Range(CV)</b>	
4	Intra-day (n=3)	0.5816- 1.1588
5	Inter-day (n=3)	1.0124- 1.6543
6	Limit of Detection ( $\mu\text{g/ml}$ )	0.90
7	Limit of Quantification ( $\mu\text{g/ml}$ )	2.72

### 3. RESULTS AND DISCUSSIONS

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

The linearity of the peak response versus concentration was studied from 10 to 50  $\mu\text{g/mL}$ . The representative linear equation was  $y = 130.87x + 418.7$  and correlation coefficient (r) is 0.9974.

Recovery study was performed in triplicate and was found in range of 98.55 - 101.86. The precision is usually expressed as the %RSD and it was found to be 0.7025- 1.1928. The Inter-day and intra-day precision were 1.0124- 1.6543 and 0.5816- 1.1588 respectively.

An economic, simple and rapid RP-LC method has been developed for determination of SUMA in tablet dosage forms. The proposed method is simple, accurate and precise for the quantification of SUMA

in tablet dosage form as well as bulk drugs for routine analysis.

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