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UV SPECTROPHOTOMETRIC ESTIMATION OF SUMATRIPTAN: STATISTICAL TREATMENT

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Abstract:

Three simple, sensitive, selective and rapid UV spectrophotometric method was developed and validated for quantitative estimation of sumatriptan. The effect of three different solvents on quantification of sumatriptan in bulk and pharmaceutical formulations were studied. The standard solutions of sumatriptan were prepared with water and solvent blends containing Acetonitrile: water (1:1), Methanol: water (1:1). The standard solutions are scanned in the ultraviolet region ranges from 200nm-400nm. Sumatriptan showed λmax at 226nm in water, in case of Acetonitrile:water (1:1) the λmax was slightly shifted to 228nm and in Methanol: water (1:1) the λmax was found to be 226.5nm. Th method obeyed Beer-lamberts law over the concentration range of 2-18µg/ml. The method was validated by the parameters like Linearity, Accuracy, Precision, limit of Detection (LOD), Limit ofQuantification (LOQ), Molar Absorption Co-efficient,$A_{1cm}^{1\%}$according to ICH guidelines. The validated parameters were treated statistically using ANOVA and significant differences were noticed. The study clearly indicated that the solvents having an influence on the estimation of sumatriptan succinate in bulk and formulations. The developed method was rapid and easy, so it can be applied for routine quality control analysis of sumatriptan from pharmaceutical dosage form.

Keywords: *Sumatriptan Succinate, LOD, LOQ, ANOVA and UV Spectrophotometry.*

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INTRODUCTION:

Sumatriptan Succinate chemically designated as [3-[2-(Dimethylamino) ethyl]-1H-indol-5-yl]-N-methyl methanone sulfonamide hydrogen butamedioate. Sumatriptan succinate is structurally related to the neurotransmitter serotonin. Sumatriptan succinate acts by selectively binding to serotonin type-1D receptors and rapidly terminates migraine headache. The empirical formula of sumatriptan succinate is $C_{18}H_{29}$ N_3O_6S and its molecular weight is 413.489g/mol. Sumatriptan succinate is official in BP (British Pharmacopoeia, 2009) and EP (European Pharmacopoeia, 2005) and also in USP (United States Pharmacopoeia, 2004). Literature survey reveals there are few analytical methods like high performance liquid chromatography (HPLC), liquid chromatography and mass spectroscopy (LC-MS), ultra-performance liquid chromatography (UPLC), voltammetry, visible spectrophotometry and UV Spectrophotometry were reported for quantification of sumatriptan succinate. The position as well as the intensity of absorption maximum gets shifted for a particular chromophore by changing the polarity of the solvent, by increasing the polarity of the solvent, compounds such as dienes and conjugated hydrocarbons do not experience any appreciable shift.Even though several uv spectrophotometric methods have been reported for sumatriptan succinate, influence of solvents on it has not been covered. In the present investigation three simple uv spectrophotometric methods were developed and sensitive one decided based on Limit of Detection (LOD) and Limit of Quantification (LOQ).

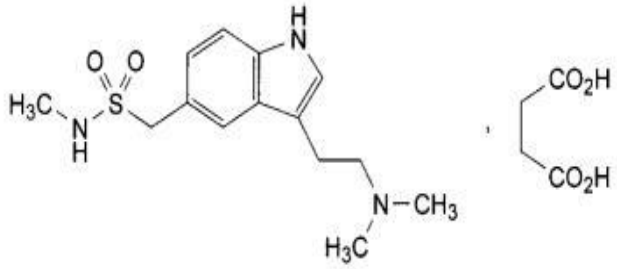

Fig.1: Structure of Sumatriptan succinate

MATERIALS AND METHODS:

Instrument used was Double Beam UV- Visible Spectrophotometer ELICO SL 244 with 10mm matched quartz cells. Absorbance of the sample solutions were carried out in the 10mm quartz cells over the range of 200-400nm. Sumatriptan succinate was gifted by NATCO pharma Ltd, Hyderabad, India. Acetonitrile of analytical grade procured from Loba- Chemiepvt Ltd, Mumbai, India. Methanol used was of government supply.

PREPARATION OF STANDARD STOCK SOLUTIONS:

100mg of sumatriptan succinate was accurately weighed three times separately and transferred into three different 100ml volumetric flasks containing small volumes of Acetonitrile: water (1:1), Methanol: water (1:1) and water, then the volume was adjusted with the same solvents. The resultant solution obtained was 1000ppm (1mg/ml- primary stock solution). From this take 10ml of three different solutions in a three different 100ml volumetric flasks and then diluted up to 100ml with same solvents and the concentration of stock solution obtained was 100ppm (100µg/ml- secondary stock solution).

DETERMINATION OF ABSORBANCE MAXIMA (λmax):

The three different secondary stock solutions were suitably diluted to get a concentration of 10µg/ml and scanned in the UV region from 200-400nm against blank.The lambda max in Actetonitrile:water(1:1) observed at 228nm (Fig no.3),in Methanol:water(1:1) was 226.5nm(Fig no.5) and in water it was found tobe 226nm(Fig no.4).

BEER'S LAMBERT LAW:

From the three different stock solutions suitable dilutions are made to get concentrations ranging from 2-18µg/ml and are scanned for absorbances at their respective λmax. Calibration curve was constructed for sumatriptan succinate in three different solvents bytakingconcentration (µg/ml) on x-axis and absorbance on y-axis (Fig no.2).

VALIDATION OF PROPOSED ANALYTICAL METHOD:

Linearity

The linear regression equations were obtained to be y= 0.0614x+0.0069 for Acetonitrile: water (1:1)

($\mathbf{R^2}$=0.999), y= 0.0603x+0.0089 for methanol: water (1:1) ($\mathbf{R^2}$ = 0.999) and y= 0.058x+0.01 for water (R^2 = 0.998).

Accuracy

The accuracy of the method was calculated in triplicate at three concentrations levels 80, 100, 120%. The percentage recovery values were in between 98.6 to 102.4%, which indicated the method was accurate.

Precision

Precision of the method was determined in terms of repeatability, intraday and interday precisions.

Repeatability

Repeatability of the method was determined by analyzing six samples of 6µg/ml, 10µg/ml and 14µg/ml concentrations in three different solvents and the %RSD and the standard error were calculated.

Intraday and Interday Precision

Intraday precision was determined by analyzing the drug at three different concentrations 4,8, 12µg/ml and each concentration for three times, on the same day. Interday precision was determined similarly, but the analysis being carried out daily for three consecutive days.

LOD and LOQ

The sensitivity of the method was measured in terms of Limit of detection (LOD) and Limit of quantification (LOQ)**.** The LOD and LOQ were calculated by the formula

LOD= 3.3σ/s & LOQ= 10σ/s

Where, σ= standard deviation of y-intercepts of regression lines; S= Slope of calibration curve

Ruggedness and Robustness

Ruggedness of a method was determined by analyzing sample solutions by change in the analytical conditions like different analyst. The Robustness of the method was determined by altering experimental conditions deliberately and assay was evaluated. Sample solutions were prepared and absorbances were observed at ±5nm from absorption maxima.

RESULTS AND DISCUSSIONS:

The methods were validated in terms of linearity, accuracy, precision and sensitivity and the validation parameters were depicted in Table no.2. The accuracy of proposed methods was proved by performing the recovery studies in the commercially available formulations. The recovery studies were satisfactory and the percentage of drug recovered was in the range of 98.6 to 102.4%.The linearity was studied by preparing standard solutions of sumatriptan succinate at the different concentration levels. The linearity range was found in three different solvent systems were 2-18µg/ml (Fig no.2). The standard calibration curve was generated by using regression analysis. The response was judged to be linear as the correlation coefficient was greater than 0.998 by least square method.

%RSD values were less than 1 indicates the proposed methods were more precise. Based on the LOD and LOQ values sensitivity of the method improved in the presence of organic solvents, among them Acetonitrile offered lowest LOD and LOQ. The LOD and LOQ values of the three methods were treated statistically and the data shown in Table No.1. Significant differences were observed with the solvents used for the determination of drug. The LOD and LOQ values of sumatriptan succinate in three different solvents were treated with ONE-way ANOVA. The calculated value compared with F-Table value. The calculated value greater than table value indicates the significant differences between LOD and LOQ values of drug in the three different solvents.

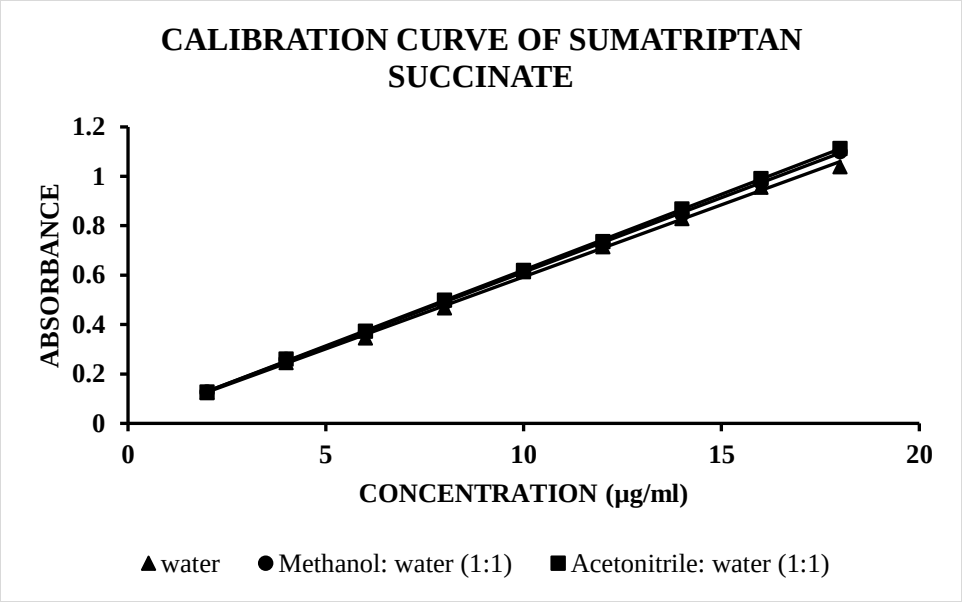

Fig.2: Calibration curves of Sumatriptan succinate

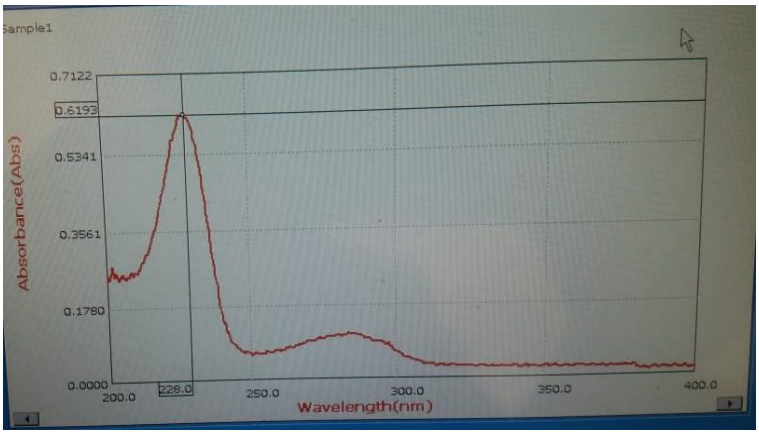

Fig.3: Determination of λmax of Sumatriptan in Acetonitrile: Water(1:1)

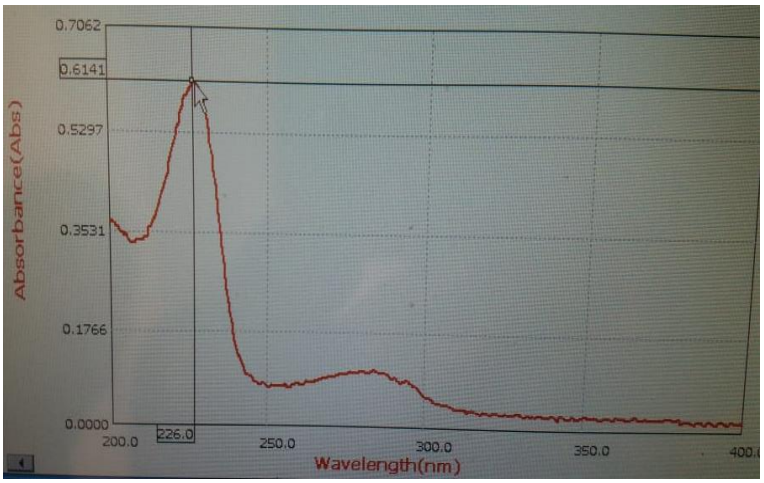

Fig.4: Determination of λmax of Sumatriptan in Water

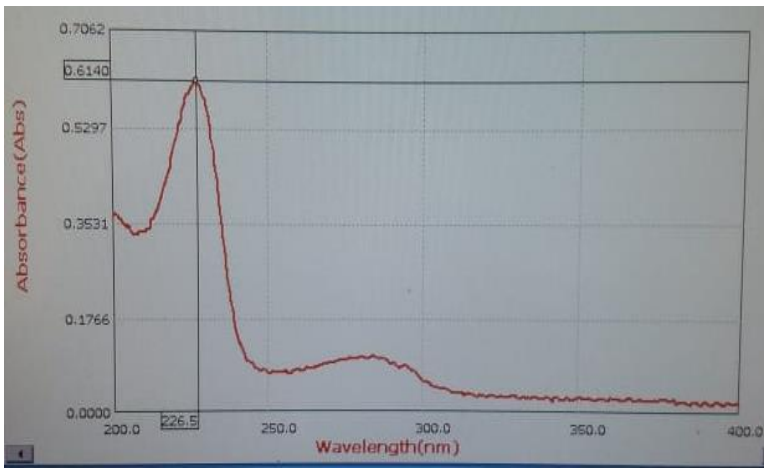

Fig.5: Detemination of λmax of Sumatriptan inMethanol:Water(1:1)

Table 1: Limit of Detection and Limit of Quantification

S. NO	Parameters	A:W	M:W	W	D/F
1.	LOD	$0.0109\pm2.357\times10^{-6}$	$0.01447\pm1.92\times10^{-5}$	$0.02749\pm1.73\times10^{-5}$	2/9
2.	LOQ	$0.033\pm1.62\times10^{-5}$	$0.0438\pm0.78\times10^{-5}$	$0.0833\pm1.81\times10^{-5}$	2/9

A:W- Acetonitrile:water, M:W- Methanol:water, W-Water, D/F:Degress of freedom

Table 2: Validation Parameters of Proposed UV methods

S. NO	Parameter	Acetonitrile: water	Methanol: water	Water
1.	λmax	228nm	226.5nm	226nm
2.	Range	2-18µg/ml	2-18µg/ml	2-18µg/ml
3.	Regression Equation	Y= 0.0614x+ 0.0069	Y= 0.0603x+ 0.0089	Y= 0.058x+ 0.01
4.	Slope	0.0614	0.0603	0.058
5.	Intercept	0.0069	0.0089	0.01
6.	$A^{1\%}_{1cm}$	624.41	617.04	597.7
7.	R^2	0.999	0.999	0.998
8.	ε	2.5820×10^4	2.5540×10^4	2.4712×10^4
9.	LOD	0.0109µg/ml	0.01447 µg/ml	0.02749 µg/ml
10.	LOQ	0.033 µg/ml	0.0438 µg/ml	0.0833 µg/ml
11.	Sandell's Sensitivity	0.01655	0.01733	0.0182

ANALYSIS OF COMMERCIAL TABLETS:

Marketed STS tablets were analyzed using proposed methods and also by an official method (USP, 2004). The official method describes chromatographic detection of STS using UV- detector at 282nm. The results obtained were compared statistically by student's t- test and variance F- ratio test (ICH- Q1A (R1), 2005). The calculated 't' and F- values did not exceed the tabulated values of 2.77(t) and 6.39 (F) at 95% confidence level and four degrees of freedom (table), indicating close similarity between the developed methods and the reference method with respect to accuracy and precision.

Table 3: Analysis of Tablets by Proposed Methods

S.NO	Brand Name	Label claim (mg/tablet)	Found (% of label claim± SD)^N			
			Reference method	Proposed Method		
				A:W	M:W	W
1.	**Suminat**	**50**	**99.69± 0.78**	**100.9± 0.98 t= 1.84 F= 2.06**	**99.85± 0.74 t= 0.96 F= 1.18**	**99.34± 0.57 t= 0.92 F= 1.14**
2.	**Migratan**	**50**	**100.8± 1.13**	**101.2± 1.23 t= 1.04 F= 1.86**	**100.5± 0.93 t= 1.58 F= 1.92**	**99.88± 0.87 t= 0.98 F= 1.24**

Table t value at the 95% confidence level is 2.77, Table F value at the 95% confidence level is 6.39.

N- Mean value of five determinations.

RECOVERY STUDY:

The accuracy and reliability of the developed methods further confirmed by recovery experiment by standard addition method. Pre-analyzed tablet powder was spiked with pure STS at three different levels and the total was found by proposed methods. Each determination performed in triplicate manner.

Table 4: Results of Recovery Study by Standard Addition Method

Brand Name	Acetonitrile: water				Methanol: Water				Water			
	STS in Tablets (µg/ml)	Pure STS Added (µg/ml)	Total found (µg/ml)	Pure STS recovered (%± SD)	STS in Tablets (µg/ml	Pure STS Added (µg/ml)	Total found (µg/ml)	Pure STS recovered (%± SD)	STS in Tablets (µg/ml	Pure STS Added (µg/ml)	Total found (µg/ml)	Pure STS recovered (%± SD)
Suminat-50	4	2.5	6.56	102.4± 0.61	4	2.5	6.55	102± 0.82	4	2.5	6.48	99.2± 0.51
	4	5.0	9.07	101.4± 0.86	4	5.0	8.97	99.4± 0.46	4	5.0	8.95	99± 0.83
	4	7.5	11.62	101.6± 1.30	4	7.5	11.54	100.5± 1.12	4	7.5	11.47	99.6± 0.34
Migratan-50	6	2.5	8.54	101.6± 1.25	6	2.5	8.52	100.8± 1.03	6	2.5	8.47	98.8± 0.72
	6	5.0	10.97	99.4± 0.07	6	5.0	10.96	99.2± 0.71	6	5.0	10.93	98.6± 0.83
	6	7.5	13.48	99.73± 0.66	6	7.5	13.46	99.46± 0.62	6	7.5	13.41	98.8± 1.21

STS: Sumatriptan succinate

CONCLUSION:

The proposed methods were easy to perform and applicable for estimation of Sumatriptan succinate in bulk and pharmaceutical formulations in Quality control laboratories.

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