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Original Article

Development and Optimization of Eletriptan Hydrobromide Sublingual Tablet Using Central Composite Design and *in vitro* Characterization

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ABSTRACT

Background: In the current research, the sublingual tablets were formulated by utilizing a solid dispersion by physical mixture technique using sodium starch glycolate works as a super disintegrant and cyclodextrin works as a solubility enhancer, which can provide a rapid onset of action. **Objectives:** To prevent first-pass metabolism sublingual drug delivery of an Eletriptan hydrobromide which is considered to be one of the finest surrogate routes of administration. Additionally, it will lead to patient adherence as well as increased therapeutic efficacy. **Materials and Methods:** The undeviating (direct) compression technique was used to develop the tablet formulation. The amount of sodium starch glycolate (X1) as well as PVP K-30 (X2) was chosen as the unconventional (independent) variable, while the dependent variables were the disintegration time (Y1) in seconds and the fraction of medication released *in vitro* (Y2). This was accomplished using a central composite design. The prepared tablets were assessed for a number of parameters, comprising hardness testing, friability testing, thickness, weight variation method, wetting time analysis and water absorption ratio. **Results:** The solid core dispersion of eletriptan hydrobromide escorted by β-cyclodextrin ratio 1:2 in distilled water and phosphate buffer pH 6.8 showed improved solubility (3.632±0.006, 11.327±0.003) than that of corresponding pure eletriptan (1.936±0.004, 8.471±0.007). **Conclusion:** The SLT4 formulation showed the best results in terms of disintegration time of 01 min and *in vitro* drug release of 96.36% in 15 min implying that the sublingual route of eletriptan hydrobromide direction can be a better alternative for migraine disease.

Keywords: Sublingual tablet, Super disintegrant, Migraine, Solid dispersion, Solubility enhancement, Rapid disintegration.

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INTRODUCTION

Formulation development involves a major assent and experimental work to get optimum results. The choice of excipients, drug stability, drug solubility according to dose form, drug bioavailability, manufacturing issues, cost-effectiveness and last but not least one crucial characteristic, i.e., patient compliance and convenience, are all important to take into account while executing.[1,2]

Now a day's formulation research is breaking the hurdles of conventional methods. Active ingredients are now administered with a level of efficacy, bioavailability and convenience.[3-5]

Migraine is a neurological condition that frequently causes nausea and moderate to severe headaches. Even though there isn't a therapy for migraines as of yet, there are lifestyle adjustments and therapies that can help individuals manage their migraines and lead normal lives. In order to avoid unwarranted expectations, effective migraine therapy depends on providing proper patient education. As soon as the illness is recognized, the patient should get a thorough explanation of it. There are now more options for treating various conditions.[6,7] At present, triptans and ergot-based direct treatments are often used to treat abortive migraines (analgesics and non-inflammatory drugs). Several other substances are often used for this symptom, which shows different levels of proof of efficacy and tolerance, in addition to the medications that are officially recommended for migraine prevention by international regulatory authorities. Recent guidelines providing evidence-based clinical data on migraine prophylaxis are a good source of information, especially for neurologists and medical professionals without a specialty in headache management.[8,9]

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MATERIALS AND METHODS

Materials

Eletriptan hydrobromide (Enaltec Labs Pvt. Ltd., Indore), Sodium Starch Glycolate, β- Cyclodextrin, PVP K-30, Microcrystalline Cellulose, Menthol, Sodium saccharine, Magnesium Stearate, Talc (Lobachem Pvt. Ltd., Indore).

Methods

Preparation of inclusion complex by physical mixture method

The solid complexes of Eletriptan hydrobromide were prepared with β-Cyclodextrin by physical mixture method with molar ratios 1:1 and 1:2. In this method faultlessly weighed quantity of Eletriptan hydrobromide and β-Cyclodextrin was taken separately in two different pestle-mortar. Therefore, the drug was slowly blended into both pestle-mortars one by one with continuous trituration for about 1 hr and passed through sieve number 60.

Optimization of sublingual tablet

The polymer PVP K-30 was selected owing to its solid dispersion ability and compatibility with the drug. Successful use of polymer is known to provide the immediate drug release property. The sublingual tablet was optimized by Design Expert 13 software using Central composite design. The concentrations of sodium starch glycolate (X1) and PVP K-30 were used in the design to statistically optimize the independent variable (X2). For the dependent variables, disintegration time (Y1) as well as *in vitro* drug release (Y2), the main effect, interaction effects and linear effects of these formulation constituents were assessed.

The selected factors show the independent variables and by taking the above 2 factors with their different concentration (levels) 9 batches were formulated and evaluated on the basis of response which is given in Table 1 below.

The selection of factors and their levels is mentioned below;

For Independent Variables

The Concentration of SSG (X1) in mg, the low level is 1.5 and the high level is 8.

The Concentration of PVP K-30 (X2) in mg, the low level is 0.62 and the high level is 1.25.

Preformulation study

Melting point

Gallen Kamp (Electronic-Digital) melting point apparatus was used to determine the melting point.

Solubility

The solubility of eletriptan hydrobromide in distilled water and phosphate buffer was assessed using the shake-flask method (pH 6.8) Using a UV-visible spectrophotometer, the drug's concentration was examined at 216 and 219 nm.

Drug-Excipient's interaction study using TLC

The drug sample and excipients sample were dissolved in a ratio of 1:1 in methanol and distilled water respectively. A capillary tube was used to spot the sample on TLC plates. The diameter of each spot was limited to 0.3 cm and was spotted at 1cm above the bottom of the plate.

Pre-coated silica gel for the stationary phase-G

Methanol: water (1:1) for the mobile phase

The iodine chamber was prepared and TLC plates were placed in the same chamber. The plates were removed from the chamber after spots appeared. The appeared spots were observed and R_f values were calculated accordingly.[10,11]

Formulation of sublingual tablet

Precompression parameter

All pre-compression characteristics, including bulk density test, tapped density test, angle of repose calculation, Carr's index and Hausner's ratio, were assessed for formulation blends. The evaluation was done using all the methods as specified in pharmacopeias.[12,13]

Preparation of Eletriptan hydrobromide Sublingual Tablet by Direct Compression Method

All ingredients were accurately weighed as shown in Table 1, passed through sieve number 80 and collected in polybags individually.

Cyclodextrin inclusion complex and all other additives were combined with the drug step by step and continuously triturated for 15 min.

Therefore, magnesium stearate and talc were added to them and blended for 5 min in a pestle mortar. Then passed through sieve number 60.

The compressed tablet was prepared by compressing the blend with a rotary tablet compression machine (Aidmach) using 6 mm round-shaped dies and punches of B-B-tooling.

Evaluation of Sublingual Tablet

Weight variation

The average weight of the tablets (n=20) was determined by comparing the individual tablet weight with the average weight.

Friability and hardness

A Roche friability and a hardness tester of the Monsanto type were used, respectively, to quantify friability (n=20) and hardness (n=3).[14]

Thickness

A Vernier caliper was used to measure the thickness of tablets (n=10) and the mean tablet thickness was calculated.[15]

Wetting Time

Two layers of absorbent paper were arranged like a Petri dish with the tablet in the middle. Excess water was fully drained from the dish after the paper had been properly saturated with distilled water. A stopwatch was used for recording the time required for water to diffuse from the wetted absorbent paper throughout the entire tablet. The wetting time of the tablet was performed by using absorbent paper in this the tablet was placed between the absorbent paper and distilled water was used to wet the tablet, then the excess amount of water was removed out and the time was recorded.[16,17]

Water absorption ratio

To determine the tablet's water absorption ratio in this case, tissue paper was employed. 6 mL of water was added to a little piece of paper that had been folded and placed in a petri dish. after properly wetting the tablet before placing it on the paper. The tablet was weighed and a formula was used to determine the water absorption.[18] Disintegration time one tablet and a disc were inserted to each of the six glass tubes. The assembly was submerged in a beaker of clean water. The device was run until the tablets were entirely destroyed. The amount of time needed for the pill to completely dissolve was recorded.

Drug Content

The calibration curve method was used to calculate the drug content. The mortar and pestle were used to break 10 tablets. Next, a 100 mL volumetric flask containing 20 mg of the drug was filled and the drug was dissolved in phosphate buffer (pH 6.8). 100 mL were added to the capacity. 1 mL of this solution was taken in a volumetric flask with a capacity of 10 mL and 100 mL of a suitable solvent were added. A UV spectrophotometer calibrated at 219 nm was used to analyze 1 mL after it had been diluted up to 10 mL.[19]

In vitro drug release

The USP Dissolution Apparatus II was used for the *in vitro* drug release and it was run at 50 rpm with a temperature range of 37±0.5°C, the shaft was positioned such that its axis was within 2 mm and the bottom edge of the blade was 23-27 mm. The paddle descended. The tablet was placed in the basket; the equipment was switched on at 50 revolutions per minute for 30 min; 5 mL samples were taken at 5 min intervals; and volume equal to the sample volume was replenished with dissolving media. Whatman filter paper was used to filter the samples. The proper dilutions were made and they were then examined using a UV spectrophotometer at a maximum of 219 nm. The cumulative amount of drug release was determined.[20]

RESULTS

Preformulation study

Determination of melting point

Eletriptan hydrobromide melting point has been shown to be 169-170°C, which is matching published data.

Solubility determination of Eletriptan hydrobromide in various mediums

Eletriptan hydrobromide solubility in distilled water as well as phosphate buffer (pH 6.8) was investigated and the results are presented in Table 2 below. The study's results suggested that eletriptan hydrobromide had low solubility in water at pH 6.8 and distilled water.

Table 1: Composition of each sublingual tablet as per Central Composite Design.

Ingredient (mg)	SLT 1	SLT 2	SLT 3	SLT 4	SLT 5	SLT 6	SLT 7	SLT 8	SLT 9
Eletriptan hydrobromide	20	20	20	20	20	20	20	20	20
β-Cyclodextrin	40	40	40	40	40	40	40	40	40
Sodium starch glycolate	4.75	8	4.75	9.34	8	0.15	1.5	1.5	4.75
PVP K-30	0.48	0.93	0.62	1.37	1.25	0.93	0.62	1.25	0.93
Microcrystalline cellulose	26.02	22.32	25.8	20.54	22	30.17	29.13	28.5	25.57
Sodium saccharine	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Menthol	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Magnesium stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Talc	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25
Total	100	100	100	100	100	100	100	100	100

Table 2: Solubility data of Eletriptan hydrobromide in different mediums and Solubility data of solid dispersion of Eletriptan hydrobromide in distilled water and phosphate buffer pH 6.8.

Name of drug	Ratio	Medium	
		Distilled water (mg/mL) Mean±SD	Phosphate buffer pH 6.8 (mg/mL) Mean±SD
Eletriptan hydrobromide		0.170±0.002	1.847±0.005
Eletriptan hydrobromide+β - cyclodextrin solid dispersion	1:1	0.936±0.004	8.471±0.007
	1:2	3.632±0.006	11.327±0.003

Table 3: Evidence of drug-excipient interaction study.

Sl. No.	Drug/drug+Excipient Ratio (1:1)	Preliminary day (R_f) (cm)	Later 14 days (R_f) (cm)	Inference
1.	Drug (Eletriptan Hydrobromide)	0.54	0.54	No change
2.	Drug+β-cyclodextrin	0.51	0.51	No change
3.	Drug+SSG	0.55	0.55	No change
4.	Drug+PVP K-30	0.52	10.53	No major change
5.	Drug+Magnesium Stearate	0.57	0.57	No change
6.	Drug+MCC	0.53	0.54	No major change
7.	Drug+Talc	0.56	0.56	No change
8.	Drug+ Sodium saccharine	0.54	0.54	No change
9.	Drug+Menthol	0.50	0.50	No change

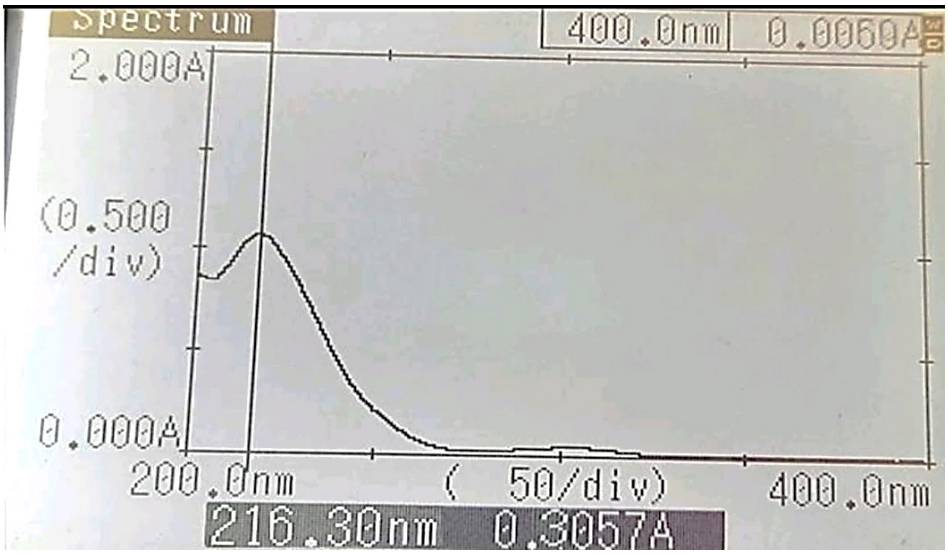

Figure 1a: UV Spectrum of Eletriptan hydrobromide in distilled water.

In Table 2, the results of an investigation on the solubility of a solid dispersion of eletriptan hydrobromide with β-cyclodextrin (1:1, 1:2) in distilled water and phosphate buffer pH 6.8 are shown.

Drug-Excipient interaction study using TLC

TLC analyzed that there was no interaction between the Eletriptan hydrobromide and excipients. Hence it has been proved that the drug was authentic and free from impurities and the results are shown in Table 3.

Determination of wavelength using UV-visible spectroscopy

The absorption maxima of Eletriptan hydrobromide in distilled water and phosphate buffer (pH 6.8) were 216 nm and 219 nm

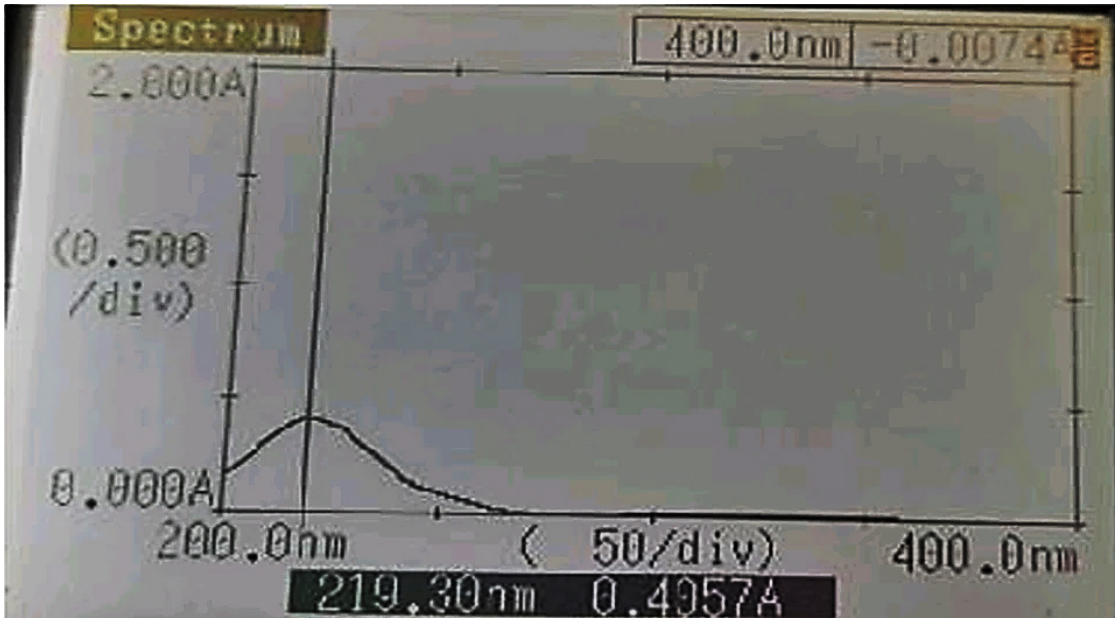

Figure 1b: UV Spectrum of Eletriptan hydrobromide in phosphate buffer pH 6.

Table 4: Observed response of central composite design for a sublingual tablet of Eletriptan hydrobromide.

Formulation code	Independent variables		Dependent variables	
	Sodium starch glycolate in mg (X_1)	PVP K-30 in mg (X_2)	Disintegration time in sec. (Y_1)	*In vitro* % drug release (Y_2)
SLT1	4.75	0.48	70±0.41	73.25±1.7
SLT2	8	0.93	65±2.56	87.39±0.6
SLT3	4.75	0.62	73±0.52	79.13±1.4
SLT4	9.34	1.38	60±0.74	96.36±0.5
SLT5	8	1.25	66±1.67	93.65±0.3
SLT6	0.15	0.93	88±1	81.12±0.2
SLT7	1.5	0.62	82±0.377	76.38±0.7
SLT8	1.5	1.25	84±1.526	90.36±0.1
SLT9	4.75	0.93	74±1.88	84.33±1.6

Table 5: Hardness, Thickness, Percentage friability, Average weight Drug content, Wetting time, Water absorption ratio and Disintegration time of Batch SLT1- SLT9.

Batch	Hardness (kg/cm^2)±SD	Thickness (nm)±SD	Percentage friability (%)±SD	Average weight (mg)±SD	Drug content ±SD	Wetting time (seconds)±SD	Water absorption ratio±SD	Disintegration time (seconds)±SD
SLT1	2.53±0.67	0.58±1.48	0.68±0.54	96.23±0.4	96.6±1.23	33.66±0.62	35.05±3.605	70±0.41
SLT2	2.62±0.108	0.65±0.42	0.76±0.36	94.6±0.02	95.32±0.568	34.23±1	36.65±2.514	65±2.56
SLT3	2.6±0.04	0.56±0.76	0.90±0.053	95.7±1.63	96.85±0.762	32.41±0.3	40±1	73±0.52
SLT4	2.5±0.27	0.55±0.38	0.91±0.015	98.3±0.03	98.73±0.747	30.4±0.4	49.30±0.78	60±0.74
SLT5	2.85±2.16	0.61±0.14	0.65±1.35	97.57±0.41	97.34±1.145	34.67±0.6	44.66±4.163	66±1.67
SLT6	2.35±0.48	0.57±0.1	0.75±4.2	94±1.8	97.6±1.59	31.08±0.59	34.66±0.377	88±1
SLT7	2.56±0.13	0.66±0.48	0.68±0.65	97.5±0.78	95±1	35.4±1.45	42±0.46	82±0.377
SLT8	2.63±0.36	0.56±0.063	0.85±0.19	95.43±0.23	90.66±0.52	34.5±2.6	37.55±0.08	84±1.526
SLT9	2.7±0.01	0.59±0.051	0.74±0.25	93.2±0.59	95.77±0.74	36.8±0.59	31.23±0.46	74±1.88

Table 6: Percentage drug release data of SLT1 to SLT9 formulations for sublingual tablets.

Time (in min)	0	3	6	9	12	15
SLT1	0	43.02±0.3	54.7±0.4	60.92±0.2	70.89±0.6	73.25±1.7
SLT2	0	47.53±0.5	57.8±0.2	61.74±0.6	79.82±1.5	87.39±0.6
SLT3	0	42.93±0.2	51.05±0.5	66.18±1.8	72.56±0.1	79.13±1.4
SLT4	0	61.57±0.4	67.89±0.3	75.62±0.3	86.54±0.7	96.36±0.5
SLT5	0	59.57±0.7	63.04±0.1	74.58±0.7	85.78±0.4	93.65±0.3
SLT6	0	49.48±0.9	52.47±0.6	69.27±0.5	75.67±0.6	81.12±0.2
SLT7	0	40.21±0.3	50.12±0.4	61.5±1.34	70.71±0.2	76.38±0.7
SLT8	0	59.4±0.1	60.92±0.9	73.46±0.1	82.21±0.4	90.36±0.1
SLT9	0	49.47±0,6	50.49±1.4	69.25±0.8	71.31±0.3	84.33±1.6

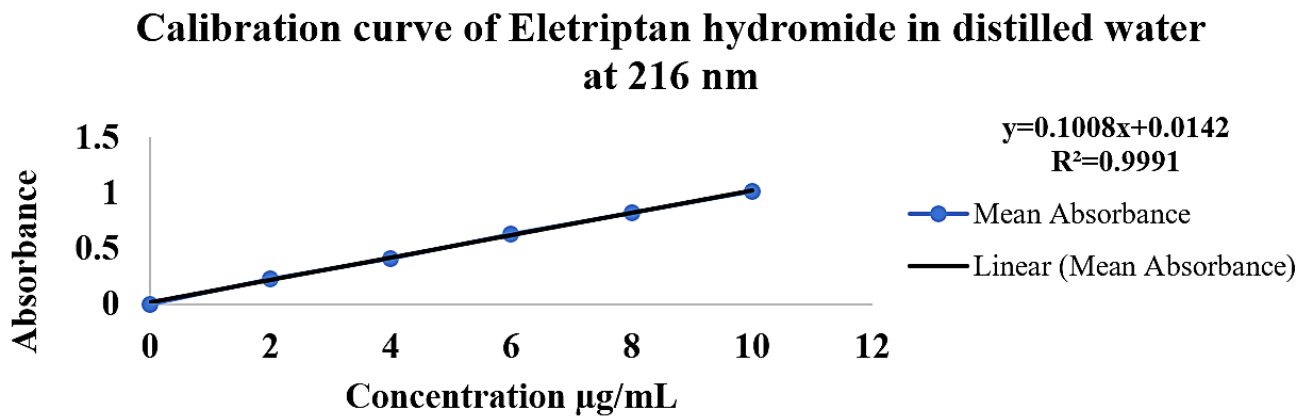

Figure 2a: Calibration curve of Eletriptan hydrobromide in distilled water at 216 nm.

which matches the reported wavelength as mentioned in Figure 1 (a and b).

Preparation of calibration curve

Eletriptan hydrobromide calibration curve was developed using phosphate buffer (pH 6.8) and distilled water Figures 2a and 2b.

Formulation, Development and Optimization of sublingual tablet

Evaluation of solid dispersion

Solid dispersion formulation percentage drugs concentration was found to be 80.5%.

The given formulation variables were optimized using a central composite experimental design because the response surface approach involves trials. The 3D response surface plots were obtained using Design Expert 13 Software (software for the design of experiments) DOE by Stat-Ease, Inc. which were shown in Figures 3a and 3b and data transformation, responses were shown in Table 4 PVP K-30 and sodium starch glycolate were used as independent variables (X1) and (X2), respectively and their effects on the dependent variables (Y1) and (Y2) were investigated. The results are presented in Table 4.

Evaluation of sublingual tablet

The results of the study are shown in Table 5. Various physicochemical characteristics were evaluated, including hardness, thickness, weight variation, friability, disintegration time, wetting time, water absorption ratio and drug content.

In vitro % drug release study for sublingual tablet

The percentage drug release from formulations SLT1 to SLT9 within a range of 73.25 % to 96.36% after 15 min. The *in vitro* % drug release data is shown in Table 6 and Figure 4.

DISCUSSION

Optimization of sublingual tablet

Disintegration time (Y1) and *in vitro* drug release (Y2) were determined to be in the ranges of 60 to 88 seconds and 73.25% to 96.36%, respectively, for the response. To evaluate the quantitative effects of the various combinations of factors and levels on disintegration time and *in vitro* drug release, the response models were developed using Design Expert software by applying coded values of the factors and levels. Full model equations can be used to represent the model that was selected.

Disintegration time=74.44-8.92A+1.21B

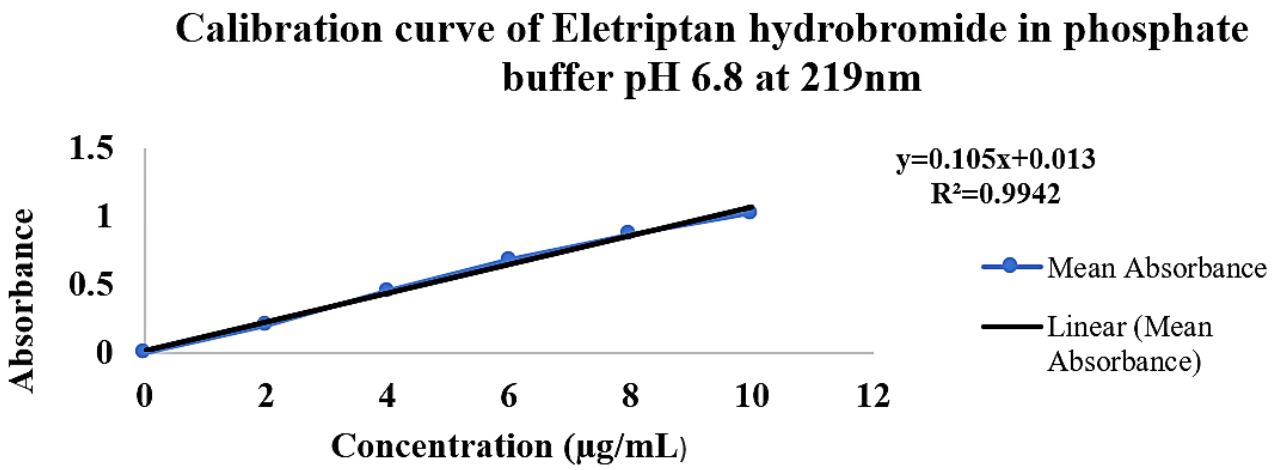

Figure 2b: Calibration curve of Eletriptan hydrobromide in phosphate buffer pH 6.8 at 219 nm.

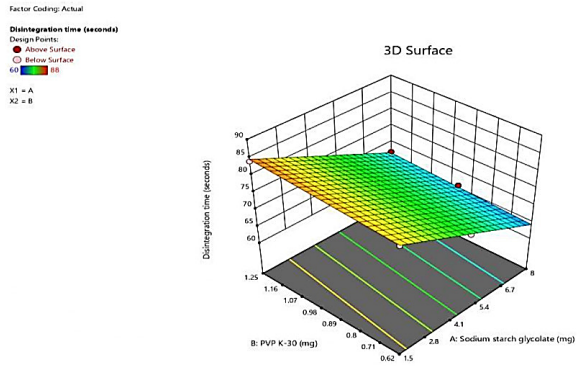

Figure 3a: 3D surface plot of sublingual tablet for disintegration time.

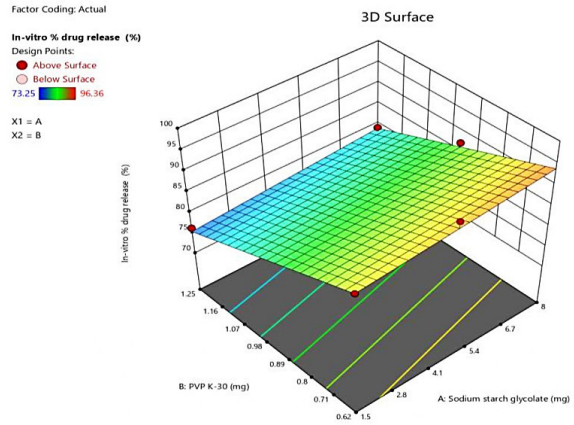

Figure 3b: 3D surface plot of sublingual tablet for *in vitro* % drug release.

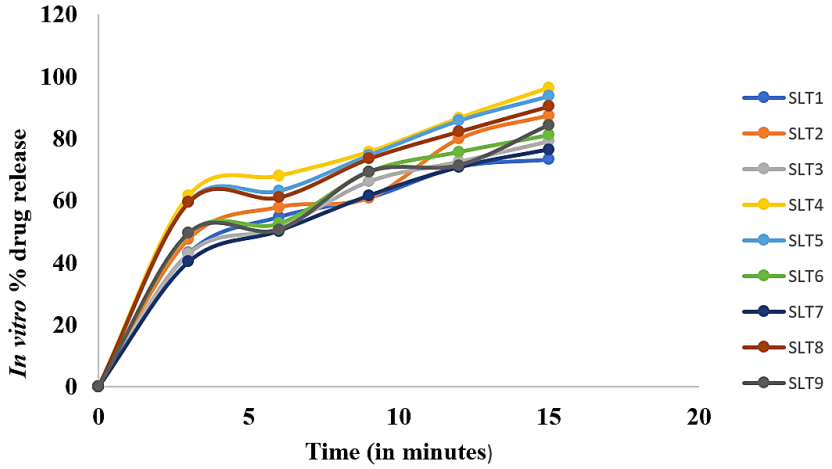

Figure 4: *In vitro* % drug release of SLT1 to SLT9 formulation.

In vitro % drug release=84.66+1.74A-7.43B

Data analysis

With values of R^2 for disintegration time and *in vitro* % drug release of 0.9581 and 0.9327, respectively, for each indicating good fit, an Analysis of Variance (ANOVA) also shows the effect of individual parameter and interaction of variable on the sublingual tablet in order to investigate the significance and fitness of the model. With values of R^2 for disintegration time and *in vitro* % drug release of 0.9581 and 0.9327, respectively, for each indicating good fit, an ANOVA also shows the effect of individual parameters and interaction of parameters on the sublingual tablet in order to investigate the significance and fitness of the model.

CONCLUSION

To prevent first-pass metabolism and provide rapid onset of action, sublingual drug delivery of Eletriptan hydrobromide is considered to be one of the best surrogate routes of administration. Additionally, it will lead to patient compliance as well as increase therapeutic efficacy. To attain this, a central composite design was used with a combination of sodium starch glycolate and PVP K-30 which gives the best result in the SLT-4 batch with respect to disintegration time and *in vitro* % drug release.

ACKNOWLEDGEMENT

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ABBREVIATIONS

SSG: Sodium starch glycolate; **PVP:** Polyvinyl pyrrolidine; **MCC:** Microcrystalline; **RPM:** Revolution Per Minute; **TLC:** Thin layer chromatography; **ANOVA:** Analysis of variance; **DOE:** Design of experiment; **R^2:** Correlation coefficient.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

SUMMARY

In migraine, a fast pharmacological response is necessary; the sublingual route not only overcomes the problem of dysphagia (difficulty in swallowing) but also gives the rapid onset of action by enhancing permeability through the site of administration. Sublingual administration is an effective, safe method and gives a rapid onset of action. Hence, rapid dissolution may be achieved through sublingual tablets which result in increased bioavailability/rapid absorption through pre-gastric absorption of drugs from the mouth, pharynx and esophagus as saliva passes down.

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