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Formulation and in Vitro Evaluation of Sublingual Films of Eletriptan

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ABSTRACT:

Objective: The objective of the present investigation was to develop and evaluate sublingual films of Eletriptan in order to enhance its bioavailability and provide rapid onset of action in the treatment of migraine. **Materials and Method:** Sublingual films of Eletriptan were prepared by solvent casting method using hydroxypropyl methylcellulose (HPMC E15) as film-forming polymer. Compatibility studies were carried out using FTIR spectroscopy. Prepared films were evaluated for various physicochemical parameters such as thickness, weight variation, folding endurance, surface pH, drug content, in vitro disintegration time and in vitro drug release. **Results and Discussion:** FTIR studies revealed no significant interaction between drug and excipients. Among all formulations, films prepared using HPMC E15 showed better mechanical properties and rapid disintegration. The optimized formulation exhibited a minimum disintegration time of 25 ± 1.5 seconds and cumulative drug release of 99.44% within 10 minutes. Stability studies indicated no significant changes in the properties of films after one month. **Conclusion:** The study concluded that sublingual films of Eletriptan are a promising dosage form which can improve patient compliance, provide rapid onset of action and enhance bioavailability in migraine therapy.

INTRODUCTION:

Migraine is a chronic neurological disorder characterized by recurrent episodes of severe headache often accompanied by nausea, vomiting and sensitivity to light and sound. It significantly affects the quality of life and daily activities of patients. Conventional oral dosage forms used in migraine therapy often show delayed onset of action and reduced bioavailability due to extensive first-pass hepatic metabolism.[1]

Eletriptan is a selective serotonin (5-HT$_1$B/$_1$D) receptor agonist used in the acute treatment of migraine. Although Eletriptan belongs to BCS class I, its oral bioavailability is limited due to metabolism by cytochrome P450 enzyme CYP3A4. Therefore, an alternative route of administration is required to bypass first-pass metabolism and improve therapeutic efficacy.[2]

Sublingual drug delivery system offers several advantages such as rapid onset of action, avoidance of hepatic first-pass metabolism, improved bioavailability and enhanced patient compliance. Sublingual films are thin, flexible dosage forms that rapidly disintegrate in the oral cavity without the need of water, making them suitable for paediatric, geriatric and dysphagic patients.[3]

Considering these advantages, the present study was undertaken to formulate and evaluate sublingual films of Eletriptan to achieve rapid drug release, improved bioavailability and better patient acceptability. [4]

MATERIALS AND METHODS:

Materials:

Hydroxypropyl methylcellulose E15, Sodium Starch Glycolate (SSG), aspartame, PEG 400, Citric acid, Tween 80 and Methanol were procured from Chemdyes Corporation, Rajkot, Gujarat, India.

Fabrication of Sublingual Films [5]:

Sublingual films were prepared by solvent casting method. The required quantity of polymer was dissolved in suitable solvent with continuous stirring to obtain a clear solution. Drug and other excipients were added to the polymeric solution and mixed uniformly. The prepared solution was cast on a leveled surface and allowed to dry. The dried films were carefully removed and cut into required dimensions. Each Film contained 166 milligrams of Eletriptan. All formulations' compositions were listed in Table 1.

Dose Calculation for formulation of Film in Petri dish:

The dose of Eletriptan is 20 mg and thus amount of Eletriptan required in the Film of 4 cm^2 is 20 mg. Calculate the area of Petridish using diameter identified with the help of ruler. The diameter was found to be 6.5 cm (radius r was 3.25) and thus its area can be calculated using the formula πr^2 and thus it was found out to be 33.17 cm^2. As the drug required in the 4 cm^2 area is 20 mg, the amount of drug required in the area of 33.17 cm^2 would be:

$$\text{Total amount of drug required} = \frac{(33.17 \text{ X } 20)}{4}$$

= 165.85 mg ≈ 166 mg

Thus, the total amount of drug required would be 166 mg in the Petri dish of 33.17 cm^2 area.

Table 1: Formulation batches of Eletriptan Sublingual Film

Ingredients	Formulation code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Eletriptan (mg)	166	166	166	166	166	166	166	166	166
HPMC E15 (% W/V)	200	300	400	200	300	400	200	300	400
SSG (mg)	2	2	2	4	4	4	6	6	6
Aspartame (%w/v)	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
PEG 400 (ml)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Citric acid (mg)	4	4	4	4	4	4	4	4	4
Tween 80 (ml)	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Water (ml)	3	3	3	3	3	3	3	3	3
Methanol (ml)	7	7	7	7	7	7	7	7	7

Determination of Melting point of Eletriptan[6]:

The melting point of Eletriptan was determined using a melting point apparatus by placing a small amount of the drug in a sealed thin-walled capillary tube and recording the temperature range at which it melts.

Estimation of Eletriptan by UV-Visible Spectrophotometry[7]:

Determination of λ_{max} of Eletriptan in phosphate buffer at pH 6.8:

Appropriate amounts (accurately weighed) of Eletriptan (10 mg) were quantitatively measured and then make the stock solution concentration of 100 µg/ml per IP. For determination of λ_{max}, stock solution was scanned between 200-400 nm against phosphate buffer (pH 6.8) as a blank in the UV-Visible spectrophotometer. Working solutions of concentration 2, 4, 6, 8 and 10 ppm were prepared by pipette outing 0.2, 0.4, 0.6, 0.8 and 1 ml respectively from the stock solution of 100 ppm and diluted up to 10 ml volumetric flask. Absorbance of working solutions

was measured in triplicate at λ_{max} at 272 nm against phosphate buffer (pH 6.8) as a blank.

Evaluation of Sublingual Films [8-16]:

Thickness of Films:

By using micrometer screw gauge the thickness of the Film was measured at five different places; an average of these five values was calculated. This is essential to ascertain uniformity in the thickness of the Film this is directly related to the accuracy of dose in the Film.

Weight variation:

10 Film were randomly selected and weighed on analytical balance and average weight was determined for each Film. It is desirable that Film should have nearly constant weight. It is useful to ensure that a Film contains the proper amount of excipients and API.

Folding Endurance:

Folding endurance was determined by repeated folding of the Film at the same place till the Film breaks. The number of times the Film was folded without breaking is computed as the folding endurance value.

Surface pH:

Formulated Film was placed in the center of petridish. It was then moistened with 0.5 ml phosphate buffer and kept for 30seconds. pH was then measured with the help of electrode by allowing to attain equilibrium.

***In-vitro* Disintegration Time:**

A Film was placed on stainless steel wire-mesh placed in a petridish containing 10ml of phosphate buffer pH 6.8 and the time required for the Film to break was noted. An average of three readings was taken into consideration.

% Moisture Uptake:

Films were cut in desired size and were exposed to an environment at room temperature for 1 week. The moisture uptake was calculated as difference in final weight and initial weight and percentage of moisture uptake was calculated.

$$\%\ \textbf{Moisture uptake} = \frac{\textbf{Final weight} - \textbf{Initial weight}}{\textbf{Initial weight}} \times \mathbf{100}$$

Drug Content:

The Film was dissolved in 10ml of Phosphate buffer pH 6.8 and it was then filtered. Drug content was estimated using double beam UV Visible Spectrophotometer at 272 nm. An average of triplicate was taken and then concentration was calculated from calibration curve.

***In vitro* Dissolution studies:[17]**

In vitro dissolution studies were carried out using USP type II Dissolution apparatus. It was filled with 500ml phosphate buffer pH 6.8 and maintained at 37 ± 5 ˚C temperature and 50rpm. The Film was place on watch glass and it was covered by nylon wire mesh and clamped properly. This unit was then dropped into dissolution flask. Five ml aliquots were withdrawn at different time intervals and was replaced with same volume of fresh buffer solution. The samples were analyzed at 272 nm using UV Visible Spectrophotometer.

Stability Studies:[18] The optimized batch was wrapped in aluminum foil and loaded in the Stability Chamber as per ICH Guidelines for 1 month at 40˚C ± 2˚C and 75 % ± 5% relative humidity. After completion on 1 month the film was taken out and evaluated for all parameters.

RESULTS:

Melting point of Eletriptan:

Melting point determination is one of the popular techniques used to identify drug using melting point apparatus and melting point of Eletriptan was found in the range of 165-179°C.

Reported melting point of Eletriptan is 168-173°C and is thus similar to the melting point of Eletriptan. (Table 2)

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Table:2 Melting point of Eletriptan

Sr. No.	Reported Melting Point	Observed Melting point
1.	168-173°C	173-179°C
2.		171-176°C
3.		165-169°C

Identification of drug by UV Spectroscopy Method:

Analytical method for Eletriptan in phosphate buffer at pH 6.8:

For the determination of λ_{max}, stock solution was scanned between 200-400 nm against phosphate buffer (pH 6.8) as a blank in the UV-Visible spectrophotometer. Working solutions of concentration 2, 4, 6, 8 and 10 ppm were prepared. Absorbance of working solutions was measured in triplicate at λ_{max} at 272 nm against phosphate buffer (pH 6.8) as a blank (Table 3 and figure 1).

Table 3: Absorbance of different concentrations of Eletriptan in phosphate buffer at pH6.8

Sr. No.	Concentration (ppm)	Absorbance			Mean Absorbance ± S.D.
		I	II	III	
1	2	0.166	0.170	0.165	0.167 ± 0.003
2	4	0.330	0.335	0.332	0.332 ± 0.003
3	6	0.486	0.493	0.490	0.489 ± 0.004
4	8	0.650	0.647	0.649	0.648 ± 0.002
5	10	0.811	0.813	0.817	0.813 ± 0.003

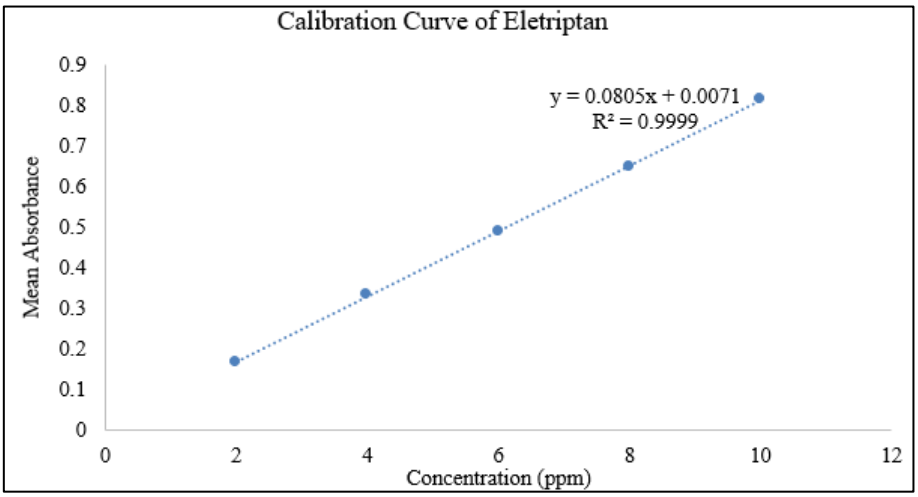

Figure 1: Calibration curve of Eletriptan in phosphate buffer at pH 6.8

Evaluation Parameters

Physical Appearance

From physical appearance parameters it was seen that batches F1, F4 and F7 having 200 mg of polymers were slightly sticky in nature and all other batches were non-sticky. All Batches were smooth & transparent. (Table 4)

Table 4: Stickiness, Surface Appearance, Film clarity Data

Batch	Stickiness	Surface Appearance	Film clarity
F1	Sticky	Smooth	Transparent
F2	Non-sticky	Smooth	Opaque
F3	Non-sticky	Slightly rough	Transparent
F4	Sticky	Smooth	Transparent
F5	Non-sticky	Smooth	Slightly Opaque
F6	Non-sticky	Smooth	Transparent
F7	Sticky	Slightly rough	Transparent
F8	Non-sticky	Smooth	Transparent
F9	Non sticky	Smooth	Transparent

Thickness of the film was measured using micrometer screw gauge showed that the thickness of the film was in the range of 0.134 ± 0.0010 mm to 0.152 ± 0.0005 mm. Weight variation tests for all prepared films shown range of weight from 35.8 ± 1.32 mg to 67.2 ± 1.32 mg. The folding endurance value of the films prepared with ranged

from 101 ± 2.52 folds to 123 ± 2.65 folds. In the formulations as polymer concentration increases folding endurance values were also increased. Surface pH of the prepared films were in the range of 6.5 to 6.7. Thus, all the films had pH in the desired range (Table 5).

Table 5: Thickness, Weight variation, Folding endurance, Surface pH Data

Batch	Thickness (mm ± S.D.)	Weight variation (mg ± S.D.)	Surface pH	Folding endurance (mean ± SD)
F1	0.134 ± 0.0010	35.8 ± 1.32	6.7 ± 0.15	101 ± 2.52
F2	0.139 ± 0.0004	41.4 ± 1.17	6.7 ± 0.06	103 ± 3.51
F3	0.141 ± 0.0005	48.5 ± 3.47	6.6 ± 0.17	107 ± 3.21
F4	0.139 ± 0.0009	42.9 ± 1.29	6.7 ± 0.06	153 ± 2.08
F5	0.143 ± 0.0008	49.4 ± 1.51	6.5 ± 0.06	109 ± 1.15
F6	0.146 ± 0.0009	56.2 ± 1.75	6.6 ± 0.15	119 ± 3.21
F7	0.141 ± 0.0004	51.6 ± 0.97	6.6 ± 0.21	111 ± 2.08
F8	0.147 ± 0.0009	59.2 ± 1.62	6.6 ± 0.10	115 ± 2.52
F9	0.152 ± 0.0005	67.2 ± 1.32	6.7 ± 0.06	123 ± 2.65

* All values are expressed as mean ± SD; (n=6)

The % moisture uptake value of prepared films was ranging from 2.10 ± 0.13 % to 2.41 ± 1.19 %. It showed that as the polymer grade and ratio is increased, the moisture uptake is increased. The disintegration time ranged between 25 ± 1.5 secs 61 ± 3.2 seconds. Disintegration time of the F9 batches having HPMC E15: SSG in ratio of 400:6 mg was found to be lowest, i.e. 25 ± 1.5 secs. Drug Content of all prepared film was found in the range of 97.22 % to 99.65 %. Thus, all films had drug content in acceptable limits. (Table 6)

Table 6: Percentage Moisture uptake, Disintegration time, Drug Content Data

Batch	Percentage moisture uptake (% ± S.D.)	Disintegration time (sec ± S.D.)	Drug Content (%)
F1	2.10 ± 0.13	61 ± 3.2	97.22 ± 0.06
F2	2.11 ± 0.54	58 ± 1.5	98.58 ± 0.02
F3	2.23 ± 0.63	49 ± 1.5	98.23 ± 0.03
F4	2.17 ± 0.71	53 ± 3.1	99.7 ± 0.03
F5	2.29 ± 1.16	44 ± 2.1	98.3 ± 0.03
F6	2.38 ± 1.73	26 ± 1.5	97.38 ± 0.03
F7	2.34 ± 1.16	39 ± 1.5	97.84 ± 0.02
F8	2.36 ±0.25	31 ± 2.1	98.21 ± 0.03
F9	2.41 ± 1.19	25 ± 1.5	99.65 ± 0.03

* All values are expressed as mean ± SD; (n=6)

***In vitro* Drug release:**

In vitro Drug release is performed by using dissolution test apparatus type II (paddle) in 500 ml of the phosphate buffer at pH 6.8 as a dissolution medium at 37° ± 0.5 °C at 50 rpm. Batch F1, F2 and F3 showed drug release of 97.08 %, 98.27 % and 96.36 % in 14, 14 and 12 minutes respectively. Batch F4, F5 and F6 showed drug release of 99.29 %, 97.38 % and 97.29 % in 14, 12 and 10 minutes respectively. Whereas batch F7 to F9 showed drug release of 98.73 %, 99.18 % and 99.44 % of drug release in 12, 12 and 10 minutes respectively (Figure. 2,3 and 4).

Thus, from the above results it was concluded that the drug release of batch F9 was faster in only 10 mins as compared to all other batches. On the basis of all above parameters it was concluded that the batch F9 was an optimized batch, as it had good surface appearance, pH, Mechanical strength and Drug Content.

Moreover, it showed 99.44% of drug release in just 10 minutes and its *In vitro* disintegration time was just 25 seconds which was least as compared to all other batches.
Thus, batch F9 was selected as an optimized batch.

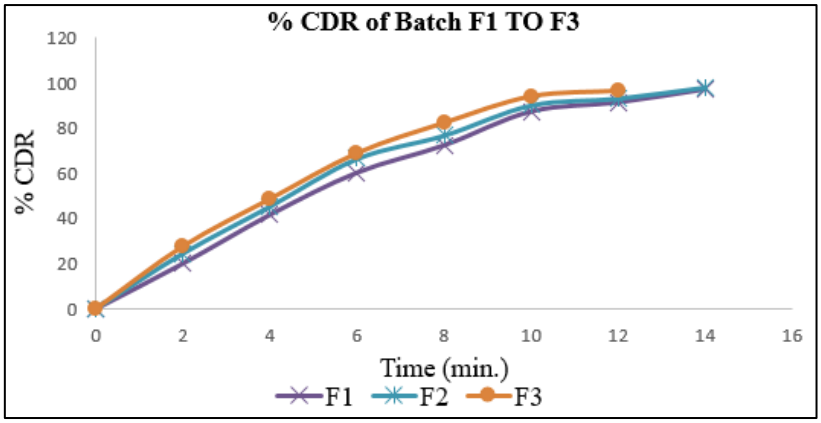

Fig. 2: *In vitro* Drug release of batch F1 to F3

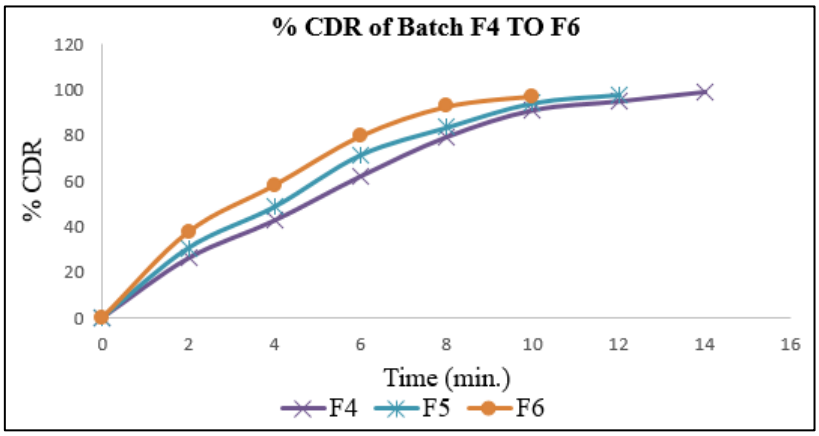

Fig. 3: *In vitro* Drug release of batch F4 to F6

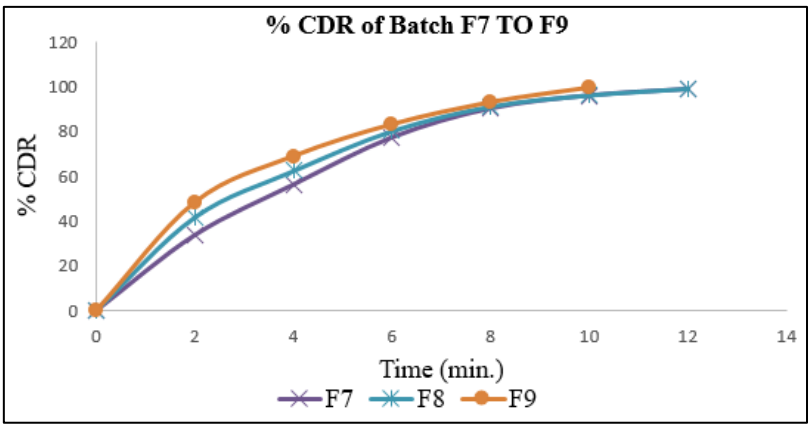

Fig. 4: *In vitro* Drug release of batch F7 to F9

RESULT OF STABILITY STUDY:

- A stability study was carried out to check the stability of films of the Optimized batch. A stability study carried out at 40°± 2 °C and 75 ± 5% RH for one month.
- After time period of one month evaluation of *In vitro* Disintegration time, *In vitro* Drug release, Folding Endurance, % Moisture Uptake, Drug Content and Drug release was carried out and their results are shown in (Table 7 and 8).
- Comparison study between the result of optimized batch and after period of stability of optimized batch is graphically illustrated in (Figure 5)

Table 7: Result of the Stability study

Sr. No.	Evaluation parameter	Results of optimized batch F9	Result after 1 month
1.	**Weight Variation**	67.2 ± 1.32	68.0 ± 1.60
2.	**Folding Endurance**	123 ± 2.65	120 ± 1.15
3.	**% Moisture Uptake**	2.41 ± 0.16	2.97 ± 0.82
4.	***In Vitro* Disintegration Time**	25 ± 1.5 sec.	27 ± 1.0 sec.
5.	**Drug Content**	99.65 ± 0.03%	98.57 ± 0.03%

Table 8: *In vitro* Drug release of Stability Batch

Time (Min.)	*In vitro* Drug release of Optimized Batch F9 (% ± S.D.)	*In vitro* Drug release of batch F9 After 1 Month (% ± S.D.)
0	0	0
2	48.66 ± 0.21	47.50 ± 1.41
4	68.62± 1.43	66.55±1.28
6	83.46 ±0.27	82.56 ±1.32
8	92.62 ±1.46	91.55 ± 1.27
10	99.44 ±0.28	98.85 ±1.28

*** All values are expressed as mean ± SD; (n=6)**

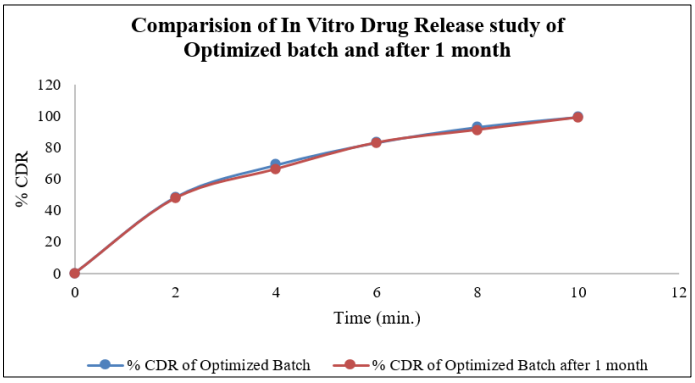

Fig. 5: Comparison of *In vitro* Drug release of Optimized batch initial and after Stability study

CONCLUSION:

The present study was aimed at developing sublingual films of Eletriptan using HPMC E15 polymer to achieve rapid drug release and improved bioavailability. Sublingual films were prepared by the solvent casting method using PEG as plasticizer, citric acid as saliva-stimulating agent, and Tween 80 as surfactant. FTIR studies confirmed the compatibility of Eletriptan with all excipients. Among the polymers evaluated, HPMC E15 exhibited superior film-forming ability and an optimal drug release profile. Formulation F9, containing 400 mg of HPMC E15 and 6 mg of SSG, was identified as the optimized batch, exhibiting a minimum disintegration time of 25 ± 1.5 seconds and 99.44% drug release within 10 minutes. Stability studies conducted for one month under accelerated conditions indicated no significant changes in the physicochemical properties of the films. Overall, the study concludes that sublingual films of Eletriptan are a stable, effective, and patient-friendly dosage form and may serve as a promising alternative for the treatment of migraine.

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CONFLICT OF INTEREST:

The authors declare that there is no conflict of interest.

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