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## Formulation and Evaluation of Mouth Dissolving Film of Empagliflozin

Sachin R. Choriya<sup>1</sup>, Asutosh R. Rathod<sup>2</sup>, Bhumi A. Raval<sup>3</sup>, Suraj R. Chauhan<sup>4</sup>, Jitendra O. Bhangale<sup>5</sup><sup>1,2</sup>Student, Smt. N. M. Padalia Pharmacy College, Navapura, Ahmedabad, Gujarat, India 382210<sup>3</sup>Professor, Smt. N. M. Padalia Pharmacy College, Ahmedabad, Gujarat, 382210, India<sup>4</sup>Associate Professor, Smt. N. M. Padalia Pharmacy College, Ahmedabad, Gujarat, 382210, India<sup>5</sup>Professor and Principal, Smt. N. M. Padalia Pharmacy College, Ahmedabad, Gujarat, 382210, India**Article Information**

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**Keywords***Mouth Dissolving Films, Empagliflozin, HPMC E5, Sodium Starch Glycolate, solvent casting method..***ABSTRACT****ABSTRACT**

The primary aim of this research was to create Mouth Dissolving Films of anti-diabetic drug Empagliflozin using various polymers like HPMC E5, along with Sodium Starch Glycolate (SSG) as a superdisintegrant by solvent casting method. Empagliflozin mouth-dissolving films are expected to provide quicker drug action and improved bioavailability due to rapid absorption and avoidance of extensive hepatic metabolism. After assessing different physicochemical properties, it was observed that the batch with HPMC E5 as the polymer and SSG as the superdisintegrant exhibited superior film-forming ability and an appropriate drug release profile. Based on the findings, Batch F9, comprising 50 mg of HPMC E5 and 6 mg of SSG, emerged as the optimized batch, demonstrating an In-vitro disintegration time of  $19 \pm 1.5$  seconds and % CDR of 99.73% at 14 minutes. Additionally, stability assessments conducted over period of one month at  $40^\circ\text{C} \pm 2^\circ\text{C}$  and  $75\% \pm 5\%$  relative humidity indicated that formulation F9 remained stable, with no significant alterations in the properties of the Mouth Dissolving Films. Overall, the study suggests that Mouth Dissolving Films of Empagliflozin represent a viable dosage form, potentially expanding treatment for conditions like diabetes mellitus.

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**INTRODUCTION:**

Diabetes mellitus is the commonest endocrine metabolic disorder characterised by deficiency of insulin in the body. Metabolic abnormalities in carbohydrates, lipids and proteins results from insulin as an anabolic hormone. Diabetes can harm multiple body systems, especially the blood vessels, eyes, kidneys, heart, and nerves. Diabetes mellitus is categorised into three types Type I Insulin Dependent Diabetes Mellitus (IDDM) and type II Non-Insulin Dependent Diabetes Mellitus (NIDDM) and type III Gestational diabetes mellitus (GDM).<sup>1-5</sup>

Empagliflozin is a sodium–glucose cotransporter-2 (SGLT-2) inhibitor prescribed for the management of type II diabetes mellitus. It is a potent, reversible, and highly selective inhibitor of SGLT-2. The drug acts by reducing renal glucose reabsorption, thereby promoting urinary excretion of excess glucose, and improving glycaemic control in patients with type II diabetes mellitus. Despite its therapeutic effectiveness, empagliflozin belongs to the Biopharmaceutics Classification System (BCS) class III, indicating high solubility but low permeability, which limits its oral bioavailability to approximately 78%. Additionally, empagliflozin has a half-life of about 12.9 hours and is administered as a once-daily dose of 5–10 mg. These pharmacokinetic limitations highlight the need for formulation strategies aimed at improving drug permeability, bioavailability and fast onset of action, thereby justifying the selection of empagliflozin for the present study.<sup>6</sup>

Conventional oral tablets of empagliflozin undergo first-pass hepatic metabolism, which can reduce the amount of drug reaching systemic circulation. In

contrast, a mouth-dissolving film administered via the sublingual route allows rapid drug absorption through the rich network of sublingual blood vessels. This route partially bypasses hepatic first-pass metabolism, thereby enhancing bioavailability. Direct absorption into the systemic circulation, and possibly the lymphatic system, results in a faster onset of therapeutic action compared to conventional oral dosage forms. Therefore, empagliflozin mouth-dissolving films are expected to provide quicker drug action and improved bioavailability due to rapid sublingual absorption and avoidance of extensive hepatic metabolism.<sup>7-11</sup> The main objective of current research work was to formulate and evaluate mouth dissolving film of empagliflozin.

## MATERIALS AND METHODS:

### Preformulation Studies Of Empagliflozin:<sup>12</sup>

#### Determination of Melting point of Empagliflozin<sup>13</sup>

Melting point of Empagliflozin was measured by melting point apparatus. Minimum amount of drug was placed in a thin-walled capillary tube closed at one end. This capillary was then mounted in a melting point apparatus with thermometer and then their temperature range over which Empagliflozin melts is measured. The readings were taken in triplicate.

#### Estimation of Empagliflozin by UV-Visible Spectrophotometry<sup>14</sup>

**Standard stock solution in phosphate buffer pH 6.8 were prepared by:** Standard stock solution of Empagliflozin was prepared by dissolving 10 mg of Empagliflozin in 100 ml phosphate buffer (pH 6.8), which make the stock solution of concentration of 100 µg/ml.

**$\lambda_{max}$  of Empagliflozin in phosphate buffer pH 6.8 were determined by:** For determination of  $\lambda_{max}$ , stock solution was scanned between 200-400 nm against phosphate buffer (pH 6.8) as a blank in the UV-Visible spectrophotometer.

**Working solutions were prepared by:** Working solution of concentration 5, 10, 15, 20 and 25 ppm were prepared by pipette outing 0.5, 1, 1.5, 2 and 2.5 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  $\lambda_{max}$  at 224 nm against phosphate buffer (pH 6.8) as a blank.

### Formulation Design Of Empagliflozin Mouth Dissolving Films<sup>15-24</sup>

#### Dose Calculation for formulation of Film in Petri dish

The dose of Empagliflozin is 25 mg, so 25 mg of Empagliflozin is needed for a 4 cm<sup>2</sup> film. Measure the diameter of the Petri dish using a ruler. The diameter was determined to be 6.5 cm (radius r = 3.25 cm), and its area was calculated using the formula  $\pi r^2$ , resulting in 33.167 cm<sup>2</sup>. Since 25 mg of the drug is needed for a 4 cm<sup>2</sup> area, the amount required for an area of 33.167 cm<sup>2</sup> is calculated accordingly.

$$\text{Total amount of drug required} = \frac{(33.17 \times 25)}{4} = 207.3 \text{ mg}$$

Thus, the total amount of drug required would be 207.3 mg in the Petri dish of 33.17 cm<sup>2</sup> area.

#### Formulation Design of Empagliflozin Mouth Dissolving Films by Solvent Casting method

Mouth dissolving Films of Empagliflozin were prepared by using Solvent Casting method. In solvent casting method initially, the water-soluble HPMC E5 and PEG 400 were dissolved in water at 1,000 rpm and was heated up to 50°C. All the other excipients like colors, flavoring agent, sweetening agent, etc., were dissolved separately. Then both the solutions obtained were mixed thoroughly stirring at 1,000 rpm. The obtained solution was incorporated with the Empagliflozin dissolved in suitable solvent. The entrapped air was removed by sonicating the prepared solution. The resulting solution was casted as a film and allowed to dry, which was then cut into pieces of the desired size (Table 1).

**Table 1: Formulation of Mouth Dissolving Films of Empagliflozin**

Ingredients	Formulation code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Empagliflozin (mg)	207.3	207.3	207.3	207.3	207.3	207.3	207.3	207.3	207.3
HPMC E5 (mg)	40	45	50	40	45	50	40	45	50
SOG (mg)	3	3	3	4.5	4.5	4.5	6	6	6
Aspartame (%w/v)	5	5	5	5	5	5	5	5	5
PEG 400 (%w/v)	10	10	10	10	10	10	10	10	10
Water (ml)	6	6	6	6	6	6	6	6	6
Methanol (ml)	6	6	6	6	6	6	6	6	6

#### Evaluation Parameters Of Mouth Dissolving Film<sup>15-18</sup>

**Physical Appearance:** Formulated batches were analyzed for Stickiness, Surface appearance and Film clarity.

**Weight variation:** Films were randomly selected and weighed using an analytical balance to determine the average weight of each film. It is important for the films to have a consistent weight to ensure they contain the correct amounts of

excipients and active pharmaceutical ingredients (API).

**Thickness of Films:** The thickness of the film was measured at five different locations using a micrometer screw gauge, and the average of these five measurements was calculated. This ensures uniformity in the film's thickness, which is directly related to the accuracy of the dosage within the film.

**Folding Endurance:** Folding endurance was assessed by repeatedly folding the film at the same spot until it broke. The folding endurance value is the number of times the film could be folded without breaking.

**Surface pH:** The formulated film was placed in the center of a petri dish and moistened with 0.5 ml of phosphate buffer. After being left for 30 seconds, the pH was measured using an electrode, allowing it to reach equilibrium first.

**In-vitro Disintegration Time:** A film was positioned on a stainless steel wire-mesh within a petri dish containing 10 ml of phosphate buffer at pH 6.8, and the time taken for the film to rupture was recorded. An average of three readings was taken into account.

**% Moisture Uptake:** The films were cut to the desired size and left in a room temperature environment for one week. The moisture uptake was determined by subtracting the initial weight from the final weight, and the percentage of moisture uptake was then calculated.

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

**Drug Content:** The film was dissolved in 10 ml of phosphate buffer at pH 6.8 and subsequently filtered. The drug content was assessed using a double-beam UV-Visible spectrophotometer at 224 nm. An average of triplicate measurements was obtained, and the concentration was calculated from a calibration curve.

**In Vitro Dissolution studies:** In Vitro dissolution experiments were conducted using a USP type II Dissolution apparatus. The apparatus was filled with 500 ml of phosphate buffer at pH 6.8 and maintained at a temperature of  $37 \pm 5$  °C, with a stirring speed of 50 rpm. The film was positioned on a watch glass, covered with nylon wire mesh, and securely clamped. This assembly was then immersed into the dissolution flask. Five milliliter aliquots were withdrawn at various time intervals and replaced with an equal volume of fresh buffer solution. The samples were analyzed at 224 nm using a UV-Visible spectrophotometer.

**Stability Studies:** The optimized batch was wrapped in aluminium foil and loaded in the Stability Chamber as per ICH Guidelines for 1 month at  $40^\circ\text{C} \pm 2^\circ\text{C}$  and  $75\% \pm 5\%$  relative humidity. After completion on 1 month the Film was taken out and evaluated for all parameter.

#### Estimation of drug by UV overlay spectra

The overlay spectra of the drug were generated by scanning solutions of various concentrations, namely 5, 10, 15, 20, and 25 ppm, revealing peak absorption at 224 nm. with a reported  $\lambda_{\text{max}}$  of 224 nm, it can be inferred that the identified drug corresponds to Empagliflozin (Table 2 and Figure 1).

**Table 2: Absorbance of different concentration of Empagliflozin in phosphate buffer at pH 6.8**

Sr. No.	Concentration (ppm)	Absorbance			Mean Absorbance $\pm$ SD (n=3)
		I	II	III	
1	5	0.318	0.321	0.317	0.319 $\pm$ 0.0035
2	10	0.439	0.436	0.438	0.438 $\pm$ 0.0038
3	15	0.587	0.587	0.586	0.587 $\pm$ 0.0042
4	20	0.701	0.704	0.702	0.702 $\pm$ 0.0051
5	25	0.86	0.86	0.862	0.861 $\pm$ 0.0057

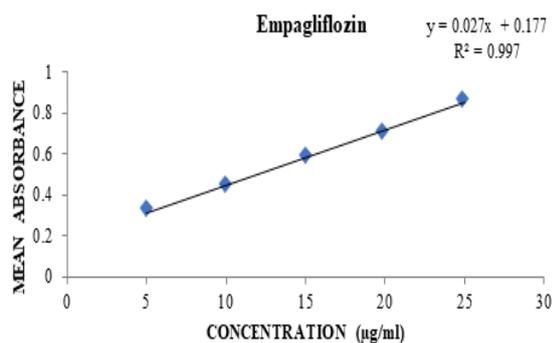


Figure 1: Calibration curve of Empagliflozin in phosphate buffer at pH 6.8

### Evaluation of Mouth Dissolving Film of Empagliflozin

#### Physical Appearance

From physical appearance parameters it was seen that batches F1, F2, F4 and F8 having 40 mg of polymers were slightly sticky in nature and F5 and F6 were sticky while F3, F6 and F9 were non sticky in nature. Batches F1, F3, F4, F5, F7, F8 and F9 were Smooth, whereas batches F2 was Slightly Opaque whereas F6 were Slightly rough in appearance. Batches F1, F3, F4, F5, F7, F8 and F9 were Transparent, whereas batches F2 was Slightly Opaque rough F6 were Slightly Opaque in appearance (Table 3).

Table 3: Stickiness, Surface Appearance, Film clarity data.

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

Table 4: Weight variation, Thickness, Folding endurance and Surface pH

Batch Code	Thickness (mm ± S.D.)(n=3)	Weight variation (mg ± S.D.)(n=3)	Folding Endurance (n=3)	Surface pH (n=3)
F1	0.125 ± 0.0009	45.8 ± 1.32	117 ± 3.51	6.4 ± 0.15
F2	0.128 ± 0.0010	51.4 ± 1.17	123 ± 2.08	6.7 ± 0.06
F3	0.132 ± 0.0004	57.9 ± 1.29	135 ± 1.15	6.6 ± 0.17
F4	0.127 ± 0.0004	58.5 ± 3.47	120 ± 2.52	6.8 ± 0.06
F5	0.134 ± 0.0010	59.4 ± 1.51	125 ± 2.52	6.5 ± 0.06
F6	0.139 ± 0.0005	66.2 ± 1.75	137 ± 2.08	6.6 ± 0.15
F7	0.130 ± 0.0009	61.6 ± 0.97	130 ± 3.21	6.6 ± 0.21
F8	0.136 ± 0.0005	69.2 ± 1.62	133 ± 3.21	6.6 ± 0.10
F9	0.141 ± 0.0010	77.2 ± 1.32	142 ± 2.65	6.7 ± 0.06

#### Percentage Moisture uptake, Disintegration time and Drug Content

The % moisture uptake value of prepared Film was ranging from 0.44 ± 0.63 % to 2.19 ± 0.25 %. It showed that as the polymer grade and ratio is increased, the moisture uptake is increased.

#### Thickness, Weight variation, Folding endurance and Surface pH

Thickness of the film was measured using micrometer screw gauge showed that the thickness of the film was in the range of 0.125 ± 0.0009 mm to 0.141 ± 0.0010 mm. Weight variation tests for all prepared films shown range of weight from 45.8 ± 1.32 mg to 77.2 ± 1.32 mg. The folding endurance value of the films prepared with ranged from 117 ± 3.51 folds to 142 ± 2.65 folds. In the formulations as polymer concentration increases folding endurance values were also increased. Surface pH of the prepared Film was in the range of 6.4 ± 0.10 to 6.8 ± 0.06. Thus, all the Film had pH in the desired range (Table 4).

The disintegration time ranged between 19 ± 1.5 secs to 71 ± 3.2 seconds. Disintegration time of the F9 batches having HPMC E5 and SSG in ratio of 17:2.8 % was found to be lowest, i.e. 19 ± 1.5 secs. Drug Content of all formulations were found in the range of 97.05 % to 99.45 %. Thus, all films had drug content in acceptable limits (Table 5).

Table 5: Percentage Moisture uptake, Disintegration time and Drug Content

BatchCode	% moisture uptake(% ± S.D.) (n=3)	In-vitro Disintegration time(sec ± S.D.) (n=3)	Drug Content(%)
F1	0.44 ± 0.63	71 ± 3.2	97.37
F2	0.89 ± 0.35	52 ± 1.5	98.88
F3	2.10 ± 0.13	36 ± 1.5	97.05
F4	0.63 ± 0.24	59 ± 1.5	98.44
F5	1.32 ± 0.29	51 ± 1.5	99.29
F6	2.11 ± 0.54	24 ± 2.1	99.02
F7	1.49 ± 0.23	49 ± 3.1	99.45
F8	1.88 ± 0.16	44 ± 2.1	98.38
F9	2.19 ± 0.25	19 ± 1.5	98.55

**In Vitro Drug Release Profile**

In vitro drug release studies were conducted using a type II (paddle) dissolution test apparatus in 500 ml of phosphate buffer at pH 6.8, maintained at 37° ± 0.5 °C and 50 rpm. Batches F1, F2, and F3 showed drug releases of 98.62%, 96.72%, and 97.28% in 18, 16 and 16 minutes. Batches F4, F5, and F6 exhibited drug releases of 99.21%, 97.88%, and 96.09% in 18, 16, and 14 minutes, respectively. Batches F7 to F9 demonstrated drug releases of 98.69 %, 99.18 %, and 99.73 % in 16, 16, and 14 minutes, respectively. From these results, it was concluded that batch F9 had the fastest drug release, achieving it in just 14minutes compared to all other batches (Figure 2, 3 and 4).

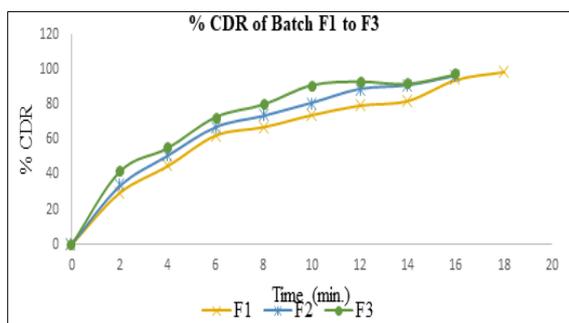


Figure 2: % Cumulative Drug Release profile of batch F1 to F3

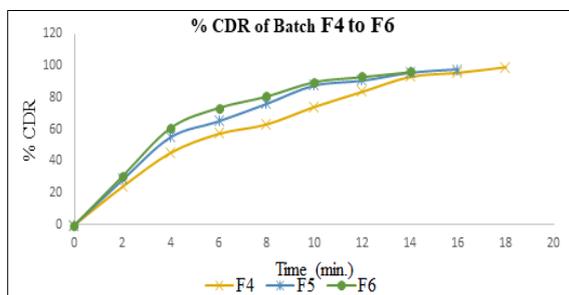


Figure 3: % Cumulative Drug Release profile of batch F4 to F6

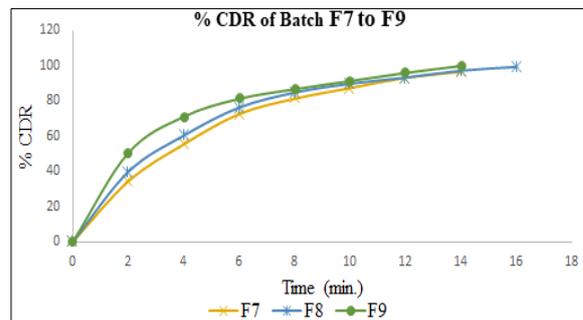


Figure 4: % Cumulative Drug Release profile of batch F7 to F9

**STABILITY STUDY:**

Based on the all parameters of batches, it was concluded that batch F9 was the optimized batch due to its good surface appearance, pH and drug content. Batch F9 exhibited 99.73% drug release in just 14 minutes, and its in vitro disintegration time was only 19 ± 1.5 seconds, the shortest among all batches. Thus, batch F9 was selected as the optimized batch. A stability study was conducted to assess the stability of the films from the optimized batch at 40° ± 2°C and 75 ± 5% RH for one month. After one month, evaluations of in vitro disintegration time, in vitro dissolution time, folding endurance, percentage moisture uptake, and drug content were performed. The stability studies concluded that there were no significant differences in the values of the various evaluation parameters. The films maintained their texture and mechanical strength. Minor, negligible changes were observed in the values of all the data, which remained within acceptable limit (Tables 6 and Table 7; Figure 5).

Table 6: Result of the Stability study

Sr. No.	Evaluation parameter	Results of optimizedbatch F9	Result after 1 month
1.	Physical Appearance	Non Sticky Smooth Transparent	Non Sticky Smooth Transparent
2.	Weight Variation	77.2 ± 1.32	73.0 ± 1.60
3.	Folding Endurance	142 ± 2.65	140 ± 1.15
4.	% Moisture Uptake	2.19 ± 0.25	2.03 ± 0.15
5.	In Vitro Disintegration Time	19 ± 1.5 sec.	23 ± 1.0 sec.
6.	Drug Content	98.55 %	97.18 %

Table 7: In Vitro Drug Release Study of Stability Batch

Time (Min.)	% CDR of Optimized Batch F9 (%)	% CDR of batch F9 After 1 Month (%)
0	0	0
2	50.41±0.215	42.69±0.185
4	70.93±0.445	65.71±0.215
6	81.08±0.170	75.91±0.476
8	86.54±0.262	82.15±0.05
10	91.15±0.278	88.65±0.05
12	95.77±0.256	91.21±0.01
14	99.73±0.246	98.63±0.03

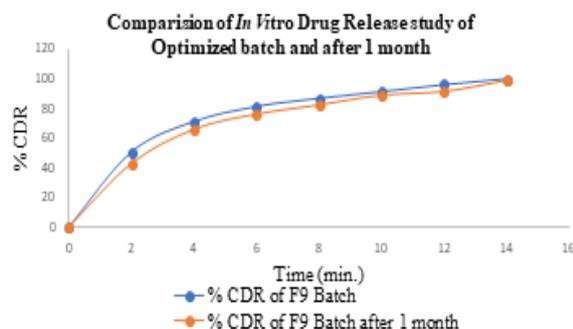


Figure 5: Comparison of *In Vitro* Drug Release study of Optimized batch and Stability batch

## CONCLUSION:

The main objective of the study was to develop the Mouth Dissolving Films of Empagliflozin by solvent casting method with the hydrophilic polymers which can swell easily and give instant drug release. Formulations by using HPMC E5 as polymer and SSG as superdisintegrant could significantly reduce the disintegration time and increase the dissolution time. Thus, based on these studies, these films formulations appear better than conventional Formulations. Preliminary studies were carried out to find out suitable Mouth Dissolving Film forming polymer HPMC E5 was used in different concentration ranges. Prepared Mouth Dissolving Films were evaluated for various physicochemical properties and from the results it was concluded that formulation Batch F9 shows better Mouth Dissolving Films forming capacity and appropriate drug release profile. On the basis of all the results it was concluded that Batch F9 having 50 mg of HPMC E5 and SSG 6 mg an optimized batch Which shows *In-vitro* disintegration time  $19 \pm 1.5$  sec and % CDR at 98.55 at 14 minutes. Further stability study of this optimized batch was carried for 1 months at  $40^\circ\text{C} \pm 2^\circ\text{C}$  and  $75\% \pm 5\%$  relative humidity and after 1 months it was evaluated for different parameters. The results of stability studies suggested that the formulation F9 was stable for the period of 1 months as there are no significant changes in the properties. From the whole study it was concluded that Mouth Dissolving Films of Empagliflozin is an acceptable dosage form which suggests that it is likely to become one of the choices of Empagliflozin preparations for the treatment of Diabetes.

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## CONFLICT OF INTEREST:

The authors declare that there is no conflict of interest.

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