Development and Characterization of Empagliflozin Oro Dispersible Film by Solvent Casting Method

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ABSTRACT

The objective of this study was to develop an oro dispersible film (ODF) of the antidiabetic drug Empagliflozin, using a solvent casting method and incorporating key excipients such as polymers, plasticizers, sweeteners, and a saliva-stimulating agent. As Empagliflozin is a BCS Class III drug, its solubility was enhanced by preparing an inclusion complex with β-Cyclodextrin via physical blending. The optimized formulation (F8) demonstrated excellent mouth feel, mechanical strength, and rapid disintegration (20 seconds), with 90.5% of the drug released within 3 minutes. These films were characterized for parameters such as thickness, weight uniformity, drug content, dissolution rate, and mechanical properties, with stability studies showing promising results for shelf-life stability. The development of Empagliflozin ODFs presents a significant advancement in diabetes management, offering an effective, convenient, and patient-friendly dosage form that improves medication adherence and therapeutic outcomes.

Keyword: *Empagliflozin, Oro-dispersible films, Solvent Casting Method, Compatibility, Antidiabetic etc.*

1. INTRODUCTION

Oro-dispersible films (ODF), also known as orally disintegrating films, are tiny polymeric films about the size of a postage stamp that cling to saliva-wet mucosa ,dissolve their matrix, and release absorbable active ingredients. Thin, flexible, manageable, and stable for production, packing, and shipping procedures are requirements. Together with a short disintegration period (up to one minute), they must also have a taste and mouthfeel that are acceptable. A prevalent problem amongst younger and older patients is dysphagia, which makes it impossible to provide medication in solid dose forms. To swiftly and effectively administer medications orally without requiring the consumption of water, a novel dosage form has been created. Oro dispersible films (ODFs) are a convenient and appealing mode of administration that enhances patient compliance by delivering medications at the site of action with fast dissolving, administration, and disintegration, eliminating the need for swallowing and chewing.

According to the ninth edition of the European Pharmacopoeia (Ph. Eur.), Oro dispersible films are formulations that are intended for the delivery of drugs by oral administration via the oral cavity. The Ph. Eur. states that ODFs mainly consist of a polymer with film-forming capacity, which serves as an active pharmaceutical ingredient or drug carrier. Plasticizers are also used to ensure the flexibility of the prepared films.

Oro-dispersible films are also defined as dosage forms that can be given to the patient without the use of water because ODFs consist of polymers that allow them to be broken down rapidly by saliva and disintegrate in a few seconds, dissolving easily and being absorbed through the oral cavity or the tongue. After mucosal absorption, the drug enters the thin membranes of the oral cavity and is promptly bioavailable due to fast blood flow. The Food and Drug Administration (FDA) defined ODFs as dosage forms consisting of one or more APIs with an elastic nature so that, when placed on the tongue, they allow quick disintegration or dissolution by saliva.

ODFs are prepared using hydrophilic polymers that rapidly dissolves on the tongue or buccal cavity, ODF is a thin film of 1-10 mm thickness and its surface area can be 1 to 20 cm 2. Drugs can be incorporated up to a single dose of about 15 mg. Oral fast dissolving dosage form have started gaining popularity and acceptance as new drug delivery system due to better patient compliance.

There is a rising interest in the development of Oro-dispersible films (ODFs) as an alternative to fast dissolving tablets, which is attributed to their faster dissolution rate, higher durability, and better patient compliance. Recently, research work on the use of ODFs as promising carriers for multiple active pharmaceutical ingredients has emerged. Marketed ODF products have also become available including Listerine®, Chloraseptic®, Triaminic®, and multi-vitamins.

1.1 Special features of Oro-dispersible film

- Thin elegant films
- Available in various size and shape
- Unobstructive
- Excellent muco-adhesion
- Fast disintegration
- Rapid release.

1.2 Advantages of Oro-dispersible films

- Convenient dosing or accurate dosing
- No water needed to swallow or chewed so it has better acceptability among the
- dysphagic patients.
- No risk of chocking.
- Taste masking.
- Enhanced stability.
- Improved patient compliance
- Site specific and local action.
- Rapid disintegration and dissolution within oral cavity.
- Dose accuracy in comparison to syrup.
- The drug enters the systemic circulation with reduced hepatic first pass effect.

1.3 Disadvantages of Oro-dispersible films

- Drugs which are unstable at buccal Ph cannot be administered.
- Dose uniformity is a technical challenge.
- Hygroscopic in nature so it must be kept in dry place.
- Packaging of films requires special equipment and it is difficult to pack.
- Stability and safety.

1.4 Ideal properties of Oro-dispersible film

- It should be compatible with the other ingredients.
- The therapeutic dose of the drug should not be greater than 40mg.
- It should be quickly dissolved to release instantaneously in mouth.
- It should have an acceptable taste with pleasing mouth feel.
- Drugs which irritate the oral mucosa cannot be administered.
- It should be partially unionized at the pH of oral cavity.

2. Methods for Preparation of Oro-dispersible film

Manufacturing methods for producing Oro-dispersible film (ODFs)

A) CASTING
1) Solvent
2) Semio Solid

B) **EXTRUSION**
1) Hot Melt Extrusion
2) Solid dispersion extrusion
3) Freeze dried
4) Rolling

2.1 Solvent Casting Method

Solvent Casting is the century film making process. It is a generally applied technique for preparing Oro-dispersible films. This technique is employed to manufacture films of size 2×2 cm2 and 3×2 cm2

- **Process**

❖ Water soluble ingredients are dissolved in water
❖ API and other agents are dissolved in soluble solvent to form a clear viscous solution
❖ Both the solutions are mixed
❖ Stirring for 10 min
❖ Resulting solution is cast as a film**.**

- **Advantages**

❖ Great uniformity of thickness and great clarity than extrusion.
❖ Films have fine gloss & freedom from defect such a die liner.
❖ Films have more flexibility & better physical properties.
❖ Finished film thickness is 12-100µm

- **Disadvantages**

❖ Polymer must be soluble in volatile solvent or water.
❖ The stable solution with reasonable minimum solid content.

Table 1: Components of mouth dissolving film.

Drug (API)	5-30%
Film forming Polymer	45%
Plasticizer	0-20%
Saliva stimulating agents	2-6%
Surfactants	Q.S
Sweetening Agent	3.6%
Flavors, Colours, Fillers	Q.S

3. AIM AND OBJECTIVES

Aim: Development and Characterization of Empagliflozin Oro-dispersible film by Solvent Casting Method.

Objectives: The objectives of the Proposed work is,

1. To Prepare Oro-dispersible film i.e. fast dissolving film of Anti Diabetic drug by solvent casting method by using different concentrations of film forming polymers and Plasticizers.
2. The formulations are developed and evaluated for pre-compression parameters such as Solubility, Melting Point, FT-IR studies and post compression parameters such as Weight Variation, Thickness, Folding Endurance, Tensile Strength, Drug Content, Disintegration Time, Dissolution Test.
3. To improve the patient compliance.
4. To get the quick onset of action to relieve the symptoms of hyperglycaemia.

4. DRUG PROFILE

- **EMPAGLIFLOZIN**

Empagliflozin is used clinically as an adjunct to diet and exercise, often in combination with other drug therapies, for the management of type 2 diabetes mellitus.

It is an inhibitor of sodium-glucose co-transporter-2 (SGLT2), the transporter primarily responsible for the reabsorption of glucose in the kidney.

- **Synonyms:**

• (1S)-1,5-anhydro-1-(4-chloro-3-{4-[(3S)-tetrahydrofuran-3-yloxy] benzyl} phenyl) -D-glucitol

- 1-chloro-4-(glucopyranos-1-yl)-2-(4-(tetrahydrofuran-3-yloxy) benzyl) benzene
- Empagliflozin
- Empagliflozine
- Empagliflozinum.

- **Chemical formula:** $C_{23}H_{27}ClO_7$.
- **IUPAC Name:** (2S,3R,4R,5S,6R)-2-[4-chloro-3-({4-[(3S)-oxolan-3- yloxy]phenyl} methyl)phenyl]-6-(hydroxymethyl)oxane-3,4,5-triol.
- **Mol. Mass**: 450 g/mol.
- **Melting Point:** 151º C.
- **BCS Class:** Class – III.
- **Solubility:** very slightly soluble in water, slightly soluble in acetonitrile and ethanol, sparingly soluble in methanol and practically insoluble in toluene.
- **Physical Properties:** White color powder.
- **Drug Category:** sodium-glucose co-transporter 2 (SGLT2) inhibitors.
- **Uses:** Antidiabetic.

5. MATERIALS AND METHODS

5.1 Materials:

All the materials used in this study were of analytical grade and procured from following source as shown in the table below,

Table 2: List of Chemicals

Sr. No.	Materials	Role	Manufacturer/Supplier
1	Empagliflozin	API	Jardiance, Mumbai
2	Beta-Cyclodextrin	Polymer	Gift sample by Dadasaheb Balpande college, Nagpur
3	Pullulan	Polymer	Gift sample by Dadasahe Balpande college, Nagpur
4	Polyethylene glycol	Plasticizer	Research lab-fine chem industries, Mumbai
5	Stevia	Sweetener	Tanmatra Venturies pvt, ltd, Kolkata
6	Citric acid	Saliva stimulating agent	Research lab-fine chem industries, Mumbai

5.2 Equipments :

The different types of equipment are used in the preparation of formulation are given in below table,

Table 3: List of Equipment's with manufacture

Sr. No.	Name of Equipment's	Manufactured By	Calibration date
1	Film Former	VJ Instruments, Karanja (Lad),Maharashtra	6 May 2024
2	UV-Visible Spectrophotometer	UV-1800 Shimadzu, Japan	29 April 2024
3	FT-IR Spectrophotometer	Agilent technologies, Shimadzu, Japan	20 May 2024
4	PḤ-Meter (Elico-Li- 120)	Elico	Daily
5	Analytical Balance	Contech	Daily

5.3 Formation Inclusion Complex:

For making of Inclusion Complex, A Physical blending method has been used. A 1:1 ratio of Empagliflozin and beta-cyclodextrin has been taken.

A taken ratio of API and beta cyclodextrin has put in mortar pestle and triturated for 30 minutes to make an uniform Inclusion complex.

5.4 Drug-Excipients Compatibility Studies:

Before formulation of a drug substance into a dosage form, it is essential that it should be chemically and physically compatible.

Compatibility studies give the information needed to define the nature of the drug substance and provide a frame work for the drug combination with pharmaceutical excipients in the fabrication of a dosage form. One of the requirements for the selection of suitable excipients or carrier for pharmaceutical formulation is its compatibility. Therefore, in the present work, a study was carried out by using infrared spectrophotometer to find out if there is any possible chemical interaction between empagliflozin and excipients.

Assessment of possible incompatibilities between an active drug substance and different excipients plays an important part of the formulation stage during the development of solid dosage form. Fourier Transformer Infra-Red Spectrum (FTIR), can be used to asses possible drug excipient interaction.

5.5 Preparation of Empagliflozin Oro-dispersible films:

Solvent Casting Method involves the water-soluble polymers are dissolved in water. All the other excipients like colours, flavouring agent, sweetening agent, etc., are dissolved separately. Then both the solutions obtained are mixed thoroughly stirring and kept aside to remove all air bubbles entrapped.

The obtained solution is incorporated with the API dissolved in suitable solvent. Then resulting solution is cast as a film and allowed to dry, which is then cut into pieces of the desired size.

The formulation codes are given in the table,

Table 4: Composition of Oro-dispersible films of Empagliflozin.

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Inclusion Complex (mg) (Empagliflozin + Beta Cyclodextrin)*	400	400	400	400	400	400	400	400	400
Pullulan (mg)	400	500	600	400	500	600	400	500	600
Polyethylene Glycol 400 (ml)	0.5	0.5	0.5	1.0	1.0	1.0	1.5	1.5	1.5
Stevia (g)	0.125	0.125	0.125	0.125	0.125	0.125	0.125	0.125	0.125
Citric acid (g)	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
Flavouring agent (g)	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S
Colouring agent (g)	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S
Distilled water (ml)	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S	Q. S

*** - quantity sufficient to prepare film (4 cm^2) containing 10 mg Empagliflozin drug.**

5.6 CHARACTERIZATION OF FILMS:

5.6.1 Weight Variation

Mouth dissolving oral films were weight on analytical balance and average weight can be determined for each film. It is desirable that films should have nearly constant weight. It is useful to ensure that a film contains the proper number of excipients and API.

5.6.2 Thickness of films

By using micro-meter screw gauge, the thickness of the film was measured at five different places; an average of three values was calculated. This is essential to ascertain uniformity in the thickness of the film this is related to the accuracy of dose in the film.

5.6.3 Folding Endurance

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

5.6.4 Drug content uniformity
This test was performed by dissolving a 4 cm2 area of a thin film in 50 ml of 6.8 pH phosphate buffer with stirring. This solution was filtered using a Whatman filter paper, and the filtrate was diluted to 100 ml with same buffer in a volumetric flask. This solution was analysed using UV spectrometer.

5.6.5 Surface pH
The film to be tested was placed in a petri dish and was moistened with 1 ml of distilled water and kept for 30 sec. The pH was noted after bringing the electrode of the pH meter in contact with the surface of the formulation and allowing equilibration for 1 min. The average of three determinations for each formulation done.

5.6.6 In Vitro disintegration test
Disintegration time is the time when an oral film starts breaking when brought in contact with water or saliva. The disintegration time was visually determined by dipping the film in 25 ml water in a beaker. The beaker was shaken gently and the time was noted when the film starts to breaks or disintegrates.

5.6.7 In vitro dissolution test
900 ml of 6.8 pH phosphate buffer was used as media, at was maintained at 37 ± 0.5o C while the beaker was set at 100 rpm. A film sample of 4 cm2 (2×2 cm) was cut & taken into the basket. 5 ml of the sample were taken every 30 sec & same amounts was replaced with fresh 6.8 pH phosphate buffer. Withdrawn sample were filtered and analysed by UV spectrometer at wavelength of 224 nm.

6. RESULTS & DISCUSSION

6.1 Preformation Studies:

6.1.1 Solubility
Solubility is expressed in terms of parts per million of solvent in which 1 gm solid is soluble. Solubility of the powder in different solvent like ethanol, methanol and water was determined.

6.1.2 Melting point
The melting point was carried out by using capillary tube method.

Table 5: API Characterization – Empagliflozin

Sr. No	Test	Specification	Result
1	Description	White Powder	White Powder
2	Solubility	Slightly soluble in ethanol, sparingly soluble in methanol, very slightly soluble in water.	Complies
3	Taste	Bitter	Complies
4	Odour	Odourless	Complies
5	Melting Point	148 ºC-151ºC	151ºC

6.2 Characterization Method to Determine Empagliflozin

Characterization of Empagliflozin using UV spectroscopy
A 10 mg empagliflozin in 10 ml distilled water was taken to form 1000 ppm stock solution. From above stock solution 1 ml was taken and diluted up to 10 ml with distilled water to get 100 ppm solution. From above 100 ppm, prepare serial dilution by taking 0.5, 1, 1.5, 2, 2.5 ml and diluted up to 10 ml form a 5, 10,15, 20 and 25 ppm respectively, (5 µg/ml25 µg/ml) by appropriate dilution stock solution.
The absorbance of various concentrations measured at 224 nm by using water as a blank.
The graph was plotted taking concentrations on x-axis and respective absorbance on y-axis. The regression coefficient (R^2) and straight-line equation were calculated with application of Microsoft Excel Statistics.
Standard curve of empagliflozin is shown in **figure no.1**

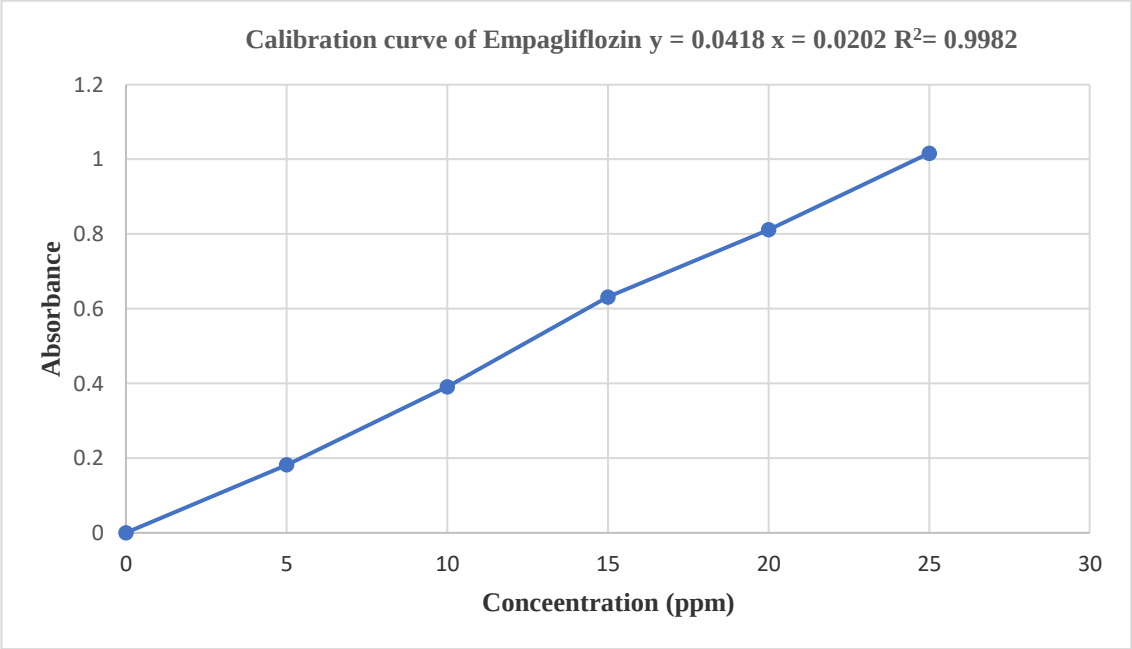

Figure 1 : Standard graph of Empagliflozin

Table 6: Standard graph of Empagliflozin

Sr. No.	Concentrations (µg/ml)	Absorbance at 224 nm
1	0	0
2	5	0.182
3	10	0.391
4	15	0.631
5	20	0.811
6	25	1.016

6.3 Compatibility Studies by FT-IR

The compatibility study between drugs and excipients was carried out using an FT-IR spectrometer. FT-IR spectra of powder Empagliflozin shows its signature peak of their functional group at 2928.7 cm−1 (Aromatic C-H Stretch), 1684 cm−1 (C=O Stretch of Ketone), 1058 cm−1 (C-O Stretch of Ether), 1488.8 cm−1 and 1505.8 cm−1 (C-C Stretch of Aromatic Rings), and 3250.2 cm−1 (O-H Stretch of Alcohol). **Fig no.2**

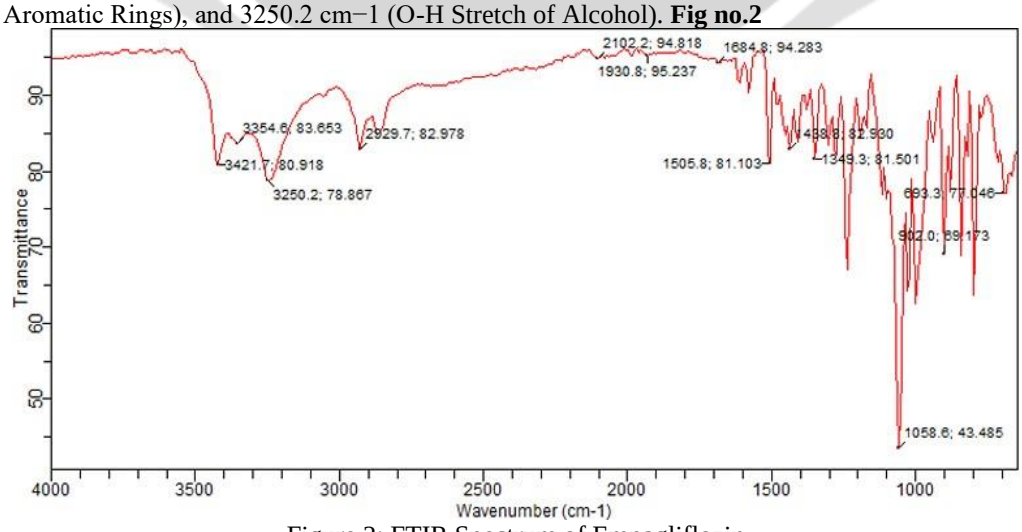

Figure 2: FTIR Spectrum of Empagliflozin

Beta-cyclodextrin powder shows its signature peak of functional group at 3280 cm−1 (OH Stretch of Hydroxyl Groups (Alcohols)), 2922.2 cm−1 (C-H Stretch of Alkane), 1640 cm−1 (C=O Stretch of Carbonyl Group (Acetates)), cm−1 (C-O Stretch of Ether), 1021 cm−1 (C-O Stretch of Primary Alcohol), 1416.4 cm−1 (C-H Bending of Alkane), 1392.4 cm−1 (O-H Bending of Hydroxyl Groups (Alcohols)), and 1001.5 cm−1 (C-C Stretch of the Glucose Ring). **Fig no.3.**

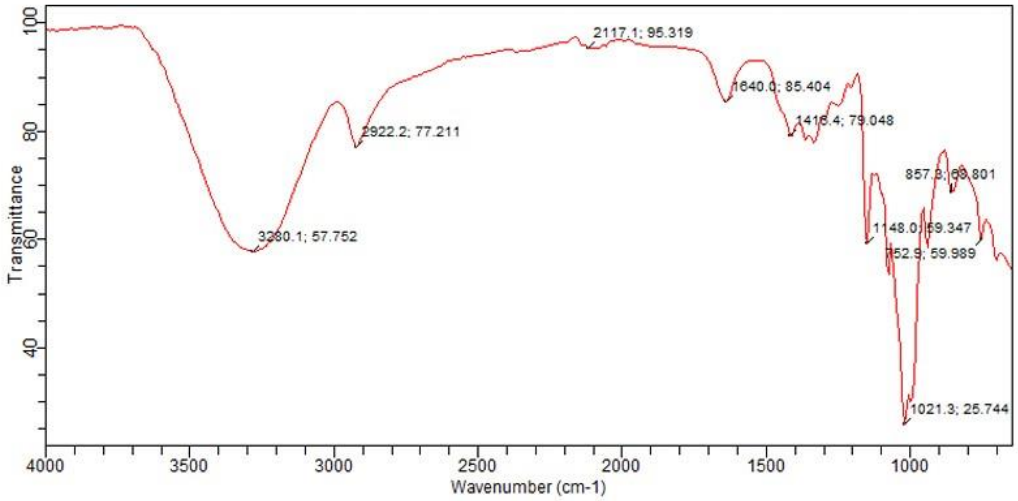

Figure 3: FT-IR Spectrum of Beta-Cyclodextrin

And the powder of the inclusion complex of empagliflozin and beta-cyclodextrin shows a reduction in the intensity of the peak of the drug in the C-O stretch of ether around 1000 cm−1, which indicates the formation of an inclusion complex between empagliflozin and beta-cyclodextrin**. Fig no.4**.

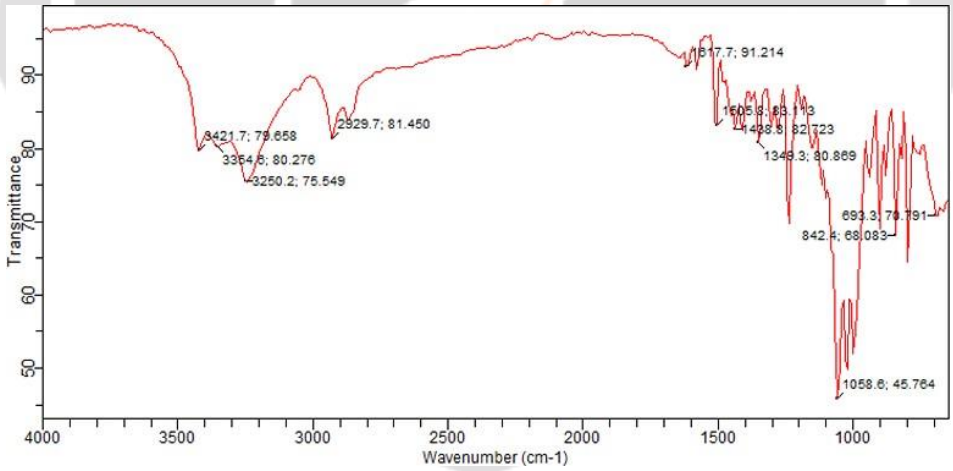

Figure 4: FTIR Spectrum of Empagliflozin with Beta-Cyclodextrin (Inclusion Complex)

The powder sample of pure pullulan shows its signature peak at 3257 cm−1 (Hydroxyl Groups (OH)), 1640 cm−1 (Carbonyl Groups (C=O)), 1148 cm−1 (C-H Stretching), 2922 cm−1 (C-O Stretching), and 991 cm−1 (C-C Stretching). **Fig no.5.**

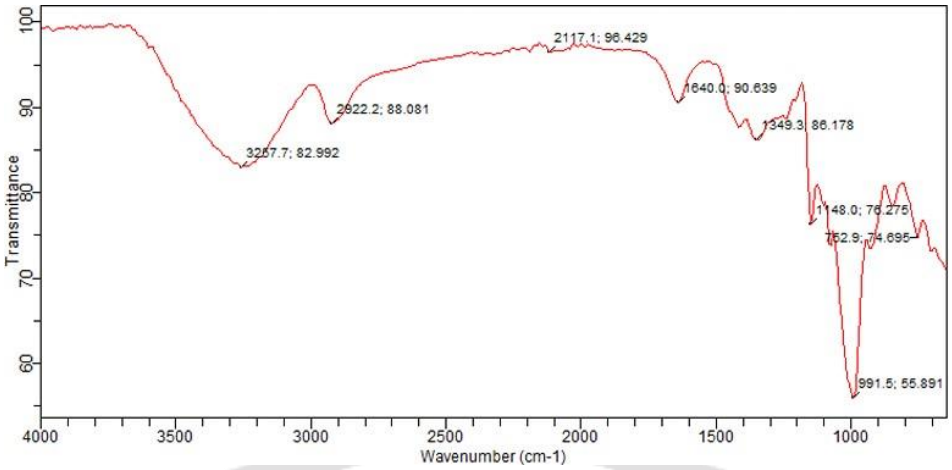

Figure 5: FTIR Spectrum of Pullulan

In a physical mixture of inclusion complex and pullulan in a 1:1 ratio, the signature peak of inclusion complex and pullulan does not show any extra peak or loss of peak; it shows there is no interaction between inclusion complex and pullulan. **Fig no.6**

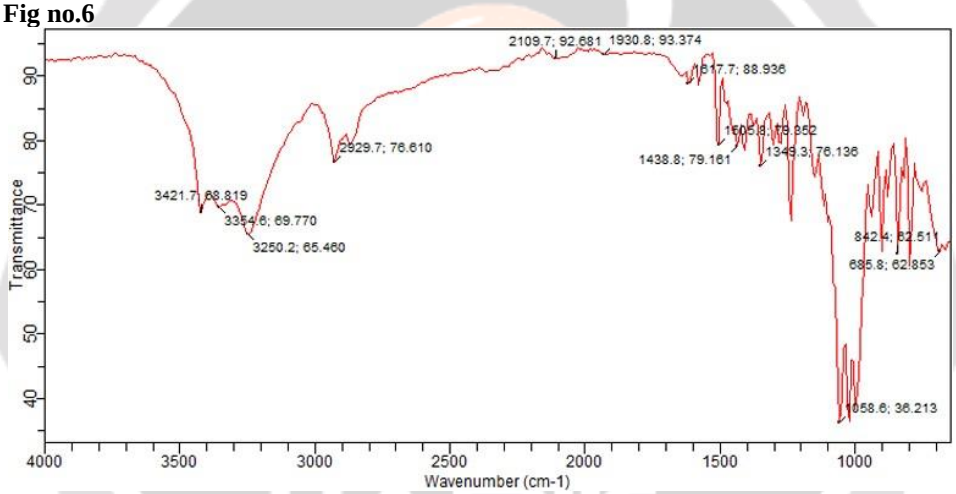

Figure 6: FTIR Spectrum of Inclusion Complex with Pullulan

6.4 EVALUATION PARAMETERS OF FILM:

6.4.1 Thickness

The thickness of all formulation F1-F9 was found by using digital micro-meter and the results were shown in table.

Table 7: Determination of thickness for different formulation of Empagliflozin films (F1-F9)

Formulation	Thickness (mm)
F1	0.02 ± 0.005
F2	0.03 ± 0.003
F3	0.05 ± 0.004
F4	0.03 ± 0.006
F5	0.04 ± 0.002
F6	0.05 ± 0.001
F7	0.03 ± 0.002
F8	**0.04 ± 0.002**
F9	0.05 ± 0.004

6.4.2 Folding Endurance

Folding Endurance was determined by repeatedly folding a small strip of film at the same place till it breaks.

The number of times, the film could be folded at the same place without breaking gave the value of folding endurance.

Table 8: Determination of folding endurance for different formulation of Empagliflozin films (F1-F9)

Formulation	Folding Endurance
F1	08 ± 2
F2	10 ± 3
F3	13 ± 1
F4	18 ± 4
F5	21 ± 2
F6	22 ± 1
F7	31 ± 1
F8	**33 ± 2**
F9	34 ± 1

6.4.3 Weight Variation

Ten films were randomly selected and their average weight was weight. Individual films were weighed and compared with the average weight for the deviation.

The weight variation of fast dissolving films of all formulations given in table.

Table 9: Determination of weight variation for different formulation of Empagliflozin films (F1-F9)

Formulation	Weight Variation (mg)
F1	35.00 ± 0.05
F2	35.78 ± 0.04
F3	36.86 ± 0.01
F4	35.36 ± 0.02
F5	36.02 ± 0.03
F6	36.94 ± 0.02
F7	35.48 ± 0.02
F8	**36.56 ± 0.03**
F9	37.02 ± 0.03

6.4.4 Surface pH

The film to be tested was placed in a petri dish and was moistened with 1 ml of distilled water and kept for 30 s. The pH was noted after bringing the electrode of the pH meter in contact with the surface of the formulation and allowing

equilibration for 1 min. The average of three determinations for each formulation was done.

Table 10: Determination of Surface pH for different formulation of Empagliflozin films (F1-F9)

Formulation	Surface pH
F1	6.45
F2	6.48
F3	6.56
F4	6.50
F5	6.54
F6	6.55
F7	6.52
F8	**6.54**
F9	6.56

7.4.5 *In vitro* disintegration test

Disintegration time is the time when an oral film starts breaking when brought in contact with water or saliva. The disintegration time was visually determined by dipping the film in 2 ml water in a beaker. The beaker was shaken gently and the time was noted when the film starts to breaks or disintegrates.

Table 11: Determination of disintegration time for different formulation of Empagliflozin films (F1-F9).

Formulation	Disintegration time (sec)
F1	22 ± 3
F2	29 ± 1
F3	30 ± 1
F4	27 ± 3
F5	25 ± 2
F6	21 ± 2
F7	22 ± 1
F8	**20 ± 2**
F9	23 ± 2

6.4.6 *In – vitro* dissolution

900 ml of 6.8 pH phosphate buffer was used as a media, at was maintained at 37+0.5ºC while the basket was set at 100 rpm. A film sample of 4 cm2 (2×2cm) was cut and taken into the basket. 5 ml of the sample were taken every 30 sec and the same amount was replaced with fresh 6.8 pH phosphate buffer.

The withdrawn samples were filtered and analysed using a UV spectrometer at a wavelength of 224 nm. The percentage drug release was calculated and plotted against time.

Table 12: Determination of in-vitro dissolution study of different formulations of Empagliflozin Oro-dispersible film

Time (min)	Percentage drug release of Empagliflozin Oro-dispersible film (% drug release)								
	F1	F2	F3	F4	F5	F6	F7	**F8**	F9
0	0	0	0	0	0	0	0	**0**	0
0.5	16	18	23	17	20	22	25	**29**	32
1.0	29	34	43	33	41	42	48	**56**	58
1.5	37	50	59	43	59	55	68	**75**	74
2.0	48	63	78	52	81	73	79	**83**	81
2.5	60	70	88	64	86	84	85	**92**	93
3.0	88	91	91	92	93	92	95	**97**	95

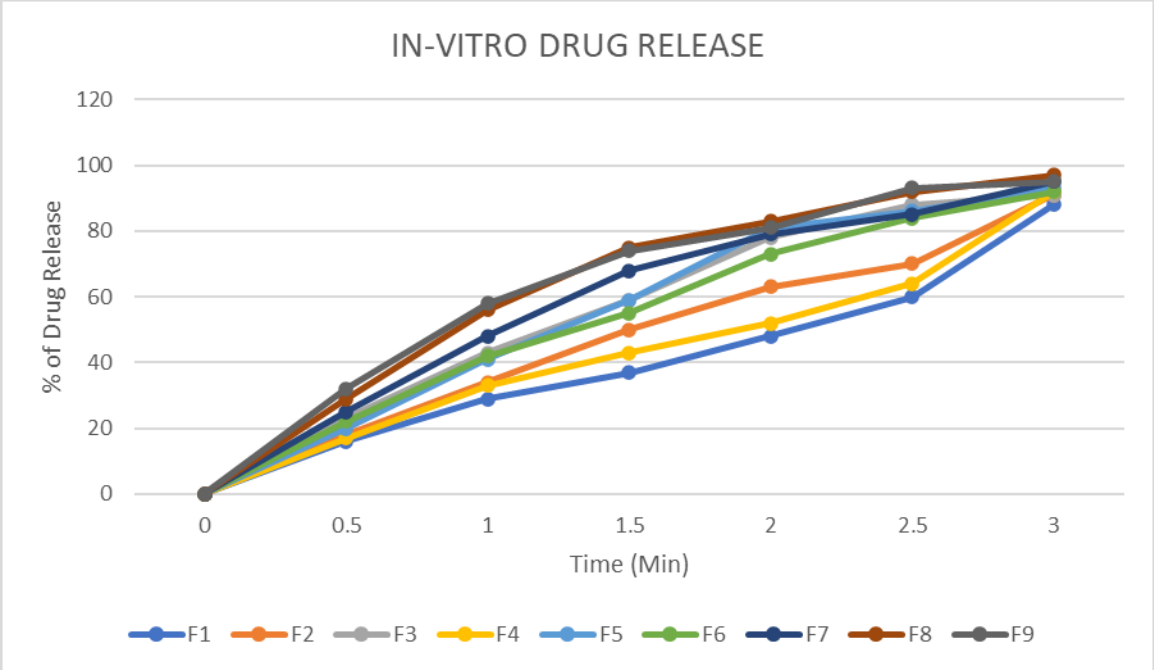

Figure 7: IN-Vitro Dissolution Graph

6.4.7 Drug Content

This test was performed by dissolving a 4 cm2 area of a film in 50 ml of 6.8 pH phosphate buffer with stirring. This solution was filtered using a Whatman filter paper, the filtrate was diluted to 100 ml with same buffer in a volumetric flask. This solution was analysed using UV spectrometer.

Table 13: Determination of drug content for different formulation of Empagliflozin films (F1-F9).

Formulation	Drug Content %
F1	85.0
F2	83.8
F3	84.7
F4	85.6
F5	86.2
F6	86.8
F7	88.9
F8	**90.5**
F9	89.0

6.5 DISCUSSION

The present investigation was undertaken to formulate Oro-dispersible film of anti-diabetic drug (Empagliflozin), with the formation of Inclusion Complex of drug (Empagliflozin) and β-Cyclodextrin for the treatment of Diabetes mellitus.

Among all the formulations F8 shown good mechanical properties and less disintegration time of 20 seconds. All the parameters of film were found to be satisfactory, and the dissolution profile was found to be desirable and reproducible.

The film (F8) samples evaluated gave maximum release within 3 minutes indicating the rapid drug release profile which entails in faster onset of action for the medication.

7. CONCLUSION

The primary aim of this study was to develop an oro dispersible film (ODF) of the antidiabetic drug Empagliflozin, incorporating essential excipients like polymers, plasticizers, sweeteners, and a saliva-stimulating agent. The films were prepared using the solvent casting method. Given that Empagliflozin is a BCS Class III drug, we enhanced its solubility by forming an inclusion complex with β-Cyclodextrin through physical blending. The optimized formulation (F8) demonstrated excellent mouth feel, folding endurance, rapid drug release, and favorable mechanical properties. Specifically, F8 exhibited a disintegration time of just 20 seconds and released 90.5% of the drug within 3 minutes.

The development and characterization of an orodispersible film of Empagliflozin entails several crucial steps. First, the formulation must be carefully optimized to ensure even distribution of the drug throughout the film, enabling rapid dissolution in the mouth without the need for water. Various excipients, such as polymers, plasticizers, and disintegrants, are used to achieve the desired film properties. Additionally, comprehensive characterization is essential to assess key parameters like thickness, weight uniformity, drug content, dissolution rate, and mechanical properties. Stability studies are also critical to ensure the films maintain their efficacy and integrity throughout their shelf life, accounting for factors such as temperature, humidity, and light exposure.

In conclusion, the development of orodispersible films of Empagliflozin presents a promising approach to improving patient compliance and convenience in diabetes treatment. These films, offering a rapid, water-free dissolving dosage form, have the potential to enhance medication adherence and ultimately improve therapeutic outcomes for patients with diabetes.

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