EJPMR, 2026, 13(5), 271-281 **Research Article** **Impact Factor: 8.158**

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

ISSN (O): 2394-3211
ISSN (P): 3051-2573
Coden USA: EJPMAG

FORMULATION AND EVALUATION OF ORAL DISPERSIBLE FILM OF DAPAGLIFLOZIN

Jinal Patel[1]*, Bhavana A. Patel[2], Dr. Shailesh T. Prajapati[3]

[1]Department of Pharmaceutics, Shree Swaminarayan Sanskar, Pharmacy College, Zundal, Gandhinagar -382421.
[2]Associate Professor, Department of Pharmaceutics, Shree Swaminarayan Sanskar, Pharmacy College, Zundal, Gandhinagar -382421.
[3]Principal, Shree Swaminarayan Sanskar Pharmacy College, Zundal, Gandhinagar -382421.

***Corresponding Author: Jinal Patel**

Department of Pharmaceutics, Shree Swaminarayan Sanskar, Pharmacy College, Zundal, Gandhinagar -382421.

DOI: https://doi.org/10.5281/zenodo.19885378

How to cite this Article: Jinal Patel[1]*, Bhavana A. Patel[2], Dr. Shailesh T. Prajapati[3]. (2026). Formulation and Evaluation of Oral Dispersible Film of Dapagliflozin. European Journal of Biomedical and Pharmaceutical Sciences, 13(5), 274–281.

Article Received on 30/03/2026 **Article Revised on 20/04/2026** **Article Published on 01/05/2026**

ABSTRACT

Objective: The objective of this research work was to formulate and evaluate oral dispersible film of Dapagliflozin by enhancement of Permeability by preparing inclusion complex of Dapagliflozin with β-CD and to increase patient compliance which is useful in the treatment of Diabetes. **Materials and Methods**: In this research, the method used to prepare oral dispersible films was solvent casting to decrease time and cost. Preliminary batches were evaluated for Physico-chemical parameters.β-CD inclusion complex with Dapadliflozin in 1:1 ratio to increase permeability of drug. 3^2 Full Factorial design was used for optimization by selecting two independent factors –concentration of film forming agent (HPMC E5)-XI and concentration of plasticizer (Propylene glycol)-XII and their effect on Disintegration time- (R I), and % drug release- (R II). Optimization of factorial batches was done using Design Expert 13 software. **Result**: Best results were obtained in Batch F1 in which HPMC E5 was 150mg and Propylene glycol was 1ml with 31.8 seconds of disintegration time and 98.45 % cumulative drug release at 15 minutes. Check point batch shows 34.72 seconds of disintegration time 97.96% cumulative drug release. A 1 month accelerated Short term stability study was done on prepared films and it is stable for 1 month. **Conclusion**: Oral dispersible film containing Dapagliflozin were formulated using HPMC E5 as a film forming agent and Propylene glycol as a plasticizer by solvent casting method. Hence, from the results it was concluded that faster disintegration and faster drug release can be achieved by the ODF.

KEYWORDS: Oral dispersible films, Dapagliflozin, HPMC E5, Propylene glycol, Solvent casting, design expert.

INTRODUCTION

Diabetes is a metabolic disorder in which there are high levels of sugar in the blood, a condition called hyperglycaemia. Under normal conditions, food is broken down to glucose which then enters the bloodstream and acts as fuel for the body. The pancreas produces a hormone called insulin which helps to carry glucose from the bloodstream into muscle, fat and liver where it can be used as fuel.[1] Dapagliflozin is BCS class III drug, characterized by high solubility and low permeability.[2] Dapagliflozin is sodium-glucose co-transporter 2(SGLT2) inhibitor used primarily for managing type 2 diabetes mellitus. Dapagliflozin works in the kidneys to prevent the reabsorption of glucose, which helps to lower blood sugar levels. Dapagliflozin uptake is improved since the oral mucosa has a richer blood supply compared to other region. Dapagliflozin undergoes first pass metabolism in liver which reduce the amount of drug that enters systemic circulation.[3] Oral dispersible films are developed to overcome problems related to difficulties with swallowing. The presence of a dense network of blood vessels in the oral lining can enhance the absorption of many drugs, resulting in swift therapeutic effects and improved bioavailability.[4] A 3^2 full-factorial design involves 2 factors each tested 3 levels creating 9 uniq treatment combination to study main effect and interation.[5]

MATEIALS AND METHODS

Dapagliflozin free gift sample was procured from Sarv

pharmaceuticals. HPMC E5, HPMC K4M, Propylene glycol, Sucrose, Peppermint oil and β-CD oxford lab fine chem. LLP and water.

Preformulation study

Organoleptic Characterization of Dapagliflozin[6]

The Dapagliflozin drug sample was checked for basic properties like colour, odour, taste, and appearance.

Melting Point Determination of Dapagliflozin[7]

Capillary melting point determination, performed either using a melting point apparatus, is one of the most commonly used techniques for measuring melting points. A small amount of the substance is placed in a thin-walled capillary tube, 10-15 cm in length, with an internal diameter of approximately 1 mm and one end sealed.

Solubility Study of Dapagliflozin[8]

To study the solubility of Dapagliflozin, begin by adding an excess amount of the drug to 10 mL of each water, phosphate buffer (pH 6.8), methanol, and 0.1N HCl in separate conical flasks. Shake each flask continuously for 10 minutes to ensure thorough mixing and dissolution. After shaking, filter the solutions through Whatman filter paper to remove any undissolved particles. Dilute the filtered samples appropriately to fall within the measurable range of the UV-visible spectrophotometer. Finally, measure the absorbance of each diluted sample at 224 nm and plot Absorbance vs. Concentration curves determine the solubility of Dapagliflozin.

Determination of UV Absorption maxima of Dapagliflozin[8]

- Prepare a stock solution of Dapagliflozin by dissolving 100 mg of the drug in 100 mL of Solvent.
- Perform serial dilutions of the stock solution to obtain appropriate concentrations for spectrophotometric analysis.
- Scan the prepared solutions in the UV-visible spectrophotometer (Analytical Technologies Limited – Spectro UV 2060 Plus) across a wavelength range (200–400 nm) to generate an absorption spectrum.
- Identify the wavelength corresponding to the maximum absorbance (λmax) from the obtained spectrum.
- Record the λ_{max} of Dapagliflozin and confirm by re-scanning at the identified wavelength to ensure accuracy.

Drug-Excipients Compatibility Study by using FTIR Study[9]

For compatibility testing, a mixture of Dapagliflozin and all excipients used in the formulation was prepared. Potassium bromide (KBr) was triturated, and a small quantity of the Dapagliflozin-excipientmixture was blended with it. The resulting sample was loaded into the sample holder and scanned to identify any potential interactions between the drug and the excipients.

Preparation of β-CD inclusion complex with Dapagliflozin

Dapagliflozin and β-CD were combined in 1:1,1:2 and 1:3 molar weight ratios.A methanol wasused as the solvent system.Initially,50% of the solvent was taken in a mortar,and the calculated amount of polymer was added.

Differential Sacnning Calorimetry[10]

DSC study was carried out using DSC instrument. The instrument comprises of calorimeter, flow controller, thermal analyzer and operating software. The drug was heated in sealed aluminum pans under airflow (30 ml/min) at a scanning rate of 20° C / min from 50 - 300°C Empty aluminum pan was used as a reference. The heat flow as a function of temperature was measured for the sample.

Method of preparation of fast dissolving oral film[11,12]

The film-forming polymer is dissolved in a water, and thoroughly mixed to ensure complete dissolution. The dapagliflozin and permeation enhancer, plasticizers, other excipients (such as flavourings and permeation enhancers) are added to the polymer solution, with continuous stirring to ensure a uniform mixture. The resulting homogeneous solution is poured onto a flat surface or casting plate, where it is evenly spread using an applicator to achieve the desired film thickness. The cast solution is dried at a controlledtemperature to evaporate the solvent, solidifying thefilm.

Selection of Factors, Levels, and Responses of 3^2 Full-Factorial Designs

It is best to create pharmaceutical products with minimal amounts of labor and ingredients, but this requires effective product development. When several factors influencing a pharmaceutical formulation at different stages are known, an appropriate formulation is always achieved. The conventional trial-and-error approach of optimization is today seen as time-consuming, arduous, and ingredient-wasting. An experimental design ought to be used in the development of pharmaceutical goods. As a result, it assists in avoiding the waste of labor and ingredients. The One Factor at a Time (of AT) design was utilized in the past, but it takes a long time to complete and is only capable of checking the effects of interactions. Using statistical analysis, the generated formulation's complexity and interactive responses were assessed. Full factorial design is used to optimize the oral dispersible film of Dapagliflozin. The table below illustrates the factors and levels. The two factors that were chosen as independent variables were: X I (concentration of HPMC E5, a film-forming agent) and X II (concentration of Propylene glycol, a plasticizer). For each criteria, three levels have been chosen: -1, 0. +1. The responses, or dependent variables, were:Y1: Disintegration Time, Y2: in vitro drug release at 15 min.

The impact of factors (independent variables) on dependent factors (responses) was examined using the Design Expert 13 programme.

Table 1: Layout of 3^2 full factorial designs.

Independent variable					
X1			X2		
HPMC E5(concentration)(mg)(film forming polymer)			Propylene glycol(concentration)(ml)(plasticizer)		
-1	0	1	-1	0	1
145	150	155	0.5	1	1.5
Dependent variable					
Y1			Y2		
Disintegration-Time (sec)			In vitro drug release at 15 min		

Table 2: Final formulation table for factorial batches.

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Dapagliflozin + β-Cyclodextrin (1:1)	37.8	37.8	37.8	37.8	37.8	37.8	37.8	37.8	37.8
HPMC E5	145	145	145	150	150	150	155	155	155
Propylene glycol	0.5	1	1.5	0.5	1	1.5	0.5	1	1.5
Sucrose	20	20	20	20	20	20	20	20	20
Peppermint oil	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Water	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15

Evaluation parameter[13,14,15]

- **Film Thickness**

To assess the thickness of the oral film, a micrometer screw gauge is used at multiple critical points across the strip. Consistency in thickness directly relates to uniformity in drug dosage, as there is a proportional relationship between strip thickness and drug content.

- **Strip Weight**

The individual weights of the films are measured using an analytical balance. The average weight is then calculated to ensure uniformity. Consistent strip weight indicates proper formulation and dosage precision.

- **Moisture Content**

To determine residual moisture, the film is weighed and stored in a desiccator for 24 hours. The process continues until the weight stabilizes, indicating that the moisture has been effectively removed. The difference in weight is used to calculate the moisture percentage.

- **pH Measurement**

To evaluate pH, the strip is immersed in distilled water for approximately one hour. After soaking, the pH of the resulting solution is measured using a calibrated pH meter. This test ensures the formulation's compatibility with oral tissues.

- **Disintegration Time**

Disintegration time is an essential parameter for oral dispersible films (ODFs). Though no specific pharmacopoeial standard exists for these films, a benchmark of 30 seconds used for orodispersible tablets is commonly applied. A standard disintegration test apparatus may be employed, with typical disintegration times ranging from 5 to 60 seconds.

- **Folding Endurance**

This parameter evaluates the film's flexibility and resistance to mechanical stress. The film is repeatedly folded at a 180° angle until it tears. The number of successful folds before rupture is recorded as the folding endurance value.

- **In Vitro Dissolution Study**

The dissolution profile is assessed using a beaker containing 125 ml of phosphate buffer (pH 6.8) as the dissolution medium. The film is affixed to the beaker wall using adhesive tape. A magnetic stirrer operates at 200 rpm, and samples of 5 ml are withdrawn at intervals of 3,5,7,9.12 and 15 minutes. Each sample is replaced with fresh buffer. Drug release is analyzed spectrophotometrically by measuring absorbance at a specific wavelength.

Generating of Quadratic Model for 32 FFD (Full Factorial Design)

A quadratic polynomial model was used for assess the influence of independent factors on dependent variables. From the acquired data of disintegration time and percent (%) drug release, a quadratic model equation was generated using polynomial regression analysis. The process of finding the polynomial equation that best fits a set of data is known as quadratic regression.

Selection of optimized batch

The final formulation was selected based on the lowest disintegration time and highest drug release at 15 min. According to desirability value, the optimized levels of HPMC E5 concentration and Propylene glycol concentration. According to the selected levels using the same methodology Dapagliflozin containing oral dispersible film were prepared.

Short-term Stability Study

Stability study aims to ascertain how different environmental factors, including temperature, humidity, and light, affect the quality of therapeutic substances or medication formulations over time. To ascertain the product's shelf life and recommended storage conditions, a stability study is carried out. An "accelerated stability study" was carried out on prepared films at 40 °C 2 °C/75 percent RH 5% (percent) RH, in accordance with the ICH Q1A guideline. The "ICH Q1A guideline" governs the stability assessment of innovative pharmaceutical compounds and products. An expedited stability study should last at least six months, according to the ICH Q1A standard, but due to scheduling constraints, the study only lasted one month. A month later, the films were examined for a number of characteristics, including foldthrough durability, disintegration time, drug percentage content, and percentage CDR.

RESULT AND DISCUSSION

Organoleptic Properties of Dapagliflozin

The drug sample of dapagliflozin was assessed for organoleptic properties, including color, odor, taste, and appearance, under controlled conditions to ensure accuracy. Observations were compared with reference standards to confirm identity and suitability for formulation development.The result is as per table 3.

Table 3: Organoleptic Properties of Dapagliflozin.

Properties	Observation
Color	White
Odour	Odour less
Taste	Bitter
Appearance	Powder

Melting point determination

The melting point of dapagliflozin was determined using a capillary tube method. A small sample was placed in a sealed capillary tube and gradually heated in a melting point apparatus. The temperature range at which the substance transitioned to a liquid was recorded, ensuring precise measurement. The melting point of drug is determined as shown in table 4.

Table 4: Melting Point of Dapagliflozin.

Parameter	Reference(℃)	Test (℃)
Melting point	65°-70℃	67℃

Determination of absorption maxima of drug (λ_{max})

The maximum absorption of drug in phosphate buffer at 224nm which is shown in fig.1 and on it's based we form the calibration of Benfotiamine which is shown in fig.2.

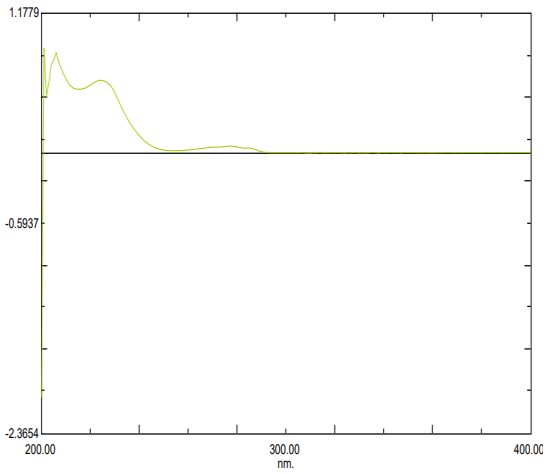

Fig. 1: Absorption maxima of drug (λmax).

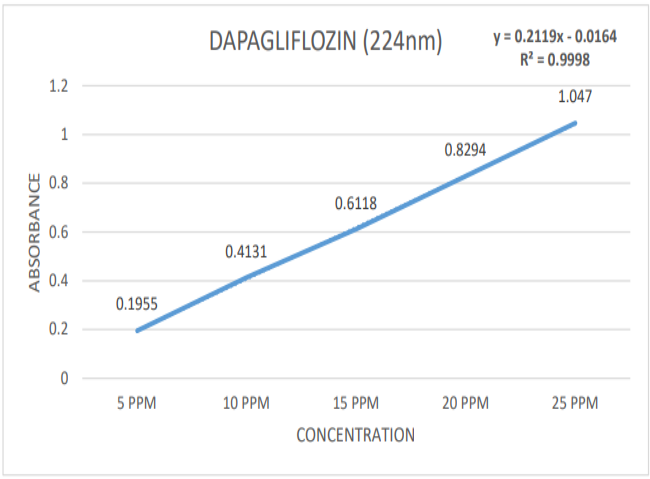

Fig. 2: Calibration curve of dapagliflozin.

FTIR study of Dapagliflozin and other excipient

Infrared spectroscopy was conducted using FT-IR spectrophotometer and the spectrum was recorded in the wave number region of 4000 to 400 cm-1. The procedure consisted of dispersing the sample (drug alone, mixture of drug and excipients and the optimized formulation) in Potassium bromide and compressed into discs by applying a pressure of 5 tons for 5 minutes in a hydraulic press. The pellet was placed in the light path and the spectrum was recorded which is shown in fig.3.

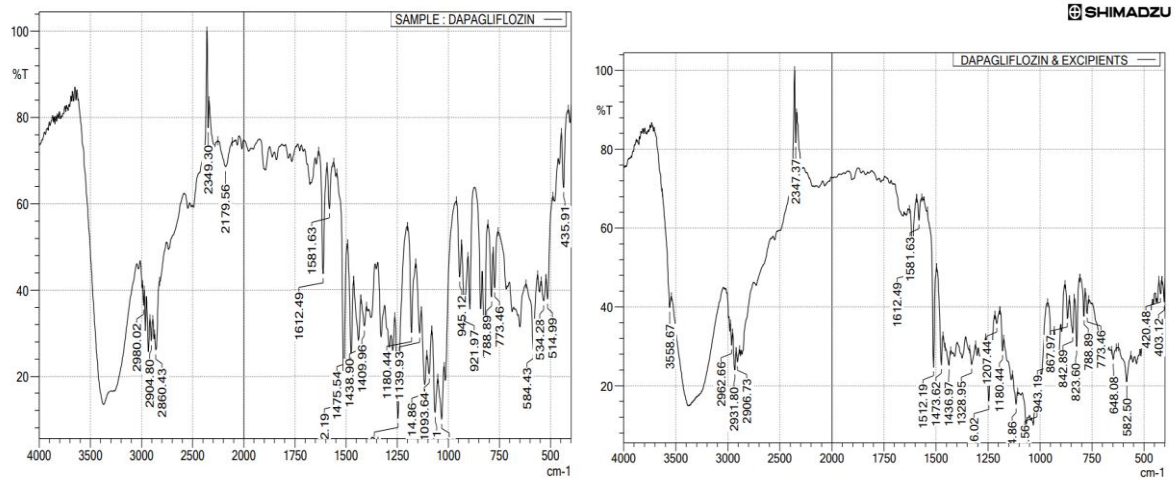

Fig. 3: FTIR of Dapagliflozin and FTIR of Dapagliflozin + all excipients.

Result of solubility of β-CD inclusion complex with Dapagliflozin

Dapagliflozine and β-CD were combined in 1:1, 1:2, and 1:3 molar weight ratio. A Methanol was used as the solvent system the result is as per table 5.

Table 5: Result of solubility of β-CD inclusion complex with Dapagliflozin.

Formulation	Ratio	Solubilityμg/ml
Dapagliflozin + β-CD	**1:1**	**56.23**
Dapagliflozin + β-CD	1:2	42.39
Dapagliflozin + β-CD	1:3	35.65

Result of Differential scanning calorimetry (DSC)

DSC (Differential Scanning Calorimetry) study was carried out using DSC instrument. The instrument comprises of calorimeter, flow controller, thermal analyzer and operating software. The drug was heated in sealed aluminum pans under airflow (30ml/min) at a scanning rate of 20ºC/min from 50-300ºC. Empty aluminum pan was used as a reference. The heat flow as a function of temperature was measured for the sample**.** The graphical representation of DSC is shown in fig 4.

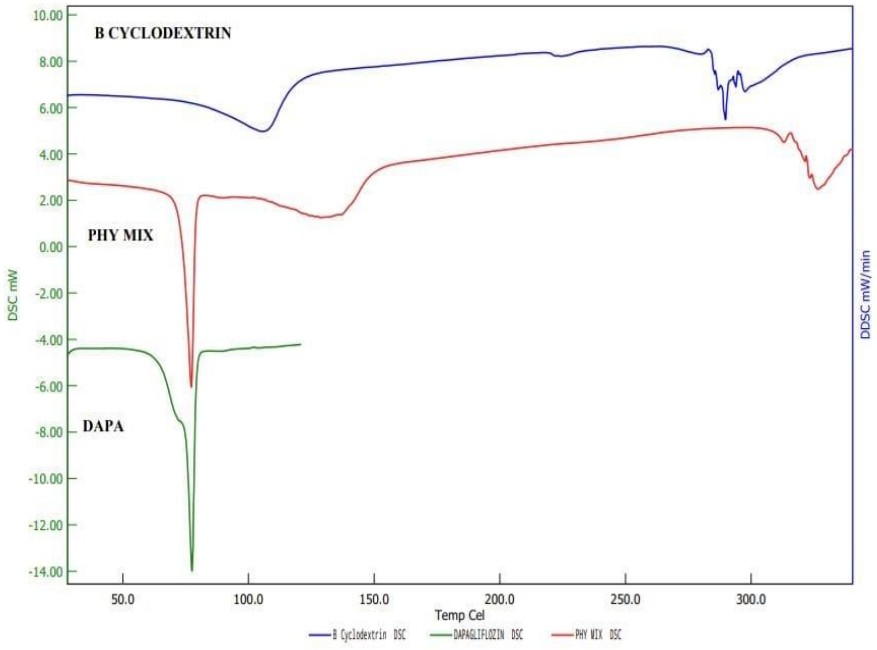

Fig. 4: Overlay of DSC.

Evaluation of factorial batch

As we discuss the method and the equations of evaluation parameter in method and material section we find out the result as per table 6 and 7.

Table 6: Evaluation of factorial batch.

Factorial batches	Appearance	Smoothness	peel ability	Disintegration time (sec)
F1	**Translucent**	**Smooth**	**Good**	**31.85±0.81**
F2	Translucent	Smooth	Good	34.36±0.53
F3	Translucent	Smooth	Good	36.93±0.65
F4	Translucent	Smooth	Average	37.58±0.68
F5	Translucent	Smooth	Average	39.11±0.91
F6	Translucent	Smooth	Average	43.11±0.18
F7	Translucent	Smooth	Good	62.86±0.63
F8	Translucent	Smooth	Average	73.03±1.95
F9	Translucent	Smooth	Poor	77.97±0.85

n=3±SD

Table 7: Evaluation of factorial batch.

Factorial batches	Thickness (mm)	Folding endurance	Surface pH	Weight variation (mg)	Drug content (%)	% Moisture content
F1	**0.36±0.05**	**150±3.41**	**7.2±0.21**	**75±1.13**	**98.26±0.21**	**1.864±0.029**
F2	0.42 ±0.2	145±4.13	6.9±0.19	74±3.15	99.14±0.36	1.613±0.042
F3	0.32±0.11	179±5.25	7.1±0.21	74±2.24	99.14±0.36	1.547±0.010
F4	0.36±0.2	146±3.25	6.6±0.16	73±2.32	99.32±0.45	1.691±0.021
F5	0.31±0.03	158±2.12	6.7±0.52	74±2.23	99.21±0.36	1.681±0.059
F6	0.38±0.12	164±3.15	7.4±0.9	73±1.13	98.75±0.38	1.439±0.052
F7	0.41±0.05	156±2.36	7.4±0.9	76±2.36	99.78±0.98	1.549±0.064
F8	0.42±0.02	169±4.36	6.4±0.12	76±3.36	99.71±0.31	1.846±0.073
F9	0.36± 0.02	171±2.14	7.1±0.24	75±1.23	99.65±1.54	1.794±0.039

n=3±SD

In-vitro dissolution of factorial batches

The graphical representation of in vitro study is shown in fig.5.

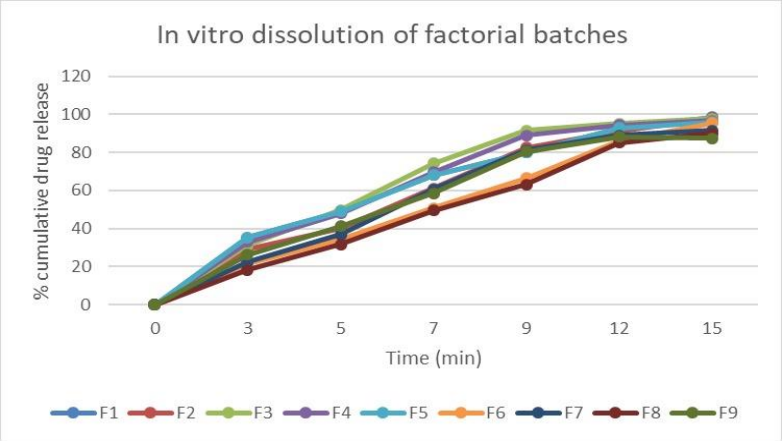

Fig. 5: In-vitro dissolution of factorial batch.

Photos of ODF of dapagliflozin

The formulation of ODF is shown in fig 6.

Fig. 6: ODF of Dapagliflozin.

Result of quadratic model

Contour plots were generated for each independent variable to visualize their individual effects on the selected responses, such as percentage yield, entrapment efficiency and particle size. These plots displayed constant contours (z-slices), enabling a two-dimensional representation of the three dimensional response surface. Additionally, 3D surface quadratic plots were created for each variable, providing a deeper insight into their interaction with the responses and highlighting the influence of different factor levels. The 3D plots are shown from fig.7.

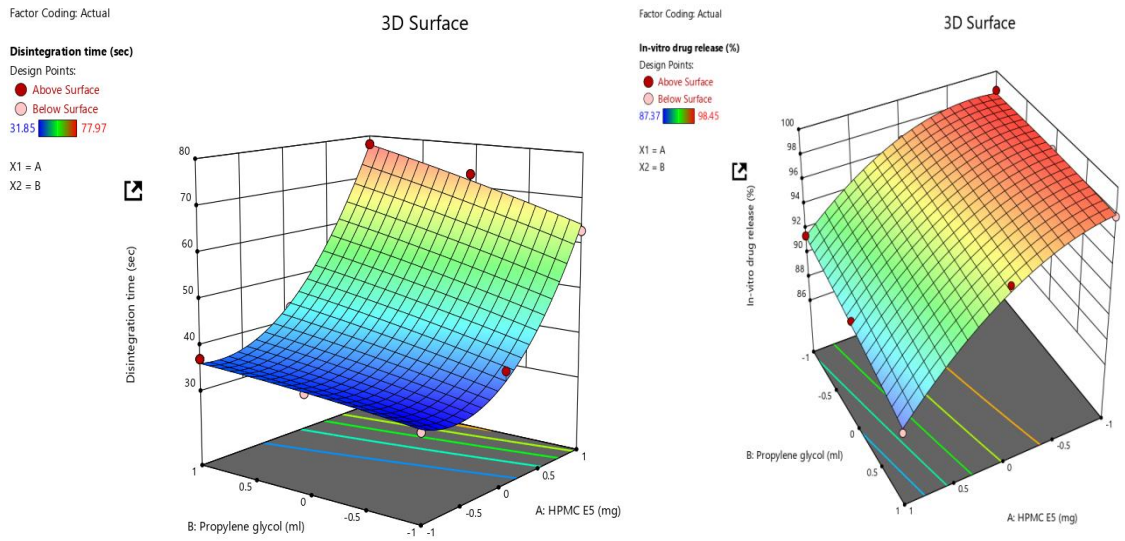

Fig. 7: 3D Surface plot of R-1 and R2.

Generation of overlay plot

To validate the accuracy of the design model, a check point batch was selected from the overlay plot for evaluation which is shown in fig.8. This batch was formulated and tested within the experimental domain to ensure model reliability. The observed experimental values of the response parameters were quantitatively compared to the predicted values, and the percentage bias was calculated to assess the deviation between them. The close agreement between experimental and predicted values confirmed the adequacy of the model, ensuring the reliability of the optimization process.

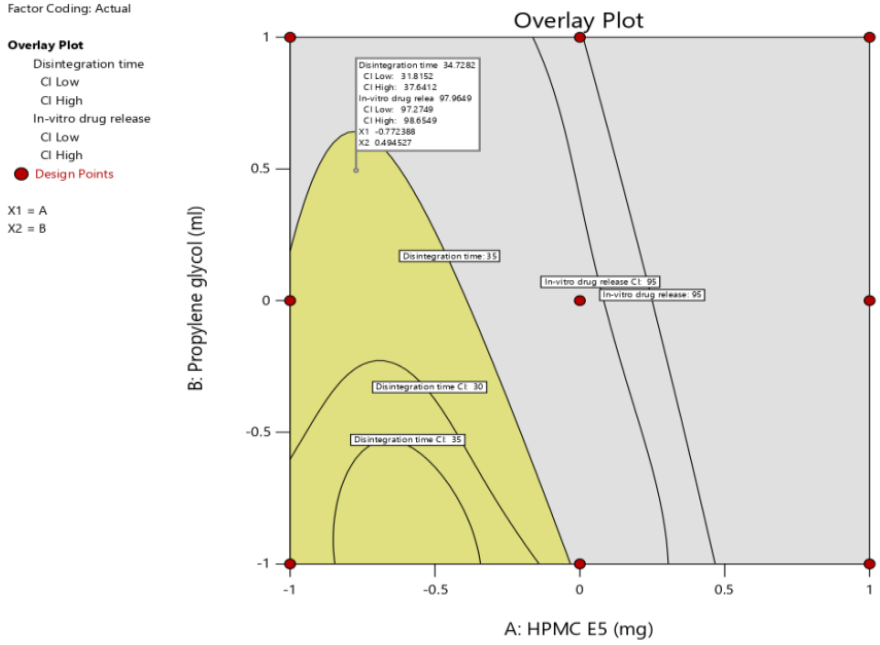

Fig. 8: Check point batch.

Short term Stability study of optimized batch

A stability study was conducted to assess the stability profile of the developed formulation under accelerated conditions (40°C ± 2°C / 75 ± 5% RH). The condition of drug is shown in table.8.

Table 8: Stability study of optimized batch.

Condition	**40°C ± 2 °C and 75% RH ± 5% RH**	
Evaluation	**Initial observation**	**After a month**
Appearance	Translucent	Translucent
% Drug content	98.26±0.21	97.55±0.12
Disintegration time(sec)	31.85±0.24	34±0.21
Folding endurance	150±3.41	148.5±0.60
%CDR at 9 min	98.45±0.41	96.2±0.48
±SD n =3		

CONCLUSION

Oral dispersiblefilm containing Dapagliflozinwere formulated using HPMC E5 as a film forming agent and Propylene glycol as a plasticizer by solvent casting method. Hence, from the results it was concluded that faster disintegration and faster drug release can be achieved by the oral dispersible film of Dapagliflozin by oral route.

ACKNOWLEDGEMENT

The author would like to thank Sarv pharmaceuticals to provide free gift sample of Dapagliflozin and we would like to thank Shree Swaminarayan Sanskar Pharmacy College, Zundal, Gandhinagar to provide facility and resources to conduct the work.

REFERENCE

1. Jacob S. Orodispersible Films: Current Innovations and Emerging Trends. Journal-pharmaceutics, 2023; 12-3.
2. Dapagliflozin- Drug bank: https://go.drugbank.com/.
3. Aloke C, Egwu CO, Aja PM.Current Advances in the Management of Diabetes Mellitus. Biomedicines. September 29, 2022.
4. Siddiqui N, Garg G, Sharma PK, Fast dissolving tablets: preparation, characterization and evaluation: an overview. Int J Pharm Sci Rev Res., 2010; 2: 87-96.
5. Jocelyn A, Stephanie C, Diane F, Heeral S, Jason B, Michael K, Nicholas P, Andrew W, Design of experiments via factorial designs. Liber texts, 14. 2., 2026.
6. Gaikwad AV, Gawade AS, Hupparage VB, Mantry S, Kale A, Kale J, Method Development and Validation of Dapagliflozin by RP-HPLC, Journal of Pharmaceutical Negative Results (J. Pharm. Neg. Resul.), 2022; 13: 4316–4335.
7. https://www.chemicalbook.com/ChemicalProductProperty_EN_CB91011730.htm?utm_
8. https://globalresearchonline.net/journalcontents/v27-1/48.pdf?utm_
9. Yadav UR, Pathade KS, Development and Validation of RP-HPLC Method for the Estimation of Drugs Dapagliflozin and Vildagliptin Phosphate by FTIR, Journal ofTechnology, 2014; 14: 201-209.
10. Mali S, Gedam S, Talele S, and Jadhav A, Design and Development of Effervescent Floating Tablet Dapagliflozin, International Journal of Trend in Scientific Research and Development (IJTSRD), 2020; 1675-1685.
11. Kumar A, Khandelwal M, Agrawal D, Goyal R, Formulation Development and Evaluation of Oral Dissolving Film of Lornoxicam, International Journal of Current Pharmaceutical Review and Research, 2024; 28-35.
12. Yadav A, Sharma V, Tripathi S, Soni SL, Oral Fast Dissolving Film: A Novel Formulation, Oral Fast Dissolving Film: A Novel Formulation, 2020; 77-82.
13. Sudhir M, Sruthi V, Reddy TV, Naveena Ch, Reddy BP, and Rahaman SA, Preparation and characterization of oral fast dissolving film of hydralazine HCL, Current Trends in Biotechnology and Pharmacy, 2022; 171-178.
14. Antar SA, Ashour NA, Sharaky M, Khattab M, Ashour NA, Zaid RT, Roh EJ, Elkamhawy A, Al-Karmalawy AA, Diabetes mellitus: Classification, mediators, and complications; A gate to identify potential targets for the development of new effective treatments. Biomedicine & Pharmacotherapy, 2023; 115-134.