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# Formulation and Evaluation of Dapagliflozin Oral Dispersible Films for Rapid Antidiabetic Action

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**Abstract:**. This study intended to design and assess dapagliflozin oral dispersible films (ODFs) for quick antidiabetic efficacy and enhanced patient convenience. Seven formulations (DF1–DF7) were developed using solvent casting utilising advanced film-forming polymers pullulan, Lycoat® RS 720, and maltodextrin combined with PEG-400 as a plasticiser and appropriate palatability enhancers. Dapagliflozin demonstrated exceptional analytical linearity in pH 6.8 phosphate buffer (2–12 µg/mL, $R^2$ = 0.9987), validating dependable drug quantification. All films exhibited consistent thickness, elevated folding endurance, almost neutral surface pH, fast breakdown, and satisfactory drug content consistency. In vitro dissolution experiments demonstrated rapid and full drug release, with optimised formulations (DF6–DF7) attaining ≥83% release within 10 minutes and nearly 100% release within 20 minutes. FTIR analyses validated the compatibility between the medication and excipient. The stability assessment of DF7 over a 90-day period revealed no significant alterations in physical attributes or drug content. Dapagliflozin ODFs provide a swift-acting, stable, and patient-focused option for antidiabetic treatment.

**Keywords:**. Dapagliflozin; Oral dispersible films; Pullulan; Lycoat® RS 720; Solvent casting; Antidiabetic delivery.

## INTRODUCTION

Oral administration is the most favoured method for medication delivery due to its ease, non-invasiveness, and high patient adherence. Traditional solid-dose formulations, including tablets and capsules, provide obstacles such as dysphagia, delayed onset of action, and complications with first-pass metabolism.[i] These characteristics often undermine therapy efficacy and patient compliance, particularly in at-risk populations such as children, the elderly, and individuals with psychiatric conditions. Orodispersible films (ODFs) provide an effective solution by swiftly disintegrating in the oral cavity without requiring water, hence improving patient convenience and accelerating therapeutic onset.[ii] Oral medicine distribution is thought to be the most practical, economical, and secure drug delivery route because it has the highest compliance rate, particularly among paediatric and elderly patients. The successful delivery of the drug to the body is the ultimate goal of every medication delivery method. The oral disintegrating dose form is the most widely used commercial product among the various dosage forms[iii].

These traditional fast-dispersing or dissolving tablets' main flaw is their solid physical structure. In certain populations, there is still a fear of

swallowing, chewing, or choking on such solid-shaped items. Additionally, it is challenging to carry, store, handle, and administer wafer-like, porous, low-pressure molded tablets to patients especially the elderly and children due to their fragility/friability, which is caused by different manufacturing processes and necessitates the use of special, costly packaging to protect the dosage forms[iv].

The development of Thin Oro Dissolving Film Technology has addressed the shortcomings of traditional fast dispersion or dissolving tablet formulations. The film has convenient packaging, is easy to create, handle, and administer, and it raises the danger of choking and the anxiety of choking. It also reduces the disagreeable flavour. Other names for these thin polymer films are mouth dissolving films (ODF), fast dissolving films (QDF), rapidly dissolving films (RDF), melt-in-mouth dosage forms (MDF), and oral dissolving films (ODF)[v].

ODFs consist of a polymeric film matrix (usually 10–150 μm thick at the product level), film-forming excipients, plasticisers, and functional additives such as sweeteners, flavours, surfactants, and taste-masking systems. Their intended function is fast wetting and breakdown in saliva (often aimed for within seconds to a minute, contingent on the design) coupled with sufficient mechanical strength for handling and packing.[vi, vii] Due to geometric and handling limitations, ODFs have conventionally been optimal for low-to-moderate dosage pharmaceuticals.[viii] The permissible drug load is significantly influenced by the polymer type, film area/thickness, and formulation procedures employed to enhance miscibility and content uniformity.[ix]

Dapagliflozin, a selective inhibitor of the sodium-glucose co-transporter 2 (SGLT2), is a significant therapeutic agent in the management of type 2 diabetes mellitus, as it reduces renal glucose reabsorption and subsequently lowers plasma glucose levels independently of insulin.[x] Dapagliflozin is swiftly absorbed following oral administration, attaining maximal plasma concentration ($T_{max}$) in roughly 2 hours under fasting conditions, with an absolute oral bioavailability of approximately 78%. Despite the increasing interest in oral dispersible films, no research have yet produced dapagliflozin ODFs utilising innovative polymeric matrix such as pullulan, Lycoat® RS 720, and maltodextrin. This study aims to fill the existing gap by creating a fast-acting, user-friendly dose form utilising these novel polymers.

## MATERIAL AND METHODS

### Chemicals

Dapagliflozin is obtained as Gift sample from UniChem laboratories Ltd., Mumbai. Pullulan and Lycoat RS720 purchased from HI media Lab Pvt Ltd., Mumbai. Poly ethylene glycol 400, Maltodextrin and Citric acid are purchased from S.D. Fine- Chemical Ltd, Mumbai. Sodium Saccharin and Natural Lemon Flavour purchased from Shilex Chemicals Pvt. Ltd., Delhi. All the used reagents and chemicals were of analytical grade.

### Calibration of DPG

A UV spectrophotometric method was used for the estimation of dapagliflozin. Standard stock solution (100 μg/mL) was prepared by dissolving accurately weighed dapagliflozin in phosphate buffer (pH 6.8). Serial dilutions (2–12 μg/mL) were made, and the absorbance was measured at 224 nm using a UV-Visible spectrophotometer.

### Formulation Design[xi]:

The ODFs of dapagliflozin were developed utilizing a blend of natural and synthetic polymers to improve dissolving speed and mechanical characteristics. Six formulations (D1–D6) were developed by altering the concentrations of film-forming polymers, while maintaining constant drug content and other excipients. Polymers like Lycoat RS 720 and Pullulan were chosen for their superior film-forming properties, mucoadhesiveness, and biodegradability. Plasticizer (PEG 400) was added to enhance flexibility, while a sweetener and citric acid were utilized for flavor enhancement and pH modulation. This design methodology guaranteed consistency, structural integrity, and swift disintegration, thus enhancing patient adherence and therapeutic effectiveness.

**Table 1:** Formulation table of Dapagliflozin ODF

| Ingredient (mg/film) | D1 | D2 | D3 | D4 | D5 | D6 |
|---|---|---|---|---|---|---|
| Dapagliflozin Propanediol | 10 | 10 | 10 | 10 | 10 | 10 |
| Pullulan | 80 | 100 | — | — | — | — |
| Lycoat RS720 | — | — | 80 | 100 | — | — |
| Maltodextrin | — | — | — | — | 80 | 100 |
| PEG-400 | 10 | 10 | 10 | 10 | 10 | 10 |
| Citric Acid | 3 | 3 | 3 | 3 | 3 | 3 |
| Sodium Saccharin | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Natural Lemon Flavor | 5 | 5 | 5 | 5 | 5 | 5 |
| Distilled Water (solvent) | q.s. | q.s. | q.s. | q.s. | q.s. | q.s. |

*The above formulation was calculated for one film of 2x2 cm size.

**Preparation of Dapagliflozin Oral Disintegrating Films (Solvent Casting Technique)**

Dapagliflozin ODFs were synthesized via the solvent casting method. The specified amounts of Lycoat RS 720 and Pullulan were precisely measured and dissolved in 70 mL of distilled water while being magnetically stirred for 4–5 hours to guarantee thorough swelling. Dapagliflozin was dissolved in 30 mL of water, and the resulting drug solution was subsequently included into the polymer dispersion. Subsequently, PEG 400 (plasticizer), sodium saccharin (sweetener), citric acid (salivary stimulant), and raspberry flavor were incorporated. The finished solution was blended using a cyclo mixer for 15 minutes, followed by magnetic stirring for 2 hours to eliminate entrapped air bubbles. The solution was applied to a flat glass plate (10 cm x 10 cm) and air-dried at ambient temperature for 24 hours. Upon drying, the films were meticulously peeled and sectioned into 2×2 $cm^2$ pieces, each including 10 mg of dapagliflozin. Films were examined for imperfections such as air bubbles, roughness, or cracks, and only uniform films were selected for subsequent testing.

**Drug -Polymer Compatibility Studies**

It is crucial that a drug material be compatible both chemically and physically before it is formulated into a dosage form. When a drug is combined with pharmaceutical excipients to create a dosage form, compatibility studies provide the framework for the combination and the information required to characterize the nature of the drug substance. Compatibility is one of the criteria for choosing appropriate excipients or carriers for pharmaceutical formulation. Consequently, an investigation was conducted in the current work utilizing an infrared spectrophotometer to determine whether DPG and excipients could potentially interact chemically.

**Fourier Transform Infrared (FT-IR) Spectroscopy:**

Using the ATR FTIR spectrometer (Shimadzu FTIR-8400S, Japan) drug's FT-IR spectra were recorded. When using the diffuse reflectance technique, the mid-IR 4000-400 cm-1 spectral region was covered. The sample was placed in sample holder made from Zinc Selenide. The position and relative strength of the absorption maximums in the spectrum produced with the substance under examination match those in the reference spectrum. To create a transparent film, the mixture was taken and compressed in a hydraulic press at a pressure of 10 tons. The particle was scanned in an infrared spectrophotometer between 4000-400 cm-1. Following the light route, the film was placed, the spectrum was recorded twice, and the characteristic peaks associated with the functional groups were determined.

**Evaluation of oral dissolving films formulations:**

For ODF formulations, various quality control tests were carried out.

**Thickness measurement[xii]:**

A micrometer screw gauge was used to measure the thickness of the film five times, and an average of three readings was calculated. Maintaining uniformity in the film's thickness is essential because it has a direct impact on the

dose's accuracy within the film. The film's thickness ought to be less than 5%.

**Weight variation**[xiii]

A weight was determined by selecting ten prepared films at random and averaging them. Weighing each film, we compared its weight to the deviation's average. Making sure a film has the right amount of API and excipients is helpful.

**Folding endurance**[xiv]

To test folding endurance, a film is divided and folded immediately till it breaks. Film folding repetitions in the same place without breaking is what determines the folding endurance value. The topical folding endurance of the film was 100–150. The total number of folds the film can withstand without breaking is used to calculate the folding endurance value.

**Uniformity of drug content**

This is determined by any conventional pharmacopoeia API assay technique. Content consistency is determined by examining API content in each strip. 85–115% is the maximum content homogeneity[xv].

$$\text{Drug content} = \frac{\text{sample absorbance}}{\text{standard absorbance}} \times \frac{\text{standard dilution}}{\text{sample dilution}} \times \frac{\%\text{purity of drug} \times \text{Avg.wt}}{100}$$

$$\%\ \text{Drug content} = \frac{\text{Drug content} \times 100}{\text{Label claim}}$$

**Surface pH**

The film was moistened with 0.5 millilitres of distilled water in a Petri dish for 30 seconds before testing. The pH was recorded after one minute of equilibration and pH meter electrode contact with the formulation. An average of three measurements per formulation made[xvi].

**Assay**

The drug content of the prepared Oro dissolving films was tested. One film, chosen at random from the five, was weighed, then added to 100 milliliters of 6.8 pH buffer in a volumetric flask. For thirty minutes, a volumetric flask was submerged in a sonicator. The finished solution's absorbance was measured at 224 nm utilising a UV Visible spectrophotometer against a 6.8 pH buffer blank. Concentrations and formulation amount were calculated using a standard graph.

***In vitro* disintegration studies**

Disintegration test equipment was used. Disintegration time indicates film disintegration and decomposition. In a stainless steel wire mesh with 25 ml of pH 6.8 simulated salivary fluids, place the desired film size (2x2 $cm^2$). The time it takes the film to dissolve is called disintegration time.[xvii]

***In vitro* Dissolution test**[xviii]

The in-vitro dissolution study of the developed amlodipine oral disintegrating films (ODFs) was performed using a USP type II (paddle) dissolution apparatus (EI-1916, Electronics India, Pune, India). The films were placed in 500 mL of pH 6.8 phosphate buffer maintained at 37 ± 0.5 °C with a paddle rotation speed of 50 rpm. Samples (5 mL) were withdrawn at predetermined time intervals (2–20 minutes), replaced with an equal volume of fresh dissolution medium, and analyzed using a UV–Visible spectrophotometer (EI-1372, Electronics India, Pune, India). The amount of drug released was calculated from the standard calibration curve and expressed as the percentage cumulative drug release. All dissolution studies were carried out in six replicates, and the mean values were reported.

**Release Kinetics**[xix]

Utilising the results of the in-vitro diffusion study, the order and mechanism of drug release kinetics of DPG films were examined. Plotting of the kinetic models included the zero order, first order, and Higuchi equations; the release was calculated using the Korsmeyer-Peppas equations.

**Stability Studies**

Drug stability refers to the ability of a formulation to retain its physical, chemical, and therapeutic properties within specified limits throughout its shelf life. Stability studies were conducted in accordance with ICH Q1A guidelines to ensure product quality and performance. Accelerated stability testing of the optimized formulations was carried out at 40 ± 2

°C / 75 ± 5% RH for three months**.** The samples were packed in aluminum foil strips and stored under controlled conditions. At predetermined intervals, formulations were evaluated for appearance, drug content, and in-vitro drug release**,** confirming their stability over the study period.[xx]

## RESULTS & DISCUSSION

### Calibration of DPG

Combine 50 mg of DPG in 100 ml of water to get the stock solution. To make 100 millilitres, 10 millilitres of the stock solution were removed and diluted with water. Using several concentrations (2–12 µg/ml) and the appropriate stock solution dilution, a calibration curve was produced. The absorbance was obtained at 224 nm. The curve that results from calibrating DPG in a pH 6.8 phosphate buffer is shown in Figure 1.

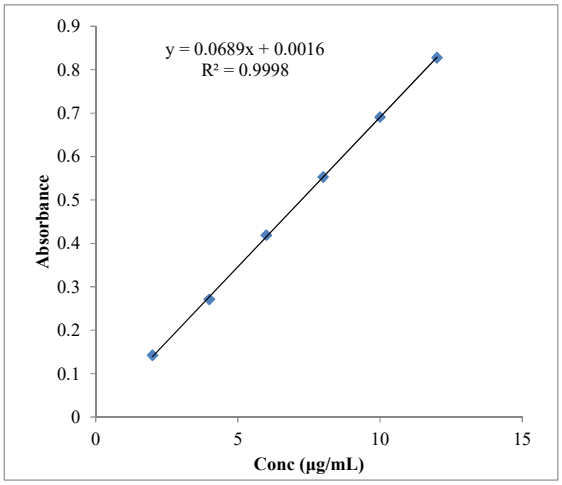


**Fig 1:** DPG standard calibration curve in phosphate buffer with a pH of 6.8

The calibration curve of dapagliflozin in phosphate buffer (pH 6.8) was found to be linear in the concentration range of 2–12 µg/mL. The absorbance increased proportionally with the increase in drug concentration. The correlation coefficient ($R^2$ = 0.9987) indicates excellent linearity and suitability of the method for further estimation of drug content in the prepared ODFs.

### Drug – excipient Compatibility Studies

FTIR spectroscopy was used to determine the drug excipient compatibility, and the graphs were displayed figure 2 to 5. To find out if there is any interaction between the excipients and DPG, the physical mixture was put through FTIR analysis. The lack of a drug-carrier chemical interaction is confirmed by the absence of any drug-characteristic peak appearance or disappearance. Drug polymer and other excepient's physical mixtures all had their Fourier transform infrared spectra recorded and examined for chemical interactions. All samples, which were pure DPG, underwent FTIR analysis to determine the presence of the pure API in the mixtures and to describe it.

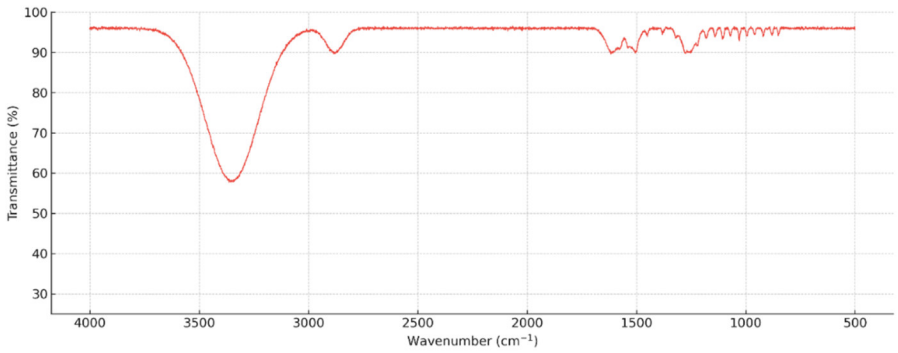


**Fig 2:** FTIR Spectral analysis of pure DPG.

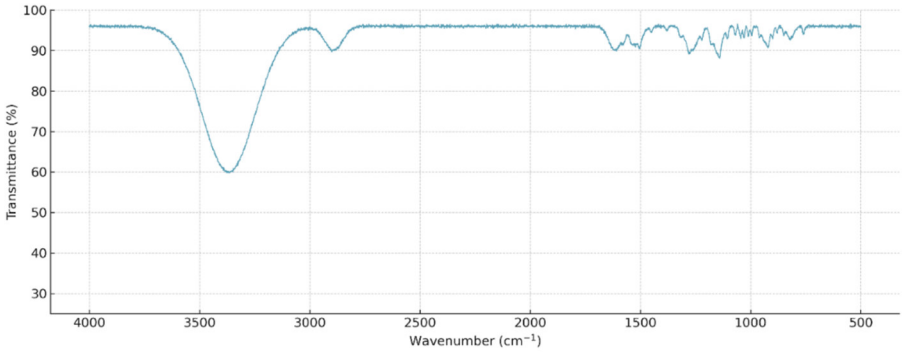


**Fig 3:** FTIR Spectral analysis of DPG+Pullulan

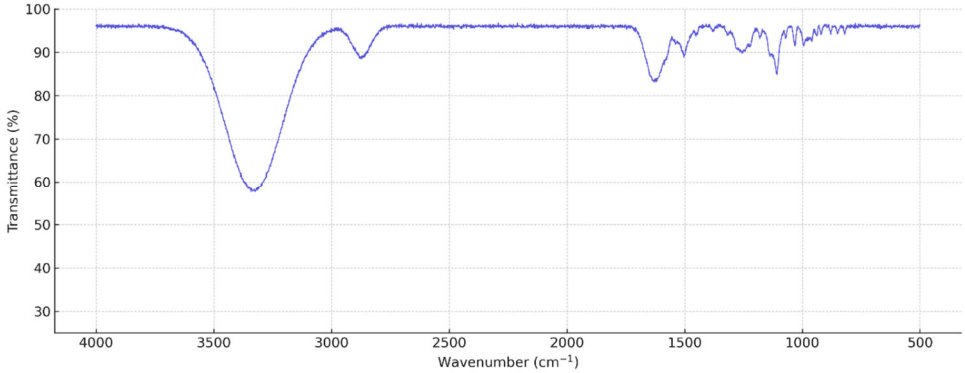


**Fig 4:** FTIR Spectral analysis of DPG+ Lycoat RS720

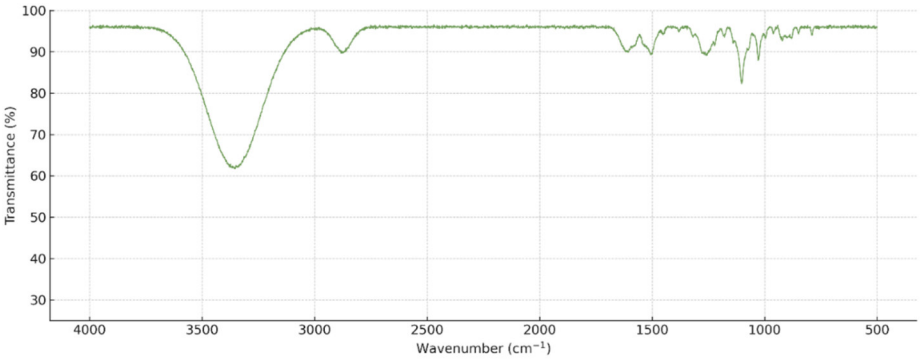


**Fig 5:** FTIR Spectral analysis of DPG+ Maltodextrin

The acquired FTIR spectra are overlapped in the figure 2-5. The FTIR spectrum of pure dapagliflozin exhibits distinctive characteristics: a wide OH band approximately at 3350 $cm^{-1}$, aliphatic C–H stretches in the range of 2860–2880 $cm^{-1}$, aromatic/C=C absorptions within the 1610–1510 $cm^{-1}$ region, and C–O–C/fingerprint signals in the 1260–1000 $cm^{-1}$ range. In the polymer-containing formulations, each polymer induces specific, reproducible spectral alterations: pullulan causes the OH band to broaden and shift slightly upward, while new or intensified glycosidic C–O–C bands emerge around 1150–1040 $cm^{-1}$, indicative of polysaccharide overlap and hydrogen bonding; Lycoat RS720 exhibits downward shifts in certain drug bands and the appearance of a bound-water/starch-related feature near ~1640 $cm^{-1}$, along with enhanced C–O signatures (~1120 $cm^{-1}$), suggesting interaction with the modified starch matrix; and with maltodextrin, both upward and downward minor shifts occur, accompanied by intensified C–O bands (~1100–1025 $cm^{-1}$), reflecting maltodextrin's saccharide contributions. The spectrum shifts and polymer-specific bands indicate physical interactions, such as hydrogen bonding and matrix entrapment, potentially alongside electrostatic effects,

demonstrating the compatibility of dapagliflozin with the selected excipients rather than any chemical alteration of the active pharmaceutical ingredient.

**Evaluation of ODF:**

**Thickness**

Each formulation's thickness (DF1–DF7) was examined; the findings are displayed in the table 2. The thickness of the films ranged from 121 ± 3.4 μm to 198 ± 5.3 μm, increasing progressively with polymer concentration.

**Table 2:** Finding the thickness, folding endurance, and pH of the surface and disintegration time of all formulations

| Formulation Code | Thickness (μm) | Folding Endurance (Folds) | Surface pH | Disintegration Time (sec) |
|---|---|---|---|---|
| DF1 | 121 ± 3.4 | 125 ± 4 | 6.78 ± 0.10 | 32 ± 2 |
| DF2 | 132 ± 3.6 | 138 ± 5 | 6.74 ± 0.08 | 30 ± 3 |
| DF3 | 144 ± 3.8 | 151 ± 6 | 6.71 ± 0.09 | 28 ± 2 |
| DF4 | 158 ± 4.2 | 163 ± 5 | 6.68 ± 0.11 | 25 ± 2 |
| DF5 | 172 ± 4.5 | 174 ± 6 | 6.65 ± 0.10 | 24 ± 3 |
| DF6 | 186 ± 4.9 | 185 ± 7 | 6.63 ± 0.09 | 23 ± 2 |
| DF7 | 198 ± 5.3 | 192 ± 8 | 6.60 ± 0.11 | 22 ± 2 |

**Folding Endurance:**

The results are displayed in Table 2. Folding endurance values showed good mechanical strength, increasing from 125 ± 4 to 192 ± 8 folds, indicating enhanced film flexibility and resistance to breakage.

**Surface pH of Films:**

The surface pH values of all formulations were found between 6.60 ± 0.11 to 6.78 ± 0.10, which is within the acceptable range for application, minimizing irritation risks.

**In-vitro disintegration:**

The findings are displayed in the table 2. Disintegration times were rapid, ranging from 22 ± 2 to 32 ± 2 seconds, with formulation D7 showing the fastest disintegration, which is beneficial for faster drug release and onset of action.

**Weight variation:**

Table 3 demonstrates the weight variation across all Dapagliflozin ODF formulations ranged between 97.3 ± 2.1 mg and 108.6 ± 2.9 mg, indicating good uniformity within acceptable pharmaceutical limits.

**Drug Content Uniformity:**

Table 3 shows the results of calculating the percentage of DPG content for different formulations. Drug content uniformity was consistent across batches, with values ranging from 94.8 ± 2.4% (DF1) to 99.3 ± 2.0% (DF5), suggesting efficient and homogenous drug distribution within the polymer matrix.

**Assay:** A UV spectrophotometer was used to analyse this solution. The assay values followed a similar trend, with DF5 showing the highest accuracy at 99.0 ± 2.0%, confirming the integrity of the formulation process.

These results validate the reproducibility and reliability of the solvent casting method used in preparing the ODFs, particularly for optimized formulations like DF5 and DF6.

**Table 3:** Weight variation, drug content uniformity, and assay determination

| F. Code | Weight Variation (mg) | Drug Content Uniformity (% ± SD) | Assay (% ± SD) |
|---|---|---|---|
| DF1 | 97.3 ± 2.1 | 94.8 ± 2.4 | 95.1 ± 2.0 |
| DF2 | 99.2 ± 2.3 | 96.5 ± 2.1 | 96.4 ± 2.2 |

| | | | |
|---|---|---|---|
| DF3 | 100.8 ± 2.5 | 97.9 ± 1.9 | 97.8 ± 1.8 |
| DF4 | 103.5 ± 2.4 | 98.6 ± 2.3 | 98.4 ± 1.9 |
| DF5 | 105.9 ± 2.7 | 99.3 ± 2.0 | 99.0 ± 2.0 |
| DF6 | 107.1 ± 2.8 | 98.7 ± 2.5 | 98.6 ± 1.7 |
| DF7 | 108.6 ± 2.9 | 97.4 ± 2.6 | 97.1 ± 1.9 |

**In-vitro dissolution**

For DF1 through DF7, figure 6 displays the cumulative drug release percentage. Utilizing a Type II USP paddel apparatus, the in vitro dissolution investigations were conducted in phosphate buffer with a 6.8 pH.

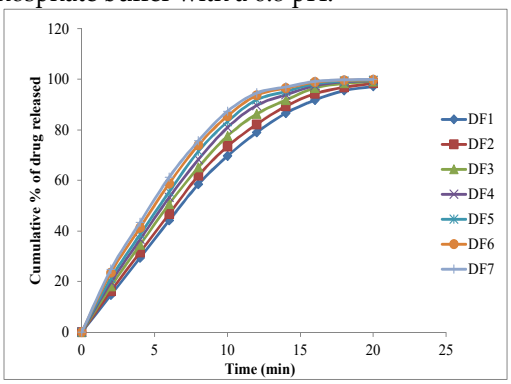


**Fig 6:** In-vitro dissolution studies of DPG formulations (DF1-DF7)

**Application of Release Rate Kinetics to Dissolution Data:**

The kinetics of drug release were investigated using a range of models. The drug release rate mechanism of the dose form kinetics was examined by fitting a variety of release models, such as first-order, zero-order, higuchi, and Korsmeyer-Peppas, to the collected data. The kinetics results were displayed in figures 7-10.

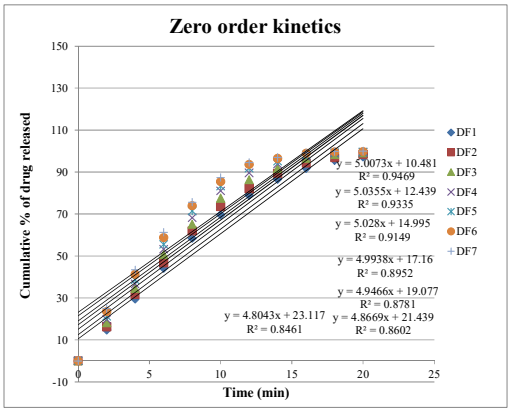


**Fig 7:** Zero order release kinetics graph of DPG formulations (DF1-DF7)

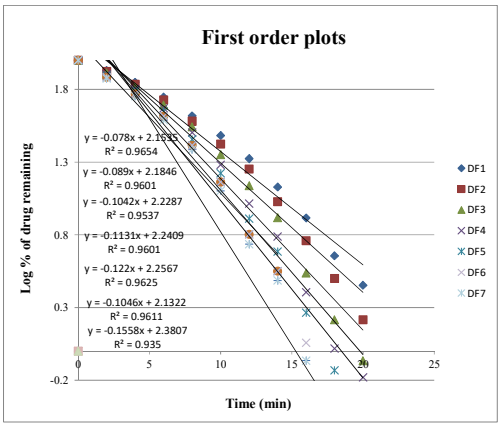


**Fig 8:** First order release kinetics graph of DPG formulations (DF1-DF7)

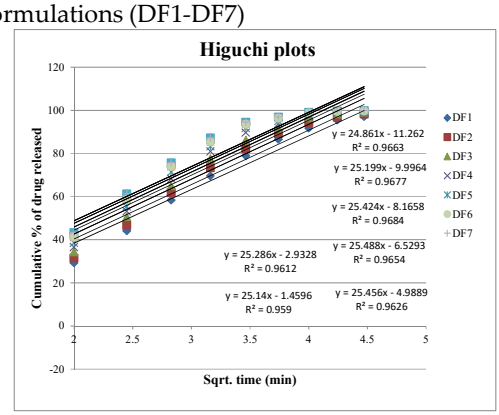


**Fig 9:** Higuchi release kinetics graph of DPG formulations (DF1-DF7)

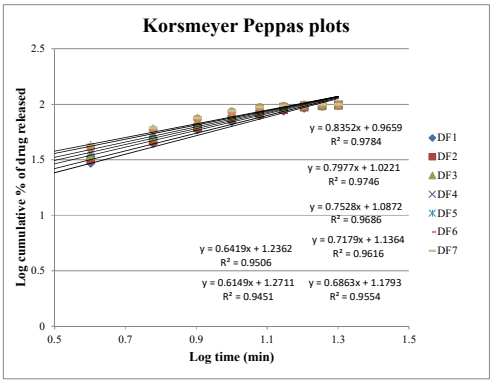


**Fig 10:** Korsmeyer-Peppas graph of DPG formulations (DF1-DF7)

The drug-release kinetics for Dapagliflozin ODFs (Figs. 7-10). In DF1–DF7, the drug-release results most accurately conform to

first-order ($R^2$ = 0.935–0.965) and Higuchi ($R^2$ ≈ 0.959–0.968) models, signifying a concentration-dependent, diffusion-controlled release from hydrated film matrices. DF1 exhibits the highest zero-order contribution ($R^2$ = 0.9469) and the most robust Peppas fit ($R^2$ = 0.9784) with n = 0.8352, indicating significant anomalous behavior (diffusion combined with polymer relaxation/erosion). As the polymer system/composition progresses toward DF7, n progressively decreases, and Peppas $R^2$ experiences a slight reduction, indicating a shift towards quasi-Fickian diffusion predominance while still exhibiting robust first-order/Higuchi correlations. These trends indicate that all films are released predominantly through diffusion within an expanded network, with initial batches (e.g., DF1–DF3) exhibiting greater polymer-relaxation involvement, while subsequent, more rapid films (DF5–DF7) achieve diffusion-driven, nearly complete release in accordance with the dissolution rankings.

**Stability Studies:**

In compliance with ICH recommendations, stability experiments were carried out to assess the pharmaceutical formulation's stability. The optimised DF4 and DF6 formulation was packaged in aluminium with a polyethylene lamination. The Samples were stored for three months at 40°C and 75% relative humidity. DF7 retained drug content well over 90 days under both conditions, showing only a small, progressive decline under accelerated storage. All values remained within typical assay acceptance limits (95–105% of label claim), indicating good chemical stability of dapagliflozin in the film matrix. No visual changes (clarity, color, integrity) or functional issues (disintegration/handling) were noted during monitoring, supporting that DF7 is physically and chemically stable for routine use; accelerated data suggest acceptable shelf-life at ambient conditions.

## CONCLUSION

Dapagliflozin oral dispersible films were effectively developed utilising advanced polymer systems, resulting in mechanically resilient, swiftly disintegrating, and agreeable films. The optimised formulation (DF7) exhibited rapid hydration, nearly whole drug release within 20 minutes, exceptional content uniformity, and adequate stability in both real-time and accelerated circumstances. FTIR analyses verified the lack of drug-excipient interactions, affirming formulation compatibility. This study identifies dapagliflozin ODFs as an effective patient-centered dose form that offers swift glucose-lowering effects and enhanced adherence, especially advantageous for paediatric, geriatric, and dysphagic groups.

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