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Original Research Article

FORMULATION AND CHARACTERIZATION OF CANAGLIFLOZIN-LOADED FAST DISSOLVING ORAL FILMS

Ahmed Najib Yahya Qasem *, Steffi Thomas, Akhlesh Kumar Singhai
School of Pharmacy, LNCT University, J K Town, Kolar Road, Sarvadharam C Sector, Bhopal, Madhya Pradesh, India-462042

***Correspondence Info:**
Ahmed Najib Yahya Qasem
School of Pharmacy, LNCT University, J K Town, Kolar Road, Sarvadharam C Sector, Bhopal, Madhya Pradesh, India-462042
Email:
ahmednajibyahya17@gmail.com

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ABSTRACT

The present study aimed to develop and evaluate Canagliflozin-loaded fast dissolving oral films to enhance drug solubility, rapid drug release, and patient compliance. Physical mixtures of the drug were prepared in different ratios to improve solubility, and the results showed a significant increase in solubility, with the highest enhancement observed in the 1:3 ratio. Fast dissolving oral films were prepared using the solvent casting method and evaluated for various physicochemical and mechanical properties. All formulations exhibited uniform thickness, weight, and good transparency, indicating successful film formation. Drug content was found to be within acceptable limits, confirming uniform distribution of the drug. Mechanical properties such as folding endurance and tensile strength demonstrated that the films were strong and flexible. The disintegration time of the films was found to be rapid, with formulation F6 showing the fastest disintegration. *In-vitro* drug release studies revealed that formulation F6 exhibited maximum drug release (99.25% within 10 minutes), indicating enhanced dissolution behavior. Drug release kinetics followed first-order kinetics, suggesting concentration-dependent release. Stability studies confirmed that the optimized formulation remained stable over a period of three months. In conclusion, the developed fast dissolving oral film of Canagliflozin showed improved solubility, rapid drug release, and good stability, making it a promising drug delivery system for effective management.

Keywords: Canagliflozin, Fast dissolving oral film, Solubility enhancement, Solvent casting method, *In-vitro* drug release, Stability study, Drug delivery system.

INTRODUCTION

Oral drug delivery remains the most preferred route of administration due to its convenience, patient compliance, and cost-effectiveness (Baryakova *et al.*, 2023). However, conventional oral dosage forms such as tablets and capsules often present challenges like difficulty in swallowing, delayed onset of action, and variable bioavailability. These limitations are particularly significant in pediatric, geriatric, and dysphagic patients (Lopez *et al.*, 2015).

Fast dissolving oral films (FDOFs) have emerged as a novel drug delivery system designed to overcome these issues. These thin, flexible films rapidly disintegrate or dissolve when placed on the tongue without the need for water, releasing the drug for quick absorption (Kathpalia and Gupte, 2013). This leads to faster onset of action and improved patient compliance. FDOFs offer

several advantages, including ease of administration, accurate dosing, enhanced stability, and improved bioavailability compared to conventional dosage forms (Wilkins *et al.*, 2024).

Canagliflozin is an oral antidiabetic drug belonging to the class of sodium-glucose co-transporter-2 (SGLT2) inhibitors. It works by reducing renal glucose reabsorption, thereby increasing urinary glucose excretion and lowering blood glucose levels. Despite its effectiveness, Canagliflozin exhibits certain limitations such as moderate solubility and delayed onset of action, which may affect its therapeutic performance (Devineni and Polidori, 2015).

Incorporating Canagliflozin into fast dissolving oral films can enhance its solubility, improve dissolution rate, and provide rapid drug release, leading to better therapeutic outcomes. Additionally, this dosage form can improve patient compliance, especially for individuals who have difficulty swallowing conventional tablets.

The formulation of fast dissolving oral films involves the use of suitable film-forming polymers, plasticizers, and other excipients to achieve desired mechanical strength, flexibility, and rapid disintegration. Various techniques such as solvent casting method are commonly employed for the preparation of oral films (Kshirsagar *et al.*, 2021).

Therefore, the present study focuses on the formulation and characterization of Canagliflozin-loaded fast dissolving oral films to enhance drug delivery, improve patient compliance, and achieve better therapeutic efficacy.

MATERIALS AND METHODS

Materials

Canagliflozin was obtained as a gift sample from a reputed pharmaceutical company. Film-forming polymers such as Hydroxypropyl methylcellulose (HPMC) were used for the preparation of oral films. Plasticizers like polyethylene glycol (PEG 400) or glycerin were incorporated to improve flexibility. Other excipients including sweetening agents, flavoring agents, and saliva-stimulating agents were used to enhance palatability and disintegration. Solvents such as methanol and distilled water were used during formulation. All chemicals and reagents used in the study were of analytical grade.

Methods

Preparation of solid dispersions

Optimization of drug: polymer ratio

In order to optimize the drug is to polymer ratio, we have prepared the matrices by both i.e. physical mixture method and solid dispersion method.

Physical mixture method: All the ingredients were weighed accurately and passed through sieve no. 85 in order to obtain powder of fine particle size with narrow size distribution. The physical mixtures of drug with carrier PEG 4000 was prepared indifferent concentration by slightly grinding the drug and carrier in mortar for 2 min. The drug: PEG 4000 ratio which was taken as 1:1, 1:2, and 1:3 respectively. Then the resultant powder was passed through sieve no 85 and was stored in desiccator for 2-6 hrs to carry out further analysis. The prepared physical mixture was subjected to spectrophotometric method.

Preparation of solid dispersion of Canagliflozin

For the preparation of Canagliflozin-PEG 4000 solid dispersion by conventional method, PEG 4000 was weighed and a measured amount of Canagliflozin was added and stirred, sample was pulverized with use of a pestle and mortar and sieved through a 400-mm mesh. 10mg of Canagliflozin - PEG 4000 powder (containing 75mg of Canagliflozin and 275mg of PEG 4000) and was used for further investigations (Meka *et al.,* 2012).

Evaluation of dispersion

Percentage drug content:

For the determination of drug content, dispersion equivalent to 10 mg of Canagliflozin, were weighed and extracted with 10 ml of methanol by mechanical mixing for 5min followed by centrifugation at 10,000 rpm for 5 min on a centrifuge. The supernant was filtered through 0.45µ membrane filter, and the filtered solutions were suitably diluted and analyzed at 298nm using a validated UV spectrophotometric method.

Formulation development of oral film of Canagliflozin

Casting process of fast disintegrating film

Various methods are available for casting of oral films. This is fast disintegrating oral film hence on the laboratory scale solvent casting technique was adopted for films formulation.

Solvent casting technique

Canagliflozin containing fast dissolving films were fabricated by the solvent casting method (Bhikshapathi *et al.,* 2014). HPMC is known for its good film forming properties and has excellent acceptability. Various grades of HPMC namely HPMC K4, and HPMC K15 were evaluated as film formers. For the fabrication of films, glycerin was used as a humectant. PEG 400 is also reported as lubricant and solubilizer. Therefore PEG 400 along with glycerol was also used for fabrication of films. Citric acid for saliva stimulating agent and mannitol as sweeteners used to fabricate the films. The polymer was soaked in water for 30 min or heated in water bath to 80° to get a clear solution. Then a plasticizer was added to it and mixed so as to get homogeneous solution. This solution was then casted onto glass moulds (15×5cm) and was dried in hot air oven at 45° for 24 h (Sruthi *et al.,* 2025).

Evaluation of prepared Film

Thickness

The thickness of patches was measured at three different places using a vernier caliper (Bilal *et al.,* 2005).

Weight uniformity

For each formulation, three randomly selected patches were used. For weight variation test, 10 films from each batch were weighed individually by digital electronic balance and the average weight was calculated (Gohel *et al.,* 2007).

Folding endurance

This was determined by repeatedly folding one film at the same place until it broke. The number of times the film could be folded at the same place without breaking cracking gave the value of folding endurance (Patil and Shrivastava, 2014).

Percentage of moisture content

The films were weighed individually and kept in desiccators containing activated silica at room temperature for 24 hrs. Individual films were weighed repeatedly until they showed a constant weight. The percentage of moisture content was calculated as the difference

between initial and final weight with respect to final weight (Nagar *et al.,* 2011).

Drug content analysis

The film taken into a 10 ml volumetric flask and dissolved in methanol and volume was made up with 10 ml methanol. Subsequent dilutions were made and reacted by UV spectrophotometer at 298nm (Dinge and Nagarsenker, 2008).

Disintegrating time

The most important criteria of present work is that dosage form should be dissolved within few seconds. The incorporation of super disintegrating agent was done to minimize the disintegrating time. Three super disintegrating agent (Sodium starch Glycolate, Crospovidone and Croscarmellose Sodium) were selected for this work (Sharma *et al.*, 2007; Joshi *et al.,* 2013).

***In vitro* dissolution study**

The *in vitro* dissolution test was performed using the USPXXX dissolution apparatus II (Paddle with sinker) (Peppas, 1985). The dissolution studies were carried out at 37±0.5°C with stirring speed of 50 rpm in 900 ml phosphate buffer (pH 6.8). Film size required for dose delivery (2.5×2.5 cm^2) was used. Five ml aliquot of dissolution media was collected at time intervals of 1, 2, 4, 6, 8, and 10 minutes and replaced with equal volumes of phosphate buffer (pH 6.8). The collected samples were filtered through 0.45 µm membrane filter and the concentration of the dissolved drug was determined using UV-Visible spectrophotometer at 298nm. The results were presented as an average of three such concentrations.

Stability studies

Stability studies were carried out with optimized formulation F6 which was stored for a period of one, two and three months at 40±2°C temperature and 75±5% relative humidity for a period 3 months (Akbari *et al.,* 2017). The % Assay of formulation was determined by U.V. spectrophotometer using calibration curve method. The % assay of film was found to slightly decrease at higher temperature. Minor difference was found between evaluated parameters before and after ageing/storage and all was in acceptable limits. Therefore formulation remains stable for sufficient time.

RESULTS AND DISCUSSION

The present study focused on the formulation and evaluation of canagliflozin-loaded fast dissolving oral films to enhance solubility, drug release, and patient compliance.

The solubility study of physical mixtures showed a significant improvement in drug solubility as the ratio of carrier increased. The 1:3 ratio exhibited the highest relative solubility (2.65) and percentage solubility enhancement (264.70%) compared to the pure drug. This indicates that the presence of carrier improves the wettability and dispersion of the drug, thereby enhancing its solubility.

Drug content analysis demonstrated uniform distribution of the drug in all formulations, with values ranging from 99.60% to 99.90%. The low standard deviation confirms the accuracy and reproducibility of the method.

Evaluation of prepared films showed that all formulations were transparent with uniform thickness and weight, indicating good film-forming properties and consistency in the casting method. The thickness ranged from 50 to 65 µm, and weight variation was within acceptable limits.

Mechanical properties such as folding endurance and tensile strength indicated that

the films possessed adequate strength and flexibility. Folding endurance values were satisfactory, suggesting that films can withstand handling without breaking. Tensile strength values confirmed good mechanical integrity of the films.

Disintegration time is a critical parameter for fast dissolving films. Among all formulations, F6 showed the fastest disintegration time (54 ± 3 sec), which is desirable for rapid drug release. Moisture content was within acceptable limits, indicating stability of films under normal conditions.

The *in-vitro* drug release study revealed that all formulations showed rapid drug release; however, formulation F6 exhibited the highest drug release (99.25% within 10 minutes), indicating its superior performance. The enhanced release may be due to optimal polymer concentration and improved drug dispersion.

Kinetic modeling of the optimized formulation F6 showed that the drug release followed first-order kinetics (R^2 = 0.9785), suggesting that the release rate depends on the concentration of the drug. Higuchi and Peppas models also indicated diffusion-controlled release mechanism.

Stability studies of the optimized formulation (F6) showed minimal decrease in drug content over a period of 3 months, confirming good stability of the formulation.

The results indicate that formulation F6 is the optimized batch with desirable physicochemical properties, rapid disintegration, enhanced drug release, and good stability, making it a promising candidate for fast dissolving oral film delivery of Canagliflozin.

Table 1: Selection and optimization of film forming agents

Name of ingredients (mg) (mg for 12 strips)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Canagliflozin solid dispersion (Equivalent to 50mg for one film)	600	600	600	600	600	600	600	600	600
HPMC K4	50	100	150	-	-	-	25	50	75
HPMC K15	-	-	-	50	100	150	25	50	75
PEG-400	50	50	50	50	50	50	50	50	50
Sodium Alginates	-	-	-	-	-	-	20	30	40
Mannitol	20	20	20	20	20	20	20	20	20
Citric acid	20	20	20	20	20	20	20	20	20
DM water qs to (ml)	30	30	30	30	30	30	30	30	30

Dose calculations

- Width of the plate = 5cm
- Length of the plate = 12cm
- No. of 2.5 x 2.5 cm^2 films present whole plate = 12
- Each film contains 50 mg of drug.
- 12 no. of films contains mg of drug = 50×12 = 600mg
- The amount of Canagliflozin added in each plate was approximately equal to 600mg.

Table 2: Percentage cumulative drug release of physical mixture

S. No.	Parameter	1:1 Ratio	1:2 Ratio	1:3 Ratio	Pure Drug
1	Absorbance	0.133	0.148	0.225	0.085
2	Relative Solubility (A/A_0)	1.56	1.74	2.65	1.00
3	% Solubility Enhancement	156.47%	174.11%	264.70%	----

Relative Solubility (A/A_0) = Absorbance of formulation / Absorbance of pure drug

% Solubility Enhancement = $(A / A_0) \times 100$

Table 3: Results of drug content

S. No.	Formulation	Label Claim (mg)	Amount Found (mg)*	Drug Content (%) ± SD
1	Pure Drug	10	9.96	99.60 ± 0.15
2	Physical Mixture (1:1)	10	9.98	99.80 ± 0.12
3	Physical Mixture (1:2)	10	9.97	99.70 ± 0.10
4	Physical Mixture (1:3)	10	9.99	99.90 ± 0.11

*****Average of three determination (n=3±SD)

Table 4: Evaluation of prepared film for general appearance, thickness and weight

S. No.	Formulation Code	General Appearance	Thickness* (µm)	Weight* (mg)
1	F1	Transparent	52 ± 3	75.2 ± 0.5
2	F2	Transparent	54 ± 4	74.6 ± 0.4
3	F3	Transparent	56 ± 2	79.8 ± 0.5
4	F4	Transparent	50 ± 3	74.1 ± 0.3
5	F5	Transparent	52 ± 3	82.5 ± 0.6
6	F6	Transparent	59 ± 4	84.3 ± 0.5
7	F7	Transparent	62 ± 3	76.9 ± 0.4
8	F8	Transparent	64 ± 2	80.7 ± 0.5
9	F9	Transparent	65 ± 3	83.6 ± 0.6

***Average of three determination (n=3±SD)**

Table 5: Result of Folding Endurance, Disintegrating time, Tensile strength, Percentage Moisture Content and % Assay

Formulation Code	Folding Endurance (Times)	Disintegrating Time (Sec.)	Tensile Strength (kg/cm^2)	% Moisture Content	% Assay
F1	148 ± 5	76 ± 4	0.82 ± 0.04	4.72 ± 0.18	97.65 ± 0.32
F2	158 ± 6	68 ± 5	0.80 ± 0.03	5.42 ± 0.22	96.85 ± 0.28
F3	165 ± 4	58 ± 3	0.77 ± 0.05	4.25 ± 0.20	95.78 ± 0.35
F4	162 ± 5	69 ± 4	0.86 ± 0.04	6.10 ± 0.30	98.65 ± 0.26
F5	175 ± 6	62 ± 4	0.75 ± 0.03	4.85 ± 0.25	95.45 ± 0.30
F6	182 ± 5	54 ± 3	0.83 ± 0.05	4.05 ± 0.18	99.05 ± 0.20
F7	138 ± 4	83 ± 5	0.79 ± 0.04	5.55 ± 0.27	98.45 ± 0.24
F8	150 ± 5	74 ± 4	0.78 ± 0.06	5.60 ± 0.23	98.20 ± 0.22
F9	162 ± 3	68 ± 3	0.87 ± 0.04	5.50 ± 0.26	97.85 ± 0.29

Table 6: *In-vitro* drug release study of Formulation F1-F9

	***In-vitro* drug release study**								
Time (Min.)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
1	20.32	24.65	26.65	22.25	25.65	32.45	20.32	23.36	25.65
2	41.15	44.69	46.65	48.85	53.32	68.75	42.32	52.25	55.65
4	55.65	59.98	60.32	69.98	73.32	78.85	69.98	73.32	76.65
6	73.32	75.65	88.85	76.45	79.95	92.65	76.65	81.15	83.32
8	86.65	89.98	92.25	85.65	92.25	96.85	88.85	89.98	91.15
10	90.25	93.32	94.65	90.23	95.65	99.25	93.32	94.45	95.65

Table 7: Comparative study of regression coefficient for selection of optimized formulation F6

Zero order		First order	Higuchi	Peppas model
R^2	0.7713	0.9785	0.8676	0.8678

Table 8: Characterization of stability study of Optimized formulation

Time (Month)	% Drug Content
Initial	99.12±0.15
1 Month	98.45±0.36
2 Month	98.32±0.46
3 Month	98.10±0.22

CONCLUSION

The present study successfully formulated and characterized canagliflozin-loaded fast dissolving oral films with the aim of enhancing solubility, rapid drug release, and patient compliance. Solubility studies revealed that the drug-carrier physical mixture significantly improved the solubility of canagliflozin, especially at the 1:3 ratio, which showed maximum solubility enhancement. All prepared formulations exhibited satisfactory physicochemical

characteristics including transparency, uniform thickness, acceptable weight variation, and excellent drug content uniformity, indicating successful preparation by the solvent casting method. Mechanical evaluation confirmed that the films possessed adequate tensile strength and folding endurance, ensuring sufficient flexibility and durability. Among all the formulations, batch F6 was identified as the optimized formulation due to its shortest disintegration time of 54 ± 3 seconds and highest in-vitro drug release of 99.25% within 10 minutes. The rapid release profile suggests efficient dissolution and faster availability of the drug. Drug release kinetic studies showed that the optimized formulation followed first-order kinetics with a diffusion-controlled release mechanism. Stability studies further confirmed that formulation F6 remained stable with minimal changes in drug content and film properties over three months. Therefore, it can be concluded that canagliflozin fast dissolving oral films are a promising and effective novel drug delivery system for improved oral administration and enhanced therapeutic performance in diabetes management.

DECLARATION OF INTEREST

The authors declare no conflicts of interests. The authors alone are responsible for the content and writing of this article.

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