RESEARCH PAPER

FORMULATION AND EVALUATION OF CANAGLIFLOZIN TABLET FOR TYPE II DIABETES MELLITUS

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Abstract
The present study aimed to formulate and optimize sustained-release floating tablets of Canagliflozin for the effective management of Type II diabetes mellitus. A Box–Behnken Design (BBD) was employed to optimize the formulation by evaluating the effects of HPMC K4, HPMC K15, and PVP K30 on drug content and drug release. Thirteen formulations (F1–F13) were prepared by direct compression and evaluated for pre-compression and post-compression characteristics. The powder blends exhibited good flow properties with Hausner's ratio ranging from 1.15 to 1.16 and compressibility index between 12.80% and 13.71%, indicating suitability for tablet compression. The prepared tablets demonstrated satisfactory appearance, uniform thickness and diameter, adequate hardness (4.2–5.0 kg/cm²), low friability (0.35–0.47%), floating lag time of 25–42 seconds, and total floating time exceeding 12 hours. Drug content ranged from 94.36% to 99.45%, confirming uniform drug distribution within the tablet matrix. In vitro dissolution studies demonstrated sustained drug release over 12 hours, with cumulative drug release ranging from 97.77% to 99.76%. Statistical optimization using Design-Expert® software showed excellent agreement between predicted and experimental responses. The optimized formulation (F12) exhibited a drug content of 99.45% and drug release of 88.85% after 8 hours while maintaining prolonged buoyancy and desirable physicochemical characteristics. Drug release kinetic analysis revealed that the release profile best fitted the Korsmeyer–Peppas model (R^2 = 0.9863), followed closely by the Higuchi model (R^2 = 0.9857), indicating diffusion-controlled drug release from the hydrated polymer matrix. The study demonstrated that the optimized floating tablet formulation provides prolonged gastric residence, controlled drug release, and desirable pharmaceutical characteristics, making it a promising gastro-retentive drug delivery system for improving the therapeutic efficacy and patient compliance of Canagliflozin in the treatment of Type II diabetes mellitus.

Keywords: Canagliflozin; Sustained-release floating tablets; Gastro-retentive drug delivery system; Box–Behnken Design; HPMC K4; HPMC K15; PVP K30; Direct compression; Drug release kinetics; Type II diabetes mellitus.
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Introduction

Type II diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from impaired insulin secretion, insulin resistance, or both. The prevalence of T2DM has increased rapidly worldwide, making it one of the leading causes of cardiovascular disease, nephropathy, neuropathy, and retinopathy [1]. Effective glycemic control is essential to prevent long-term complications and improve the quality of life of diabetic patients. Consequently, the development of novel oral drug delivery systems capable of improving therapeutic efficacy and patient compliance has gained significant attention [2].

Canagliflozin is a selective sodium-glucose co-transporter-2 (SGLT2) inhibitor that lowers blood glucose levels by reducing renal glucose reabsorption and promoting urinary glucose excretion. Besides improving glycemic control, Canagliflozin has demonstrated additional benefits, including weight reduction, blood pressure lowering, and cardiovascular and renal protection. Despite these therapeutic advantages, conventional oral dosage forms may exhibit variable gastrointestinal residence time, which can influence drug release behavior and therapeutic performance. Therefore, the development of a gastroretentive sustained-release formulation represents a promising strategy to prolong gastric residence, provide controlled drug release, reduce dosing frequency, and improve patient adherence [3-4].

Floating drug delivery systems are among the most widely investigated gastroretentive approaches. These systems possess a density lower than gastric fluid, enabling them to remain buoyant in the stomach for prolonged periods [5].

Extended gastric retention enhances the duration of drug release and may improve drug absorption while maintaining more consistent plasma drug concentrations. Hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC) are extensively employed in floating matrix tablets because they rapidly hydrate upon contact with gastric fluid, forming a gel barrier that controls drug diffusion and tablet integrity. Gas-generating agents, including sodium bicarbonate and citric acid, further

facilitate buoyancy through carbon dioxide generation [6].

Optimization of pharmaceutical formulations using statistical experimental designs has become an essential component of formulation development. Among these approaches, the Box–Behnken Design (BBD) provides an efficient response surface methodology for evaluating the individual and interactive effects of formulation variables while minimizing the number of experimental trials. This approach enables systematic optimization of critical formulation parameters and improves the reliability and reproducibility of the final dosage form [7].

In the present study, sustained-release floating tablets of Canagliflozin were formulated by direct compression using HPMC K4, HPMC K15, and PVP K30 as formulation variables. The prepared formulations were evaluated for pre-compression and post-compression characteristics, floating behavior, drug content, and in vitro drug release. The formulation was optimized using a Box–Behnken Design, and the optimized batch was further evaluated for drug release kinetics to establish the mechanism of drug release. The study aimed to develop a robust gastroretentive sustained-release formulation capable of enhancing therapeutic performance and patient compliance in the management of Type II diabetes mellitus.

Experimental design

The optimization of Sustained release formulation of Canagliflozin was done by using the design expert software (Design Expert trial version 7.0.3 State Inc, Minneapolis, MN). A box behnken design (BBD) employed for formulation of sustain release tablets of Canagliflozin. HPMC K4 (A), HPMC K15 (B) and PVP K30 (C) were selected as the independent factors, studied at three levels each [8]. All other formulation and processing variables were kept invariant throughout the study. Table summarizes an account of the 13 experimental runs studied, their factor combinations, and the translation of the coded levels to the experimental units employed during the study. Percentage drug content (Y_1), % Drug Release after 12 Hrs. (Y_2) was taken as the response variables.

Table 1: Factors

Factor	Name	Units	Type	Minimum	Maximum
A	HPMC K4	mg	Numeric	100.00	250.00
B	HPMC K15	mg	Numeric	25.00	50.00
C	PVP K30	mg	Numeric	10.00	20.00

Table 2: Formulation of Canagliflozin Sustained release tablets

F. Code	Std	Run	Factor 1: HPMC K4 (mg)	Factor 2: HPMC K15 (mg)	Factor 3: (PVP K30)
F1	5	1	100	37.5	10
F2	13	2	175	37.5	15
F3	11	3	175	25	20
F4	8	4	250	37.5	20
F5	4	5	250	50	15
F6	9	6	175	25	10
F7	7	7	100	37.5	20
F8	3	9	100	50	15
F9	1	10	100	25	15
F10	10	12	175	50	10
F11	2	13	250	25	15
F12	12	14	175	50	20
F13	6	15	250	37.5	10

Method for preparation of sustained release tablets of Canagliflozin

Gas-generating floating tablets of Canagliflozin were prepared by the direct compression method**.** A total of thirteen different formulations (F1–F13) were designed using varying concentrations of polymers and excipients as per the experimental design.

All ingredients, including the drug and polymers, were passed through sieve no. 40 prior to formulation to ensure uniform particle size and proper mixing. The required quantities of drug, polymers, and excipients were accurately weighed according to the composition shown in Table. The ingredients were mixed thoroughly in a mortar and pestle to obtain a uniform blend. Magnesium stearate and talc were finally added as lubricants and glidants, respectively, and mixed gently for 5 minutes. The resulting blend was then compressed into tablets using a rotary tablet punching machine equipped with flat-faced punches**,** maintaining a uniform tablet weight of 500 mg [9].

Table 3: Composition of different formulation of sustained release tablets of Canagliflozin

F	S	R	D	F	F	F	C	So	M	T	L	T

. Code	**td**	**un**	**rug**	**actor 1: HPMCK4 (mg)**	**actor 2: HPMCK15 (mg)**	**actor 3: (PVPK30)**	**iritacacid**	**diumbicarbonate**	**agnesiumstearate**	**alc**	**actose**	**otalWeight**
F1	5	1	100	100	37.5	10	5	15	10	10	212.5	500
F2	13	2	100	175	37.5	15	5	15	10	10	132.5	500
F3	11	3	100	175	25	20	5	15	10	10	140	500
F4	8	4	100	250	37.5	20	5	15	10	10	52.5	500
F5	4	5	100	250	50	15	5	15	10	10	45	500
F6	9	6	100	175	25	10	5	15	10	10	150	500
F7	7	7	100	100	37.5	20	5	15	10	10	200	500
F8	3	9	100	100	50	15	5	15	10	10	195	500
F9	1	10	100	100	25	15	5	15	10	10	220	500
F10	10	12	100	175	50	10	5	15	10	10	125	500
F11	2	13	100	250	25	15	5	15	10	10	70	500
F12	12	14	100	175	50	20	5	15	10	10	115	500
F13	6	15	100	250	37.5	10	5	15	10	10	62.5	500

Evaluation of precompression parameter

Bulk density: Both loose bulk density (LBD) and tapped bulk density (TBD) were determined. Accurately weighed amount of granules taken in a 50 ml capacity measuring cylinder was tapped for 100 times on a plane hard wooden surface and estimated the LBD and TBD, calculated by using following formula:

$$\text{LBD (Loose Bulk Density)} = \frac{\text{Mass of powder}}{\text{Volume of Packing}}$$

$$\text{TBD (Tapped Bulk Density)} = \frac{\text{Mass of powder}}{\text{Tapped Volume of Packing}}$$

Compressibility index: Percent compressibility of powder mix was determined by Carr's compressibility index, calculated by using following formula:

$$\text{Carr}^{'}\text{s Index} = \frac{\text{TBD} - \text{LBD}}{\text{TBD}} \text{X } 100$$

Hausners ratio: It is determined by comparing tapped density to the bulk density by using following equation [10]:

$$\text{Housner's ratio} = \frac{\text{Tapped bulk density}}{\text{Loose Bulk density}}$$

Hausner's ratio value <1.25 shows better flow properties

Final equation in terms of coded factors

Drug Content (%) = +95.73 + 0.9225A – 0.7463B + 0.0737C – 0.9300AB – 0.0400AC – 0.3925BC + 1.75A^2 + 0.1843B^2 – 0.8057C^2

Final equation in terms of actual factors

Drug Content (%) = 89.19308 – 0.057587(HPMC K4) + 0.119660(HPMC K15) + 1.23582(PVP K30) – 0.000992(HPMC K4 × HPMC K15) – 0.000107(HPMC K4 × PVP K30) – 0.006280(HPMC K15 × PVP K30) + 0.000311(HPMC $K4^2$) + 0.001179(HPMC $K15^2$) – 0.032230(PVP $K30^2$)**.**

Final Equation in Terms of Actual Factors

Drug Release after 8 hrs (%) = 83.5406 + 0.0521(HPMC K4) + 0.3263(HPMC K15) + 0.4561(PVP K30) + 0.00194(HPMC K4 × HPMC K15) – 0.00049(HPMC K4 × PVP K30) – 0.0102(HPMC K15 × PVP K30) – 0.00042(HPMC $K4^2$) – 0.00645(HPMC $K15^2$) + 0.00600(PVP $K30^2$).

Final equation in terms of coded factors

Drug Release after 8 hrs (%) = 96.84 – 2.22875A + 0.3625B + 0.83625C + 1.8175AB – 0.185AC – 0.6375BC – 2.365A^2 – 1.0075B^2 + 0.15C^2.

Evaluation of tablets

All the tablets were evaluated for following various parameters which includes;

General appearance

Five tablets from various batches were randomly selected and organoleptic properties such as color, odor, shape, were evaluated. Appearance was judged visually. Very good (+++), good (++), fair (+) poor (-), very poor (- -).

Thickness and diameter

Thickness and diameter of tablets were determined using Vernier caliper. Five tablets from each batch were used, and an average value was calculated [11].

Drug content

Twenty tablets were taken and amount of drug present in each tablet was determined. The tablets were crushed in a mortar and the powder equivalent to 10mg of drug was transferred to 10ml standard flask. The powder was dissolved in 5 ml of 0.1 N HCl and made up to volume with of 0.1 N HCl. The sample was mixed thoroughly and filtered through a 0.45µ membrane filter. The filtered solution was diluted suitably and for drug content by UV spectrophotometer at λ_{max} of 298 nm using of 0.1 N HCl as blank.

Hardness

For each formulation, the hardness of five tablets was resolved utilizing the Monsanto hardness tester [12].

Friability

The friability of a sample of 10 tablets was estimated utilizing a Friability tester (Electro Lab). Ten tablets were weighed, rotated at 25 rpm for 4 minutes. Tablets were reweighed after removal of fines (dedusted) and the percentage of weight loss was calculated [13].

Uniformity of weight

Twenty tablets were randomly selected from each batch individually weighed, the average weight and standard deviation of 20 tablets was calculated [14].

***In vitro* buoyancy studies**

In vitro buoyancy was determined by floating lag time as per the method. The tablets were separately in a 100 ml glass beaker containing simulated gastric fluid, pH 1.2 as per USP. The time necessary for the tablet to increase to the outside and float was determined as floating lag time [15].

Dissolution rate studies

In vitro drug release of the sample was done using USP-type II dissolution apparatus (Paddle type). The dissolution medium, 900 ml 0.1N HCl was set into the dissolution flask maintaining the temperature of 37±0.5ºC and rpm of 75. One prepared Canagliflozin tablet was set in every container of dissolution apparatus. The mechanical assembly was permitted to keep running for 10 hours. Sample measuring 5 ml were pulled back after each 1 hour up to 10 hours using 10ml pipette. The new disintegration medium (37ºC) was supplanted each time with a similar amount of the sample and takes the absorbance at 298nm using UV/Visible spectroscopy.

Results and Discussion

The present investigation focused on the formulation and optimization of sustained-release floating tablets of Canagliflozin for the management of Type II diabetes mellitus using a Box–Behnken Design (BBD). Three formulation variables, namely HPMC K4 (A), HPMC K15 (B), and PVP K30 (C), were selected as independent variables based on their influence on tablet integrity, swelling behavior, buoyancy, and drug release. Thirteen experimental formulations (F1–F13) were prepared according to the experimental design, and their compositions are presented in Table 2 and Table 3.

Prior to compression, all powder blends were evaluated for their flow properties. The bulk density of the formulations ranged from 0.446 to 0.462 g/cm^3, while the tapped density varied from 0.516 to 0.531 g/cm^3. The Hausner's ratio (1.15–1.16) and compressibility index (12.80–13.71%) indicated good flowability and compressibility of the powder blends, making them suitable for direct compression. These values are within the acceptable pharmacopoeial limits, confirming that all formulations possessed satisfactory pre-compression characteristics (Table 4).

The prepared floating tablets exhibited a uniform white to off-white appearance with an odorless nature and circular shape. Formulations F1, F2, F6, F9, and F12 demonstrated excellent overall appearance (+++), whereas the remaining formulations showed acceptable visual characteristics. The consistency in tablet appearance indicated successful formulation and compression without visible defects such as capping, lamination, or chipping (Table 5).

The thickness and diameter of all formulations remained highly uniform, with thickness ranging between 3.18 ± 0.04 mm and 3.27 ± 0.02 mm, while tablet diameter remained close to 8 mm for all batches. These results confirmed the reproducibility of the compression process and uniform die filling throughout tablet manufacture (Table 6).

Drug content analysis demonstrated efficient incorporation of Canagliflozin into all formulations. Drug content ranged from 94.36% to 99.45%, indicating excellent content uniformity. Among all formulations, F12 exhibited the highest drug content (99.45%), whereas F11 showed the lowest value (94.36%). All formulations complied with acceptable pharmacopeial limits, indicating uniform drug distribution throughout the tablet matrix (Table 7).

Mechanical strength is an important quality attribute for floating tablets. Hardness values ranged from 4.2 to 5.0 kg/cm², demonstrating adequate tablet strength to withstand handling and transportation. Friability values varied between 0.35% and 0.47%, remaining well below the pharmacopoeial limit of 1%, thereby confirming satisfactory mechanical resistance. Floating lag time ranged from 25 to 42 seconds, while all formulations remained buoyant for more than 12 hours, indicating efficient gas generation by sodium bicarbonate and citric acid and successful maintenance of tablet buoyancy (Table 8).

The in vitro dissolution study demonstrated sustained drug release from all formulations over 12 hours. Drug release profiles were markedly influenced by polymer concentration. Formulations containing lower concentrations of HPMC released the drug relatively faster, whereas higher polymer concentrations prolonged drug release due to formation of a stronger gel barrier. Among all formulations, F13 exhibited the highest cumulative drug release (99.76%), closely followed by F3 (99.62%) and F7 (99.58%). In contrast, formulation F12 showed a comparatively slower release profile, releasing 88.85% drug at 8 hours and 97.77% at 12 hours, indicating effective sustained-release behavior (Table 9).

Optimization of the formulation was performed using Design-Expert® software based on drug content and drug release after 8 hours as response variables. The statistical model demonstrated good agreement between predicted and experimental values. The optimized formulation (F12) showed an experimental drug content of 99.45% compared with the predicted value of 100.26%, while the observed drug release after 8 hours was 88.85% compared with the predicted value of 89.06%, confirming excellent predictive capability of the optimization model (Table 10).

The adequacy of the statistical model was further confirmed through the diagnostic plots generated by the Design-Expert® software. The normal probability plots demonstrated random distribution of residuals, confirming normality of experimental errors. Predicted versus actual plots showed excellent agreement between observed and predicted responses. The contour plots and three-dimensional response surface plots illustrated the influence of HPMC K4, HPMC K15, and PVP K30 on drug content and drug release responses, enabling identification of the optimized design space (Figure 1 and Figure 2).

Drug release kinetics of the optimized formulation (F12) were evaluated using various mathematical models. The cumulative drug release profile demonstrated sustained release over 12 hours (Table 11). Regression analysis showed correlation coefficients of 0.9458, 0.9706, 0.9857, and 0.9863 for Zero-order, First-order, Higuchi, and Korsmeyer–Peppas models, respectively (Table 12). The highest correlation coefficient was obtained with the Korsmeyer–Peppas model, closely followed by the Higuchi model, indicating that drug release was predominantly governed by diffusion through the hydrated polymer matrix with simultaneous polymer relaxation.

Table 4: Results of pre compression parameters

Formulation Code	Bulk Density (g/cm³)	Tapped Density (g/cm³)	Hausner's Ratio	Compressibility Index (%)
F1	0.455	0.523	1.15	13.01
F2	0.462	0.531	1.15	12.99
F3	0.458	0.525	1.15	12.80
F4	0.446	0.516	1.16	13.57
F5	0.449	0.520	1.16	13.65
F6	0.454	0.526	1.16	13.68
F7	0.460	0.531	1.15	13.37

F8	0.452	0.523	1.16	13.59
F9	0.457	0.527	1.15	13.29
F10	0.448	0.518	1.16	13.51
F11	0.453	0.525	1.16	13.71
F12	**0.459**	**0.530**	**1.15**	**13.39**
F13	0.450	0.520	1.16	13.46

Table 5: Evaluation of general appearance of floating tablets of Canagliflozin

Formulation Code	Color	Odor	Shape	Overall Appearance
F1	White	Odorless	Round	+++
F2	White	Odorless	Round	+++
F3	White	Odorless	Round	++
F4	Off-white	Odorless	Round	++
F5	Off-white	Odorless	Round	++
F6	White	Odorless	Round	+++
F7	White	Odorless	Round	++
F8	White	Odorless	Round	++
F9	White	Odorless	Round	+++
F10	Off-white	Odorless	Round	++
F11	White	Odorless	Round	++
F12	**White**	**Odorless**	**Round**	**+++**
F13	Off-white	Odorless	Round	++

Table 6: Thickness and diameter of floating tablets of Canagliflozin

Formulation Code	Thickness (mm)	Diameter (mm)
F1	3.21 ± 0.02	8.02 ± 0.03
F2	3.25 ± 0.03	8.05 ± 0.02
F3	3.18 ± 0.04	8.03 ± 0.03
F4	3.23 ± 0.03	8.00 ± 0.02
F5	3.27 ± 0.02	8.06 ± 0.03
F6	3.20 ± 0.03	8.01 ± 0.03
F7	3.19 ± 0.02	8.04 ± 0.02
F8	3.24 ± 0.03	8.02 ± 0.04
F9	3.26 ± 0.03	8.05 ± 0.03
F10	3.22 ± 0.02	8.03 ± 0.03
F11	3.25 ± 0.03	8.04 ± 0.02
F12	**3.23 ± 0.03**	**8.02 ± 0.03**
F13	3.21 ± 0.02	8.01 ± 0.03

Table 7: Percentage drug content of floating tablets of Canagliflozin

Formulation Code	Drug Content (%)
F1	95.15
F2	95.85
F3	96.65
F4	98.12
F5	97.15
F6	96.12
F7	95.78
F8	97.74
F9	96.32
F10	95.74
F11	94.36
F12	**99.45**
F13	97.65

Table 8: Hardness, Friability, Floating Lag Time, Total Floating Time of floating tablets of Canagliflozin

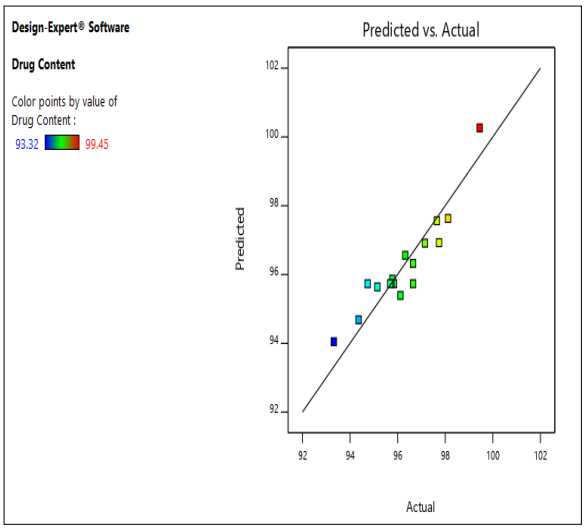
Formulation Code	Hardness	Friability (%)	Floating Lag	Total Floati

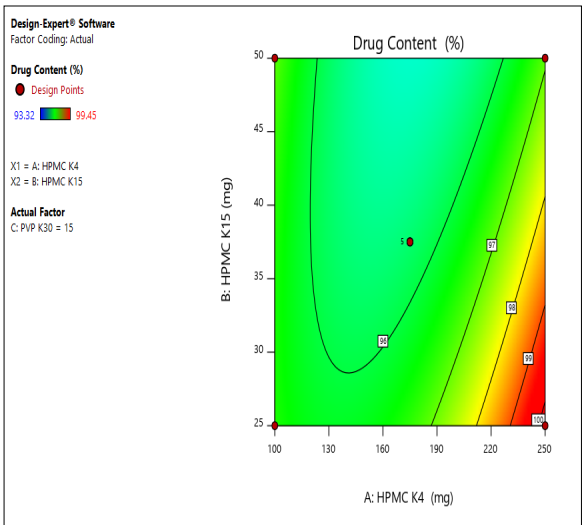
	(kg/cm²)		**Time (sec)**	**ng Time (hrs)**
F1	4.2 ± 0.1	0.45	42	>12
F2	4.5 ± 0.2	0.41	38	>12
F3	4.3 ± 0.1	0.47	35	>12
F4	4.8 ± 0.1	0.39	30	>12
F5	5.0 ± 0.2	0.36	28	>12
F6	4.4 ± 0.1	0.42	40	>12
F7	4.6 ± 0.2	0.43	32	>12
F8	4.5 ± 0.1	0.38	31	>12
F9	4.3 ± 0.2	0.44	36	>12
F10	4.7 ± 0.2	0.40	29	>12
F11	4.9 ± 0.1	0.37	27	>12
F12	**4.8 ± 0.2**	**0.35**	**25**	**>12**
F13	4.6 ± 0.2	0.39	30	>12

Table 9: Results of percentage drug release of formulaion F1 to F13

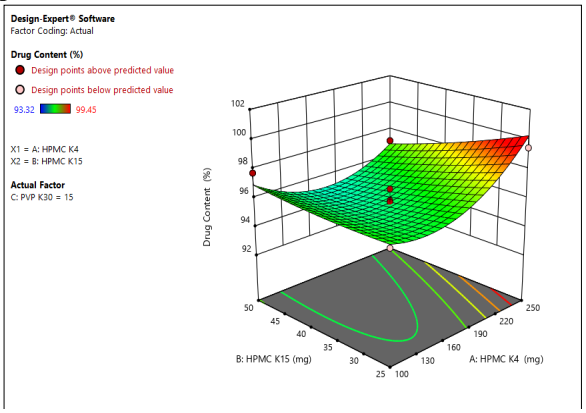
Formulation	**0.5 h**	**1 h**	**2 h**	**4 h**	**6 h**	**8 h**	**10 h**	**12 h**
F1	5.80	11.60	27.06	53.16	75.39	96.65	98.16	99.33
F2	5.73	11.47	27.76	53.57	76.55	98.58	98.57	99.12
F3	5.89	11.77	27.47	53.97	76.53	98.12	98.97	99.62
F4	5.53	11.07	25.82	50.73	71.94	92.23	95.73	98.45
F5	5.67	11.33	26.45	51.95	73.67	94.45	96.95	98.89
F6	5.66	11.32	26.42	51.90	73.60	94.36	96.90	98.87
F7	5.87	11.75	27.41	53.83	76.35	97.88	98.83	99.58
F8	5.67	11.33	26.45	51.95	73.67	94.45	96.95	98.89
F9	5.77	11.53	26.91	52.87	74.97	96.12	97.87	99.22
F10	5.86	11.73	27.37	53.76	76.24	97.74	98.76	99.55
F11	5.71	11.41	26.63	52.32	74.19	95.12	97.32	99.02
F12	5.33	10.66	24.88	48.87	69.30	88.85	93.87	97.77
F13	5.93	11.85	27.66	54.33	77.05	98.78	99.33	99.76

Graphs for drug content





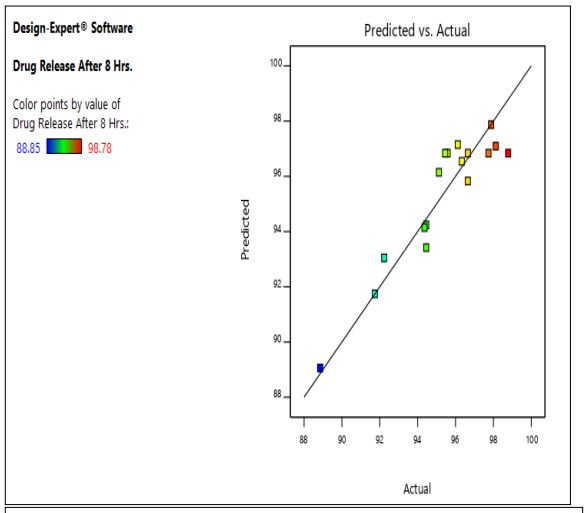
Normal plots Predicted vs Actual Contour plots between HPMC K4 and HPMC K4

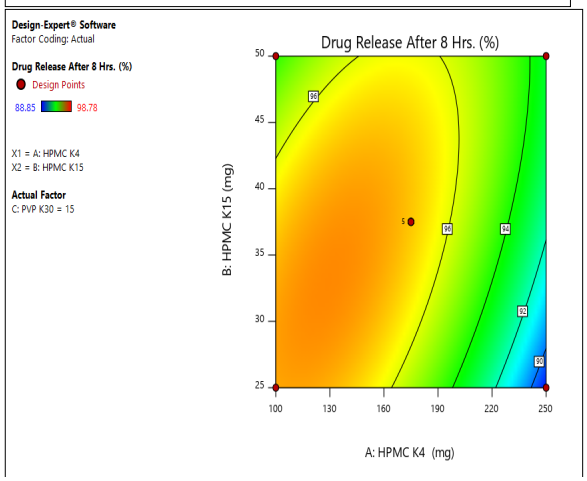


3D plots for drug content between HPMC K4 and HPMC K4

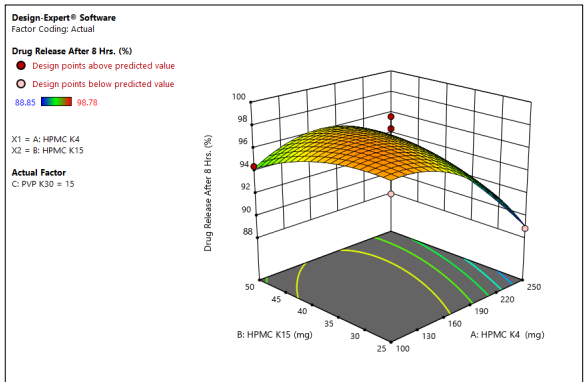
Figure 1: Graphs for drug content after 8 hrs. obtained by DOE

Graphs for drug release after 8 hrs





Normal plots Predicted vs Actual Contour plots between HPMC K4 and HPMC K4



3D plots for drug content between HPMC K4 and HPMC K4

Figure 2: Graphs for drug release after 8 hrs. obtained by DOE

Table 10: Results of Experimental data with predicted response

F. Code	Run order	Parameters	Actual Value	Predicted value

F12	12	% Drug content	99.45	100.26
		Drug release after 8 Hrs.	88.85	89.06

Table 11: *In-vitro* drug release data for optimized formulation F12

Time (h)	Square Root of Time(h)$^{1/2}$	Log Time	Cumulative* % Drug Release	Log Cumulative % Drug Release	Cumulative % Drug Remaining	Log Cumulative % Drug Remaining
0.5	0.707	-0.301	5.33	0.727	94.67	1.976
1	1.000	0.000	10.66	1.028	89.34	1.951
2	1.414	0.301	24.88	1.396	75.12	1.876
4	2.000	0.602	48.87	1.689	51.13	1.709
6	2.449	0.778	69.3	1.841	30.7	1.487
8	2.828	0.903	88.85	1.949	11.15	1.047
10	3.162	1.000	93.87	1.973	6.13	0.787
12	3.46	1.	97.77	1.990	2.23	0.348
	4	079				

Table 12: Regression analysis data of sustain release Tablets

Batch	Zero Order	First Order	Higuchi	Peppas
F12	R^2	R^2	R^2	R^2
	0.9458	0.9706	0.9857	0.9863

Conclusion

The present study successfully developed and optimized sustained-release floating tablets of Canagliflozin using a Box–Behnken Design. The optimized formulation (F12) exhibited satisfactory pre-compression and post-compression characteristics, excellent buoyancy, acceptable mechanical strength, uniform drug content, and controlled drug release over 12 hours. Drug release followed the Korsmeyer–Peppas kinetic model, indicating diffusion-controlled release. The optimized formulation demonstrated prolonged gastric retention and desirable pharmaceutical properties, suggesting its potential as an effective gastro-retentive drug delivery system for improving therapeutic efficacy and patient compliance in the management of Type II diabetes mellitus.

References

1. DeFronzo RA, Ferrannini E, Groop L, Henry RR, Herman WH, Holst JJ, et al. Type 2 diabetes mellitus. Nat Rev Dis Primers. 2015 Jul 23;1(1):15019.
2. Muoio DM, Newgard CB. Molecular and metabolic mechanisms of insulin resistance and β-cell failure in type 2 diabetes. Nat Rev Mol Cell Biol. 2008 Mar;9(3):193-205.
3. Rosenthal N, Meininger G, Ways K, Polidori D, Desai M, Qiu R, et al. Canagliflozin: a sodium glucose co-transporter 2 inhibitor for the treatment of type 2 diabetes mellitus. Ann N Y Acad Sci. 2015 Nov;1358(1):28-43.
4. Kaushal S, Singh H, Thangaraju P, Singh J. Canagliflozin: a novel SGLT2 inhibitor for type 2 diabetes mellitus. N Am J Med Sci. 2014 Mar;6(3):107.
5. Pawar VK, Kansal S, Garg G, Awasthi R, Singodia D, Kulkarni GT. Gastroretentive dosage forms: a review with special emphasis on floating drug delivery systems. Drug Deliv. 2011 Feb 1;18(2):97-110.

6. Patel N, Nagesh C, Chandrashekhar S, Jinal P, Devdatt J. Floating drug delivery system: an innovative acceptable approach in gastro retentive drug delivery. Asian J Pharm Res. 2012;2(1):7-18.
7. Politis SN, Colombo P, Colombo G, Rekkas DM. Design of experiments (DoE) in pharmaceutical development. Drug Dev Ind Pharm. 2017 Jun 3;43(6):889-901.
8. Gupta SK, Patra S. Preparation, characterization and optimization of sustained release matrix tablets of repaglinide using Box–Behnken design. Res J Pharm Technol. 2023;16(5):2403-2440.
9. Patil CC, Vekatesh J, Karajgi SR, Vitthal V, Ashwini G, Jorapur PN, et al. Formulation and in vitro evaluation of matrix tablets containing repaglinide. Res J Pharm Technol. 2021;14(8):4429-4.
10. Singh V, Kumar L, Meel RK. Formulation and development of sustained release matrix tablet of ranolazine. Int J Pharma Res Rev. 2014 Nov;3(11):22-32.
11. Lakshmi Prasanna J, Deepthi B, Rama Raon. Influence of diluents on diclofenac sodium release from gum kondagogu based matrix tablets. Int J Pharma Res Rev. 2012;1(4):12-20.
12. Purohit D, Gupta MK, Meher CP, Shukla A, Kumar A. Formulation and evaluation of sustained release tablets of propranolol hydrochloride. Int J Health Sci. 2022;6(S1):6233-6240.
13. Lee BJ, Ryu SG, Cui JH. Formulation and release characteristics of hydroxypropyl methylcellulose matrix tablet containing melatonin. Drug Dev Ind Pharm. 1999;25(4):493-501.
14. Roy H, Brahma CK, Nandi S, Parida KR. Formulation and design of sustained release matrix tablets of metformin hydrochloride: influence of hypromellose and polyacrylate polymers. Int J Appl Basic Med Res. 2013;3(1):55.
15. Wadher KJ, Kakde RB, Umekar MJ. Formulation of sustained release metformin hydrochloride matrix tablets: influence of hydrophilic polymers on the release rate and in vitro evaluation. Int J Res Control Release. 2011;1(1):9-16.