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Formulation and Evaluation of Sublingual Tablets of Dapagliflozin

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ABSTRACT:
Objective: The objective of the present investigation is to develop a formulation of Sublingual tablets of Dapagliflozin by Direct compression method. **Materials and Method**: For the preparation of Sublingual tablets various Super disintegrants were used like Croscarmellose sodium and Kyron T-314/POLACRILIN POTASSIUM. Direct compression method is used for preparation of sublingual tablet. All precompression parameters like Carr's Index, Hausner's Ratio and Angle of Repose meets the standard values of powder indicating good flow properties. The average weight, friability and hardness were within compendial limits which showed that all formulations possessed good mechanical strength. **Results and Discussion**: The optimized formulation D6 showed minimum disintegration time of 25.66±1.52 secs and drug release of 99.05±1.34 in 10 mins among all 6 batches of tablets. The result of stability study of the batch D6 showed that there was no significant change in Hardness, *In-vitro* Disintegration time, Drug content, and *In Vitro* dissolution profile for a period of one month when stored at room temperature for period of one month. **Conclusion:** From the study it was concluded that Sublingual tablets of Dapagliflozin is an acceptable dosage form which suggests that it is likely to become one of the choices of Dapagliflozin preparations for the treatment of Diabetes Mellitus.

INTRODUCTION:
Diabetes mellitus is the commonest endocrine metabolic disorder characterised by deficiency of insulin in the body. Metabolic abnormalities in carbohydrates, lipids and proteins results from insulin as an anabolic hormone. Diabetes can harm multiple body systems, especially the blood vessels, eyes, kidneys, heart, and nerves. Diabetes mellitus is categorised into three types Type I Insulin Dependent Diabetes Mellitus (IDDM) and type II Non-Insulin Dependent Diabetes Mellitus (NIDDM) and type III Gestational diabetes mellitus (GDM).[1-5]

Dapagliflozin is a sodium–glucose cotransporter-2 (SGLT-2), inhibitor prescribed for the management of type II diabetes mellitus. It is a potent, reversible, and highly selective inhibitor of SGLT-2. The drug acts by reducing

renal glucose reabsorption, thereby promoting urinary excretion of excess glucose, and improving glycaemic control in patients with type II diabetes mellitus. Despite its therapeutic effectiveness, dapagliflozin belongs to the Biopharmaceutics Classification System (BCS) class III, indicating high solubility but low permeability, which limits its oral bioavailability to approximately 78%. Additionally, dapagliflozin has a half-life of about 12.9 hrs and is administered as a once-daily dose of 5–10 mg per day. These pharmacokinetic limitations highlight the need for formulation strategies aimed at improving drug permeability, bioavailability and fast onset of action, thereby justifying the selection of dapagliflozin for the present study.[6]

There is conventional tablet of dapagliflozin is available but it undergoes to the first pass metabolism. But when absorbed by sublingual blood vessels, the medication usually takes effect more quickly when taken orally. Additionally, the part absorbed through these blood vessels avoids the hepatic first-pass metabolic processes. Sublingual tablets showed higher bioavailability in comparison to other conventional dosage forms. This phenomenon can be explained by the drug's direct absorption into the sublingual blood vessels and lymphatic system, which promotes systemic circulation without passing through the liver. Therefore, it is expected that medications will be absorbed under the tongue quickly, producing a therapeutic impact more quickly.[7-11]
The main objective of current research work is to formulate and evaluate sublingual tablets of dapagliflozin.

MATERIALS AND METHODS:

Materials

Dapagliflozin was received as gift sample from Gelmek Healthcare Private Limited, Ahmedabad, Gujarat, India. Kyron T-314 was procured from Corel Pharma Chem, Ahmedabad, Gujarat, India as gift sample. Croscarmellose sodium, Mannitol, Talc, Magnesium stearate, Aspartame, Citric acid procured from Chemdyes corporation, Rajkot, Gujarat, India.

Formulation of sublingual tablets:[12]

Direct Compression Method is commonly used in commercial manufacturing industries of sublingual tablets because it is easy and cost-effective method, as it exhibits basic substances that can be mixed well and do not require more distant granulation steps preceding to lubrication and compression. This method has good automatic strength and promotable fast disintegration.

There are two different super disintegrants are used which is Croscarmellose sodium (2%-6%) and Kyron T-314(1%-2%)[13]. Sublingual tablets were manufactured by the direct compression technique. The accurately weighed active pharmaceutical ingredient and excipients were passed through a #60 sieve and blended uniformly using geometric dilution. The resulting blend was directly compressed on a multi-rotary tablet compression machine fitted with an 8 mm flat-faced punch and die set. Tablet weight and compression force were maintained constant throughout the process. Each tablet contained 5 mg of dapagliflozin. The composition of all formulations is presented in Table 1.

Table 1: Composition of formulations of Dapagliflozin Sublingual tablets

INGREDIENTS (mg)	D1	D2	D3	D4	D5	D6
Dapagliflozin	5	5	5	5	5	5
Croscarmellose sodium	2.4	4.8	7.2	-	-	-
Kyron T-314	-	-	-	1.2	1.8	2.4
Aspartame	2.5	2.5	2.5	2.5	2.5	2.5
Citric acid	2.5	2.5	2.5	2.5	2.5	2.5
Talc	1	1	1	1	1	1
Magnesium Stearate	2	2	2	2	2	2
Mannitol	104.6	102.2	99.8	105.8	105.2	104.6
Total	120	120	120	120	120	120

Determination of melting point of Dapagliflozin[14]

The melting point of dapagliflozin was determined by the capillary method. A small amount of the powdered drug was filled into a thin glass capillary tube that was sealed at one end. The capillary tube was then placed in a melting point apparatus and heated slowly. The temperature at which the drug started to melt and completely melted was noted. This temperature was recorded as the melting point of dapagliflozin.

Compatibility Study of Drug and Excipients

FTIR spectroscopy was used for drug and excipients identification and to evaluate their compatibility. FTIR

spectroscopy of pure drug and physical mixture of drug and excipients was carried out to check the compatibility of drug and excipients.

Identification by UV Spectroscopy[15]

Standard stock solution of Dapagliflozin was prepared by dissolving 10 mg of Dapagliflozin in 100 ml phosphate buffer (pH 6.8), which make the stock solution of concentration of 100 µg/ml. For determination of λ_{max}, stock solution was scanned between 200-400 nm against phosphate buffer (pH 6.8) as a blank in the UV-Visible spectrophotometer. Working solution of concentration 1, 2, 3, 4 and 5 ppm were prepared by pipette outing 0.1, 0.2, 0.3, 0.4 and 0.5 ml respectively from the stock solution of 100ppm and diluted up to 10 ml volumetric flask. Absorbance of working solutions was measured in triplicate at λ_{max} 233 nm against phosphate buffer (pH 6.8) as a blank.

For the preparation of phosphate buffer 6.8, 11.45gm of Potassium Dihydrogen Phosphate (KH2PO4) and 28.80gm of Disodium Hydrogen Phosphate (Na2HPO4) were dissolved in about 800 mL of deionized water, Stir until fully dissolved, pH was measured with a calibrated meter, adjusting with 1N HCl or 1N NaOH if needed (expect close to 6.8) and Diluted to exactly 1000 mL with deionized water.

Determination of precompression parameters[9,16-18]

Pre-compression parameters are necessary to evaluate the flow and packing properties of the powder blend before tablet compression. They help predict uniform die filling, tablet weight consistency, and prevent problems such as poor flow, segregation, or compression defects during manufacturing.

Bulk density: Accurately weighed the powder mixture and transferred to measuring cylinder carefully measure the volume of powder without compacting. It is expressed as gm/ml.

$$\text{Bulk Density} = \frac{\text{Mass of powder (gm)}}{\text{Bulk Volume of powder (ml)}}$$

Tapped density: Tapped density was measured by placing graduated cylinder containing formulation blend on mechanical tapping apparatus. Tapped volume was measured until constant tapped volume is not achieved. It is expressed as gm/ml.

$$\text{Tapped Density} = \frac{\text{Mass of powder (gm)}}{\text{Tapped Volume of powder (ml)}}$$

Compressibility index: Compressibility index is a ratio of difference of tapped density and bulk density to tapped density. It is expressed in percentage (%).

$$\text{Compressibility Index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

Table 2: Relationship between % compressibility and powder flow

% compressibility	Powder flow
5-15	Excellent
12-16	Good
18-21	Fair too passable
23-35	Poor
33-38	Very poor
>40	Extremely poor

Hausner's ratio: Hausner's ratio is a ratio of tapped density to bulk density. Value of 1.25 Hausner's ratio indicates good powder flow and more than 1.25 indicated poor powder flow. Generally, glidant were added to improve the powder flow of the material.

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Angle of repose: Angle of repose was determined by funnel method. Powder blend was poured from funnel that can be raised vertically until it reaches maximum cone height (h) was obtained. Radius (r) of the pile was measured. Angle of repose was measured by following formula.

$$\mathbf{Tan\ \theta = \frac{h}{r}} \qquad \mathbf{\theta = \tan^{-1}\frac{h}{r}}$$

Where,
θ = Angle of repose,
h = Height of pile,
r = Radius of pile

Table 3: Relationship between Angle of repose and powder flow

Angle of repose	Powder flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Determination of post compression parameters[17-21]

Thickness and diameter: Tablet thickness and diameter were measured by Digimatic Vernier callipers. Five tablets were randomly collected and their thickness and diameter were measured by placing between two arms of Vernier callipers.

Weight variation: Twenty tablets were randomly collected and average weight was determined by using an electronic balance. There are limits of weight variation according to Indian pharmacopoeia is mentioned in table 4.

Table 4: Weight variation limit according to Indian Pharmacopoeia

Average weight of tablet	% Deviation
80 mg or less	±10
More than 80 mg but less than 250 mg	±7.5
250mg or more	±5

Hardness: Tablet hardness has been defined as the force required to break a tablet in a diametric compression test. The crushing strength of tablets was measured by using Monsanto type hardness tester.

Friability test: The friability of tablets was measured by Roche type friabilator. Twenty tablets were initially weighed and then tablets were placed in friabilitor at 25 rpm for 4 min then tablets were deducted and weighed again. Loss in weight should not be more than 1%. % friability determined by using following equation.

$$\%\ \mathbf{Friability} = \frac{\mathbf{Initial\ weight - Final\ weight}}{\mathbf{Initial\ weight}} \times \mathbf{100}$$

***In Vitro* Disintegration test:** This test performed on six tablets using tablet disintegration test apparatus. Phosphate buffer (pH 6.8) at 37°±0.5 °C was used as a disintegration media and time in second was recorded for complete disintegration of tablet with no residue remaining in apparatus.

Drug content: Ten tablets were powdered and equivalent to 5 mg of Dapagliflozin was weighed and dissolved in 100 ml of phosphate buffer pH 6.8. The solution was filtered and 2 ml from filtrate was diluted to 10 ml and absorbance of this solution was analysed by UV spectrophotometer at 233 nm.

***In Vitro* Drug release study:** The percentage drug release of dapagliflozin from the sublingual tablets was evaluated using a USP type II (paddle) dissolution apparatus. The study was conducted in 500 mL of phosphate buffer (pH 6.8) maintained at 37 ± 0.5 °C with a paddle speed of 50 rpm. At predetermined time intervals, 5 mL samples were withdrawn and replaced with an equal volume of fresh dissolution medium to maintain sink conditions. The withdrawn samples were filtered through a 0.45 µm membrane filter, and the absorbance was measured using a UV spectrophotometer at 233 nm.

Stability study of optimized batch: In the present study, stability study of optimized batch was carried out at 40° ± 2°C/ 75 ± 5% RH for time of 1 month by wrapping the formulation in aluminium foil to prevent the formulation from exposure to light under the 40° ± 2 °C/ 75 ± 5% RH for 1 month as prescribed by ICH guidelines for accelerated stability study. After completion of 30 days tablets were evaluated for Hardness, Friability, Drug content, *In Vitro* Disintegration time and *In Vitro* Drug Release study.

RESULTS AND DISCUSSION:

Melting point of Dapagliflozin

Melting point determination is one of the popular techniques used to identify drug using melting point apparatus and melting point of Dapagliflozin was found in the range of 74 – 78 °C. Reported melting point of Dapagliflozin is 74 – 78 °C and is thus like the melting point of Dapagliflozin.

Identification of drug by FTIR

Fourier Transform Infrared (FTIR) spectroscopy was employed for drug identification. The FTIR spectra confirmed the identity of dapagliflozin and were consistent with that of the pure drug. No significant changes or shifts in characteristic IR peaks were observed when dapagliflozin was mixed with polymers, indicating compatibility between the drug and the excipients.

Identification of Dapagliflozin by FTIR Spectra

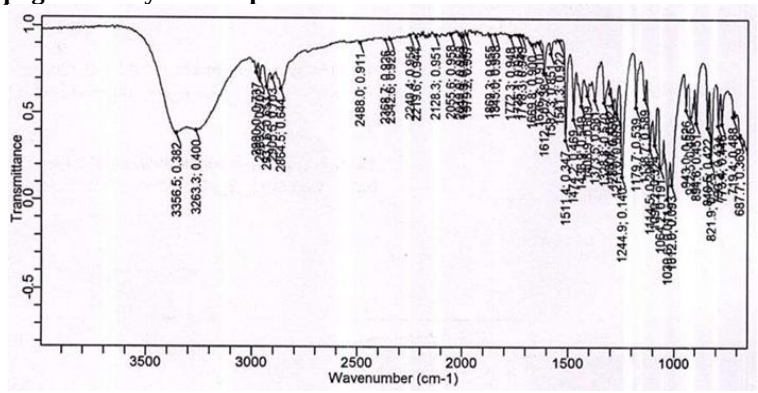

Figure 1: FTIR of Dapagliflozin

Table 5: Interpretation of FTIR spectra of Dapagliflozin

Sr. No.	Functional group	Standard value(cm^{-1})	Observed value(cm^{-1})
1.	O-H	1420-1330	1408.93
2.	C-Cl	850-550	821.87
3.	C-O	1150-1085	1138.70
4.	C-H	3100-3000	2980
5.	C=C	1670-1600	1612.07

Compatibility study of Dapagliflozin with excipients by FTIR Spectra

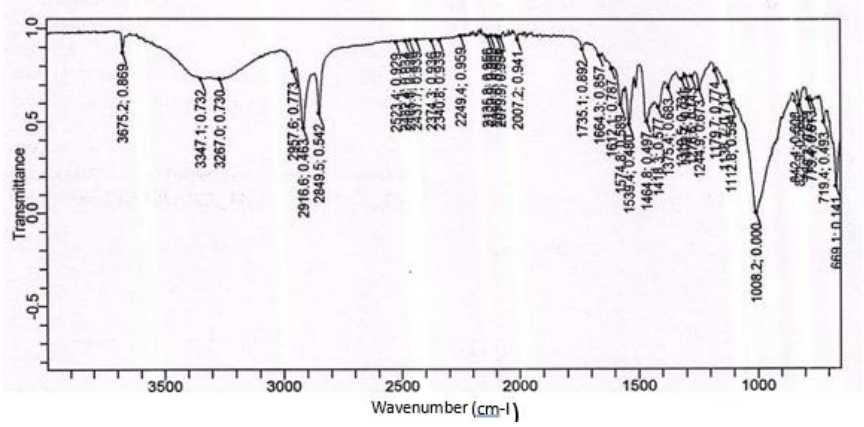

Figure 2: FTIR Spectra of Pure Dapagliflozin with Croscarmellose sodium

Table 6: Interpretation of FTIR Spectra of Dapagliflozin with Croscarmellose sodium

Sr. No.	Functional group	Standard value(cm^{-1})	Observed value(cm^{-1})
1.	O-H	1420-1330	1418.25
2.	C-Cl	850-550	669.05
3.	C-O	1150-1085	1112.61
4.	C-H	3100-3000	2957.64
5.	C=C	1670-1600	1612.07

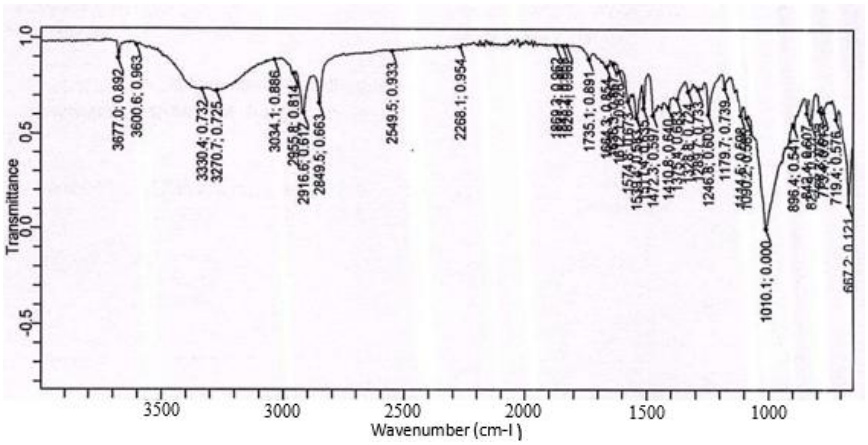

Figure 3: FTIR Spectra of Pure Dapagliflozin with Kyron T-314

Table 7: Interpretation of FTIR Spectra of Dapagliflozin with Kyron T-314

Sr. No.	Functional group	Standard value(cm^{-1})	Observed value(cm^{-1})
1.	O-H	1420-1330	1375.38
2.	C-Cl	850-550	842.37
3.	C-O	1150-1085	1114.47
4.	C-H	3100-3000	3034.05
5.	C=C	1670-1600	1636.30

Estimation of drug by UV overlay spectra

The overlay spectra of drug were obtained by scanning different concentrations of solutions viz. 1,2,3,4 and 5 ppm showed maximum absorption at 233nm. Reported λ_{max} is 233nm so it can be concluded that the given drug was Dapagliflozin.

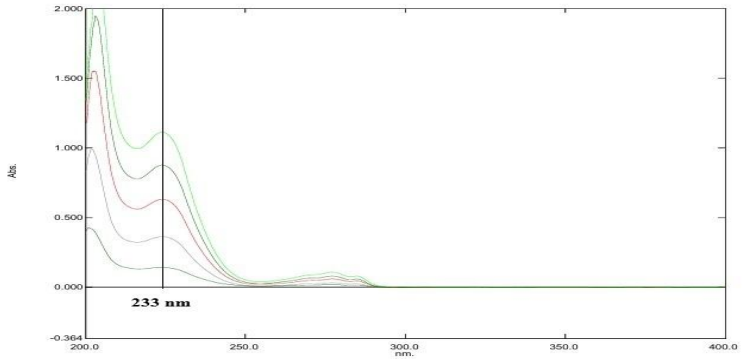

Figure 4: Overlay Spectra of Dapagliflozin

Table 8: Absorbance of different concentration of Dapagliflozin in phosphate buffer at pH 6.8

Sr. No.	Concentration (ppm)	Absorbance			Mean Absorbance ± SD
		I	II	III	
1	1	0.137	0.136	0.139	0.137±0.0015
2	2	0..355	0.354	0.356	0.355±0.0010
3	3	0.631	0.631	0.633	0.631±0.0011
4	4	0.869	0.867	0.870	0.868±0.0015
5	5	1.10	1.10	1.120	1.106±0.0115

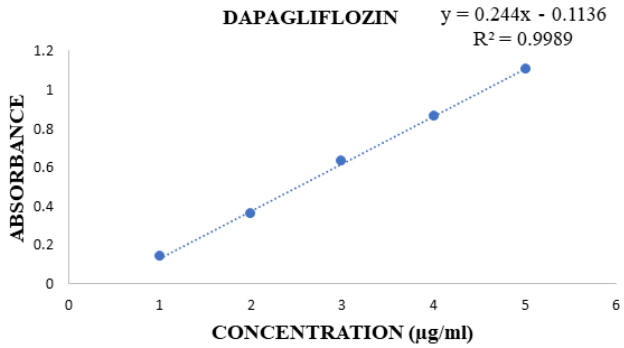

Figure 5: Calibration curve of Dapagliflozin in phosphate buffer at pH 6.8

Precompression parameters:

Formulation blend was evaluated by precompression parameters such as Bulk density, Tapped density, Hausner's ratio, % Compressibility index (car's index) and Angle of repose. Precompression parameters of powder blend of Sublingual Tablet of Dapagliflozin formulated by direct compression method as shown in Table are discussed below. There are results of precompression parameters are presented in table 9.

Table 9: Precompression Parameters

Batch code	Bulk density (gm/ml) ± SD	Tapped density (gm/ml) ± SD	Carr's index (%) ± SD	Hausner's ratio (%) ± SD	Angle of repose (°θ) ± SD
D1	0.57±0.03	0.63±0.02	9.87±2.3	1.10±0.04	32.61±2.5
D2	0.54±0.01	0.65±0.02	16.74±3.1	1.20±0.06	34.21±3.1
D3	0.51±0.02	0.58±0.04	13.24±2.8	1.15±0.05	33.42±2.8
D4	0.48±0.04	0.60±0.03	19.17±3.5	1.23±0.04	37.23±2.4
D5	0.46±0.03	0.57±0.04	20±3.8	1.25±0.05	35.37±2.6
D6	0.52±0.01	0.62±0.02	15.94±2.2	1.18±0.03	33.42±1.9

*All values are expressed as mean ± SD; (n=3)

All formulation blends were evaluated for bulk density and tapped density. Bulk density was found to be 0.46 gm/ml to 0.57 gm/ml and tapped density was found to be 0.57 gm/ml to 0.65 gm/ml. Percentage Compressibility Index was determined by using bulk density and tapped density. Carr's index of all formulation blend lies within the range of 9.87 to 20%. From Carr's Index, flow of powder was found to be excellent fair to passable. Hausner's ratio of all formulation was evaluated from bulk and tapped density and it was found in the range of 1.10 to 1.25. From Hausner's ratio, flow of powder was found to be good. Angle of repose of all formulation was in the range of 32.61 °θ to 37.23 °θ. From observed Angle of repose, flow of powder was found to be good.

Post-compression parameter

The formulated tablets were evaluated for Weight variation, Thickness, Diameter, Hardness, Friability, *In Vitro* Disintegration test and Drug content. These all data are available in table 10.

Table 10: post-compression parameter

Batch code	Thickness (mm ± S.D.)	Diameter (mm ± S.D.)	Weight variation (mg ± S.D.)	Hardness (kg/cm^2± S.D.)	Friability (%)
D1	2.01 ± 0.010	8.08 ±0.005	120.50 ± 3.41	3.30 ± 0.10	0.45
D2	2.10 ± 0.010	8.12 ±0.010	121.05 ± 5.54	3.30 ± 0.10	0.46
D3	2.35 ± 0.476	8.10 ±0.015	121.22 ± 3.22	2.20 ± 0.10	0.60
D4	2.09 ± 0.010	8.11 ±0.015	119.61 ± 4.08	2.14 ± 0.10	0.81
D5	2.08 ± 0.010	8.13 ±0.005	121.83 ± 4.17	3.20 ± 0.10	0.59
D6	2.09 ± 0.010	8.10 ±0.010	120.50 ± 5.23	2.10 ± 0.10	0.82

*All values are expressed as mean ± SD; (n=3)

Thickness (mm): Thickness of the formulated batches was found to be in the range of 2.01 ± 0.010 to 2.35 ± 0.476mm.

Diameter (mm): Diameter of the formulated batches was in the range of 8.08 ± 0.005mm to 8.13 ± 0.005mm.

Weight variation (mg): Weight variation limits for tablet Weight is 120 mg ± 7.5 mg according to Indian Pharmacopoeia. Weight variation range was found to be from mg 119.61 ± 4.08 to 121.83 ± 4.17 mg. Thus, all the formulated batches prepared comply with the Weight variation limits of the pharmacopeia.

Hardness (kg/cm^2): It is well known that tablets with more hardness shows longer disintegration time. Since mechanical integrity is of paramount importance in successful formulation of sublingual tablet, hence hardness of tablets was determined. Hardness of sublingual tablets prepared by direct compression method was found in the range of 2.10 ± 0.10 kg/cm^2 to 3.30 ± 0.10 kg/cm^2.

Friability (%): Friability of the tablets was found in the range of 0.45 to 0.82 %. According to IP, Limits of Friability is less than 1%. Observed values of friability indicated that tablets were having a good mechanical stability.

Table 11: In-Vitro disintegration time and Drug Content

Batch code	*In Vitro* disintegration time (sec. ± S.D.)	Drug content (%)
D1	30.34±1.52	97.24
D2	31.33± 2.08	97.05
D3	35.66± 1.52	96.09
D4	33.34± 1.52	97.07
D5	29.67± 2.08	97.96
D6	25.66± 1.52	98.51

*All values are expressed as mean ± SD; (n=3)

***In Vitro* Disintegration time (second):** *In vitro* Disintegration time of the batches formulated using 2% to 10% Kyron T-314 was found to be in the range of 25.66± 1.52 seconds to 33.34± 1.52 seconds, 2% to 6% Croscarmellose sodium was found to be in the range of 30.34 ± 1.52 seconds to 35.66 ± 1.52 seconds. Thus, it indicates that as the concentration of disintegrant increases *In-vitro* Disintegration time of formulated batches was decreased. There are data for disintegration time is described in table 11.

Drug content (%): Drug content of the tablets prepared by direct compression method was found to be 96.09% to 98.51 %. These results of drug content indicated that sublingual Tablet had uniform distribution and proper dose of active ingredient. There are data for drug content is described in table 11.

In Vitro Drug Release Profile of sublingual tablets: In Vitro Drug Release study is performed by using dissolution test apparatus type II (paddle) in 500 ml of the phosphate buffer at pH 6.8 as a dissolution medium at 37° ± 0.5 °C at 50 rpm. Results shown in Table 12 indicated that as the concentration of super disintegrant increases there is increase in the drug release from the tablet also more than 30% of drug released in less than 4 mins and more than 90 % drug released in 10 min. Formulations D1 to D3 shows drug release of 28.95±1.45, 34.45±1.67 and 38.91±1.34 at 2 min to 96.24±1.28, 96.05±1.84 and 93.09±1.34 at the end of 12 mins of using croscarmellose sodium as super disintegrant, respectively. Formulation D4 to D6 shows drug release of 32.94±1.52, 35.22±1.26 and 40.64±1.45 at 2 min to 96.07±1.64, 97.46±1.80 and 99.05±1.34 at the end of 12, 12 and 10 minutes of using Kyron T-314 as super disintegrant, respectively. There are data of Percentage drug release is described in table 12.

Table 12: Percentage drug release of batches D1 to D6

Time(min)	%CDR ± SD					
	D1	**D2**	**D3**	**D4**	**D5**	**D6**
0	0	0	0	0	0	0
2	28.95± 1.45	34.45±1.67	38.91±1.34	32.94±1.52	35.22±1.26	40.64±1.45
4	31.55±1.64	39.16±1.97	42.92±1.64	41.61±1.25	45.69±1.07	51.26±1.34
6	39.29±1.32	44.37±1.86	50.58±1.38	51.38±1.34	59.37±1.09	69.33±1.75
8	51.16±1.54	62.31±1.58	68.29±1.34	72.65±1.62	78.64±1.06	85.16±1.56
10	81.74±1.01	81.68±1.64	86.75±1.91	86.39±1.62	92.17±1.67	99.05±1.34
12	96.24±1.28	96.05±1.84	93.09±1.34	96.07±1.64	97.46±1.80	-

*All values are expressed as mean ± SD; (n=3)

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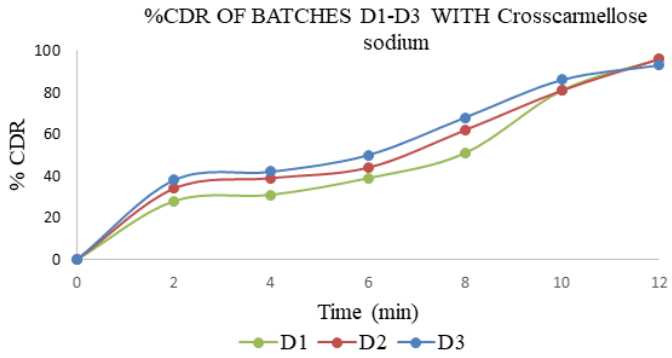

Figure 6: In-vitro drug release of Batches D1 to D3 with CCS

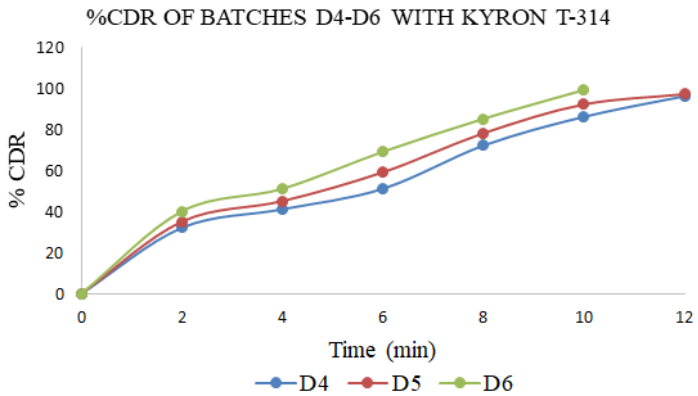

Figure 7: In-vitro drug release of Batches D4 to D6 with Kyron T-314

Based on all above parameter, it was concluded that the batch D6 was an optimized batch, as it had good surface appearance, Mechanical strength, and Drug Content. Moreover, it showed 99.05% of drug release in just 10 mins and In-vitro disintegration time was just 25.66± 1.52sec which was least as compared to all other batches. Thus, batch D6 containing Kyron T-314 (2%) was selected as an optimized batch.

Stability studies:

Table 13: Result of the Stability study

Sr. No.	Evaluation parameter	Results	
		optimized batch D6	after 1 month at 40° ± 2 °C and 75 ± 5 % RH
1	Hardness (kg/cm^2 ± S.D.)	2.10 ± 0.10	2.03 ± 0.08
2	In Vitro Disintegration Time (sec. ± S.D.)	25.66± 1.52	27.12 ± 2.52
3	Drug Content (%)	98.51	97.64

*All values are expressed as mean; (n=3)

Table 14: *In Vitro* Drug Release study ± SD of Stability batch

Time (Min.)	% CDR of Optimized Batch D6 (%) ± SD	% CDR of batch D6 After Time Period of 1 Month (%) ± SD
0	0	0
2	40.64±1.45	39.68 ± 1.25
4	51.26±1.34	49.24 ± 2.21
6	69.33±1.75	67.93 ± 1.54
8	85.16±1.56	84.55 ± 1.03
10	99.05±1.34	98.89 ± 1.05

*All values are expressed as mean ± SD; (n=3)

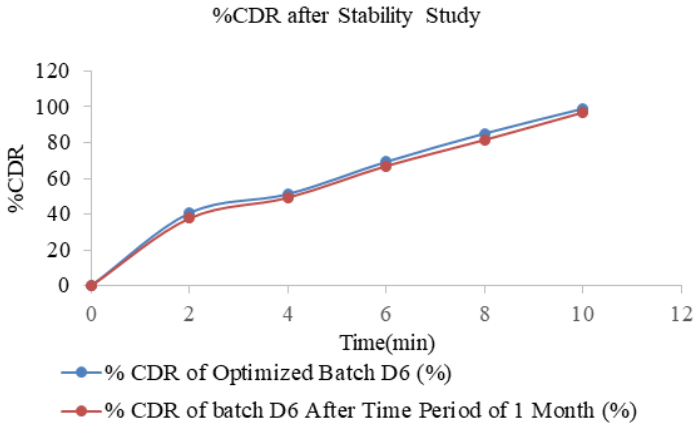

Figure 8: Comparison of *In Vitro* Drug Release study of Optimized batch and Stability batch

Batch D6 was selected for stability study based on all evaluation parameters like hardness, disintegration time, dissolution time, drug content. Stability data showed that all the parameters were in acceptable limits as there was minor change in the results. Thus, the prepared batch D6 was stable over period of 1 month.

CONCLUSION:

The concept of sublingual tablet containing Dapagliflozin offers a suitable and practical approach in serving the desired objective of management of Diabetes mellitus type II. The excipients used in the formulation were inexpensive and are easily available. Most of the excipients used in formulation are water-soluble and hence have a better patient acceptability. The result of FTIR showed that there was no interaction between drug and selected excipients used. Sublingual tablets of Dapagliflozin were prepared by direct compression method using Super disintegrants. All precompression parameters like Carr's Index, Hausner's Ratio and Angle of Repose meets the standard values of powder indicating good flow properties. The average weight, friability and hardness were within compendia limits which showed that all formulations possessed good mechanical strength. Drug content uniformity was within acceptable limits, which indicates a homogeneous distribution of drug in tablets. For the preparation of Sublingual tablet various Super disintegrants were used like Croscarmellose sodium and Kyron T-314. They were screened to achieve faster disintegration and acceptable hardness, Mannitol as binder and diluent, Aspartame as sweetening agent, Magnesium stearate as lubricant and Talc was used as glidant, Citric acid was used as effervescent forming agent. The formulation D6 was optimized from minimum disintegration time of 25.66± 1.52 secs, and drug release of 99% in 10 mins among all other six batches of tablets because of Kyron T-314 used in Highest concentration (2%). The result of stability study of the batch D6 showed that there was no significant change in Hardness, In-vitro Disintegration time, Drug content, and In Vitro dissolution profile for a period of one month when stored at 40° ± 2 °C and 75 ± 5% RH for period of one month. From the study it was concluded that Sublingual tablet of Dapagliflozin can be successfully prepared using Super disintegrants, which can provide rapid drug release within a short period time. Thus, it will be an important factor in improving patient compliance which is prerequisite for the treatment of Diabetes Mellitus II for all age groups.

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CONFLICT OF INTEREST:

The authors declare that there is no conflict of interest.

REFERENCES:

1. Reddi M. N., Dr. Vijaykumar N., and Keserla B., "A Review on Diabetes Mellitus- An Annihilatory Metabolic Disorder" *J. Pharm. Sci. & Res.,* **2020**, *12(2)*, 232-235.
2. Okur M. E., Ioannis D. K., and Panoraia L. S., "Diabetes Mellitus: A Review on Pathophysiology, Current Status of Oral Medications and Future Perspectives" *Acta Pharm. Sci.* **2017,** *55(10)*, 1-5.
3. Kumar R., Saha P., Kumar Y., Sahana S., Dubey A., and Prakash O., "A Review on Diabetes Mellitus: Type1 & Type2" *World Journal Of Pharmacy And Pharmaceutical Sciences*, **2020**, *9(10)*, 838-850.
4. Deepthi B., Sowjanya K, Lidiya B, Bhargavi RS and Babu PS, "A Modern Review of Diabetes Mellitus: An Annihilatory Metabolic

Disorder" *J. In Sil. In Vit. Pharmaco.* **2017,** *2(1:14)*, 1-5.
5. Baynest H.W., "Classification, Pathophysiology, Diagnosis and Management of Diabetes Mellitus" *Baynes J. Diabetes Metab.* **2015,** *6(5)*, 1-9.
6. Rafaela Z.C.M., Aline B.M., Fabio S.M., Paulo R.O. and Larissa S.B., "In Vitro Dissolution Profile of Dapagliflozin: Development, Method Validation, And Analysis of Commercial Tablets." *Int. J. of Analytical Chem.,* **2017**, *1(1)*, 1-6.
7. Prathusha P. and Praneeth K., "A Review on Sublingual Tablets." *J Formula Sci Bioavailab.,***2017**, *1(1),* 1-2.
8. Narang N. and Sharma J., "Sublingual Mucosa as A Route for Systemic Drug Delivery." *Int. J. Pharm. Sci*., **2011**, *3(2),* 18-22.
9. Prajapati B., Kaur S., and Roopini S.A., "Formulation and Evaluation of Mouth Dissolving Sublingual Tablets of Cimetidine to Treat Abdominal Cramps." *Int. J. of Pharm. Sci. Inven*., **2014**, *3(9),* 41-46.
10. Nayak Z. R., Narkhede K. B., and Narkhede S. B., "A Review Article on Sublingual Tablet of Lansoprazole" *Journal of Pharmacognosy and Phytochemistry*, **2019**, *8(6)*, 714-721.
11. Rode P. A., Malode A. J., "A Review: On Sublingual Tablets" *Ind. J. Res. Methods Pharm. Sci.*, **2022**, *1(6)*, 01-11.
12. Singh M., Chitranshi N., and Arora V. "An Overview on fast Disintegrating Sublingual Tablets" Singh et al. *International Journal of Drug Delivery*, **2012**, *4(4),* 407-417.
13. Raymond CR., Paul JS. And Marian EQ. in handbook of excipients; 6th Edn; RPS publication, united states of America, 2009.
14. Reddy C, Khan A K.K. and Nagaraja C, "A Review on the Determination of Melting Point Measurement System." International Journal of Advanced Research in Electrical, Electronics and Instrumentation Engineering. 2016, 5(2), 975-979. Doi 10.15662/IJAREEIE.2016.0502059. Narwariya S.S and Jain S, "Development And Evaluation Of Mouth Dissolving Anti-inflammatory Tablet Containing Fenoprofen." Journal of Advanced Scientific Research. 2021, 12(3), 254-255.
15. Narwariya S.S and Jain S, "Development And Evaluation Of Mouth Dissolving Anti-inflammatory Tablet Containing Fenoprofen." Journal of Advanced Scientific Research. 2021, 12(3), 254-255.
16. Kanade T, Gupta A, Darwhekar GN, "Formulation and evaluation of sublingual tablets of Meclizine Hydrochloride." *International Journal of Newgen Research in Pharmacy & Healthcare*, **2023**, 1(2), 48–55.
17. Patel JK, Patel D, Patel YK, Patel VK, Patel R, Shah T, Yadav P, Akbari JA, "Formulation and evaluation of sublingual tablets of clopidogrel bisulphate." *Neuro Quantology,* **2022**, 20(14), 1-8.
18. Indian Pharmacopoeia. Government of India, ministry of health and family welfare. Delhi: Controller of Publications. 2022.
19. Prajapati S.T., Patel M.V. and Patel C.N., "Preparation and Evaluation of Sublingual Tablets of Zolmitriptan." *Int. J. of Pharm. Invest*., **2014**, *4(1),* 27-31.
20. Godbole A.M., Somnache S.N., Thakker S.P., Iliger S.R., Joshi A.S. and Patel B.V., "Formulation and In-Vitro Evaluation of Sublingual Tablets of Ondansetron Hydrochloride Using Coprocessed Excipients," *Ind. J. of Pharm. Edu. & Res.,* **2014**, *48(1),* 7-17.
21. Srinivas G Y, Varun M S, Kumar KT S, Varma M, "Formulation and evaluation of sublingual tablets of losartan potassium by using natural and synthetic super disintegrants." *Journal of Pharma Insights and Research*, **2023**, 1(2), 145–153.