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Formulation, Evaluation, and Performance Optimization of Patient-Centric Orodispersible Tablets of Empagliflozin

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Abstract

Background: Type 2 diabetes mellitus (T2DM) demands lifelong pharmacological management, and patient compliance is a primary factor in therapeutic success. Empagliflozin, a selective sodium-glucose cotransporter-2 (SGLT2) inhibitor, provides powerful glycemic control along with significant cardioprotective and renoprotective benefits. However, conventional oral tablets can present swallowing challenges (dysphagia) for geriatric and pediatric patient populations, potentially leading to non-adherence. Orodispersible tablets (ODTs) offer an ideal solution by disintegrating rapidly within the oral cavity without the need for water.

Objective: The objective of this study was to conduct preformulation evaluations and to design, optimize, and evaluate patient-friendly orodispersible tablets of Empagliflozin using the direct compression method to achieve rapid disintegration and efficient drug release.

Methods: Preformulation studies were performed to evaluate the organoleptic and physicochemical properties of pure Empagliflozin, including melting point determination and calibration via UV-Spectrophotometry. Drug–excipient compatibility was investigated using Fourier Transform Infrared (FTIR) spectroscopy. Nine formulations (F1–F9) were prepared via direct compression using combinations of superdisintegrants (such as crospovidone, croscarmellose sodium, or sodium starch glycolate), microcrystalline cellulose, mannitol, and aspartame as a sweetener. The powder blends were evaluated for pre-compression flow properties (bulk/tapped density, angle of repose, Carr's index, and Hausner ratio). Post-compression properties including weight variation, thickness, hardness, friability, wetting time, water absorption ratio, *in-vitro* disintegration time, and *in-vitro* dissolution studies (in pH 6.8 phosphate buffer) were rigorously assessed and compared with conventional marketed tablets. Accelerated stability studies were conducted on the optimized formulation as per ICH guidelines.

Results :Pure Empagliflozin was confirmed to be a crystalline white powder with a sharp melting point of 155 ± 1°C. FTIR analysis demonstrated structural compatibility, indicating no chemical interactions between the drug and selected excipients. Pre-compression evaluation indicated excellent flow properties and compressibility for all formulations. Among the designed tablets, the optimized batch (F6) met all pharmacopeial standards, displaying optimal weight uniformity, sufficient mechanical hardness, and a friability profile well below 1%. The optimized ODT formulation (F6) exhibited rapid *in-vitro* disintegration within 15 to 26 seconds, which was significantly superior to traditional commercial film-coated formulations that require several minutes to disintegrate. Consequently, *in-vitro* dissolution experiments of the optimized ODT demonstrated an accelerated drug release profile compared to conventional oral formulations.

Furthermore, stability testing over a 3-month accelerated period confirmed that the optimized formulation remained physically and chemically stable, with no significant alterations in morphology, drug content, or disintegration time.

Conclusion:The study successfully developed a stable, robust, and highly efficient orodispersible tablet formulation of Empagliflozin via direct compression. By combining rapid disintegration without water, expedited drug release, and excellent palatability, this alternative dosage form provides a practical and patient-centric strategy to enhance clinical compliance and therapeutic efficacy in type 2 diabetes management, particularly for geriatric patients suffering from dysphagia.

Keywords: Empagliflozin, SGLT2 Inhibitor, Orodispersible Tablets (ODTs), Direct Compression, Superdisintegrants, Rapid Disintegration, Patient Compliance.

1. Introduction

Diabetes mellitus represents a critical, chronic metabolic disorder categorized by persistent systemic hyperglycemia originating from deficits in insulin synthesis, Insulin action, or combined operational pathologies. It stands among the primary and expanding non-communicable clinical conditions globally, inducing severe abnormalities in carbohydrate, lipid, and protein pathways. These disruptions translate into prolonged structural and cellular degradation across multiple microvascular and macrovascular architectures, including neuropathy, nephropathy, retinopathy, advanced cardiomyopathy, and highly compromised wound-healing biology.

The World Health Organization (WHO) projects a compounding escalation in global diabetes prevalence, distinctly localized within rapidly changing low- and middle-income industrial environments due to escalating urbanization, sedentary lifestyle patterns, and modern shifts in nutritional behaviors. Historically, the clinical presentation is categorized as Type 1 Diabetes Mellitus (T1DM),Type2 Diabetes Mellitus (T2DM), and gestational variations.T2D M comprises approximately 90% to 95% of all officially diagnosed cases, principally propelled by peripheral tissue insulin resistance combined with a chronic, progressive decline in pancreatic beta-cell function. Crucially, India is recognized as the 'diabetes capital of the world,' exhibiting an immense public health challenge with more than 77 million individuals actively diagnosed under Indian Council of Medical Research (ICMR) assessments.

Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors & Empagliflozin

A foundational paradigm shift in management occurred with the introduction of Sodium-Glucose Co transporter-2 (SGLT2) inhibitors as modern therapeutic agents. These drugs deploy a distinct, insulin-independent physiological mode of action, inhibiting systemic glucose reabsorption across the proximal renal convoluted tubules of the nephron. Under standard filtration biology, SGLT2 accounts for the reabsorption of approximately 90% of the filtered glycemic load from the glomerular space. By blocking this transporter, agents accelerate urine glucose excretion (glucosuria), achieving reliable reductions in plasma glucose entirely disconnected from pancreatic beta-cell capacity or peripheral insulin sensitivity. Beyond glycemic regulation, SGLT2 inhibition initiates a mild osmotic diuresis and natriuresis, which successfully provides multi-system cardio-renal protection, dropping arterial pressure, reducing heart failure hospitalization, and slowing diabetic nephropathy.

Empagliflozin (C23H27ClO7) is a highly selective benzyl-glucoside derivative exhibiting more than a 2500-fold specificity selectiveness for SGLT2 over SGLT1. The landmark EMPA-REG OUTCOME clinical trial definitively confirmed its pleiotropic potential, validating a 38 % decrease in cardiovascular mortality and a 35 % reduction in heart failure hospitalizations. Mechanistically, the drug improves arterial compliance, attenuates endothelial oxidative stress, restores tubule glomerular feedback loops, and shifts myocardial substrate selection toward energy- efficient ketone pathways.

Rationale for Orodispersible Tablets (ODTs)

Despite exceptional systemic efficacy, commercial Empagliflozin is conventionally formulated as standard film-coated oral tablets, which present definitive adherence and compliance constraints within specialized patient settings. Dysphagia (swallowing difficulty) is exceptionally prominent among geriatric cohorts, pediatric patients, and individuals experiencing neurodegenerative disorders, directly compromising therapy continuity for chronic diseases.

Orodispersible Tablets(ODTs),which rapidly dissolve inside the oral cavity via saliva interaction without external water, offer a highly optimized solution. By using advanced superdisintegrants that integrate swelling and capillary wicking mechanisms, an ODT can split apart within 30 seconds, presenting an elegant, patient-centric solution to traditional pill burdens while accelerating initial disintegration-absorption dynamics.

2. Materials And Methods

Empagliflozin was acquired as a generous gift sample from Indo Pharma Industries (Mumbai, India). The key superdisintegrants investigated included Crospovidone (obtained from Signet Chemical Corporation, Mumbai), Croscarmellose Sodium (Loba Chemie Pvt. Ltd., Mumbai), and Sodium Starch Glycolate (SD Fine Chemicals Ltd., Mumbai). Additional pharmaceutical-grade excipients included Mannitol as a cooling diluent, Microcrystalline Cellulose (MCC PH-102) as a compactable binder, Aspartame as an intense sweetening agent, with Magnesium Stearate and Talc acting as lubricant and glidant modalities, respectively.

Preformulation Protocols

Preformulation evaluations were systematically conducted to establish baseline identity, purity, and solid-state characteristics. Organoleptic parameters were determined via standardized sensory analysis. Melting point verification was conducted using a calibrated capillary tube apparatus (Shimadzu digital assembly) under a steady temperature ramp. Equilibrium solubility profiles were constructed using the shake-flask method over 24 hours at 25°C across distilled water, 0.1 N HCl, phosphate buffer (pH 6.8), methanol, and pure ethanol. The maximum absorption wavelength (λmax) and linear calibration matrices were mapped utilizing a Shimadzu UV-1800 spectrophotometer across concentration boundaries of 5–25 µg/mL. Solid-state chemical stability and drug-excipient compatibility were structurally examined via Fourier Transform Infrared (FTIR) Spectroscopy (PerkinElmer Spectrum 2) using the standard KBr pellet matrix method from

4000 to 400 cm[1].

Formulation and Preparation via Direct Compression

A series of nine detailed formulations (F1–F9) were strategically created by varying the specific selection and structural ratios of the superdisintegrants (Crospovidone, Croscarmellose Sodium, and Sodium Starch Glycolate) from 2% to 6% w/w. All dry components were passed through a fine #60 mesh sieve. The active pharmaceutical ingredient was homogeneously combined with the selected superdisintegrant, Mannitol, and MCC PH-102 via geographic dilution principles within a mortar. Finally, Magnesium Stearate and Talc were introduced, followed by an additional 3 minutes of lubrication blending. Compression was executed using a single-punch Rimek Mini Press machine equipped with 6 mm polished flat-faced tooling, targeting nominal tablet weights between 96 mg and 100 mg.

3.3 Results And Discussion

Preformulation Metrics

Organoleptic evaluations confirmed that the Empagliflozin sample was a white to off-white crystalline,odorless powder with a mildly bitter taste profile, confirming its baseline identity. The structural melting point was recorded consistently at 155 ± 1°C, aligning perfectly with standard reference data (154–156°C), thereby verifying exceptional crystalline purity and freedom from polymorphic variations. Equilibrium solubility data confirmed that the drug exhibits modern Biopharmaceutics Classification System (BCS) Class III characteristics, demonstrating poor absolute aqueous solubility (0.28 mg/mL) but substantial solubility within organic matrices, with a baseline increment in phosphate buffer pH 6.8 (0.65 mg/mL), which validated its selection as the dissolution medium. Spectrophotometric evaluation established a distinct λ max at 224nm, exhibiting a highly linear calibration profile (R^2 = 0.9992) mapping the equation Absorbance = 0.0211 × Concentration + 0.007.

Physicochemical Parameter	Experimental Description &Value
Chemical Classification	Benzyl-glucoside derivative; BCS Class III
Molecular Formula &Mass	C23H27ClO7; 450.91 g/mol
Organoleptic Profile slightly bitter	White to off-white crystalline powder, odorless,
Melting Point Boundary	155 ± 1°C (Reported: 154–156°C)
Water Solubility (pH 6.8) Solubility	0.28 mg/mL (Poorly soluble) Phosphate Buffer 0.65 mg/mL (Slightly soluble)
Methanol / Ethanol Solubility Analytical Wavelength (λ max)	8.12mg/mL/7.68mg/mL (Freely soluble) UV 224 nm (Linear correlation R^2 = 0.9992

Systemic Protein Binding & Half-Life kinetics	86% plasma binding; ~12 hours elimination

Table 3.1: Comprehensive Physicochemical and Pharmacokinetic Profile of Empagliflozin.

FTIR compatibility screening verified the lack of solid-state chemical interactions. The primary characteristic infrared stretching markers of pure Empagliflozin—including the prominent O-H stretching band at 3334 cm^{1}, the carbonyl C=O stretching vibration at 1704 cm^{1}, the aromatic C-H stretching peak at 2920 cm^{1}, and the C-O ether link stretching at 1160 cm^{1}—remained fully stable and un shifted within the spectra of the optimized blend. This explicitly confirmed that no covalent modification, tracking degradation, or polymorphic transformations occurred during processing.

Functional Group assignment	Pure Drug Peak (cm^{1})	Optimized Blend Peak (cm^{1})	Structural Inference
O–H Stretching (Alcoholic)	3334	3330	Compatible/No hydrogen bond disruption
C=O Stretching (Carbonyl)	1704	1702	Stable structural architecture
Aromatic C–H Stretching	2920	2918	No change storing configuration
C–O Stretching (Ether link)	1160	1161	Fully preserved configuration

Table 3.2: FTIR Spectral Interrogation and Compatibility Matrix.

Pre-Compression Powder Optimization

Pre-compression testing confirmed excellent flow properties. The bulk density ranged between 0.41 and 0.44 g/cm^{3}, while the tapped density settled between 0.47 and 0.50 g/cm^{3}. This small differential yielded excellent compressibility indices, with Carr's Index values dropping well below 13 % for all trials. Crucially, the optimized formulation blend F6 displayed a Carr's Index of 10.2% and a Hausner Ratio of 1.11, alongside a static angle of repose of 25.5°. This excellent flow configuration ensures uniform die filling and consistent tablet weight during high-speed manufacturing scales.

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Ba	Bulk Den sity	Tap ped Den	Carr's Index	Haus ner	Angle of
F1	0.42	0.48	12.5	1.14	27.2
F2	0.43	0.49	12.2	1.13	26.4
F3	0.44	0.50	12.0	1.13	25.8
F4	0.41	0.47	12.7	1.14	28.1
F5	0.42	0.48	12.5	1.14	27.0
F6 (Optimized)	0.44	0.49	10.2	1.11	25.5
F7	0.43	0.49	12.2	1.13	26.2
F8	0.42	0.48	12.5	1.14	27.5
F9	0.41	0.47	12.8	1.15	28.0

Table 3.3: Rheological and Micromeritic Evaluation of Pre-Compression Powder Blends.

Post-Compression Quality Control and Disintegration Kinetics

Post-compression quality monitoring confirmed strict alignment with international pharmacopeial limits. All tablets presented a smooth, defect-free physical appearance. Batch weights were uniform across all runs, adhering to the standard target matrix. Dimensional evaluation showed tight thickness profiles spanning from 2.44 to 2.54 mm. Mechanical resistance evaluations returned hardness profiles between 3.0 and 3.4 kg/cm², providing appropriate durability against structural shocks. Corresponding friability scores remained within safe margins (≤ 0.43%), confirming high structural integrity without risking friability failures.

Disintegration profiles varied substantially based on the superdisintegrant selection and structural ratios. Wetting times dropped concurrently with expanding superdisintegrant loading, reflecting enhanced matrix porosity. Batch F6 (incorporating 6% w/w Croscarmellose Sodium) achieved the fastest wetting cycle of 12 seconds, translating into a rapid in-vitro disintegration phase of just15 seconds. This behavior highlights the superior swelling, hydration velocity, and water-absorption capacity of Croscarmellose Sodium compared to Crospovidone and Sodium Starch Glycolate.

Chemical assay profiling confirmed uniform drug distribution, with absolute values spanning from 98.4% to 101.2% w/w.

Batch	Weight (mg)	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	Disintegration (s)	Wetting Time (s)	Water Abs. (%)	Drug Content (%)
F1	96	2.45	3.2	0.41	26	21	68.5	99.3
F2	98	2.47	3.3	0.38	22	18	70.3	99.6
F3	100	2.50	3.4	0.36	18	14	73.9	100.2
F4	96	2.46	3.1	0.42	25	20	69.1	98.9
F5	98	2.48	3.2	0.39	21	16	72.4	99.8
F6	100	2.53	3.3	0.35	15	12	75.8	101.2
F7	96	2.44	3.0	0.43	24	19	69.6	98.4
F8	98	2.49	3.1	0.40	20	16	72.1	99.0
F9	100	2.54	3.2	0.37	17	13	74.2	99.7

Table 3.4: Comprehensive Post-Compression Physical and Functional Characterization Matrix.

In-Vitro Dissolution Profiles and Mathematical Release Kinetics

In-vitro dissolution profiles confirmed exceptionally rapid active release across all nine formulations. Every ODT variant successfully surpassed 80 % cumulative drug release within the initial 8-minute window. This accelerated release profile is primarily driven by the ultra-fast disintegration time, which increases the effective surface area available for dissolution.

Specifically, the optimized formulation F6 achieved an outstanding dissolution efficiency of 98.9 % cumulative active release at the10-minute marker, representing an ideal candidate for immediate clinical delivery configurations.

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Time	F1	F2	F3	F4	F5	F6	F7	F8	F9
2 min	12%	18%	24%	14%	19%	25%	13%	20%	23%
4 min	38%	47%	56%	42%	50%	58%	39%	48%	55%
6 min	62%	72%	81%	65%	75%	84%	63%	73%	80%
8 min	84%	91%	97%	86%	92%	99%	83%	91%	95%

Table 3.5: Cumulative In-Vitro Dissolution Profiles (% Active Release vs. Time Interval).

Mathematical modeling of the dissolution profile of the optimized batch F6 confirmed strict adherence to first-order kinetic behavior (R^2=0.996), indicating that active release occurs as a direct function of remaining core concentration over time. Evaluation using the Korsmeyer-Peppas model returned an exponent 'n' of 0.47,confirming classical Fickian diffusion mechanisms operating concurrently with rapid erosion-swelling phenomena.

Mathematical Model Variant	Correlation Coefficient (R^2)	Exponent Metrics (n)	Primary Structural Mechanism
Zero Order Model	0.962	—	Non-linear release profile
First Order Model	0.996	—	Concentration-dependent active release (Best Fit)
Higuchi Diffusion Model	0.981	—	Matrix diffusion processing
Korsmeyer–Peppas Model	0.984	0.47	Classical Fickian diffusion mechanisms

Table 3.6: Dissolution Release Kinetics Modeling for the Optimized Formulation F6.

Stability Evaluation
Accelerated stability testing executed over 90 days under controlled climate conditions (40 ± 2°C / 75 ± 5% RH) as per standard ICH guidelines confirmed excellent architectural and chemical stability for batch F6. The tablets maintained their white crystalline appearance and structural clarity. Mechanical strength metrics showed minimal degradation, with hardness staying within

acceptable parameters. Furthermore, no new peaks or unexpected structural shifts appeared in the follow-up FTIR scans, confirming excellent chemical compatibility and long-term product shelf-life.

StabilityTest Parameter	0 Days Initial	30 Days Interval	60 Days Interval	90 Days Terminal	Structural Inference
Physical Appearance	White, intact	No change	No change	Slight dullness	Physically robust configuration
Hardness Metric (kg/cm²)	3.3	3.2	3.2	3.1	Negligible loss of matrix strength
Friability Metric (%)	0.35	0.36	0.37	0.38	Maintains safe limits(≤ 1.0%)
Absolute Drug Assay (%)	101.2	100.6	99.8	99.2	Excellent resistance to chemical degradation
Disintegration Phase (s)	15	16	17	18	Maintains high porosity patterns
Dissolution Status (10 min)	98.9%	98.4%	98.0%	97.6%	Preserves rapid immediate release

Table 3.7: Accelerated Stability Evaluation Profile for the Optimized Formulation (F6).

Comparative Evaluation Against Commercially Marketed Products

A comprehensive comparative evaluation was conducted under identical laboratory parameters to contrast the optimized orodispersible formulation F6 against traditional commercial formulations, including innovator Jardiance® alongside leading domestic generic alternatives (Sun Pharma and Lupin). The experimental data demonstrated a substantial difference in performance. The optimized ODT F6 achieved rapid disintegration within 25–30 seconds, whereas the standard commercial tablet variants required 140 to 160 seconds due to their conventional high-density film-coated architectures.

Furthermore, dissolution profiling confirmed that while standard commercial alternatives delivered only 79.8 % to 83.5 % of their active dose at the10-minute interval, the optimized ODT batch F6 released an outstanding 97.2% of its active drug. This rapid dissolution behavior is highly advantageous, facilitating faster initial dispersion and accelerated clinical onset, while offering an exceptional, water-free solution for geriatric and dysphagic patient populations.

Critical Performance Parameter	**Optimized ODT (F6 Variant)**	**Jardiance® (Innovator)**	**Sun Pharma (Generic Alternative)**	**LupinLtd. (Generic Alternative)**
Disintegration Profile	25–30 seconds	150 seconds	140 seconds	160 seconds
Absolute Chemical Assay (%)	99.1%	98.4%	97.9%	98.2%
Dissolution Efficiency(10	97.2%	83.5%	79.8%	81.6%

min)				
Requirement for Water	Completely Absent	Mandatory / Essential	Mandatory / Essential	Mandatory / Essential
Patient Adherence Potential	Outstandingly High	Compromised in Dysphagia	Compromised in Dysphagia	Compromised in Dysphagia

Table 3.8: Performance Comparison: Optimized Formulation F6 vs. Commercially Available Products.

Summary And Conclusion

This investigative study successfully achieved the systematic formulation and comprehensive performance optimization of patient-centric Orodispersible Tablets of Empagliflozin utilizing a simplified, industrially callable direct compression method. Preformulation analysis confirmed the identity, high crystalline purity, and solid-state stability of the drug, alongside perfect chemical compatibility with the selected superdisintegrants and excipients, as confirmed by FTIR spectroscopy. The powder mixtures demonstrated excellent flow properties, ensuring exceptional weight uniformity and structural precision during compression.

The optimized formulation variant, F6, containing 6% w/w Croscarmellose Sodium combined with a cooling Mannitol matrix, exhibited an excellent wetting cycle of 12 seconds and an ultra- fast in-vitro disintegration phase of 15 seconds. Crucially, batch F6 achieved an outstanding dissolution efficiency of 98.9% cumulative active drug release within 10 minutes, following premium first-order kinetic patterns driven by Fickian diffusion. Furthermore, comparative evaluations against leading commercial alternatives confirmed the clear superiority of the developed ODT system, exhibiting a multi-fold acceleration in disintegration and dissolution velocity. These properties make it an exceptional option for clinical use, substantially improving patient convenience and therapy adherence for individuals suffering from chronic Type 2 Diabetes Mellitus.

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