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Research Article

FORMULATION AND EVALUATION OF A NOVEL ORAL OSMOTIC PUMP TABLET FOR CITALOPRAM HYDROBROMIDE

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ABSTRACT

Depression affects over 280 million people globally, with significant prevalence among women and elderly populations. Citalopram hydrobromide, a widely prescribed SSRI antidepressant, often causes side effects like tachycardia and drowsiness due to fluctuations in plasma concentration from traditional dosage forms. This study developed an Elementary Osmotic Pump (EOP) tablet to achieve controlled citalopram release, reducing these adverse effects. The formulation used potassium chloride (25-100 mg) as an osmogent and a semi-permeable membrane of cellulose acetate (3% w/v) plasticized with PEG-400. Core tablets (120 mg) were prepared via non-aqueous granulation with PVP-K30 as the binder and coated with 2.5% or 5% polymer solutions. The optimized formulation (50 mg KCl, 5% coating) showed zero-order kinetics (R^2>0.98) with 90-97% release over 12 hours in pH 7.4 buffer (Table 5), outperforming higher osmogent concentrations that caused burst release (Table 4). Tablets met pharmacopeial standards for hardness (3.5-5.5 kg/cm²), friability (<0.73%), and content uniformity (92-101%). FTIR confirmed drug-excipient compatibility, while SEM verified precise orifice drilling (0.8-1.0 mm) necessary for controlled release. Dissolution studies in 0.1N HCl and pH 7.4 buffer confirmed pH-independent release, important for consistent GI absorption. The 5% coating provided more stable release than 2.5%, with PEG-400 improving membrane flexibility. Kinetic analysis showed formulations with ≤50 mg KCl best fit zero-order models, while higher concentrations followed first-order or Higuchi kinetics due to rapid osmotic diffusion. This EOP system effectively addresses the limitations of immediate-release citalopram by maintaining therapeutic levels and reducing dosing frequency. Future studies should evaluate in vivo pharmacokinetics and long-term stability to confirm clinical potential for depression treatment.

Keywords: Citalopram hydrobromide, Elementary osmotic pump, Controlled release, Osmogent, pH.

INTRODUCTION

Depression is the most prevalent psychiatric disorder in the world, affecting millions of individuals (WHO, 2023). It occurs in 5.7% of the population aged 60 years or older (GBD, 2021) and in 5% of adults in general, with 4% of men and 6% of women suffering from it. More than 280 million people are affected by depression globally (WHO, 2023). Women are nearly 50% more likely to experience depression than men (Albert, 2015). Additionally, over 10% of pregnant women and new mothers worldwide suffer from this condition (Gavin *et al*., 2020). Suicide claims the lives of over 700,000 individuals each year, making it the fourth leading cause of death among those aged 15 to 29 (WHO, 2023). Despite the availability of effective treatments for mental illnesses (Patel *et al*., 2022), over 75% of individuals in low- and middle-income countries do not receive the care they need.

Citalopram, a highly potent serotonin reuptake inhibitor, is used as a tricyclic antidepressant derivative to treat depression in patients (Garnock-Jones & McCormack, 2010). Citalopram hydrobromide served as the model drug for elementary osmotic pump (EOP) systems due to its absorption capabilities throughout the entire gastrointestinal tract (Sanchez *et al*., 2020). Chronic

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depression patients typically take citalopram daily, but repeated dosing can lead to undesirable side effects (Gupta *et al*., 2019). The controlled-release delivery system of citalopram can help reduce these adverse effects, as demonstrated by the optimized EOP formulations (Pachauri *et al*., 2023).

Moreover, there are significant secondary effects associated with citalopram. The controlled-release formulation aims to minimize the peaks and troughs associated with multiple dosage forms, which often trigger more side effects due to elevated drug levels (Tangri & Khurana, 2020). One of the primary goals in developing controlled-release dosage forms is to reduce the common side effects of tablets. Therefore, using osmotic technology to control the medication release rate is advantageous (Singh *et al*., 2022). This drug delivery system helps lower dose-related side effects, such as somnolence, sinus tachycardia, dizziness, excessive sweating, and rare occurrences of amnesia, convulsions, hyperventilation, among others (Choudhury *et al*., 2019).

This research focuses on developing elementary osmotic pump tablets of citalopram to achieve controlled drug release over extended periods, aiming to minimize dose-dependent side effects, including somnolence, sinus tachycardia, dizziness, excessive sweating, and rare incidents of amnesia, convulsions, hyperventilation, cyanosis, ECG alterations, and acute renal failure. The drug delivery from pharmaceutical dosage forms can be controlled through various design strategies. Osmotic drug delivery is particularly noteworthy as it utilizes principles of osmotic pressure to administer medications effectively, both orally and parenterally (Chauhan *et al*., 2019).

MATERIALS AND METHODS

The formulation contains Citalopram hydrobromide along with Microcrystalline cellulose, Potassium chloride (KCl), Sodium lauryl sulphate, Di butyl phthalate (DBP), Magnesium stearate, Talc, Cellulose acetate with 39.8% acetyl content, Poly ethylene glycol 400, Polyvinyl chloride K30, Potassium di hydro ortho phosphate, Sodium hydro Oxide, and several other chemicals.

The study utilized a variety of research instruments, including an electronic weighing balance, a 16-station rotary tableting machine, a bulk density apparatus, a Monsanto hardness tester, a Vernier caliper, a U.S.P. dissolution apparatus, a UV-VIS 1800 spectrophotometer, and sieves. The development process for the elementary osmotic pump tablets containing citalopram hydrobromide involved using different concentrations of osmogents. The prepared formulations were evaluated based on several parameters, including measurements of thickness and hardness, weight variation tests, and friability examinations (Gupta & Kumar, 2021). The researchers maintained a constant drug amount of 10 mg while increasing the concentration levels of potassium chloride to assess its effects (Raza & Ansari, 2014). All instruments and chemicals are provided by Vishwakarma University, Pune and handled under the expertise.

Assay of Citalopram Hydrobromide

An accurate weight measurement, followed by powdering of twenty tablets, served as the basis for pharmaceutical assessment. The solution received 100mg of citalopram hydrobromide powder while stirring with 30ml methanol, then it reached a volume of 50ml through the volumetric flasks. The researcher used Watman Filter Paper No. 1 to prepare and cleanse the solution from its preparation stage (Verma *et al*., 2020). An aliquot from the filtered solution requires dilution to 100 milliliters using methanol in a volumetric flask. Research scientists measured the solution absorbance at a wavelength of 231 nm using both sample and reference test solutions.

Preparation of Core Tablets

Laboratory personnel employed a nonaqueous granulation method to prepare EOP tablets. The core tablets were produced using sieved citalopram hydrobromide that passed through a #60 sieve, along with potassium chloride which was sieved through a #100 sieve (Janugade *et al*., 2020). A total of 30 tablets were prepared for each batch. The mixing process of all the weighed ingredients lasted five minutes to ensure proper blending.

The EOP tablets underwent final production through non-aqueous granulation, utilizing a PVP-K-30-alcohol system for granule preparation. The mixture was treated with a 5 percent PVP-K-30 solution as a wetting agent to achieve homogeneous blending over five minutes. The wet mass required extensive kneading before forming the granules (Sharma *et al*., 2021). After kneading, the granules were screened using a #18 sieve. They were then subjected to a drying process in a tray dryer at 50ºC for 30 to 40 minutes before measuring their moisture content. Once dried, the granules were mixed with magnesium stearate and talc, both of which passed through a #60 mesh, for 10 minutes. The tablet production process involved compressing the blended mixture into concave-shaped tablets using a 16-station rotary machine equipped with 8 mm round standard concave punches.

Evaluation of Developed Core Formulations

Tests were conducted on the final core tablets, including evaluations of tablet appearance, wet variation, assay determination, diameter measurement, friability testing, and thickness measurement. According to IP 1996 guidelines, the total tablet weight is set at 120 mg, with a permissible variation of ±7.5% applicable to no more than two of the twenty tablets tested. Additionally, USP 2004 indicates that a ±10% weight variation can be accepted for two tablets within a group of twenty tablets (Kumar *et al*., 2019).

Coating of the prepared core tablets with a semi-permeable polymer

The laboratory-sized coating pan facilitated the coating process for core tablets. The coating solution consisted of a mixture of acetone and cellulose acetate (3% w/v), along with specific amounts of PEG-400 (Mahajan & Deshmukh,

2018). To prepare the solution, cellulose acetate was first added and mixed thoroughly. Then, the plasticizer was added dropwise, continuing until the cellulose acetate was fully dissolved. The addition of plasticizer improved the flexibility of the film properties in the coating solutions. A filtering process finalized the preparation of the coating solution (Deshmukh *et al*., 2020). During the coating operation, the core tablets of citalopram hydrobromide were exposed to hot air from a gun, which distributed airflow across the tablet bed for five minutes. The RPM setting on the pan coater machine was maintained between 14 and 16 throughout the process.

Evaluation of coated formulations

The coated tablets were visually evaluated for film smoothness and coating uniformity. Additionally, measurements of weight variation, thickness, and diameter were recorded using a screw gauge. The researchers conducted the formulation release studies following the procedure outlined by Mangal *et al*. (2022).

Characterization

The characterizations of prepared EOP included in vivo drug release studies and FTIR analysis and Scanning electron microscopy evaluation.

Kinetic Analysis of Dissolution Data

Various kinetic models were used to study the data yielded by in vitro release experiments. The zero-order rate Eq. The release rate of the drug is independent of its concentration upon following equation (1). The zero-order rate Eq. The release rate of the drug is still independent of the drug concentration as per (1) (Costa & Lobo, 2001). The initial order Eq. The mathematical formulation used in concentration-dependent release profiles (2) has been discussed. Higuchi (1963) reported the drug release mechanism from insoluble matrices per Fickian diffusion laws to yield a square root of time relation depicted by equation (3). The Hixson-Crowell cube root law Eq. Eq. (4) holds for systems that exhibit a change in surface area as well as the particle or tablet diameter (Kumar *et al*., 2018).

$$C = K_o t \quad (1)$$

Where K_o is a zero-order rate constant expressed in units of concentration/time, and t is the time.

$$\log C = \log C_o - (k_1 t / 2.303) \quad (2)$$

Where C_o is the initial concentration of the drug and k_1 is the first-order constant

$$Q=K_h t (1/2) \quad (3)$$

Where K_h is the constant reflecting the design variables of the system.

$$Q_0(1/3)- Q_t (1/3) = KHCt \quad (4)$$

The Hixson-Crowell rate equation rate constant KHC, along with Q0 initial drug quantity and time-dependent Qt measure, are used in this calculation. The in vitro drug release data were used as the reference in making the following plots. The drug release data indicate an interaction between time and drug build-up (Zero order kinetic model). The curve illustrates the drug amount remaining against time on a plot of log cumulative % drug and time (First order kinetic model). Cumulative % drug release against the square root of time (Higuchi model). The correlation explains how the cube root of the initial concentration of drug changes proportionally with the cube root of the drug amount remaining within the matrix throughout the study (Hixson-Crowell cube root model).

RESULTS AND DISCUSSION

Assay of Citalopram Hydrobromide- In a pH 7.4 buffer, drug concentration is quantified using UV spectrophotometry for pharmaceutical analysis. The formulation of EOP tablets of citalopram hydrobromide includes 30 mg of SLS and a 5% coating solution, incorporating varying KCl and magnesium stearate to optimize drug release (Table 2, Table 3) and osmotic pressure for controlled delivery.

Table 1. Assay of Citalopram Hydrobromide in pH 7.4 Buffer.

Concentration (µg /ml)	Absorbance(nm)
2	0.074
4	0.147
6	0.217
8	0.292
10	0.375

Formulation of EOP tablets of citalopram hydrobromide- It includes 30 mg SLS and 2.5% coating solution, with varying KCl and constant magnesium stearate to optimize drug release and osmotic pressure for controlled delivery.

Table 2. Formulation of EOP tablets of citalopram hydrobromide containing 30 mg_SLS, with 5%coating solution with different concentrations of osmogents.

S. No	Ingredients(mg)	F1A	F2A	F3A	F4A	F1B	F2B	F3B	F4B
1.	Citalopram –Hydrobromide	10	10	10	10	10	10	10	10
2.	KCl	25	50	75	100	25	50	75	100
3.	MCC	170	170	170	170	170	170	170	170
4.	SLS	30	30	30	30	30	30	30	30
5.	Mg. stearate	2.5	3	2.5	2.5	2.5	2.5	2.5	2.5
6.	Talc	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
PVP-Alcohol 5% binder (non-aqueous granulation),									

Evaluation parameters for the core tablet of EOP formulations with 5% and 2.5% coating solution include hardness, friability, weight variation, drug content uniformity, dissolution profile, swelling index, and in-vitro release kinetics.

Table 3. Formulation of EOP tablets of citalopram hydrobromide containing 30 mg SLS, with 2.5%coating solution with different concentrations of osmogents.

S. No	Ingredients(mg)	F1C	F2C	F3C	F4C	F1D	F2D	F3D	F4D
1.	Citalopram –Hydrobromide	10	10	10	10	10	10	10	10
2.	Kcl	25	50	75	100	25	50	75	100
3.	MCC	170	170	170	170	170	170	170	170
4.	SLS	30	30	30	30	30	30	30	30
5.	Mg. stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
6.	Talc	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
PVP-Alcohol 5% binder (Nonaqueous granulation)									

Table 4. Evaluation Parameters of the core tablet of the above formulations of EOP containing 5% & 2.5% coating solution.

Formulation Code	Thickness (mm)	Weight Variation(mg)	Friability (%)	Hardness (Kg/cm^2)	Diameter (mm)	%Drug content
F1A	3.4±0.042	224.3±0.50	0.6	3.9±0.09	7.32	95.40
F2A	3.9±0.057	247±0.48	0.42	4.2±0.15	7.26	96.37
F3A	4.4±0.023	273±0.20	0.08	4.7±0.21	7.38	94.38
F4A	4.8±0.010	296±0.47	0.46	4.3 ±0.10	7.31	101.03
F1B	3.5±0.057	223±0.35	0.5	3.5±0.20	7.20	93.08
F2B	3.9±0.023	248±0.32	0.6	3.9±0.37	7.22	93.45
F3B	4.2±0.010	271±0.54	0.45	4.3±0.65	7.31	92.45
F4B	4.7±0.23	297± 0.33	0.5	4.8±0.3	7.28	94.35
F1C	3.4±0.042	224.3±0.50	0.6	3.9±0.09	7.26	95.40
F2C	3.9±0.057	247±0.48	0.42	4.2±0.15	7.30	96.37
F3C	4.4±0.023	273±0.20	0.08	4.4±0.21	7.28	94.38
F4C	4.8±0.010	296±0.47	0.46	4.5 ±0.10	7.33	95.28
F1D	3.5±0.057	223±0.35	0.5	4.3±0.20	7.31	93.08
F2D	3.9±0.023	248±0.32	0.73	5.5±0.37	7.22	97.45
F3D	4.2±0.010	271±0.54	0.65	4.9±0.65	7.30	92.45
F4D	4.7±0.23	297± 0.33	0.56	5.4±0.3	7.28	94.35

The applied model assessed drug release kinetics, with R^2 values indicating fit quality. Different formulations showed varying R^2, suggesting diverse release patterns and optimization potential for the best predictive model in formulation design.

Table 5. Model applied and the R^2 values for different formulations.

Model applied	F1A	F2A	F3A	F4A	F1B	F2B	F3B	F4B
Zero-order	0.984	0.988	0.991	0.986	0.907	0.989	0.976	0.929
First order	0.974	0.987	0.988	0.982	0.806	0.867	0.971	0.981

Model applied	F1C	F2C	F3C	F4C	F1D	F2D	F3D	F4D
Zero-order	0.990	0.991	0.956	0.944	0.989	0.954	0.954	0.951
First order	0.905	0.923	0.952	0.901	0.962	0.951	0.856	0.978

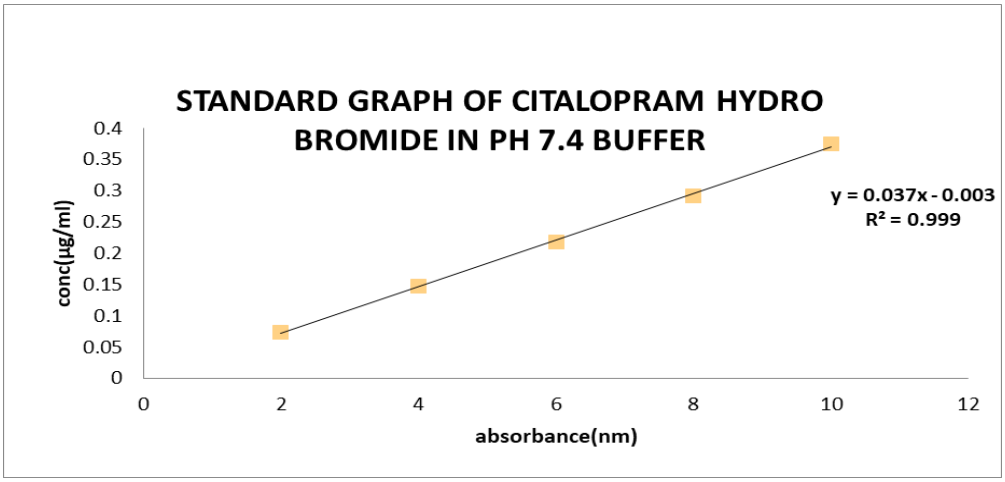

Figure 1. Standard Graph of Citalopram Hydrobromide in Ph 7.4 Buffer.

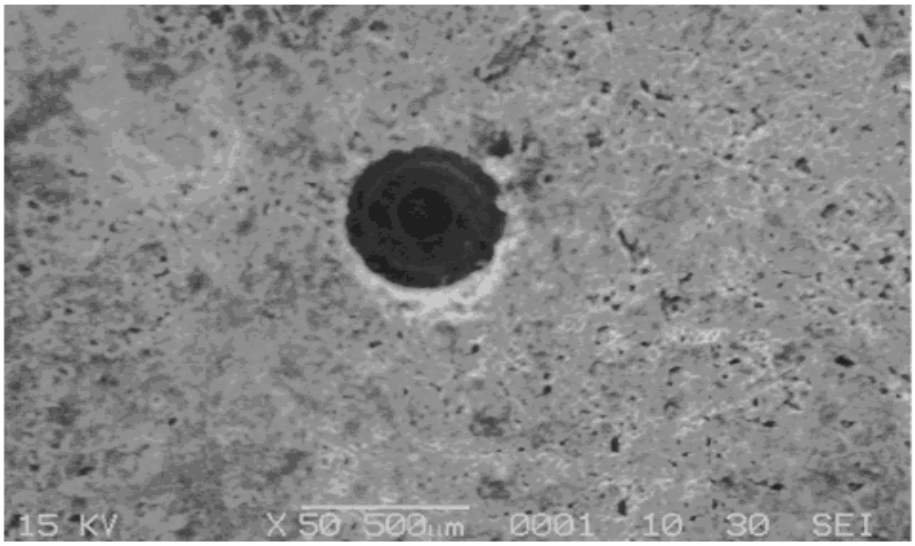

Figure 2. Scanning electron microscope (SEM) picture of EOP showing orifice size, which was mechanically drilled.

The SEM image shows a precisely drilled orifice on the Elementary Osmotic Pump (EOP) tablet. The well-defined, circular opening ensures controlled drug release by allowing consistent fluid entry. This structural accuracy is crucial for achieving zero-order kinetics and confirms the effectiveness of the mechanical drilling technique used. The SEM image displays the surface morphology of an Elementary Osmotic Pump (EOP) tablet, highlighting multiple micropores and a uniform porous texture. The 200 µm scale indicates controlled pore distribution, which facilitates water ingress and drug release. These microstructural features are crucial for ensuring consistent and sustained drug delivery performance.

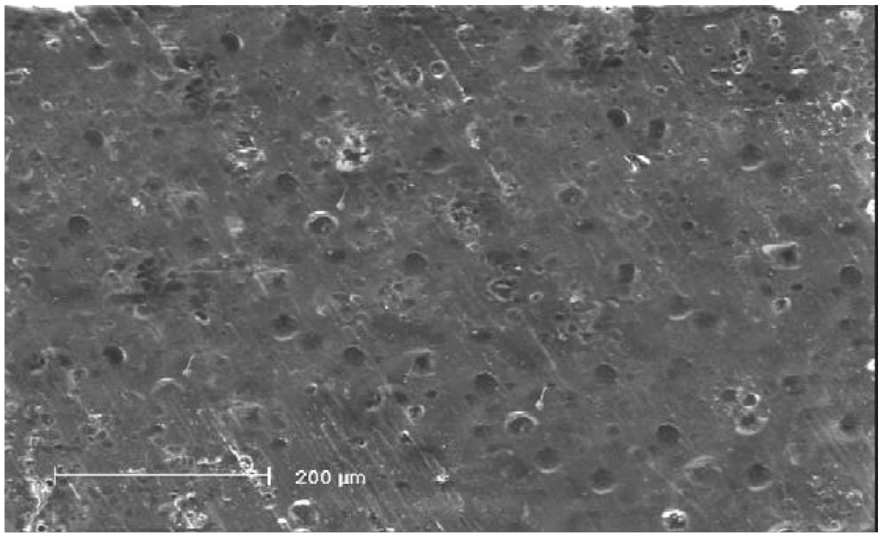

Figure 3. Scanning electron microscope (SEM) picture of EOP showing orifice size which was mechanically drilled.

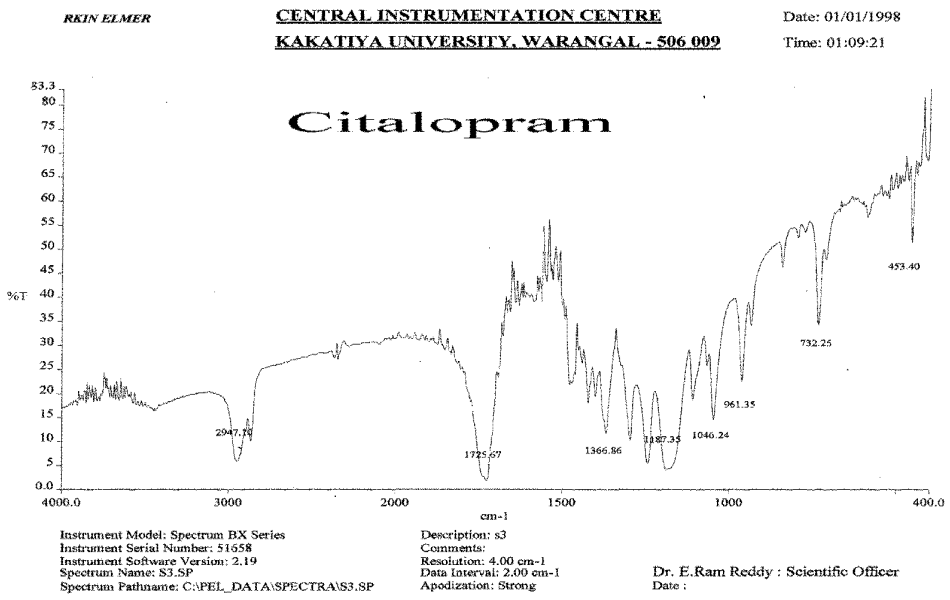

Figure 4. FTIR Spectra of Citalopram.

The FTIR spectrum of citalopram exhibits characteristic peaks confirming its functional groups. A sharp absorption at 2947 cm^{-1} corresponds to C–H stretching, while the prominent peak at 1725 cm^{-1} indicates C=O stretching of the ester group. Additional bands at 1365, 1040, 961, and 732 cm^{-1} represent C–N, C–O, and aromatic vibrations. These peaks validate the chemical identity and structural integrity of citalopram, confirming its purity and compatibility for formulation purposes.

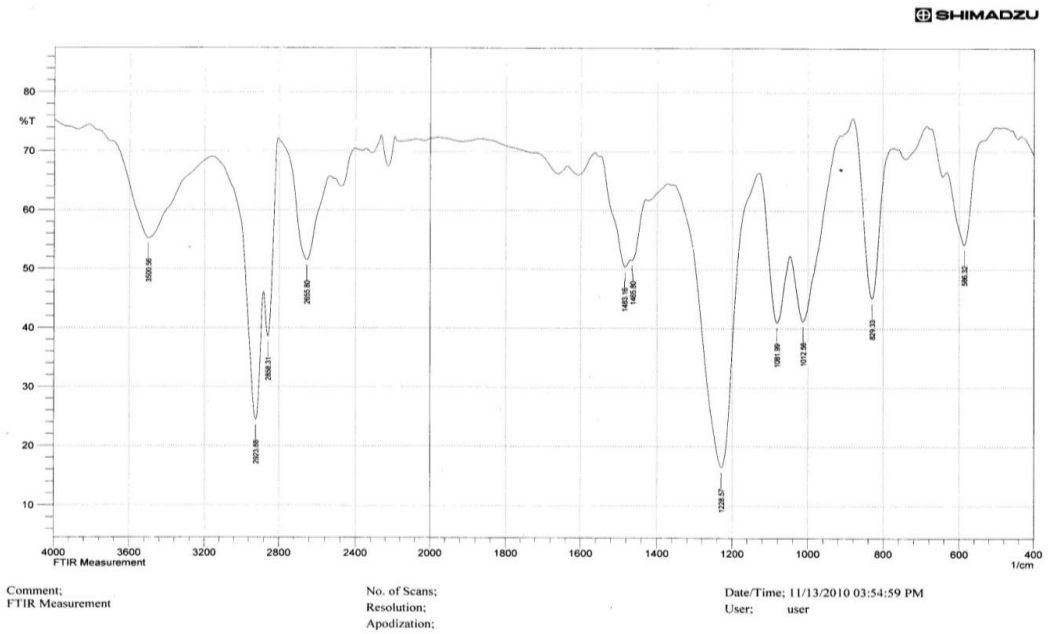

Figure 5. FTIR spectra of the drug and SLS.

The FTIR spectrum of the drug and sodium lauryl sulfate (SLS) combination displays characteristic peaks of both components. Broad bands near 3400 cm^{-1} indicate O–H or N–H stretching. Peaks at 2921 cm^{-1} and 2850 cm^{-1} correspond to C–H stretching. The intense absorption at 1040–1150 cm^{-1} represents S=O stretching of SLS. The absence of significant peak shifts or new bands confirms no chemical interaction between the drug and SLS, indicating compatibility for formulation.

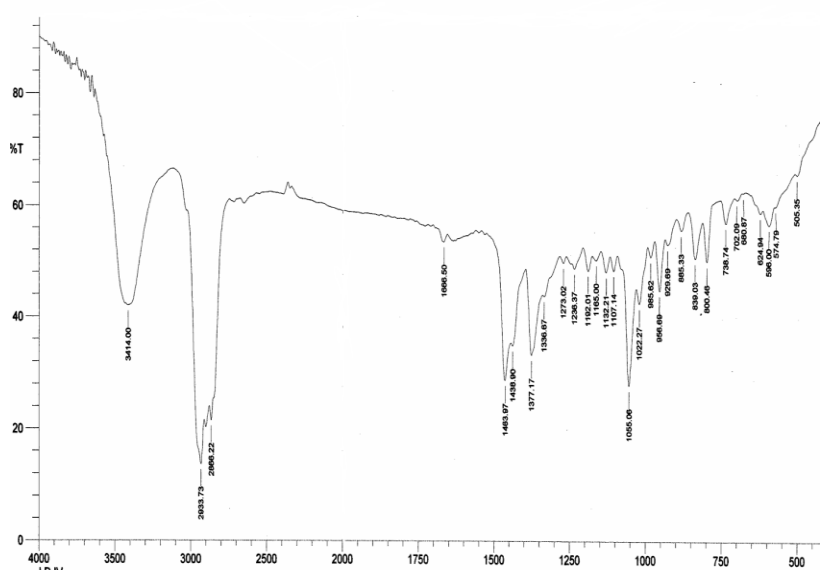

Figure 6. FTIR Spectra of Drug And Peg-400

The FTIR spectrum of the drug and PEG-400 shows distinct peaks corresponding to both components. A broad band near 3441 cm^{-1} indicates O–H stretching of PEG. Peaks around 2881–2922 cm^{-1} represent C–H stretching vibrations. The fingerprint region (1300–800 cm^{-1}) shows multiple PEG-related ether (C–O–C) vibrations. No significant shifts or new peaks were observed, suggesting the absence of chemical interaction and confirming compatibility between the drug and PEG-400 for formulation stability.

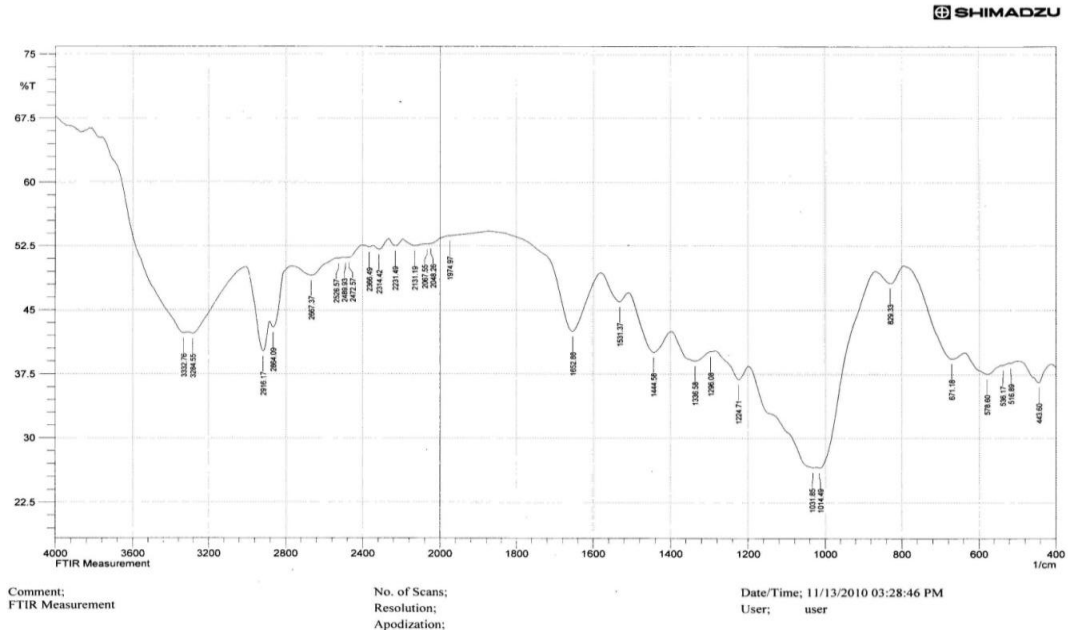

Figure 7. FTIR Spectra of an Optimized Tablet.

The FTIR spectrum of the optimized tablet formulation demonstrates characteristic peaks of all formulation components, including the drug and excipients. Peaks at 3390 cm^{-1} (O–H/N–H stretching), 2921 cm^{-1} (C–H stretching), and 1720 cm^{-1} (C=O stretching) confirm the presence of the drug. Additional peaks near 1100–1050 cm^{-1} (C–O stretching) are attributed to PEG-400 and SLS. The absence of peak shifts or disappearance of functional group bands indicates no significant chemical interactions, confirming the physicochemical compatibility and stability of the optimized formulation. To address the issues associated with traditional dosage forms of citalopram hydrobromide-particularly fluctuations in plasma drug levels that can cause side effects like tachycardia, drowsiness, and dizziness simple osmotic pump (EOP) tablet was developed. The study used potassium chloride (KCl) as the osmogent to control the drug's release rate. By applying osmotic pressure as the driving force for controlled release, the formulation's performance was tested by altering the KCl concentration from 25 to 100 mg per tablet (Choudhury *et al*., 2019). Higher doses of osmogents (75–100 mg) caused unintended burst release, disrupting the intended zero-order kinetics (Saini *et al*., 2018). Although these higher doses sped up drug release due to increased osmotic pressure, the formulation with 50 mg of KCl performed best, closely following zero-order kinetics ($R^2 > 0.98$) and providing continuous release of 90–97% over 12 hours. This suggests that 50 mg of KCl produced enough osmotic pressure to sustain a steady release without putting too much strain on the system. The semi-permeable membrane was made using polyethylene glycol 400 (PEG-400) and cellulose acetate at a concentration of 3% w/v (Sharma *et al*., 2021). This membrane is key in regulating drug release. As a plasticizer, PEG-400 improved the membrane's porosity and flexibility, aiding controlled drug diffusion and water intake. Additionally, the effect of coating thickness was examined, revealing that a 5% coating solution resulted in more consistent drug release than a 2.5% solution (Rahman *et al*., 2020). The tablets' durability was confirmed through physicochemical tests (Table 4), showing their drug content, hardness, and friability met pharmacopeial standards. FTIR spectroscopy also confirmed no interactions between the drug and excipients (Figure 4-6), ensuring formulation stability (Sundar *et al*., 2021). SEM images (Figures 1 and 2) verified the precision of the drilled orifice, which is crucial for reliable drug release. An important benefit for steady medication absorption in the gastrointestinal tract is the pH-independent release, demonstrated by dissolution tests in two media: 0.1 N HCl and pH 7.4 phosphate buffers (Bajracharya *et al*., 2021). Higher osmogent levels shifted the release toward first-order or Higuchi models, likely due to rapid osmotic-driven diffusion. However, kinetic analysis further supported the zero-order release mechanism of the improved formulation.

CONCLUSION

The study successfully developed an optimized Elementary Osmotic Pump (EOP) tablet for citalopram hydrobromide, providing controlled and extended drug release to reduce side effects linked to traditional formulations. Utilizing osmotic pressure principles, the formulation ensured steady drug delivery over 12 hours, following zero-order kinetics ($R^2 > 0.98$) with 50 mg KCl as the osmogent. The semi-permeable membrane, made from cellulose acetate and PEG-400, played a key role in controlling release rates, with the 5% coating solution outperforming the 2.5% in maintaining uniformity. Physicochemical tests confirmed the tablets' strength, meeting pharmacopeial standards for

hardness (3.5–5.5 kg/cm²), friability (<0.73%), and drug content (92–101%). FTIR spectroscopy confirmed no drug-excipient interactions, ensuring formulation stability, while SEM images verified the accuracy of the orifice, essential for controlled release. Dissolution testing in different pH media showed pH-independent release, a major benefit for maintaining consistent therapeutic effects in the gastrointestinal tract. Higher osmogent amounts (75–100 mg) caused burst release, deviating from zero-order kinetics, while the 50 mg KCl formulation balanced osmotic pressure and release stability. The EOP system's ability to reduce peak-trough fluctuations tackles key issues in depression treatment, such as dose-dependent side effects like tachycardia and dizziness, and enhances patient compliance. The study highlights the potential of osmotic drug delivery systems to improve the pharmacokinetic profile of citalopram. Further research is needed to assess in vivo performance, including bioavailability and pharmacokinetic studies, to confirm clinical effectiveness (Basak *et al*., 2021). Long-term stability testing under various environmental conditions will also be crucial for ensuring commercial success.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Not applicable

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AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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