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Formulation and Characterization of Cinacalcet Sustained Release Matrix Tablets

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Keywords*Sustained Release Matrix Tablets, Cinacalcet, HPMC, cumulative drug release.***ABSTRACT**

Cinacalcet is a highly effective calcium-sensing receptor agonist used to treat hyperparathyroidism and chronic kidney disease. However, as a BCS Class IV drug, it suffers from poor aqueous solubility and permeability, resulting in a low oral bioavailability of just 20–25%. Because standard conventional therapy requires frequent daily dosing that can hinder patient compliance, this study aimed to formulate and optimize a once-daily sustained-release (SR) matrix tablet of Cinacalcet to prolong drug release. Nine formulation batches were prepared via the wet granulation method using varying concentrations of hydroxypropyl methylcellulose (HPMC E5 and HPMC E15) as release-retarding polymers. These formulations were comprehensively evaluated for pre-compression flowability, post-compression physicochemical characteristics. All parameters falling well within acceptable pharmacopeial limits. The analysis demonstrated that increasing the combined concentrations of HPMC E5 and E15 significantly extended the drug's release profile. The optimized batch (F9) successfully sustained drug release for up to 18 hours (98.36% cumulative drug release). Kinetic modeling revealed that the optimized formulation followed zero-order release kinetics driven by a non-Fickian. Furthermore, the optimized batch exhibited excellent physicochemical stability over a one-month accelerated stability study at 40°C/75% RH. By maintaining steady drug release over 18 hours, this successful development of a Cinacalcet sustained-release matrix tablet offers a stable, controlled-release alternative to conventional immediate-release therapies, presenting a highly promising approach to improving patient adherence and therapeutic outcomes.

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1. INTRODUCTION:

Hyperparathyroidism is a clinically significant endocrine disorder characterized by excessive secretion of parathyroid hormone (PTH), resulting in elevated serum calcium levels and disruption of calcium–phosphate homeostasis¹. The condition may arise due to intrinsic abnormalities of the parathyroid gland, such as adenoma (primary hyperparathyroidism), or as a compensatory response to chronic conditions including chronic kidney disease (CKD) and vitamin D deficiency (secondary hyperparathyroidism)². Prolonged elevation of PTH can lead to severe complications, including bone demineralization, osteoporosis, nephrolithiasis, and increased cardiovascular risk,

thereby significantly affecting patient quality of life³.

Cinacalcet, a calcimimetic agent, has emerged as an effective therapeutic option in the management of hyperparathyroidism. It acts by allosterically activating calcium-sensing receptors (CaSR) on the parathyroid gland, thereby enhancing receptor sensitivity to extracellular calcium and suppressing PTH secretion⁴. Despite its therapeutic potential, Cinacalcet presents considerable biopharmaceutical limitations. It is classified under the Biopharmaceutics Classification System (BCS) as a Class IV drug, exhibiting both poor aqueous solubility and low intestinal permeability, which collectively contribute to its limited oral bioavailability (approximately 20–25%)⁵. Consequently, conventional immediate-release formulations necessitate frequent dosing, leading to fluctuating plasma drug concentrations and increased risk of adverse effects, ultimately compromising patient adherence⁶.

To address these limitations, sustained-release (SR) drug delivery systems have gained considerable attention. These systems are designed to modulate drug release over an extended period, thereby maintaining consistent plasma drug levels and improving therapeutic efficacy⁷. In the case of Cinacalcet, a controlled and prolonged release profile can enhance drug absorption, reduce dosing frequency, and minimize peak–trough fluctuations, ultimately improving patient compliance⁸.

Among various approaches, hydrophilic matrix systems are widely employed due to their simplicity, safety, cost-effectiveness, and regulatory acceptance. Hydroxypropyl methylcellulose (HPMC) is one of the most extensively used polymers in SR formulations owing to its excellent swelling properties, gel-forming ability, and reproducibility⁹. Different viscosity grades of HPMC, such as HPMC E5 and HPMC E15, allow precise modulation of drug release kinetics through mechanisms involving polymer hydration, gel layer formation, diffusion, and erosion¹⁰.

In this context, the present study aimed to develop, characterize, and optimize a once-daily sustained-release matrix tablet of Cinacalcet. Tablets were prepared using the wet granulation method, incorporating varying concentrations of HPMC E5 and HPMC E15 as rate-controlling polymers. The objective was to identify an optimized formulation capable of providing controlled and consistent drug release over an extended period of up to 18 hours, thereby improving therapeutic performance and patient compliance.

MATERIALS AND METHOD:

Materials: Hydroxypropyl methylcellulose (HPMC) grades E5 and E15, along with Polyvinylpyrrolidone K30 (PVP K30), Microcrystalline cellulose (MCC, Avicel PH102), talc, and magnesium stearate were purchased from Chemdyes Corporation (Rajkot, India). All other reagents and chemicals used in the study were of analytical grade.

Method: Sustained-release matrix tablets of Cinacalcet were prepared using the wet granulation technique, a well-established method for improving flowability and compressibility of poorly soluble drugs¹¹. Accurately weighed quantities of Cinacalcet, HPMC E5, HPMC E15, and MCC were passed through a #60 sieve to ensure uniform particle size distribution and subsequently blended thoroughly using a mortar or rapid mixer granulator. A binder solution was prepared by dissolving PVP K30 in purified water and was gradually incorporated into the powder blend with continuous mixing until a cohesive wet mass was formed. The wet mass was then passed through a #16 sieve to obtain granules, which were dried in a hot air oven maintained at 50–60 °C until optimal moisture content was achieved. Proper drying is essential to ensure granule stability and prevent issues during compression¹². The dried granules were further passed through a #20 sieve to achieve uniform granule size and then lubricated with talc and magnesium stearate for 3–5 minutes to improve flow properties and reduce friction during compression¹³. Finally, the lubricated granules were compressed into tablets using a suitable tablet compression machine with an appropriate punch size to obtain sustained-release Cinacalcet matrix tablets. The formulation approach was designed to achieve controlled drug release through polymer swelling, diffusion, and matrix erosion mechanisms¹⁴. Composition of different formulations of Cinacalcet Sustained Release Matrix Tablets are shown in Table 1.

Table 1: Formulation Table sustained release matrix tablet

Ingre dients (mg)	Formulation batch								
	D C	D C	D C	D C	D C	D C	D C	D C	D C
	1	2	3	4	5	6	7	8	9
Cinac alctet	60	60	60	60	60	60	60	60	60
HPM C E5	50	75	10 0	50	75	10 0	50	75	10 0
HPM C E15	50	50	50	75	75	75	10 0	10 0	10 0
MCC	15 1	12 6	10 1	12 6	10 1	76	10 1	76	51
PVP K30	30	30	30	30	30	30	30	30	30
Talc	6	6	6	6	6	6	6	6	6

Magnesium stearate	3	3	3	3	3	3	3	3	3
Purified Water	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.
Total weight	350	350	350	350	350	350	350	350	350

PREFORMULATION STUDIES:

Determination of Melting point of Cinacalcet:

The melting point of Cinacalcet was determined using a calibrated digital melting point apparatus to assess the purity and identity of the drug substance. A small quantity of finely powdered Cinacalcet was carefully filled into a capillary tube sealed at one end and placed in the apparatus. The temperature was gradually increased at a controlled heating rate, and the temperature range at which the drug sample began to melt and completely liquefied was recorded as the melting point. The determination of melting point is a fundamental physicochemical characterization technique commonly employed to evaluate the purity of pharmaceutical compounds, as pure substances typically exhibit a sharp and narrow melting range, whereas impurities tend to broaden and depress the melting point¹⁵.

Estimation of Cinacalcet by UV-Visible Spectrophotometry:

Standard stock solutions of Cinacalcet (100 µg/ml) were prepared separately in 0.1 N HCl by dissolving 10 mg of drug in 100 ml of media. From stock solution, serial dilutions were made to obtain concentrations of 10, 20, 30, 40, and 50 µg/ml. The absorbance of these solutions was measured at 281 nm using a UV-Visible spectrophotometer (Analytical Technologies Limited), with 0.1 N HCl as blank.¹⁶

Identification of Drug and Drug - Excipients

Compatibility Study: Fourier Transform Infrared (FTIR) spectroscopy was utilized to verify that Cinacalcet remains stable when combined with the chosen excipients. First, the pure drug was analyzed to identify its specific functional groups and confirm its baseline molecular structure, establishing its unique chemical fingerprint. Next, physical mixtures of the drug and the selected excipients were scanned, and these resulting spectra were compared directly against the pure drug's baseline. The analysis specifically monitored for any major shifts, missing peaks, or the appearance of new peaks, which serve as typical indicators of unwanted chemical reactions. Because the spectra of the mixtures closely mirrored the pure drug without any notable deviations, it was concluded that the active drug and the selected formulation excipients are highly compatible.¹⁷

Precompression and Post compression Parameters:

Bulk density: The apparent bulk density was assessed by pouring the blend into a graduated cylinder and measuring both the bulk volume and weight of the powder.¹⁸

Tapped density: The measuring cylinder, initially filled with a known mass of blend, underwent 100 taps. Subsequently, the minimum volume occupied in the cylinder and the weight of the blend were measured.¹⁹

Hausner's ratio: The Hausner's ratio serves as an indicator of the flow property of either particles or granules. It is calculated as the ratio of tapped density to bulk density. A value less than 1.25 indicates excellent flow, while a value greater than 1.25 suggests poor flow property. The Hausner's ratio of the granules can be determined using the equation.²⁰

Compressibility index: Carr's index is 100 times the ratio of the difference of tapped density and bulk density to tapped density.²⁰

Angle of repose (Ø): The angle of repose is defined as the maximum angle achievable between the surface of a pile of powder and the horizontal plane. It is measured using the fixed funnel standing method.²¹

Hardness: The crushing strength (in kg/cm²) of prepared tablets was determined for each batch of tablets using a Monsanto tablet hardness tester. Hardness is indicative of a tablet's ability to endure mechanical shocks during handling.²²

Thickness and diameter: Tablet thickness and diameter were measured using Digi-Matic Vernier caliper. Five tablets were randomly selected, and their thickness and diameter were measured by placing them between the two arms of the Vernier caliper.²³

Weight variation test: Twenty tablets were randomly chosen from each batch and weighed individually. The average weight of each batch of tablets was then calculated. The individual weights of the tablets were compared to the average weight. According to the Indian Pharmacopoeia (I.P.), since the tablets weighed over 250 mg, they pass the test if not more than two of the individual weights deviate from the average weight by more than 5%, and none should deviate from the average weight by more than 10%.²⁴ (Table 2)

Table 2: Standard values for weight variation

Average weight of tablet	Percentage deviation
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≤ 80 mg	10
80 - 250 mg	7.5
≥ 250 mg	5

Friability Test: The friability of tablets was assessed using a Roche friabilator, expressed as a percentage (%). Tablets were initially weighed (W_0) and then transferred into the friabilator. The friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions.²⁵

Drug content: Ten tablets were weighed, and the average weight was calculated. All ten tablets were then crushed in a mortar. The powder equivalent to 60 mg of Cinacalcet was dissolved in a small quantity of acetic acid and then made up to 10 ml with 0.1 N HCl. The drug solution was filtered through Whatman filter paper. The sample was analyzed for drug content by UV Spectrophotometry at 281 nm after suitable dilutions.²⁶

% Cumulative drug release: The release rate of Cinacalcet from the Sustained Release Tablets was evaluated utilizing the USP dissolution testing apparatus II (paddle type). The dissolution test was conducted using 900 ml of 0.1 N HCl at $37 \pm 0.5^\circ\text{C}$ with the paddles rotating at 50 rpm for up to 2 hours. A 5 ml aliquot was withdrawn from the dissolution apparatus at 2-hour intervals, and then samples were replenished with 6.8 pH buffer dissolution medium for up to 24 hours. Following filtration, the quantity of drug released was determined using the standard calibration curve of pure drug.²⁷

Stability Study: To optimize the batch, tablets were subjected to accelerated stability testing as per ICH guidelines. They were stored at $40^\circ\text{C} \pm 2^\circ\text{C}$ and $75\% \pm 5\%$ relative humidity for one month. Throughout

the study, tablets were enclosed in chambers wrapped with doubly layered aluminium foil. After one month, samples were evaluated for various parameters including drug content, weight variation, hardness, swelling study, and *In-Vitro* drug release study. These assessments were conducted to assess the long-term stability of the tablets.²⁸

RESULTS AND DISCUSSION:

Determination of melting point of Cinacalcet:

Melting point determination is a commonly employed technique to identify drugs, conducted using a melting point apparatus. For Cinacalcet, the melting point was found to be in the range of $176 - 177^\circ\text{C}$. The reported melting point of Cinacalcet is $175 - 177^\circ\text{C}$, which aligns closely with the observed melting point.

Estimation of drug by UV overlay spectra:

UV-visible spectrophotometry was utilized to determine the maximum absorbance wavelength (λ_{max}) and confirm the identity of the active pharmaceutical ingredient. Overlay spectra were obtained by scanning a series of standard drug solutions prepared at varying concentrations 10, 20, 30, 40, and 50 ppm. Across all evaluated concentrations, the maximum absorbance was consistently observed at 281 nm thereby confirming the identity of the drug sample. The corresponding absorbance data and resulting calibration curves are detailed in Tables 3 and graphically represented in Figure 1. Furthermore, regression analysis of Cinacalcet in 0.1 N HCl yielded a regression equation of $y = 0.007x + 0.032$ with a strong correlation coefficient of 0.9915 across the calibration curve range of 10 to 50 ppm (Table 3).

Table 3: Absorbance of different concentration of Cinacalcet in 0.1 N HCl

Sr. No.	Concentration(ppm)	Absorbance			Mean Absorbance \pm S. D.
		I	II	III	
1.	10	0.122	0.105	0.118	0.115 ± 0.0089
2.	20	0.159	0.156	0.161	0.159 ± 0.0025
3.	30	0.241	0.239	0.239	0.240 ± 0.0012
4.	40	0.315	0.309	0.307	0.310 ± 0.0042
5.	50	0.382	0.393	0.397	0.391 ± 0.0078

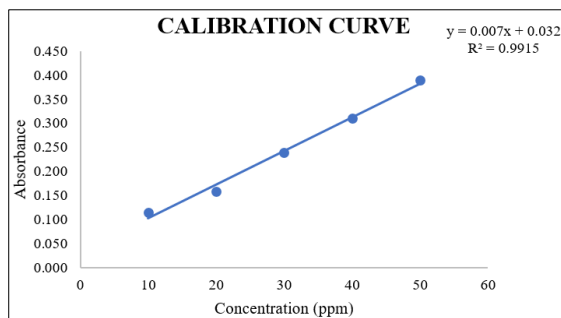


Fig. 1: Calibration curve of Cinacalcet in 0.1 N HCl

PRECOMPRESSION PARAMETERS:

The micromeritic properties of the pre-compression powder blends (Batches DC1 to DC9) were evaluated to ensure optimal flowability and compressibility, which are crucial for uniform die cavity filling and consistent tablet characteristics. The pre-compression results are summarized in Table 7. Bulk and tapped densities ranged from 0.40 ± 0.039 to 0.58 ± 0.026 g/ml and 0.47 ± 0.028 to 0.63 ± 0.054 g/ml, respectively. The relatively narrow differences between these bulk and consolidated states indicate favourable interparticulate packing and low void volumes. Flow properties were assessed via the angle of repose (θ),

which ranged from 24.96±0.028 to 36.84±0.330. Batch DC1 exhibited excellent flow dynamics ($\theta = 24.96$). The majority of the remaining batches demonstrated excellent to good flowability (i.e. 32.18). Only batch DC6 showed fair flow (36.84), which still remains within acceptable processing limits for tableting without forceful feeding. Compressibility and consolidation behaviors were quantified using Carr's Compressibility Index (CI) and Hausner's Ratio (HR). Values ranged from 9.92%±0.345 to 16.09%±0.340 for CI, and

1.13±0.024 to 1.19±0.010 for HR. Batch DC1 displayed excellent compressibility. The other formulations fell predominantly within the "good" to "fair" categories, indicating satisfactory volume reduction under pressure. Overall, the pre-compression evaluation confirms that all formulated powder blends possess adequate rheological characteristics and low cohesive forces, making them highly suitable for successful tableting operations (Table 4).

Table 4: Bulk density, Tapped density, Carr's index, Hausner's ratio and Angle of Repose data

Batch	Bulk density (g/ml ± S.D.)	Tapped density (g/ml ± S.D.)	Carr's index (%± S.D.)	Hausner's (ratio±S.D.)	Angle Of repose (°±S.D.)
DC1	0.58±0.026	0.63±0.054	9.92±0.345	1.13±0.024	24.96±0.028
DC2	0.41±0.036	0.49±0.039	15.35±0.711	1.18±0.026	30.85±0.303
DC3	0.42±0.026	0.49±0.039	14.28±0.244	1.16±0.030	29.26±0.158
DC4	0.40±0.039	0.47±0.028	14.60±0.245	1.17±0.015	29.95±0.228
DC5	0.44±0.043	0.51±0.044	12.89±0.256	1.14±0.020	27.69±0.302
DC6	0.43±0.042	0.52±0.046	16.09±0.340	1.19±0.010	36.84±0.330
DC7	0.43±0.042	0.50±0.041	14.82±0.265	1.17±0.020	32.18±0.378
DC8	0.45±0.044	0.52±0.046	14.12±0.260	1.16±0.020	30.28±0.256
DC9	0.42±0.041	0.49±0.038	14.08±0.240	1.16±0.020	30.11±0.358

Post Compression Parameters:

The formulated tablets (Batches DC1 to DC9) were systematically evaluated for post-compression parameters, including weight variation, thickness, diameter, hardness, friability, and drug content, to ensure physical integrity and uniformity. Physical uniformity was consistently maintained across all batches. Tablet weights ranged narrowly from 348.4±1.96 mg (DC2) to 352.3±0.65 mg (DC7), indicating highly consistent die cavity fill during the compression phase. Dimensional properties were also uniform, with thickness varying slightly between 4.76±0.1 mm and 4.89±0.3 mm, and diameter ranging from 12.07±0.05 mm to 12.37±0.03 mm. The mechanical strength of the tablets was highly satisfactory. Hardness values ranged from 4.58±0.21 kg/cm² to 4.91±0.26 kg/cm², ensuring adequate robustness to withstand

mechanical shocks during routine handling, packaging, and transportation. Corroborating the hardness data, friability values for all formulations were exceptionally low, ranging from 0.25%±0.050 (DC9) to 0.83±0.112 % (DC1). All batches fell well below the acceptable pharmacopeial limit of 1%, confirming excellent abrasion resistance. Finally, the percentage drug content was uniform and compliant across all formulations, ranging from 97.22±0.445 % to 99.72±0.784 %. This confirms the homogeneous distribution of the active pharmaceutical ingredient within the powder blend and the final dosage form. Overall, the post-compression parameters for all formulated batches strictly complied with standard pharmacopeial specifications, establishing their physical and chemical stability (Table 5).

Table 5: Weight variation, Thickness, Diameter, Hardness, Friability and Drug Content Data

Formulation Batch	Weight variation (mg± S.D.)	Thickness (mm±S.D.)	Diameter (mm±S.D.)	Hardnes (kg/cm ² ± S.D.)	Friability (%± S.D.)	Drug Content (%± S.D.)
DC1	350.3±1.47	4.76 ± 0.1	12.37±0.03	4.58±0.21	0.83±0.112	98.63±0.768
DC2	348.4± 1.96	4.87 + 0.6	12.22±0.06	4.67±0.15	0.66±0.080	99.28±0.679
DC3	350.3± 1.82	4.88 + 0.3	12.21±0.12	4.75±0.42	0.39±0.130	99.72±0.784
DC4	350.2± 0.29	4.84 + 0.2	12.18±0.06	4.71±0.16	0.52±0.080	98.18±0.767
DC5	351.4± 0.54	4.89 + 0.3	12.19±0.25	4.73±1.05	0.46±0.090	97.22±0.445
DC6	349.3± 0.15	4.79 + 0.4	12.26±0.06	4.83±1.05	0.28±0.100	97.82±0.564
DC7	352.3± 0.65	4.80 + 0.2	12.09±0.10	4.72±0.84	0.47±0.080	98.62±0.445
DC8	350.8± 0.89	4.86 + 0.4	12.18±0.06	4.76±0.24	0.34±0.110	97.28±0.244
DC9	349.1± 1.04	4.88 + 0.5	12.07±0.05	4.91±0.26	0.25±0.050	98.65±0.448

In-Vitro Drug Release study:

The *In-Vitro* dissolution profiles of all formulated batches (DC1 to DC9) were evaluated to determine the cumulative percentage of drug release (% CDR) over an extended period. All formulations

successfully exhibited a sustained drug release pattern, though the duration of release varied notably among the batches. Formulations DC1 through DC4 demonstrated a relatively faster release rate, achieving near-complete drug release (>98%) within

14 hours. Among these, batch DC1 exhibited the fastest overall release, reaching 99.73% at 14 hours. Conversely, modifications in the formulation variables effectively retarded the drug release rate in the subsequent batches. Formulations DC5 and DC7 prolonged the release up to 16 hours (98.62% and 99.48%, respectively). Batches DC6, DC8, and DC9 exhibited the most extended-release profiles, successfully sustaining the drug release for up to 18 hours (99.82%, 99.03%, and 98.36%, respectively). This distinct variation in the dissolution profiles indicates that the release kinetics can be precisely modulated to achieve the desired therapeutic window based on the chosen formulation parameters (Figure 2).

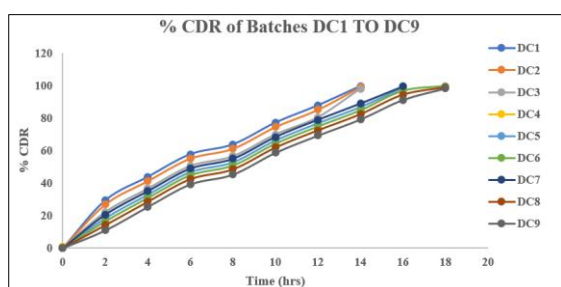


Fig. 2: *In-Vitro* drug release of Batch DC1 TO DC9

Stability studies:

On the basis of all above parameters of Factorial Design batches, it was concluded that the batch DC9 was an optimized batch, as it had good surface appearance, Mechanical strength and Drug Content. Moreover, it showed 99.78 % of drug release in 18 hrs, it was least as compared to all other batches. Thus, batch F9 was selected as an optimized batch (Table 6 ,7 and figure 3).

Table 6: Result of the Stability study

Parameters	Optimized batch (F9)	Optimized batch after 1 month
Thickness (mm)	4.88 ± 0.5	4.83 ± 0.2
Hardness (kg/cm ²)	4.73 ± 0.12	4.41 ± 0.12
Drug Content (%)	98.65	97.18

Table 7: % Cumulative Drug Release of Stability batch

Time (hrs)	% CDR of Optimized Batch (DC9)	% CDR of Optimized batch After 1 Month
0	0.00	0
2	10.25	12.64
4	25.63	28.02
6	46.93	49.32
8	56.08	59.22
10	58.84	61.23
12	71.25	73.64
14	84.25	86.64
16	97.26	99.65
18	99.78	99.97

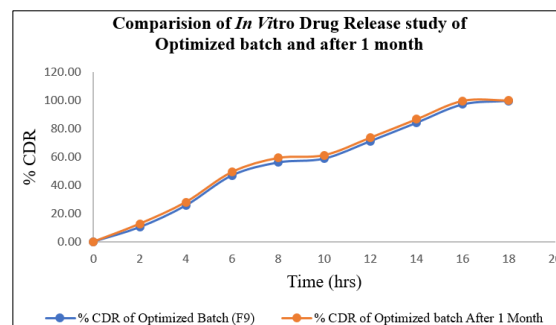


Fig. 3: Comparison of % CDR of Optimized batch and Stability batch

CONCLUSION:

Sustained release matrix tablets of Cinacalcet were successfully developed using different grades of HPMC (E3, E5, and E15) by the wet granulation method. Preliminary batches were evaluated for pre- and post-compression parameters, and HPMC E5 and HPMC E15 were identified as the most suitable polymers for achieving prolonged drug release. Dissolution studies demonstrated that increasing the combined concentration of both polymers improved the sustained release profile. Among all formulations, batch DC9 showed optimal performance, sustaining drug release up to 18 hours with 99.78% cumulative release. When compared with the marketed PTH 60 mg tablet, which released 99.68% drug within 12 hours, DC9 provided significantly prolonged release (98.36% in 18 hours). Stability studies conducted for one month indicated no significant changes in formulation characteristics, confirming the stability of batch DC9 under the tested conditions. Overall, the study concludes that sustained release matrix tablets of Cinacalcet, particularly the optimized DC9 formulation, represent a stable and effective dosage form capable of prolonging drug release, thereby offering a potentially improved therapeutic option for the management of hyperparathyroidism.

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CONFLICT OF INTEREST:

The authors declare that there is no conflict of interest.

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