

Formulation, Development and Evaluation of a Dual Coated Tablet of Metformin Hydrochloride With Sitagliptin Phosphate Combination

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Abstract

Introduction: Diabetes mellitus is a chronic metabolic disorder that often requires combination therapy for effective glycemic control. Conventional oral dosage forms frequently produce rapid drug release, fluctuating plasma drug concentrations, and require repeated dosing, which may reduce therapeutic efficacy and patient compliance. This study aimed to formulate, develop, and evaluate a dual-coated tablet containing a sustained-release core of Metformin Hydrochloride and an immediate-release outer coating of Sitagliptin Phosphate for biphasic drug delivery.

Materials and Methods: Metformin Hydrochloride core tablets were prepared by the wet granulation method using different formulations (F1–F7). The optimized core was coated with a hydroxypropyl methylcellulose (HPMC 5 cps) seal coat followed by an outer drug coating containing Sitagliptin Phosphate. The formulations were evaluated for flow properties, FTIR compatibility, physicochemical characteristics, drug content, disintegration, and in vitro dissolution.

Results: The optimized formulation (F7) demonstrated excellent flow properties with a Carr's Index of 9.09%, Hausner Ratio of 1.10, and Angle of Repose of 29.24°. FTIR analysis confirmed drug–excipient compatibility. The formulation exhibited acceptable physicochemical properties with 97.10% drug content and 95.93% assay. Dissolution studies showed rapid release of Sitagliptin Phosphate (95.00% within 15 minutes) followed by sustained release of Metformin Hydrochloride (88.83% at 540 minutes).

Discussion: The developed dual-coated tablet successfully achieved biphasic drug release and demonstrated satisfactory pharmaceutical performance. The formulation offers a promising approach for improving therapeutic efficacy, reducing dosing frequency, and enhancing patient compliance in type 2 diabetes mellitus.

Keywords: Dual-coated tablet; Metformin Hydrochloride; Sitagliptin Phosphate; Biphasic drug delivery; Controlled release; Diabetes mellitus.

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INTRODUCTION

The oral route continues to be the most widely accepted method of drug administration because of its ease of use, painless nature, and high level of patient adherence. Despite these advantages, conventional oral formulations such as immediate-release tablets and capsules exhibit several drawbacks, including rapid drug liberation, instability of acid-sensitive drugs in the gastric environment, gastric mucosal irritation, and limited duration of therapeutic action. These dosage forms frequently cause marked fluctuations in plasma drug levels, which may lead to inadequate therapeutic response and require repeated dosing to sustain effective drug concentrations.^[1] Controlled release (CR) drug delivery systems were developed to address the drawbacks associated with conventional dosage forms by enabling prolonged and controlled release of drugs over a defined duration. The main purpose of these systems is to maintain drug concentration within the desired therapeutic range

for an extended period, thereby enhancing therapeutic effectiveness while reducing the risk of adverse effects. Such formulations generally employ biocompatible polymer-based matrices that modulate drug release behavior, improve bioavailability, minimize dosing frequency, and promote better patient adherence to therapy.^[2] The performance of orally administered drug delivery systems is significantly affected by physiological conditions including gastrointestinal pH, gastric transit time, intestinal movement, mucus barrier characteristics, and the presence of food, as these factors directly influence drug absorption and systemic availability. Fluctuations in these biological parameters may result in variable therapeutic responses; therefore, careful evaluation of such factors is crucial during the development of advanced controlled release oral formulations.^[3] Combination therapy is commonly employed in the management of multifactorial disorders

where a single therapeutic agent does not provide adequate clinical response. Nevertheless, traditional combination dosage forms are frequently associated with limitations including non-targeted drug distribution, rapid elimination, and variations in the pharmacokinetic profiles of individual drugs, which can compromise synergistic action and elevate the risk of adverse reactions. To overcome these limitations, advanced drug delivery approaches, including polymeric carrier systems and controlled release formulations, have been developed to coordinate drug release patterns, enhance targeted delivery, and improve overall therapeutic outcomes.^[4] Drugs that are unstable under acidic gastric conditions frequently require specialized coating approaches, including enteric and pH-responsive coatings, to prevent degradation in the stomach and facilitate release at the desired intestinal site. In dual drug delivery systems containing therapeutically and physicochemically distinct drugs, independent release-regulating mechanisms are necessary to coordinate drug release patterns, prolong therapeutic action, minimize dosing frequency, and enhance overall treatment effectiveness.^[5]

Dual-coated tablets are an innovative oral drug delivery system designed to address the shortcomings associated with conventional single-coated formulations, especially in providing regulated and site-appropriate drug release. These dosage forms incorporate two separate coating layers that enable accurate control over drug release behavior. In general, the external functional coating allows rapid initial release of the drug, whereas the internal seal coating safeguards the tablet core and promotes prolonged drug release. This layered design minimizes release delay and enhances the predictability of pharmacokinetic performance. Owing to their biphasic release characteristics, dual-coated tablets are particularly beneficial for therapeutic agents that require both rapid onset and sustained pharmacological activity.^[6] Tablets are among the most commonly employed pharmaceutical dosage forms due to their simple administration, cost-effective production, and improved patient acceptability. The application of coating technology significantly enhances tablet performance by improving visual appearance, concealing unpleasant taste and odour, and protecting the active pharmaceutical ingredient (API) from environmental factors that may affect stability. Additionally, specialized coating systems can be designed to regulate drug release patterns, allowing controlled, delayed, or site-specific

delivery within the gastrointestinal tract.^[7]

The seal coating applied over the tablet core functions as a protective intermediate layer that reduces direct interaction between the active pharmaceutical ingredient and subsequent coating materials, thereby enhancing core stability and providing a smooth and uniform surface for further coating application. Conversely, the outer functional coating is designed to regulate therapeutic performance by enabling immediate, sustained, delayed, or targeted drug release, ultimately contributing to improved formulation efficiency and better patient acceptability.^[8] Tablet coating systems play an essential role in improving the stability, durability, and handling properties of pharmaceutical dosage forms while safeguarding them from environmental and mechanical stress. Appropriate selection of coating polymers and optimization of coating thickness enable effective regulation of drug release patterns, especially for acid-labile drugs intended for intestinal absorption. Furthermore, the incorporation of intermediate polymeric barrier layers provides additional protection to the formulation and prolongs the lag phase, thereby allowing precise control over the timing and site of drug release in advanced dual-coated tablet systems.^{9,10}

Dual-coated tablet systems provide multiple therapeutic benefits, such as targeted drug delivery, enhanced bioavailability, minimized adverse effects, and sustained maintenance of drug concentration within the desired therapeutic range. The integration of both immediate and prolonged drug release mechanisms contributes to improved therapeutic outcomes while also promoting better patient compliance.^{11,12}

Drug release kinetics play a crucial role in determining the therapeutic effectiveness of pharmaceutical dosage forms by directly affecting their pharmacokinetic and pharmacodynamic behavior. Controlled drug delivery systems can exhibit various release patterns, including zero-order, first-order, and biphasic release mechanisms. In biphasic systems, an initial rapid release phase is commonly followed by a prolonged sustained release phase to maintain effective drug concentration for an extended duration. Advanced modified release approaches such as controlled release (CR), sustained release (SR), extended release (ER), delayed release (DR), and targeted delivery systems have significantly contributed to improving therapeutic outcomes, reducing administration frequency, and enhancing patient adherence to treatment.¹³⁻¹⁵

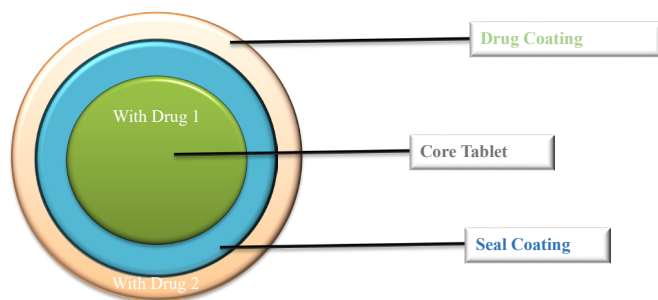


Figure 1: Schematic of the Dual-Coated Tablet concept

MATERIALS AND METHODS

Materials

Drugs

- Metformin Hydrochloride - Yarrow Chem Products, Mumbai, India.
- Sitagliptin Phosphate - Gift sample from College source.

Excipients

Table 1: List of excipients with Brand and CAS Number Equipment

Sr. No	Excipients	Brand Name	CAS No.
1	Microcrystalline cellulose	Research Lab	9004-34-6
2	Lactose Monohydrate	CDH	10039-26-6
3	D-Mannitol	CDH	69-65-8
4	Ethyl cellulose	CDH	9004-57-3
5	Starch Soluble (Ex Potato)	CDH	9005-84-9
6	Sodium Starch Glycolate	CDH	9063-38-1
7	Magnesium Stearate	Pallav	557-04-0
8	Hydroxy Propyl Methyl Cellulose 5 cPs	CDH	9004-65-3
9	Ethanol [99.9%]	CS	-

Table 2: List of Instrumentation & Equipment's

Sr. No.	Instrumentation & equipments	Make
1	Digital Balance	Model no. 91499 IND/09/08/499 PGB 600
2	pH Meter	Systronics
3	Magnetic Stirrer	Model no. EQ-771
4	Tablet Compression Machine	Karnavati RiMek 12 Station
5	Tablet Coating Machine	ACG Miniquet T
6	Dissolution Test Apparatus	Labindia DS 800
7	Disintegration Test Apparatus	Labindia DT 1000
8	Ultrasonicator	Athena technology
9	Centrifuge	REMI R-4C
10	Double Beam UV-Vis Spectrophotometer	Labindia 3092
11	FTIR Spectrophotometer	Bruker ALPHA Eco $\pm$ ATR

Procedure

Weighing and Dispensing of Ingredients

Accurate quantities of active pharmaceutical ingredients (APIs) and excipients were measured using a calibrated analytical balance to ensure uniformity of the formulation and consistency of drug content in the tablets. Separate clean and dry dispensing accessories, including spatulas, scoops, and protective poly covers, were utilized for each material to minimize the risk of cross-contamination. Prior to weighing, the analytical balance was properly leveled by checking the bubble indicator to maintain measurement precision. Each weighed ingredient was individually dispensed, securely packed, and stored under appropriate conditions to maintain stability and prevent contamination.

Formulation of Core Tablets

BLENDING and COMPRESSION (OPTIMIZATION)

Before blending, all formulation ingredients were passed through Sieve #40 to achieve a uniform particle size distribution and ensure proper mixing.

- The sieved ingredients were then transferred into a mortar and blended thoroughly to obtain a homogeneous mixture
- Ethanol was gradually added as a binder solution with continuous mixing to facilitate wet mass formation.
- The blending process was continued until a uniform dough-like mass was obtained, which was then allowed to partially dry for a few minutes.
- An additional binder solution was incorporated, if required, to maintain optimum consistency for granulation.
- The wet mass was subjected to hand granulation and passed through Sieve #20 to produce wet granules, followed by drying for 1/2 Hr.
- The dried granules were then resized by passing through Sieve #30 to obtain a uniform granule size suitable for compression.

Table 3: Qualitative and Quantitative Composition in Percent

Sr. No	Ingredients	F1		F2		F3		F4	
		w/w%	w/mg	w/w%	w/mg	w/w%	w/mg	w/w%	w/mg
1	Drug	50.00	500	50.00	500	50.00	400	50.00	400
2	Microcrystalline cellulose	20.00	200	20.00	200	20.00	160	22.00	170
3	Lactose Monohydrate	12.00	120	07.00	70	17.00	136	15.00	120
4	D-Mannitol	-	-	-	-	-	-	-	-
5	Ethyl cellulose	15.00	150	20.00	200	10.00	80	07.00	56
6	Starch Soluble (Ex Potato)	-	-	-	-	-	-	-	-
7	Sodium Strach Glycolate	02.00	20	02.00	20	02.00	16	05.00	40
8	Magnesium Stearate	01.00	10	01.00	10	01.00	08	01.00	08
	Total	100	1000	100	1000	100	800	100	800

Table 4: Qualitative and Quantitative Composition in Percent

Sr. No	Ingredients	F5		F6		F7	
		w/w%	w/mg	w/w%	w/mg	w/w%	w/mg
1	Drug	50.00	400	50.00	400	50.00	400
2	Microcrystalline cellulose	20.50	164	-	-	-	-
3	Lactose Monohydrate	13.50	108	20.00	160	20.00	160
4	D-Mannitol	-	-	07.00	56	10.00	80
5	Ethyl cellulose	10.00	80	20.00	160	10.00	80
6	Starch Soluble (Ex Potato)	-	-	-	-	05.00	40
7	Sodium Strach Glycolate	05.00	40	02.00	16	04.00	32
8	Magnesium Stearate	01.00	08	01.00	08	01.00	08
	Total	100	800	100	800	100	800

- Finally, the granules were accurately weighed and compressed under optimized parameters to produce tablets with the desired physical characteristics and quality attributes.

Formulation of Coated Tablets

Seal Coating Preparation

- HPMC 5 cps was dispersed in purified water and stirred continuously on a magnetic stirrer at 1000 rpm to ensure uniform polymer dispersion.
- Stirring was continued until a clear and homogeneous polymeric solution was obtained.
- The prepared solution was then subjected to sonication for 15 minutes to remove entrapped air bubbles and improve uniformity
- Followed by standing for 15 minutes to allow complete stabilization before coating application.

Drug Coating Preparation

- HPMC 5 cps was dispersed in purified water and stirred on a magnetic stirrer at 1000 rpm until a clear and uniform polymeric solution was formed.



Figure 2: Core tablet



Figure 3: Seal Coted tablet



Figure 4: Drug Coted tablet

Table 5: Coating Solution Composition in Gram

Sr. No	Ingredients	Quantity/Batch in Gram
		Seal Coat
1	HPMC 5cps	4.056
2	Distilled Water	56.51

Table 6: Drug Coating Solution Composition in Gram

Sr. No	Ingredients	Quantity/Batch in Gram
		Drug Coat
1	Drug	0.650
2	HPMC 5cps	9.31
3	Distilled Water	210

Table 7: Coating Parameter's Inputs

Sr. No	Parameters	Input	
		Set	Actual
1	Pump rpm	1 to 5 rpm	03.07 rpm
2	Pan rpm	1 to 10 rpm	6 rpm
3	Dp Pan	-100°C min to +100°C max	57°C
4	Inlet Temperature	57°C	41°C
5	Exhaust Temperature	57°C	41°C
6	Atomization Air	0.1 to 1 MPa	0.3MPa
7	Inlet Air Flow	0.1 to 0.50 MPa	0.25MPa
8	DP Flow Control	0.5 to 2 MPa	1.1MPa

- The stirring speed was then reduced to 500 rpm, and the drug was gradually added to the polymer solution to ensure proper incorporation and prevent agglomeration.
- After complete addition, the stirring speed was increased to 1000 rpm and continued until a homogeneous drug-polymer dispersion was obtained.
- The final coating solution was sonicated for 15 minutes to remove entrapped air and then allowed to stand for 15 minutes for stabilization before coating application.

Coating Parameters:

Table 7: Coating Parameter's Inputs

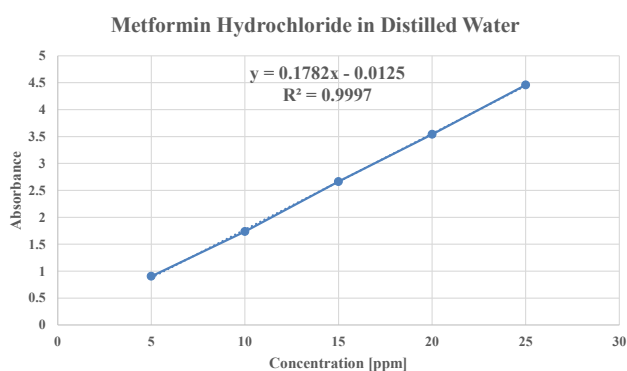
Evaluation Studies

Physical Appearance

The formulated tablets were examined visually to assess their overall physical and organoleptic properties, including colour, shape, surface texture, dimensional consistency, and the absence of visible defects such as cracks, chipping, or uneven surfaces, thereby confirming acceptable product quality and appearance.

Table 8: Concentration and Absorbance of Metformin Hydrochloride

Sr. No	Metformin Hydrochloride in Distilled Water	
	Concentration	Absorbance
1	5	0.905
2	10	1.736
3	15	2.664
4	20	3.541
5	25	4.458

**Figure 5:** Concentration vs Absorbance Graph of Metformin Hydrochloride

Thickness

Tablet thickness was determined using a vernier caliper to evaluate dimensional uniformity among the prepared formulations. Ten tablets were measured individually, and the average thickness value was calculated.

Hardness

The mechanical strength of the tablets was evaluated using a tablet hardness tester. A total of twenty tablets were analyzed, and the mean hardness value was recorded in kg/cm^2 to ensure adequate resistance to handling and mechanical stress.

Disintegration Test

Disintegration testing was performed using a USP disintegration apparatus containing 900 mL of distilled water maintained at $37 \pm 0.5^\circ\text{C}$. Six tablets were tested under standard operating conditions at a frequency of 28–32 cycles per minute with a vertical movement distance of 5–6 cm. The time required for complete tablet disintegration was recorded for each formulation.

Dissolution Conditions And Apparatus

In-vitro drug release studies were conducted using USP Dissolution Apparatus II (Paddle Method). The dissolution medium consisted of 900 mL of distilled water maintained at $37 \pm 0.5^\circ\text{C}$ to mimic physiological conditions. The paddle rotation speed was maintained consistently at 50 rpm throughout the dissolution study.

Sample Collection and Analysis

Samples of the dissolution medium were withdrawn at predetermined intervals of 5, 10, 15, 30, 45, 60, 120, up to 600 minutes. The withdrawn samples were filtered to eliminate undissolved particulate matter before analysis. Drug release was quantified using UV-Visible spectrophotometry by measuring absorbance at 233 nm and 267 nm, corresponding to the respective maximum absorption wavelengths of the drugs.

Result And Discussion

Calibration Curve of Drugs

Metformin hydrochloride

The maximum absorption wavelength ($\lambda_{\max}$) of pure Metformin Hydrochloride was identified using a UV-Visible spectrophotometer (LABINDIA UV 3092 series). A solution of the drug was prepared in distilled water and scanned within the wavelength range of 200–400 nm. The obtained spectrum demonstrated a characteristic maximum absorbance at 233 nm.

Preparation of Standard Stock Solution

An accurately weighed quantity of 10 mg of Metformin Hydrochloride was transferred into a 100 mL volumetric flask. The drug was initially dissolved in a small volume of distilled water, and the final volume was adjusted up to the mark with the same solvent to obtain a stock solution having a concentration of 100 $\mu\text{g/mL}$.

Preparation of Working Standard Solutions

Aliquots from the prepared stock solution were separately transferred into a series of 10 mL volumetric flasks and diluted with distilled water to produce working standard solutions with concentrations of 5, 10, 15, 20, and 25 $\mu\text{g/mL}$, respectively.

The absorbance of each solution was recorded at 233 nm using distilled water as the blank solution, and a calibration curve was generated. The plotted calibration graph exhibited excellent linearity across the selected concentration range with a correlation coefficient (R^2) of 0.9997.

Sitagliptin Phosphate

The absorption maximum ($\lambda_{\max}$) of pure Sitagliptin Phosphate was identified using a UV-Visible spectrophotometer (LABINDIA UV 3092 series). A solution of the drug was prepared in distilled water and scanned within the wavelength range of 200–400 nm. The obtained UV spectrum exhibited maximum absorbance at 267 nm.

Preparation of Standard Stock Solution

A standard stock solution was prepared by accurately weighing 10 mg of Sitagliptin Phosphate and transferring it into a 100 mL volumetric flask. The drug was completely dissolved in distilled water, and the volume was adjusted

Table 9: Concentration and Absorbance of Sitagliptin Phosphate

Sr.no	Sitagliptin Phosphate in Distilled Water	
	Concentration	Absorbance
1	5ppm	0.029
2	10ppm	0.051
3	15ppm	0.072
4	20ppm	0.093
5	25ppm	0.116

up to the mark with the same solvent to obtain a final concentration of 100 $\mu\text{g/mL}$.

Preparation of Working Standard Solutions

From the stock solution, appropriate aliquots were withdrawn and separately transferred into 10 mL volumetric flasks. The volume in each flask was then adjusted with distilled water to prepare working standard solutions containing 5, 10, 15, 20, and 25 $\mu\text{g/mL}$ concentrations, respectively.

The absorbance of each prepared solution was recorded at 267 nm using distilled water as the blank solution. A calibration curve of concentration versus absorbance was plotted, which demonstrated excellent linearity across the selected concentration range with a correlation coefficient (R^2) of 0.9997.

IR - Spectra Analysis:

Metformin Hydrochloride API

To verify Metformin Hydrochloride chemical integrity and compatibility with formulation excipients, an FTIR spectra analysis was performed. No anomalies or unexpected peaks were visible in the collected spectra, indicating that the medication remained stable. Furthermore, no chemical alterations or interactions were detected, guaranteeing that Metformin Hydrochloride was unaltered during the formulation procedure.

Sitagliptin Phosphate API

To verify Sitagliptin Phosphate chemical integrity and compatibility with formulation excipients, an FTIR spectra

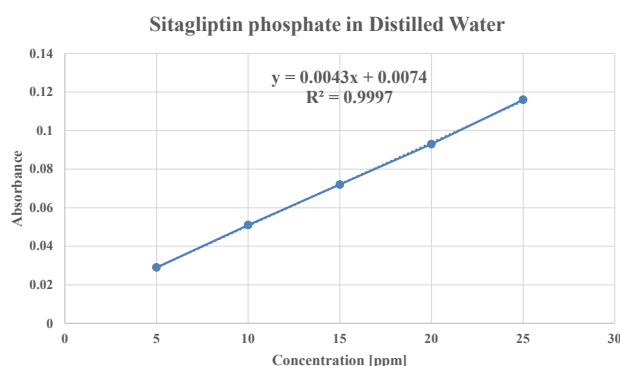


Figure 6: Concentration vs Absorbance Graph of Sitagliptin Phosphate

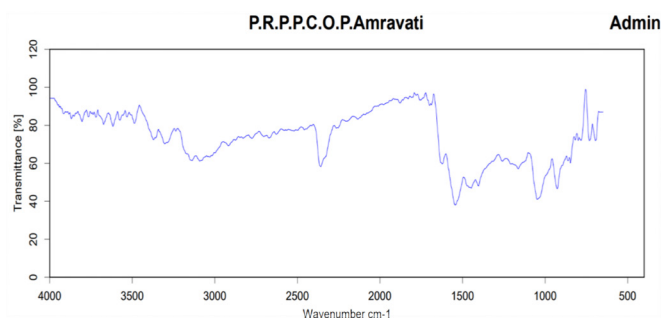


Figure 7: IR- Spectra analysis of Metformin Hydrochloride

analysis was performed. No anomalies or unexpected peaks were visible in the collected spectra, indicating that the medication remained stable. Furthermore, no chemical alterations or interactions were detected, guaranteeing that Sitagliptin Phosphate was unaltered during the formulation procedure.

Table 10: Flow and consolidation properties

Sr. No.	Tests	Mean ($\pm$ SD)	Flow
1	Bulk Density	0.6 g/ml	Excellent
2	Tapped Density	0.66 g/ml	
3	Carr's Index	09.09 %	
4	Hausner Ratio	01.10	
5	Angle of Repose (θ)	29.24°	

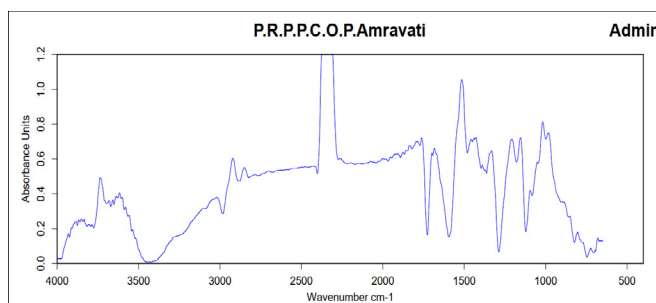


Figure 8: IR- Spectra analysis of Sitagliptin Phosphate

Preformulation Studies Result

To determine if the Metformin Hydrochloride granules were suitable for tablet compression, their flow and consolidation characteristics were examined. An adequate angle of repose suggested that the granules had Excellent / very free-flow flowability. Furthermore, the formulation's Excellent compressibility characteristics were indicated by the bulk and tapped density tests. The granule compression was further validated by the compressibility index and Hausner's ratio, which makes it effective for tablet production.

Several physical characteristics, including average weight, thickness, hardness, and disintegration time(DT), were assessed for the manufactured Fexofenadine HCl tablets. Every formulation fell within the permissible ranges for hardness, thickness, and weight fluctuation. F7 stood out as the best-performing formulation because it showed the

Table 11: Limit of flow characters

Sr. No.	Flow Property	Carr's Index	Hausner Ratio	Angle of Repose (θ)
1	Excellent / Very Free Flow	<10	1.00 - 1.11	25-30
2	Good / Free Flow	11 - 15	1.12- 1.18	31-35
3	Fair (discharging aid may not be required)	14 - 20	1.19 – 1.25	36-40
4	Passable	21 - 25	1.26 - 1.34	41-45
5	Poor Flow / Cohesive (active discharging aid required)	26 - 31	1.35 - 1.45	46-55
6	Very Poor Flow / Very Cohesive	32 - 37	1.46 - 1.59	56-65
7	Approximately no flow	>38	>1.60	> 66

Table 12: Evaluation of Core Tablet

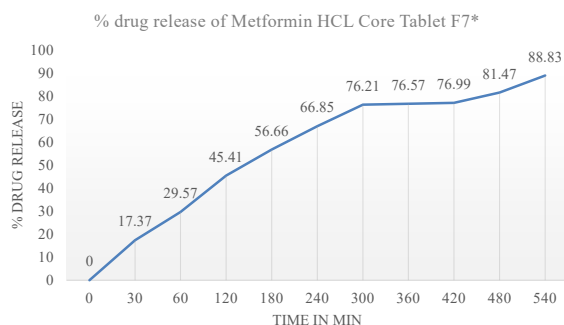
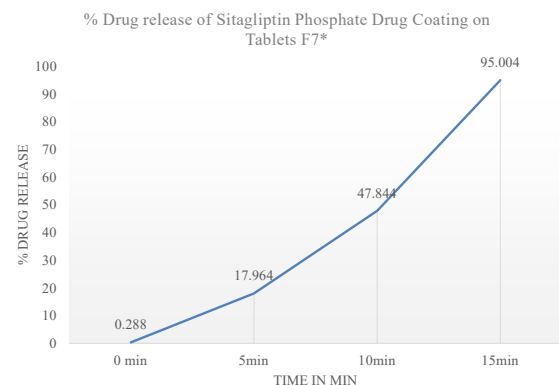
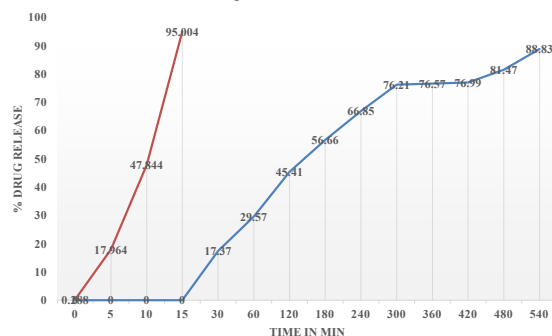
Sr. No.	Tests	Results
1	Appearance	A pale orange, oval-shaped, biconvex tablet with a bisect (score) line on both sides, and no printing or engraving.
2	Weight	798 – 808 mg
3	Thickness	05. – 05.30mm
4	Dimension	19*10mm
5	Hardness	05 – 05.50 kg/cm ²
6	Assay%	95.93%
7	Drug Content	97.10%
8	Disintegration Test	02:15 – 02:00 [Hr. : Minutes]

Table 13: % Drug release of Metformin HCL Core Tablet F7*

Sr. No.	Time in min	Absorbance	% drug release
1	0	0.00	00.00
2	30	1.364	17.37
3	60	2.329	29.57
4	120	3.582	45.41
5	180	4.474	56.66
6	240	5.284	66.85
7	300	6.023	76.21
8	360	6.052	76.57
9	420	6.086	76wt.99
10	480	6.640	81.47
11	540	7.022	88.83

Table 14: % Drug release of Sitagliptin Phosphate Drug Coating on Tablets F7*

Sr. No.	Time in min	Absorbance	% drug release
1	0	0.008	0.288
2	5	0.499	17.964
3	10	1.329	47.844
4	15	2.639	95.004

**Figure 9:** % Drug release of Metformin HCL Core Tablet F7***Figure 10:** %Drug release of Sitagliptin Phosphate Drug Coating on Tablets F7***% Drug release of Metformin HCL + Sitagliptin Phosphate Tablet F7*****Figure 11:** % Drug release of Metformin HCL + Sitagliptin Phosphate Tablet F7*

aimed disintegration time among the formulations, which makes it ideal for attaining extended drug release.

To evaluate the release profile of Metformin HCL + Sitagliptin Phosphate tablets in Distilled Water, dissolution tests were carried out. F7, performed the best out of the seven. Immediate drug release of Sitagliptin Phosphate drug coat was indicated followed by extended drug release. In comparison to the other formulations, this demonstrates that F7 satisfies the requirements.

Conclusion

The present study successfully developed and evaluated a dual-coated tablet system containing Metformin Hydrochloride core tablets with Sitagliptin Phosphate outer drug coating. Preformulation studies demonstrated excellent flow and compressibility properties, while FTIR analysis confirmed the compatibility and stability of both drugs with formulation excipients. Among all formulations, F7 exhibited satisfactory physicochemical properties, including acceptable hardness, thickness, weight variation, drug content, and disintegration behaviour within pharmacopeial limits. In-vitro dissolution studies revealed immediate release of Sitagliptin Phosphate from the outer coating followed by extended release of Metformin Hydrochloride from the core tablet, confirming the effectiveness of the dual-coating approach for biphasic drug delivery. Overall, the developed formulation demonstrated controlled and sequential drug release, improved therapeutic performance, reduced dosing frequency, and enhanced patient compliance, indicating its potential as an advanced oral drug delivery system for combination therapy.

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References

1. Adepu S, Ramakrishna S. Controlled drug delivery systems: current status and future directions. *Molecules*. 2021;26(19):5905.
2. S. Petrusic, V. Koncar. Controlled release of active agents from microcapsules embedded in textile structures, Woodhead Publishing, 2016, Pages 89-114, ISBN 9780081005743, doi: 10.1016/B978-0-08-100574-3.00005-9.
3. Giordana Salvi de Souza, Dimitri B.A. Mantovani, PASCALLE Mossel, Bartholomeus C.M. Haarman, Ana Maria Marques da Silva, Hendrikus H. Boersma, Cristiane R.G. Furini, Adriaan A. Lammertsma, Charalampos Tsoumpas, Gert Luurtsema. Oral administration of PET tracers: Current status. *Journal of Controlled Release*. Volume 357, 2023. Pages 591-605. ISSN 0168-3659, doi: 10.1016/j.jconrel.2023.04.008.
4. Ren S, Xu Y, Dong X, Mu Q, Chen X, Yu Y, Su G. Nanotechnology-empowered combination therapy for rheumatoid arthritis: principles, strategies, and challenges. *J Nanobiotechnology*. 2024 Jul 22;22(1):431. doi: 10.1186/s12951-024-02670-7. PMID: 39034407; PMCID: PMC11265020.
5. Wulf K, Goblet M, Raggl S, Teske M, Eickner T, Lenarz T, Grabow N, Paasche G. PLLA Coating of Active Implants for Dual Drug Release. *Molecules*. 2022 Feb 19;27(4):1417. doi: 10.3390/molecules27041417. PMID: 35209205; PMCID: PMC8875406.
6. Doggwiler V, Lanz M, Paredes V, Lipps G, Imanidis G. Tablet formulation with dual control concept for efficient colonic drug delivery. *Int J Pharm*. 2023;631:122499.
7. Gaikwad, S.S., Kshirsagar, S.J. Review on Tablet in Tablet techniques. *Beni-Suef Univ J Basic Appl Sci* 9, 1 (2020). doi: 10.1186/s43088-019-0027-7
8. Rahamatullah Shaikh, Dónal P. O'Brien, Denise M. Croker, Gavin M. Walker, The development of a pharmaceutical oral solid dosage forms, Elsevier, Volume 41, 2018, Pages 27-65, ISSN 1570-7946, ISBN 9780444639639, doi: 10.1016/B978-0-444-63963-9.00002-6.
9. Salawi A. Pharmaceutical Coating and Its Different Approaches, a Review. *Polymers (Basel)*. 2022 Aug 15;14(16):3318. doi: 10.3390/polym14163318. PMID: 36015575; PMCID: PMC9415771.
10. Moutaharrik S, Maroni A, Neut C, Dubuquoy C, Dubuquoy L, Foppoli A, Cerea M, Palugan L, Siepmann F, Siepmann J, Gazzaniga A. In vitro and in vivo evaluation of a pH-, microbiota- and time-based oral delivery platform for colonic release. *Eur J Pharm Biopharm*. 2023 Feb;183:13-23. doi: 10.1016/j.ejpb.2022.12.013. Epub 2022 Dec 20. PMID: 36563887.
11. Li Huang, Xue-Hua Huang, Xi Yang, Jia-Qin Hu, Yi-Zhun Zhu, Pei-Yu Yan, Ying Xie, Novel nano-drug delivery system for natural products and their application, *Pharmacological Research*, Volume 201, 2024, 107100, ISSN 1043-6618, <https://doi.org/10.1016/j.phrs.2024.107100>.
12. Liu F, Lizio R, Meier C, Petereit HU, Blakey P, Basit AW. A novel concept in enteric coating: a double-coating system providing rapid drug release in the proximal small intestine. *J Control Release*. 2009;133(2):119-24.
13. Marcos Luciano Bruschi, Strategies to Modify the Drug Release from Pharmaceutical Systems, Woodhead Publishing, 2015, Page 63-86, ISBN 9780081000922, doi: 10.1016/B978-0-08-100092-2.00005-9.
14. Adepu S, Ramakrishna S. Controlled Drug Delivery Systems: Current Status and Future Directions. *Molecules*. 2021 Sep 29;26(19):5905. doi: 10.3390/molecules26195905. PMID: 34641447; PMCID: PMC8512302.
15. Awesh K. Yadav, Keerti Jain. Novel Carrier Systems for Targeted and Controlled Drug Delivery. Springer Singapore. Edition Number 1, 2024. Page 2-15, ISBN 978-981-97-4969-0, doi: 10.1007/978-981-97-4970-6.

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