

Formulation, Development and Evaluation of Compressed-coated Tablet for the Treatment of Diabetes Mellitus

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Abstract

Introduction: Tablets are the most widely utilized solid dosage form for oral drug delivery due to their stability, convenience, and patient compliance. Among advanced drug delivery systems, modified release formulations have gained considerable attention for their ability to optimize therapeutic efficacy and reduce dosing frequency. Compression coating technology, a solvent-free and versatile approach, has emerged as an effective method for developing such systems. Compression-coated tablets, also known as tablet-in-tablet systems, consist of two distinct layers: an inner core and an outer coating. **Objective:** In the present study, a novel compression-coated tablet was designed wherein the inner core provides immediate drug release, while the outer layer is formulated to achieve extended release.

Material and Methods: The core tablet, prepared as a porous structure, ensures rapid drug release to provide an initial therapeutic effect. The formulation process involves precise positioning of the preformed core tablet within a die partially filled with coating material, followed by addition of the remaining coating powder and compression to form a uniform tablet. However, challenges such as core alignment and mechanical integrity must be carefully addressed during formulation. The developed formulation was evaluated for pre-compression and post-compression parameters, drug content uniformity, and in vitro drug release studies to assess its performance.

Results and Conclusion: The results demonstrate that the compression-coated tablet successfully achieves the desired drug release profile, making it a promising approach for combination therapy and controlled drug delivery applications.

Keywords: Tablet, Compression, Immediate release, Extended-release coating.

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Introduction

Oral drug delivery systems are the most preferred and widely utilized routes of drug administration due to their convenience, non-invasive nature, ease of self-administration, cost effectiveness, and high patient acceptance. Among various oral dosage forms, tablets are considered one of the most stable and convenient pharmaceutical formulations because of their accurate dosing, ease of handling, portability, and suitability for large-scale manufacturing. Tablets can be prepared in different forms such as immediate release, delayed release, sustained release, controlled release, chewable tablets, dispersible tablets, and modified release formulations depending upon therapeutic requirements.

Modified release drug delivery systems are specially designed formulations intended to modify the rate, site, or time of drug release in order to maintain optimum therapeutic drug concentration in the body for prolonged periods. These systems improve bioavailability, reduce dosing frequency, minimize plasma concentration fluctuations, and enhance patient compliance. Modified release systems include sustained release, controlled release, delayed release, extended release, and pulsatile drug delivery systems. Sustained release formulations release the drug slowly over an extended period, whereas controlled release systems maintain a constant drug release rate. Delayed

release systems provide a lag phase before drug release, while pulsatile systems release the drug rapidly after a predetermined lag time.

Among various modified release technologies, compression coating has emerged as a promising and versatile technique for designing advanced oral drug delivery systems. Compression-coated tablets, also known as tablet-in-tablet systems or press-coated tablets, consist of a pre-compressed inner core tablet completely surrounded by an outer coating layer by means of compression. In this technique, the coating layer is applied mechanically by compression rather than by conventional solvent-based coating methods.

Compression coating is considered a simple and efficient solvent-free coating technique. Since the process does not require organic solvents or aqueous coating solutions, it avoids problems associated with solvent toxicity, environmental hazards, hydrolytic degradation of drugs, and stability-related issues. Moreover, the method does not require sophisticated coating equipment, thereby reducing manufacturing complexity and production cost. Due to these advantages, compression coating technology has gained considerable attention in pharmaceutical formulation research and development.

Compression-coated tablets, also known as tablet-in-tablet systems, consist of an inner core surrounded by an outer coating layer, allowing for the separation of drug release profiles within a single dosage form. Compression coating is a tablet formulation approach in which a preformed inner core is completely surrounded by an outer coating layer. This outer coat acts as a barrier and controls the release of the drug from the core until the coating layer undergoes erosion, swelling, or dissolution, depending on its composition.

Compression coating technology offers several pharmaceutical advantages. It enables separation of chemically incompatible drugs within a single dosage form, protects moisture-sensitive drugs from environmental conditions, masks unpleasant taste and odour, minimizes gastric irritation, and improves overall stability of the formulation. Additionally, compression-coated systems are highly useful in achieving site-specific drug delivery, colon-targeted drug delivery, pulsatile drug release, and chronotherapeutic drug delivery.

Chronotherapeutic drug delivery systems are specifically designed to synchronize drug release with the biological rhythm of diseases. Certain diseases such as asthma, hypertension, arthritis, gastric ulcer, and diabetes mellitus exhibit circadian rhythm, where symptoms become more severe during specific times of the day. Compression-coated tablets are capable of providing a lag phase before drug release and are therefore considered suitable for chronotherapeutic applications.

In the present system, compression coating is utilized to achieve a drug release pattern, where the inner core is formulated for immediate release to provide rapid therapeutic action, while the outer coating is designed for extended release. This dual-release approach integrates the benefits of rapid drug release and sustained drug delivery into a single tablet formulation maintain drug levels over a prolonged period.^[1,2]

Materials and Method

Metformin HCL, Sitagliptin Phosphate, Sodium Starch Glycolate, Ethyl Cellulose, HPMC 50 cps, Dried starch, Lactose, Microcrystalline cellulose, Magnesium stearate.

Equipment

Electronic balance, punching machine, hardness tester, hot air oven, tablet dissolution and disintegration tester, UV spectrophotometer, and FT-IR spectrophotometer are among the tools utilized in the current study.

Drug: Metformin HCL and Sitagliptin Phosphate.

Determination of Absorption Maxima of Pure Drugs
Metformin Hydrochloride

The absorption maximum ($\lambda_{\max}$) of pure Metformin Hydrochloride was determined using a UV-Visible spectrophotometer (LABINDIA UV 3092 series). A suitable solution of Metformin Hydrochloride was prepared in phosphate buffer pH 6.8 and scanned over the wavelength

range of 200–400 nm. The spectrum obtained showed maximum absorbance at 233 nm.

Determination of Absorption Maxima of Pure Drugs Sitagliptin Phosphate

The absorption maximum ($\lambda_{\max}$) of pure Sitagliptin Phosphate was determined using a UV-Visible spectrophotometer (LABINDIA UV 3092 series). The drug solution was prepared in phosphate buffer pH 6.8 and scanned in the wavelength range of 200–400 nm. The spectrum exhibited maximum absorbance at 267 nm.^[4,5]

Calibration Curve of Metformin Hcl in Phosphate Buffer pH 6.8

Standard Stock Solution

Accurately weighed 10 mg of Metformin HCl was transferred into a 100 ml volumetric flask. The drug was dissolved in a small quantity of phosphate buffer pH 6.8 and the volume was made up to the mark with the same solvent to obtain a standard stock solution containing 100 $\mu\text{g/ml}$ of Metformin HCl.

Working Standard Solution

From the prepared stock solution, aliquots were pipetted out separately into different 10 ml volumetric flasks and the volume was adjusted up to the mark with phosphate buffer pH 6.8 to obtain concentrations of 5 $\mu\text{g/ml}$, 10 $\mu\text{g/ml}$, 15 $\mu\text{g/ml}$, 20 $\mu\text{g/ml}$ and 25 $\mu\text{g/ml}$, respectively.

The absorbance of the prepared solutions was measured at 233 nm using phosphate buffer pH 6.8 as blank, and the calibration curve was plotted.

Calibration Curve of Sitagliptin Phosphate in Phosphate Buffer 6.8pH

Preparation of Standard Stock Solution

Accurately weighed 10 mg of Sitagliptin Phosphate was transferred into a 100 ml volumetric flask. The drug was dissolved completely in phosphate buffer pH 6.8 and the final volume was adjusted to 100 ml with the same solvent to produce a standard stock solution of 100 $\mu\text{g/ml}$.

Working Standard Solution

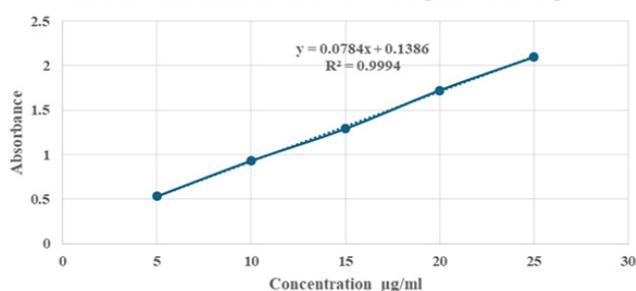
Aliquots were withdrawn from the stock solution and transferred separately into 10 ml volumetric flasks. The volume was then made up to the mark with phosphate buffer pH 6.8 to prepare working standard solutions having concentrations of 5 $\mu\text{g/ml}$, 10 $\mu\text{g/ml}$, 15 $\mu\text{g/ml}$, 20 $\mu\text{g/ml}$ and 25 $\mu\text{g/ml}$, respectively.^[6,7,8]

Wet granulation

Wet granulation is famous, complex but reliable method of granulation. Most drugs granulated by this method. It entails using a solvent to create a wet mass of drug and excipients, followed by drying and lubrication: excipients and drug are mixed together in a geometric progression pattern, and

Table 1: Concentration and Absorbance of Metformin HCL

Sr. No	Concentration (ppm)	Absorbance
1	5	0.532
2	10	0.932
3	15	1.291
4	20	1.724
5	25	2.097

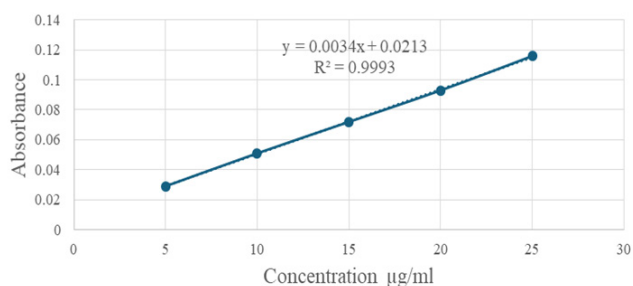
Calibration curve of Metformin HCL in Phosphate buffer 6.8 pH**Figure 1:** Calibration Curve of Metformin Hcl in Phosphate Buffer 6.8 Ph**Table 2:** Concentration and Absorbance of Sitagliptin Phosphate

Sr. No	Concentration (ppm)	Absorbance
1	5	0.029
2	10	0.051
3	15	0.072
4	20	0.093
5	25	0.116

combination is then wet massed with the adding of solvent. This wet mass is subsequently passed through the proper mesh size to get granules, which are then assessed and compressed to produce tablet. [9, 10]

Binder solution preparation

- Accurately weigh the required quantity of PVP.
- Transfer the weighed PVP into a clean beaker.
- Add Isopropyl Alcohol slowly with continuous stirring.

Calibration Curve of Sitagliptin Phosphate in Phosphate buffer pH 6.8**Figure 2:** Calibration Curve of Sitagliptin Phosphate in Phosphate Buffer 6.8 Ph**Figure 3:** Core Tablet

- Stir the solution until complete dissolution of PVP occurs.
- Continue stirring to obtain a clear and uniform binder solution.
- Use the prepared binder solution immediately for wet granulation process.

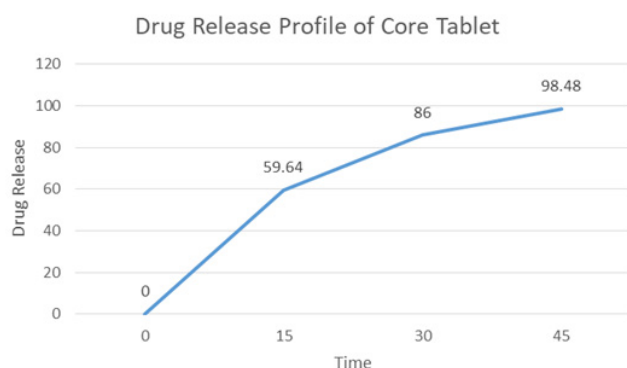
Three batches of core tablet formulations of Sitagliptin Phosphate were developed using the wet granulation technique. All the ingredients were separately sifted through sieve #30 to ensure uniformity in particle size. The weighed quantities of drug and excipients were mixed uniformly, while magnesium stearate was excluded from the initial blending process and incorporated later during lubrication. Wet

Table 3: Composition of Core Tablet

Sr. No	Ingredients	Mg/tablet			Function
		F1	F2	F3	
1	Sitagliptin Phosphate	50.00	50.00	50.00	API
2	Lactose Monohydrate	40.76	42.20	40.50	Diluent
3	Microcrystalline cellulose	42.00	40.00	40.50	Diluent
4	Sodium starch glycolate	6.75	5.00	6.50	Super disintegrant
5	Polyvinylpyrrolidone	4.50	6.75	7.00	Binder
6	Dried starch	4.50	4.55	4.00	Disintegrant
7	Magnesium stearate	1.50	1.50	1.50	Lubricant
Total		150.00	150.00	150.00	

Table 4: Composition of Outer Coat

Sr. No	Ingredients	Mg/Tablet				Function
		F1	F2	F3	F4	
1	Metformin HCL	500.00	500.00	500.00	500.00	API
2	Lactose Monohydrate	60.00	130.00	100.00	100.00	Diluent
3	Microcrystalline Cellulose	70.00	170.00	170.00	250.00	Diluent
4	Polyvinylpyrrolidone	10.00	70.00	70.00	10.00	Binder
5	Ethyl Cellulose	-	100.00	65.00	75.00	Extended Release Polymer
6	HPMC 50cps	250.00	-	65.00	25.00	Pore Forming Agent
7	Dried Starch	100.00	20.00	20.00	30.00	Disintegrant
8	Magnesium Stearate	10.00	10.00	10.00	10.00	Lubricant
		1000.00	1000.00	1000.00	1000.00	

**Figure 4:** Drug release of Core Tablet**Figure 5:** Compressed Coated Tablet**Table 5:** Granulometry of Blend (Core tablet)

Sr. No	Evaluation parameters	Results
1	Bulk density	0.96 g/cm ³
2	Tapped density	1.06 g/cm ³
3	Angle of Repose	27.68°
4	Carr's Index	9.00%
5	Hausner ratio	0.1%

Table 7: Dissolution of Core tablet

Time (Minutes)	Absorbance	% Drug Release
15	0.072	59.64
30	0.094	86.00
45	0.106	98.48

Table 8: Granulometry of blend (Outer Layer)

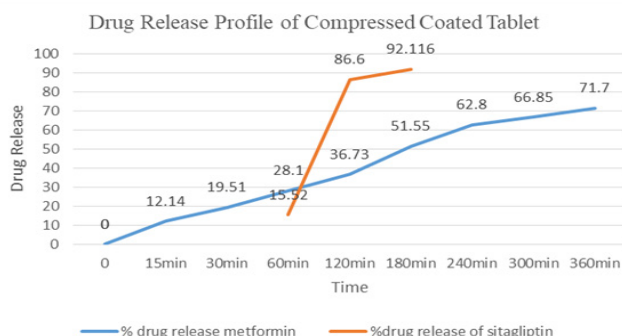
Sr. No	Evaluation parameters	Results
1	Bulk density	15.00g/cm ³
2	Tapped density	11.00 g/cm ³
3	Angle of Repose	23.2°
4	Carr's Index	9.2
5	Hausner ratio	1.5 %

Table 6: Physical Evaluation of Core Tablet

Sr. No	Evaluation parameters	F1	F2	F3
1	Appearance	White to off white round printed on both side	White to off white round printed on both side	White to off white round printed on both side
2	Diameter (mm)	7.14	7.14	7.14
3	Average Weight (mg)	144 ±5	145±5	145±5
4	Thickness (mm)	3.00-3.2	3.2-3.5	3.00-3.4
5	Hardness (kg/cm ²)	2-3 kg/cm ²	1.5-2.00	1.5-3.00
6	Disintegration Time (minutes)	2.00-4.00	1.5-2.5	1.00-3.00

Table 9: Physical Evaluation of outer layer tablet

Sr. No	Evaluation parameters	F1	F2	F3	F4
1.	Appearance	Pale orange to orange color oval shape bisect on both side	Pale orange to orange color oval shape bisect on both side	Pale orange to orange color oval shape bisect on both side	Pale orange to orange color oval shape bisect on both side
2.	Average Weight	1145±	1145±5	1145±5	1145±5
3.	Diameter (mm)	19.10	19.10	19.10	19.10
4.	Thickness (mm)	7.07-7.09	6.95-7.05	7.00-7.95	7.00-8.00
5.	Hardness (Kg/cm ²)	11-12	7-8	8-9	6-7

**Figure 6:** Drug Release of Compressed Coated Tablet

granulation was adopted to enhance the flow characteristics and compressibility of the powder blend, thereby facilitating uniform tablet formation.

- Accurately weighed Sitagliptin Phosphate and excipients were passed through sieve #30 separately.
- The sifted ingredients were blended uniformly except magnesium stearate.
- Binder solution of PVP in Isopropyl Alcohol was prepared separately.
- The binder solution was added slowly to the powder blend with continuous mixing to obtain a cohesive wet mass.
- The wet mass was passed through sieve #10 to prepare wet granules.
- The granules were dried in a hot air oven at 45 °C for 15 minutes.
- Dried granules were resized through sieve #30 to obtain uniform granules.
- Magnesium stearate, previously passed through sieve #60, was incorporated into the blend and mixed thoroughly to achieve proper lubrication.
- The lubricated granules were compressed into core tablets using tablet compression machine.^[11]

Manufacturing Steps of Compressed Coated Tablet

- The core tablet granules and outer coat granules were prepared separately by wet granulation method.
- The prepared core tablet granules were compressed using a tablet compression machine to obtain core tablets of desired weight and hardness.

Table 10: Drug release profile of Metformin HCL

Time (min)	Absorbance	% drug release
15	0.236	12.14
30	0.379	19.51
60	0.550	28.10
120	0.730	36.73
180	1.023	51.55
240	1.244	62.80
300	1.324	66.85
360	1.418	71.70

Table 11: Drug release profile of Core Tablet

Time	Absorbance	% Drug release
60min	0.032	15.52
120min	0.110	86.60
180min	0.126	92.16

- The prepared outer coat granules were used for compression coating of the core tablet.
- During the first stage of tablet-in-tablet compression, half quantity of the outer coat granules was introduced into the die cavity. The machine was rotated partially so that slight compression occurred, forming a small cavity or bed for placement of the core tablet.
- The machine was then rotated back carefully to its original position, and the prepared core tablet was placed accurately in the center of the cavity using forceps.
- The remaining quantity of outer coat granules was added into the die cavity so as to completely cover the core tablet.
- Finally, the compression cycle was completed using suitable compression force to obtain the compression-coated tablet in which the core tablet was completely enclosed within the outer coating layer.^[11]

Dissolution Method of Core Tablet

The in vitro dissolution study of the prepared core tablets was carried out using USP dissolution apparatus type II (paddle method). Dissolution study was performed in 900 ml of phosphate buffer pH 6.8 maintained at a temperature of 37 ± 0.5°C with paddle rotation speed of 100 rpm.

At predetermined time intervals of 15 min, 30 min, 45 min 10 ml samples were withdrawn and replaced with equal quantity of fresh dissolution medium maintained at the same temperature to maintain sink conditions.

The withdrawn samples were analyzed using UV-Visible spectrophotometer at respective λ_{max} values. The cumulative percentage drug release was calculated.^[13,14]

Result and Discussion

The percentage drug release of the prepared core tablets of Sitagliptin Phosphate was found to be within the acceptable range, indicating satisfactory release characteristics of the formulation. In vitro dissolution studies were performed using USP Dissolution Apparatus Type I (Basket method) in phosphate buffer pH 6.8 as the dissolution medium to evaluate the drug release profile of the formulated core tablet.

Dissolution Method of Compressed Coated Tablet

The in vitro dissolution study of the prepared compression-coated tablets was carried out using USP dissolution apparatus type II (paddle method). The dissolution study was performed in 900 ml of phosphate buffer pH 6.8 maintained at $37 \pm 0.5^\circ\text{C}$ with a paddle rotation speed of 100 rpm. At predetermined time intervals of 15 min, 30 min, 1 hr, 2 hr, 3 hr, 4 hr, 5 hr and 6 hr, 10 ml samples were withdrawn and replaced with equal quantity of fresh dissolution medium maintained at the same temperature to maintain sink conditions.

The withdrawn samples were analyzed using UV-Visible spectrophotometer at respective λ_{max} values. The cumulative percentage drug release was calculated.^[15,16]

Result and Discussion

The percentage drug release of the prepared compressed coated tablets was found to be within the acceptable limits, indicating satisfactory drug release characteristics of the formulation. In vitro dissolution studies of the compressed coated tablets containing Metformin HCl and Sitagliptin Phosphate were performed using USP Dissolution Apparatus Type I (Basket method) in phosphate buffer pH 6.8 as dissolution medium to evaluate the release profile of the developed tablet

Conclusion

The present study concluded that compressed coated tablets are a promising and effective drug delivery system for achieving controlled and modified drug release. The formulated tablet containing Metformin Hydrochloride and Sitagliptin Phosphate was successfully prepared and evaluated using compression coating technology. The formulation showed satisfactory pre-compression and post-compression parameters such as flow properties, hardness, friability, thickness, weight variation, and drug content within acceptable limits. The dissolution studies confirmed

that the formulation was capable of providing the desired release profile with sustained release characteristics. The use of suitable polymers in the coating layer helped in controlling drug release and maintaining tablet integrity for an extended period. The study also demonstrated that compression coating is a simple, solvent-free, and economical technique which improves patient compliance and provides flexibility in designing modified release dosage forms. Hence, compressed coated tablets can be considered a suitable approach for developing controlled, sustained, and pulsatile drug delivery systems for the effective management of chronic diseases like diabetes mellitus.

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