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Formulation Design and *In vitro* Evaluation of a Pitavastatin-containing Orodispersible Tablet as a Potential Cholesterol-lowering Remedy

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ABSTRACT

Orodispersible tablets ODT have been developed to resolve the issues of conventional oral formulations as well as to increase the bioavailability of the drugs. The focus of this research was to develop and evaluate the ODT using synthetic (croscarmellose sodium) or natural super-disintegrating agents for the fast release of pitavastatin. The natural super-disintegrating agent was isolated from the seeds of *Ocimum basilicum*, commonly known as sweet basil (SB). The SB mucilage (SBM) and croscarmellose sodium-containing formulations facilitate the disintegration of the tablets in less than 50 s. The pre- and post-compression parameters of the tablet prepared from these two agents are comparable and without any significant difference. The maximum drug was released from all the formulations within the standard time. The SEM images revealed the porous nature of the tablet surface. Results indicated that the SBM can be used as an alternative material to the synthetic material as an efficient super-disintegrating agent.

INTRODUCTION

Oral route and oral drug delivery systems (DDSs) offer many advantages over other routes and DDSs in terms of ease and accurate drug administration, safety, stability, economy, and easy manufacturing (Alqahtani et al., 2021). However, one major drawback associated with the oral DDSs is the low bioavailability. Many drugs are hydrophobic in nature, and the administration of such drugs through the oral route reduces the bioavailability, increases the onset of action, prolongs treatment strategies, and cost of therapy. To overcome such challenges, different strategies are being adopted, such as the development of nanoparticles, nanoemulsions, nanosuspensions, solid dispersion, orodispersible films (ODFs), tablets, mucoadhesive films, gastroretentive DDSs, etc. (Liang et al., 2001; Homayun et al., 2019; Feroze et al., 2025; Hassan et al., 2022). Among such DDSs, the orodispersible tablets (ODTs) and ODFs are mostly given preference due to easy administration, less choking hazards, acceptable in children and elderly patients, and eliminating the first pass effect. One of the main ingredients of the ODTs is the disintegrating agent, which facilitates the breakdown of the tablet and hence improves the solubility of the drug. Mostly synthetic or semisynthetic disintegrating agents are used in the marketed products. These materials can be toxic due to their non-biodegradable nature. However, naturally occurring biomaterials and especially polysaccharides are non-toxic, environmentally friendly, biodegradable, biocompatible, and economical. Recently, researchers have been focusing on the utilization of such materials in the development of different DDSs.

One of the most widely prescribed drugs to treat increased cholesterol levels is statins. Pitavastatin is used to manage hyperlipidemia and is ultimately helpful in the prevention of cardiovascular diseases. Pitavastatin belongs to the BCS class II drug, having low solubility. Different methods are adopted to increase the solubility as well as the bioavailability of this drug. Our current research aims to formulate an ODT of pitavastatin containing a natural or synthetic disintegrating agent. This research will also focus on the comparison between these two types of disintegrating agent and evaluate their efficiency and effectiveness. The croscarmellose sodium will be used as a

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synthetic disintegrating agent. The seeds of sweet basil (*Ocimum basilicum* L.) have been used for many centuries due to their many health benefits (Ahmad et al., 2015). The seeds of sweet basil (SB) extrude mucilage upon soaking in water, and the sweet basil mucilage (SBM) has been expressed in many applications in different DDSs (Amjad et al., 2025). The SBM has shown exceptionally high swelling ability, and we aim to use this property as a super-disintegrating agent in tablet formulation. The evaluation of the surface morphology of the tablet through scanning electron microscopy (SEM) will be the aim of this research work.

MATERIALS AND METHODS

Materials

The seeds of sweet basil (*Ocimum basilicum* L.) were purchased from the local market of Sargodha. Microcrystalline cellulose and talc were obtained from Sigma-Aldrich, Germany. Croscarmellose sodium, polyvinyl pyrrolidone, magnesium stearate, mannitol, and aspartame were acquired from Merck, Germany. Mint flavour (food grade) was obtained from the local market of Lahore. Pitavastatin is received as a gift from Genix Pharma (Pvt.) Ltd. Karachi. Distilled water was used in this research work.

Isolation of SBM

The SBM was isolated from the seeds following the already reported method with slight modification (Lodhi et al., 2020). Briefly, the seeds (100 g) of sweet basil were cleaned manually and soaked in distilled water (1 L) for 24 h. The soaked seeds were heated at 50 °C for 1 h to extrude a thick mucilage that adhered to the surface of the seeds. The mucilage was separated from the seed coat after pressing between two layers of nylon mesh and rubbing with the help of a stainless steel spatula. The isolated mucilage, i.e., SBM, was thoroughly and repeatedly washed with *n*-hexane and distilled water to remove lipophilic and hydrophilic impurities, respectively. The washed SBM was dried in a hot air oven at 60 °C for 48 h. The dried SBM was milled in a pestle and mortar and passed through a mesh. 40 to get uniform-sized powder. The SBM powder was kept in air air-tight container until further use.

Drug-Excipient Interaction Study

The compatibility of the drug with the excipients was assessed through Fourier transform infrared (FTIR) spectroscopy using the KBr pellet technique. A small amount of sample was mixed with potassium bromide in a pestle and mortar. The mixture was compressed under a hydraulic press to get a thin film of the sample. The film was dried at 50 °C for 30 min before being placed in a sample holder to get the FTIR spectrum using IR Prestige-21, Shimadzu, Japan. The sample was scanned between 4000-400 cm^{-1}. The FTIR spectra of the drug, excipients, and the formulation were recorded.

Formulation Development of ODT

Orodispersible tablet formulations were prepared using the wet granulation method with the help of the ingredients mentioned in Table 1. Six different formulations were prepared using different concentrations of SBM and croscarmellose sodium as a superdisintegrant. From each formulation, all ingredients except magnesium stearate and talcum were mixed in a pestle and mortar. An aqueous solution of polyvinyl pyrrolidone (2%, w/v) was prepared as a granulating agent and added small amount in the above mixture to get the damp mass. The damp mass was dried in a hot air oven at 60 °C for 6 h and then passed through a mesh no. 20 to get uniform-sized granules. The dried granules were lubricated with magnesium stearate and talcum, and kept in air air-tight container for further processing.

Table 1

Formulation Compositions of Different Orodispersible Tablets.

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Pitavastatin	2	2	2	2	2	2
Croscarmellose sodium	3	6	9			
SBM				3	6	9
Mannitol	20	20	20	20	20	20
Microcrystalline cellulose	156	153	150	156	153	150
Aspartame	2	2	2	2	2	2
Mint flavour	2	2	2	2	2	2
Magnesium stearate	10	10	10	10	10	10
Talcum	5	5	5	5	5	5
Total	200	200	200	200	200	200

Pre-Compression Parameters

The prepared granules were processed through pre-compression parameters, i.e., bulk density, tapped density, Carr's index, Hausner ratio, and angle of repose (Lachman et al., 1987).

Bulk Density

The bulk density (D_b) of the prepared granules was determined by taking a known weight (W_i) of the sample in a graduated cylinder and noting the volume, i.e, bulk volume (V_b). The bulk density of the granules was calculated using the following Eq. (1).

$$D_b = \frac{W_i}{V_b} \quad (1)$$

Tapped Density

The tapped density of the granules was determined after putting a weighed sample (W_i) of granules in a graduated cylinder. The cylinder was tapped on a hard surface to reduce the volume of the granules until no further decrease in the volume of the granules was observed. The tapped volume (V_t) was noted, and the tapped density (D_t) was calculated using Eq. (2).

$$D_t = \frac{W_i}{V_t} \quad (2)$$

Hausner Ratio

The values of the tapped and bulk density were used to determine the Hausner ratio using Eq. (3).

$$H_r = \frac{D_t}{D_b} \quad (3)$$

Carr's Index

Carr's index (C_i) or compressibility index was calculated to determine the compression ability of the granules. Carr's index is very useful to determine the strength of the granules and the binding ability of these granules in a tablet form. The Carr's index was determined using Eq. (4).

$$C_i = [1 - \frac{D_b}{D_t}] \times 100 \quad (4)$$

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Angle of Repose

Angle of repose (θ) is determined to find the flow ability of the granules. The angle of repose is calculated using the fixed funnel method. In this method, a funnel was adjusted in a tripod stand at a fixed height above a flat surface. The granules were passed through the funnel and made a heap on a flat surface. When the apex of the heap touched the tip of the funnel, the process of passing granules from the funnel was stopped. The funnel was removed and marked the boundary of the heap base. The radius (r) of the base of the heap and the height (h) of the heap were determined, and the angle of repose was calculated using Eq. (5).

$$Tan\ \theta = \frac{h}{r} \quad (5)$$

Compression of the ODT

The granules of all formulations were compressed using a single-punch machine fitted with flat surface punches having a diameter of 7 mm. The tablets were compressed at a hardness of 3-4 kg/cm^2. The compressed tablets of each formulation were kept in an air-tight jar and then evaluated through post-compression parameters.

Post-Compression Parameters

The tablets of all formulations were analysed through post-compression parameters to ascertain the quality of the tablets. Therefore, weight variation, thickness, diameter, hardness, friability, and content uniformity of the tablets of all formulations were determined (Lodhi et al., 2020).

Weight Variation

Randomly selected tablets from each formulation were weighed individually using a digital analytical balance, and the values of each tablet were recorded. The average weight and the standard deviation (SD) of the tablets of each formulation were recorded,

Thickness and Diameter

The thickness and the diameter of the tablets from each formulation were measured using a digital vernier calliper. The tablets were randomly selected, and the thickness and diameter of each tablet were measured. The average values were calculated for each formulation and reported along with SD.

Hardness

The hardness of the tablets was determined through a digital hardness tester. The tablets were selected randomly from each formulation and analysed through a hardness tester. The values of each tablet were noted, and the average value was calculated. The values of hardness were reported in kg/cm^2 with SD.

Friability

The friability (f) of the tablets was determined to assess the capability of a formulation to withstand the harsh transportation or shipment conditions. The friability of the tablets was determined through the friabilator. Randomly selected tablets from each formulation were allowed to rotate and fall from a specific height. Friabilator was operated at 25 rpm for 4 min. The weight of the tablets before (W_i) and after (W_f) 100 revolutions was determined, and the friability was calculated using Eq. (6).

The value of the friability was expressed in terms of percentage and reported as the average value with SD. The value of friability should be less than 1.

$$f = \frac{W_i - W_f}{W_i} \times 100 \quad (6)$$

Content Uniformity

The content uniformity of each formulation was determined by selecting the tablets randomly. The tablets from each formulation were crushed in a pestle and mortar, and the crushed material was dissolved in a suitable solvent. The mixture was placed in an orbital shaker to dissolve the drug. The mixture was filtered, and the filtrate was processed to determine the content of the drug, i.e., pitavastatin, using the calibration curve method.

Disintegration Test

All tablet formulations were processed through the evaluation of disintegration time. Six tablets from each formulation were taken in the vessels of the disintegration basket and allowed to disintegrate in distilled water maintained at 37 °C. The basket was moved up and down until each tablet in the vessel was converted into tiny fragments. The time taken by the tablets to convert into fragments was noted, and the average values were reported with SD.

Dissolution Study

The dissolution study of the tablets of each formulation was carried out in a USP dissolution apparatus II. The tablets were placed in the vessels of the dissolution apparatus filled with 900 mL of a buffer of pH 6.8. The dissolution study was performed at 37 °C, maintaining the rotation of the dissolution apparatus at 50 rpm. After predetermined time intervals, the aliquot was withdrawn from the dissolution vessels and the absorbance at 245 nm through a UV-vis spectrophotometer. The aliquot was filtered and suitably diluted with a buffer of pH 6.8 if required, just before the analysis through a UV-vis spectrophotometer. Freshly prepared buffer of pH 6.8 was added in the same amount that was withdrawn from the dissolution apparatus to maintain the sink condition. The concentration of the released drug from the tablets was determined through the standard calibration curve method.

Drug Release Mechanism

The release of the drug from tablet formulations was analysed through the Korysmeyer-Peppas model. The drug release data were put into Eq. (7) to determine the mechanism of drug release from the tablet at pH 6.8. The value of "n" determined the release mechanism calculated from the equation. The drug release followed the Fickian diffusion, non-Fickian diffusion, case-II transport, super case-II transport mechanism if the value of "n" is less than 0.45, between 0.45 to 0.89, 0.89, and greater than 0.89, respectively (Korsmeyer et al., 1983).

$$\frac{M_t}{M_\infty} = k_p t^n \quad (7)$$

SEM Analysis

The SEM analysis of the surface of the tablet was carried out to observe the surface morphology. The SEM images were captured using Zeiss Evo 21 after gold coating through a sputter coater Q 150.

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RESULTS

Isolation of SBM

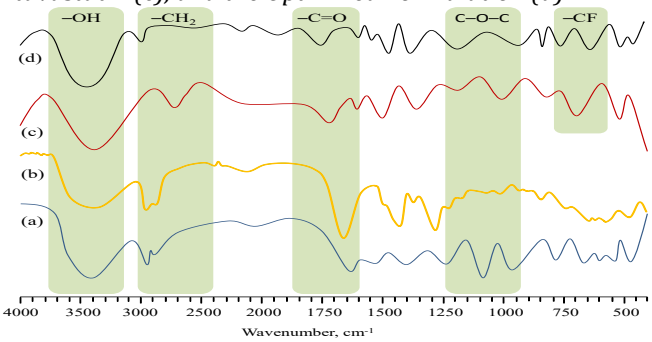
Isolation of the SBM was performed using the hot water extraction method, which resulted in maximum yield. The yield of the SBM is noted as approximately 5% w/w.

Drug-Excipient Interaction Study

The FTIR spectra of the drug, excipient, and the optimized formulation are shown in Figure 1. In the FTIR spectrum of the BSM, there are some characteristic peaks of –OH, C–O–C, and –CH_2 at 3410, 1052, and 2943 cm^{-1}. In the FTIR of the pitavastatin, the specific peaks appeared at 3390, 2963, 1735, and 745 cm^{-1} for –OH, –CH_2, C=O of carboxylic acid, and C–F, respectively. Similarly, the FTIR spectrum of croscarmellose sodium also indicates the important and characteristic peaks of –OH, C–O–C, and –CH_2 at specific points. The FTIR spectrum of the optimized formulation also shows the characteristic peaks of BSM and pitavastatin.

Figure 1

FTIR Spectra of BSM (a), Croscarmellose Sodium (b), Pitavastatin (c), and the Optimized Formulation (d).



Formulation Development of ODT

The ODT was prepared through the wet granulation method. All tablets were good in appearance without any imperfections, roughness, or brittleness.

Pre-Compression Parameters

The values of different parameters of the ODT formulations are depicted in Table 2. The value of the bulk density of all formulations ranges from 0.51 ± 0.09 to 0.62 ± 0.03 g/mL. The value of tapped density of all six formulations is found between 0.60 ± 0.07 and 0.69 ± 0.02 g/mL. Similarly, the values of Carr's index of formulations F1-F6 are found between 10.5 ± 0.2 and 15.8 ± 0.4 %. The values of the Hausner ratio are present between 1.11 ± 0.03 and 1.18 ± 0.04. The value of the angle of repose ranges from 22.5 ± 0.7 to 26.3 ± 0.8°.

Table 2

Pre-Compression Parameters of All Formulations.

Formulations	Bulk density (g/mL)	Tapped density (g/mL)	Carr's index (%)	Hausner ratio	Angle of repose (°)
F1	0.53±0.05	0.6±0.02	15.2±0.9	1.17±0.05	22.5±0.7
F2	0.51±0.09	0.60±0.07	15.8±0.4	1.18±0.04	24.7±0.7
F3	0.57±0.02	0.65±0.02	12.4±0.8	1.14±0.03	25.9±0.2
F4	0.54±0.06	0.62±0.04	13.3±0.5	1.15±0.04	24.6±0.4
F5	0.62±0.03	0.69±0.02	10.5±0.2	1.11±0.03	23.5±0.9
F6	0.58±0.02	0.66±0.03	12.1±0.5	1.14±0.04	26.3±0.8

Compression of the ODT

The prepared and lubricated granules of all formulations were compressed through a single-punch machine that resulted in a smooth surface and flat-faced tablets.

Post-Compression Parameters

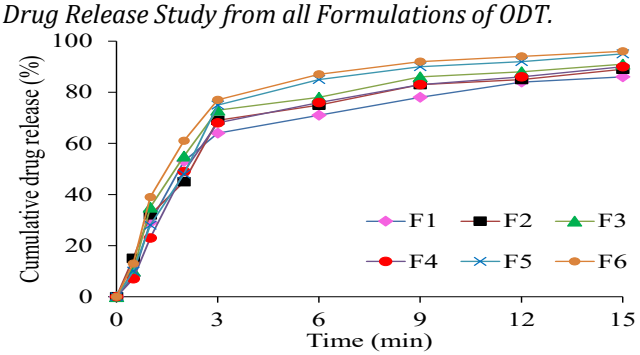
Table 3 depicts the result of various post-compression parameters. The average values of the weight of the tablets of all formulations are in the range from 198.8 ± 0.2 to 201 ± 0.5 mg. The value of the thickness of the tablet of all formulations is ranged between 5.2 ± 0.03 and 5.4 ± 0.04 mg. The diameter of all the tablets is approximately 7 mm without any significant difference. The hardness of all tablets is found in the range from 3.22 ± 0.02 to 3.30 ± 0.04 kg/cm^2. The values of the friability of the tablets of all formulations are found between 0.7 ± 0.02 and 0.9 ± 0.02%. The content uniformity of all formulations ranges from 97.5 ± 4.1 to 102.5 ± 3.3%. The value of the disintegration time of all tablets is present between 39 ± 2 and 43 ± 3 s.

Table 3. Post-compression parameters of all formulations.

Formulations	Weight (mg)	Thickness (mm)	Diameter (mm)	Hardness (kg/cm^2)	Friability (%)	Content uniformity (%)	Disintegration time (s)
F1	199.5 ± 0.2	5.2 ± 0.03	7.1 ± 0.01	3.25 ± 0.05	0.9 ± 0.02	99.5 ± 3.5	41 ± 4
F2	200.2 ± 0.4	5.3 ± 0.02	7.0 ± 0.01	3.28 ± 0.02	0.8 ± 0.03	99.7 ± 4.3	40 ± 4
F3	198.8 ± 0.2	5.2 ± 0.04	7.0 ± 0.01	3.22 ± 0.02	0.7 ± 0.02	99.9 ± 2.2	39 ± 2
F4	201.0 ± 0.5	5.3 ± 0.03	7.1 ± 0.01	3.30 ± 0.04	0.9 ± 0.02	102.5 ± 3.3	43 ± 3
F5	199.9 ± 0.2	5.4 ± 0.02	7.0 ± 0.01	3.26 ± 0.02	0.9 ± 0.02	97.5 ± 4.1	42 ± 5
F6	200.8 ± 0.5	5.4 ± 0.04	7.0 ± 0.01	3.29 ± 0.03	0.9 ± 0.02	99.6 ± 2.5	41 ± 3

Figure 2

Drug Release Study from all Formulations of ODT.



Dissolution study

The results of the dissolution study of the tablets of each formulation are represented in Figure 2. The maximum drug (> 85%) was released from all tablet formulations within 15 min. Moreover, the first 60% drug from all formulations was released in 3 min.

Drug release mechanism

The drug release mechanism was determined from the data of drug release, and the results are expressed in Table 4. The values of *n* calculated from the Korsmeyer-Peppas model ranged from 0.331 to 0.402.

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Table 4

Mathematical Data of the Korsmeyer-Peppas Model.

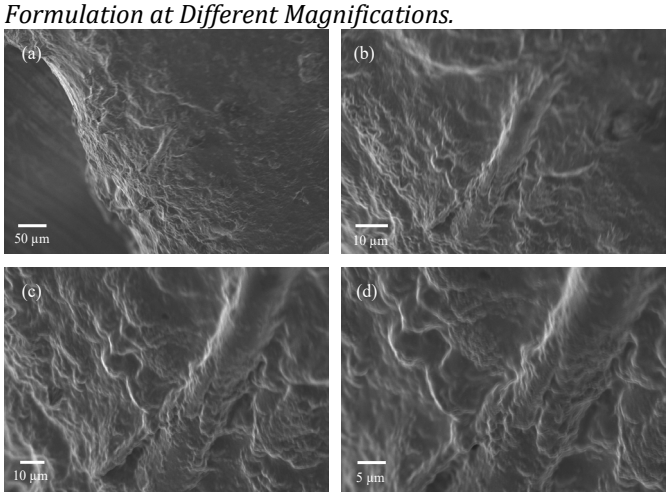
Parameters	F1	F2	F3	F4	F5	F6
K_{kp}	34.168	36.113	38.725	32.980	36.651	43.048
R^2	0.8742	0.8997	0.8553	0.8684	0.8631	0.8526
n	0.369	0.360	0.347	0.402	0.388	0.331

SEM Analysis

The SEM images of the surface of the tablet indicate the porous structure of the tablet. Figure 3 represents the SEM image of the surface of the optimized formulation of the tablet.

Figure 3

SEM Images of the Surface of the Tablet of Optimized Formulation at Different Magnifications.



DISCUSSION

The SBM was isolated using the most widely used hot water extraction method. In literature, the maximum yield of the mucilage or polysaccharide from the seeds of different plants is reported using the hot water extraction method. The extraction yield depends on the temperature of the water, soaking time, pH of the water, and seed/water ratio (Ali et al., 2022). When the seeds were soaked in the water, the microscopic pores on the surface of the seed coat allowed the water to penetrate. The polysaccharide presents in the seed coat swells after absorbing water and extrudes out of the seeds, which are collected. After drying, the water evaporated, and the pure SBM was obtained. The compatibility of all the ingredients of a formulation is ascertained through the appearance of characteristic peaks in the optimized formulation (Figure 1).

All tablet formulations were prepared using the wet granulation method, which resulted in a good tablet both in appearance and in physico-mechanical properties. The pre- and post-compression parameters are within the standard ranges (Lachman et al., 1987). The values of the Carr's index and Hausner ratio for good flow ability are between 10-15% and 1.12-1.18, respectively (Table 2). The values of the angle of repose for excellent and good flow ability are less than 25° and between 25-30°, respectively. The values of all these parameters of the tablets of all six formulations are matched with the good or excellent categories that express a good formulation design and composition of the excipients.

The post-compression parameters of the tablet formulations also indicate that the tablets follow the standard ranges. The values of hardness, weight variation, friability, content uniformity, disintegration time, diameter, and thickness of the tablet of all formulations are within the specific values of the official compendia. Moreover, there is no statistically significant difference was observed between the values of different parameters. The dissolution of all tablet formulations was completed in less than 15 min, and in all formulations, the 65% drug was released within 3 min. Such values are comparable with the values reported in the literature related to orodispersible DDSs (Sheikh et al., 2021). The drug release mechanism follows the Fickian diffusion as the value of *n* is less than 0.45. This low value, calculated from the Korysmeyer-Peppas model, indicates that the drug is released through the diffusion process from the tablet formulation (Ritger et al., 1987). The SEM images revealed the presence of microscopic pores on the surface of the tablet. Such a porous structure facilitates the entrance of dissolution media into the tablet and diffusion of the drug out of the tablet for fast release.

CONCLUSION

The ODT has been developed to solve the issues related to the conventional tablet dosage form. The ODT containing pitavastatin was prepared using two different disintegrants, i.e., synthetic (croscarmellose sodium) and natural (SBM), in different concentrations. All formulations exhibit good physico-chemical and mechanical properties. The drug release from all formulations is within the standard time duration. The comparison of the release of the drug from these tablets proved that the efficiency of both disintegrants is comparable, and no significant difference was observed in the disintegration time of the tablets of both formulations. Therefore, SBM, being a naturally occurring material, can be used as an alternative superdisintegrant to the marketed synthetic and semisynthetic materials. However, the efficiency of this novel superdisintegrant should be evaluated through an in vivo drug release study in animal models.

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