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Research Paper

Potential Use of Cashew Apple (*Anacardium occidentale* L.) Powder as a Pharmaceutical Diluent in Simvastatin Tablets

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Abstract
This research aimed to create cashew apple powder (CAP) for use as a pharmaceutical diluent in tablet formulations and evaluate its suitability with simvastatin as a model drug. CAP was produced by grinding followed by milling for size reduction. CAP was incorporated as a diluent in simvastatin 20 mg tablets formulated using wet granulation and direct compression methods. CAP had light brown irregular particles. The median particle size (D_{50}) was 282 ± 32 µm. True density was 1.408 g/cm³, bulk density was 0.405 g/cm^3, and tapped density was 0.489 g/cm^3. CAP had good flow properties and significantly better compaction properties than lactose monohydrate. There was no interaction between simvastatin and CAP based on FTIR and DSC analyses. Physical evaluation of the tablets prepared by the wet granulation method showed that hardness was 6.2 ± 0.6 kgf, disintegration time was 2.50 ± 0.75 minutes, % friability was 0.65% and assay simvastatin content was 101.22 ± 0.24 % LA. In the same manner, the tablets produced by direct compression had a hardness of 4.1 ± 0.2 kgf, disintegration time value of 0.83 ± 0.20 minutes, friability of 0.86%, and an assay simvastatin content of 102.65 ± 1.03% LA. Simvastatin tablets incorporating CAP showed complete drug release in 15 minutes. After 3 months of storage, no significant changes were recorded in the physicochemical properties, other than a slight increase in hardness for the wet granulation tablets. This study indicates that CAP can be considered a promising pharmaceutical excipient for immediate-release tablet formulations, compatible with both wet granulation and direct compression methods.

Keywords
Cashew Apple, Diluent, Pharmaceutical Excipient, Simvastatin, Stability, Tablet

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1. INTRODUCTION

The cashew apple fruit (*Anacardium occidentale* L.) belongs to the family Anacardiaceae and genus Anacardium, as illustrated in Figure 1 (Akyereko et al., 2023; Vasconcelos et al., 2015). The cashew tree, found in South America and native to Brazil, is widely cultivated in tropical regions worldwide, including Southeast Asia, India, and Africa (Dansou et al., 2023; Offia-Olua and Onwubiko, 2015; Paiva et al., 2009). There are two components to the cashew fruit: the pseudo-fruit (cashew apple) and the true fruit (cashew nut). The cashew nuts are highly valued in the world market due to their economic importance and nutritional value. In contrast, cashew apples are still not fully utilized and are often discarded as agricultural waste despite their high nutritional value due to their bad taste and perishability (Akinwale, 2000; Akyereko et al., 2022; Aslam et al., 2024). This imbalance in utilization leads to significant post-harvest losses and presents an opportunity for value-added product development from cashew apple residues.

To minimize post-harvest and processing waste, cashew apples have been utilized in the development of various products, including cashew apple juice, jam, drink, and wine (Akyereko et al., 2023; Sucupira et al., 2020). The whole cashew is pri-

marily composed of water (81.3 – 87.80%) with a significant amount of carbohydrates (11.60%) and reducing sugar (8.4 – 10.6%) (Kannan et al., 2021; Walraven and Stark, 2024). The cashew apple pomace water contains 67 – 78.8% of water and 1.8 – 4.9% of protein, 13.9 – 19% of carbohydrates, and 2.5 – 7.7% of sugars (Walraven and Stark, 2024). The reducing sugar can be increased by up to 42.89% after the freeze-drying process (Rajkumar and Ganesan, 2021).

Currently, natural substances have been widely developed as pharmaceutical excipients, such as tablet binders from *Dictyophora indusiata* mucilage (Burapapadh et al., 2021), galactomannan from *Terminalia catappa* L. (Zebua et al., 2023), tablet diluents from soybean powder (Swami et al., 2010), glidants or fillers from locust bean gum (Hadinugroho, 2024), and disintegrants from starch-rich plant seed sources (Al-Hamdani et al., 2024). Exploring new functional ingredients, such as the underutilized cashew apples, is a promising strategy for adding value to agricultural materials and potentially discovering pharmaceutical ingredients with superior properties. In pharmaceutical tablet production, fillers or diluents are essential excipients used to increase tablet weight and enhance content uniformity, particularly for low-dose drugs. Commonly employed diluents include starches, sugars, and sugar alcohols such as corn starch, hydrolyzed or partially pregelatinized starch, lactose monohydrate, anhydrous lactose, sorbitol, xylitol, and mannitol (Rowe et al., 2009). Due to its high carbohydrate and reducing sugar content, cashew apples possess promising potential for development into cashew apple powder (CAP) for use as a tablet diluent in both wet granulation and direct compression processes. Key functional characteristics required for tablet diluents include compressibility, tabletability, and compactibility, which significantly influence the manufacturability and mechanical properties of the final tablet product. Moreover, good flowability is critical for excipients intended for direct compression applications (Ren et al., 2024).

Several studies have explored the conversion of cashew apple into powder, which has been applied to diverse food applications such as composite flour for baking (Offia-Olua and Onwubiko, 2015), pasta (Nguyen et al., 2023), cereals (Preethi et al., 2021), and food ingredients (Prakoso and Mubarok, 2021; Rajkumar and Ganesan, 2021). The physicochemical properties of CAP, particularly its swelling and water absorption indices, are critical when it is utilized as a pharmaceutical diluent. These parameters directly impact the disintegration and dissolution profiles of the resulting tablets, in a manner dependent on the proportion of CAP in the formulation. However, to date, no studies have reported on the application of CAP as a pharmaceutical excipient in tablet formulations, for either wet granulation or direct compression processes. Therefore, investigating the physicochemical and functional properties of CAP as a potential tablet diluent represents a novel and promising direction in pharmaceutical excipient research.

The objective of this study was to prepare CAP and evaluate its feasibility as a tablet diluent. Simvastatin was selected as the model drug due to its low dose (20 mg per tablet), which allows for a clear observation of the effects of the diluent. Additionally, simvastatin is a widely prescribed medication, making it a suitable candidate for this investigation.

2. EXPERIMENTAL SECTION

2.1 Materials

Simvastatin (pharmaceutical grade) was kindly provided by Assoc. Prof. Dr. Namon Hirun at Thammasat University, Thailand. The USP reference standard of simvastatin was purchased from Merck & Co., Inc. (NJ, USA). Lactose monohydrate, croscarmellose sodium, polyvinylpyrrolidone (PVP K30), sodium dodecyl sulphate, and magnesium stearate were obtained from S. Tong Chemicals (1985) Co., Ltd. (Bangkok, Thailand). Acetonitrile, glacial acetic acid and several chromatographic grade solvents and reagents were acquired from RCI Labscan Ltd. (Bangkok, Thailand).

Figure 1. A Photograph of a Cashew Tree (*Anacardium occidentale Linn*) Ilustrating the Morphology of Cashew Fruit, Which Comprises the Cashew Apple (False Fruit) and the Cashew Nut (True Fruit). This Image was taken by the Author in Hat Yai District, Songkhla Province, Southern Thailand

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2.2 Plant Materials

Ripe cashew apple fruits (*Anacardium occidentale* L.) exhibiting their characteristic red or yellow coloration were selectively harvested from Hat Yai District, Songkhla Province, and Thasala District, Nakhon Si Thammarat Province, southern Thailand using the traditional practices of Thai farmers (Figure 1). The collected fruits were initially soaked in a 0.5% sodium hypochlorite solution for 30 minutes, then rinsed thoroughly with tap water to remove dirt and washed several times with deionized water. After washing, the fruits were air-dried at room temperature for 24 hours before further experiments.

2.3 Preparation of CAP

Cashew apple fruits were sliced using a stainless steel knife to a thickness of 1.0 – 2.0 mm. The sliced cashew apples were manually pressed to remove the juice, and the remaining fibrous or solid residue (cashew apple pomace) was separated and collected. The obtained cashew apple pomace was homogenized using a blender (Electrolux UltimateTaste300, Thailand), followed by drying in a vacuum oven (Binder GmbH, Germany) at 60°C for 48 hours under a vacuum pressure of 5.0 bar. The dried cashew apple pomace was subsequently ground using a ball mill at a low speed for 5 minutes, and then sieved through a #16-mesh stainless steel sieve (1.19 mm aperture) to obtain CAP as well as ensure uniform particle size. The resulting sieved CAP was stored in polyethylene (PE) plastic bags, which were then placed inside sealed glass containers. A schematic diagram of the CAP preparation process is shown in Figure 2.

2.4 Characterization of Cashew Apple Fruit Powder

2.4.1 Moisture Content

The moisture content of CAP was determined using a moisture analyzer (model HR83, Mettler Toledo, Greifensee, Switzerland). Approximately 1 g of CAP sample was placed on an aluminum plate and dried at 105°C until a constant weight was achieved (Muenraya et al., 2024). All measurements were performed in triplicate, and the results were expressed as mean ± standard deviation (S.D.).

2.4.2 Particle Size Analysis

The particle size distribution of CAP was assessed using a sieve shaker analyzer (AS200, Retsch, Retsch-Allee, Germany). A 100 g sample was placed on the top stack of sieves arranged in descending mesh size (from #40 to #400), with the coarsest sieve on top. Sieving was performed at intensity level 5 for 5 minutes. After shaking, each sieve and the corresponding retained fraction were weighed individually. The particle size distributions were plotted as the percentage of mass retained versus sieve aperture (Muenraya et al., 2024). The median particle size diameter (D_{50}), mean particle size, and S.D. were calculated from these independent determinations.

2.4.3 True, Bulk, and Tapped Density

The true density of CAP was measured using a True Density Analyzer (AccuPyc II 1340, Micromeritics, USA). A precisely weighed sample was introduced into the instrument's sample chamber, and nitrogen gas was circulated through the chamber ten times to ensure accurate measurement of the displacement volume. The true density was determined by dividing the sample's mass by the volume of gas displaced.

CAP bulk and tapped densities were measured in accordance with USP 46 and general chapter <616> (United States Pharmacopeia (USP), 2024). For each determination, 100 g of precisely weighed CAP was placed into a 250 mL graduated measuring cylinder. The cylinder was mounted in a tapped density tester (Model ETD1020, Electrolab Instruments, Mumbai, India, or Pharma Test Model PT-TD, Hainburg, Germany). The initial volume of the powder in the cylinder, without tapping, was noted as the bulk volume. The sample mass was divided by the bulk volume to determine the bulk density. For tapped density, the cylinder was tapped 500 times, and the volume was recorded. If the difference in volume between the 500th and 1250th tap exceeded 2 mL, tapping was continued up to 1250 times or more until the difference between successive tapped volumes was ≤2 mL. The final volume obtained was recorded as the tapped volume. Tapped density was calculated by dividing the sample mass by the tapped volume.

2.4.4 Porosity

The porosity of CAP was determined by using a porosity analyzer (BET, ASAP 2460, Micromeritics, USA). Samples that had been precisely weighed were put in the sample holder and sealed tightly. To ensure precise surface area and porosity measurements, samples were degassed before analysis to eliminate any adsorbed impurities. The samples were then heated to 70°C for five hours, utilizing automated nitrogen gas loading and purging in order to perform adsorption and desorption measurements. The surface area, pore size, and pore volume of each formulation were ascertained using the adsorption and desorption isotherms produced by this procedure (Aekwattanaphol et al., 2024). The percentage of porosity was calculated using Equation 1.

$$\%\text{Porosity} = \frac{\text{Total area in pores}}{\text{BET Surface area}} \times 100 \quad (1)$$

2.4.5 Flow Properties

2.4.5.1 Angle of repose

The angle of repose of the CAP was determined using the fixed-funnel method. A funnel was mounted at a fixed height on a burette stand, and the CAP sample was allowed to flow through the funnel, forming a conical heap on graph paper. The height (h) and radius (r) of the powder cone were measured, and the angle of repose (θ) was calculated using Equations 2 and 3 (United States Pharmacopeia (USP), 2024).

$$\tan\theta = \frac{\text{Height of the heap formed (h)}}{\text{Radius of the heap (r)}} \quad (2)$$

$$\theta = \tan^{-1}\frac{h}{r} \quad (3)$$

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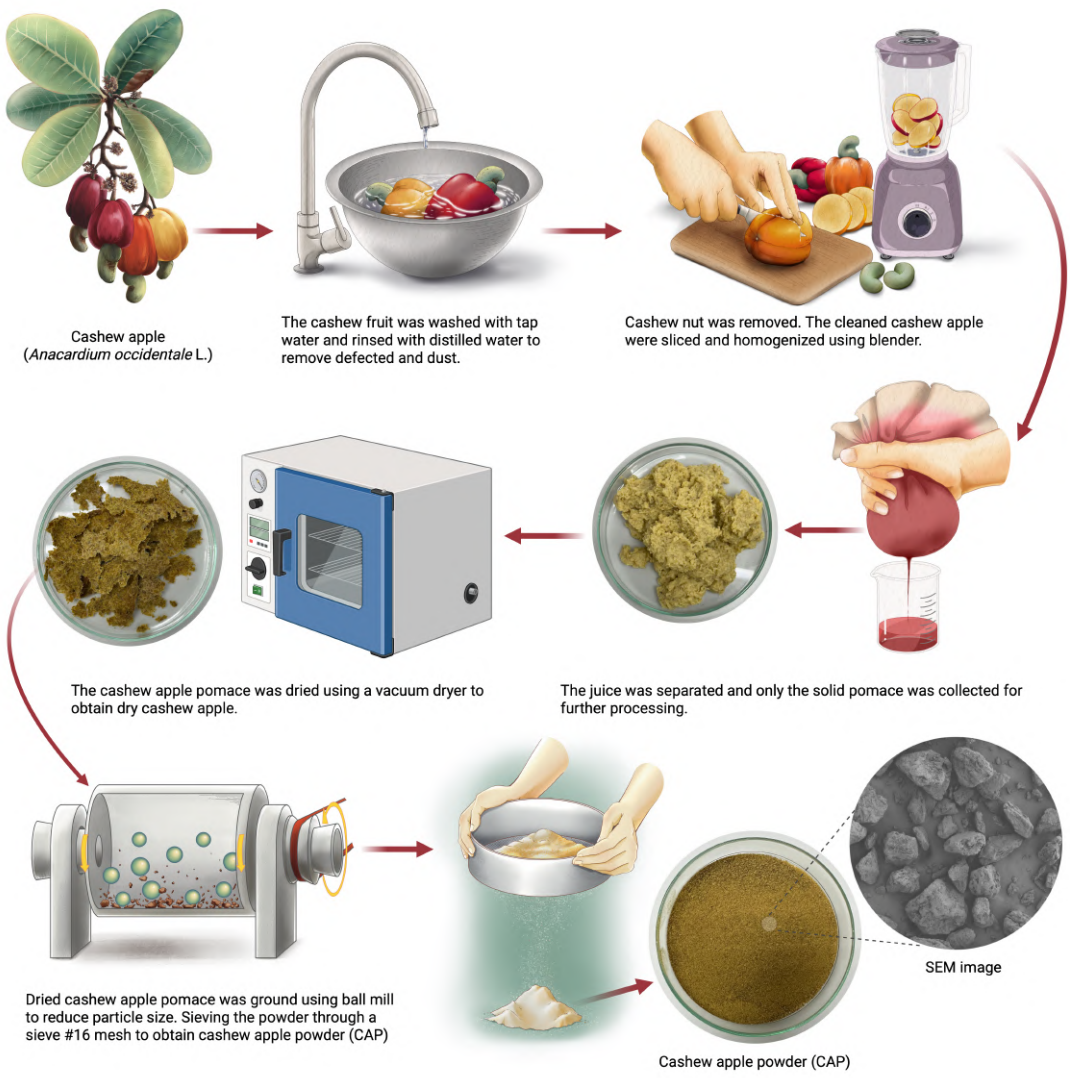

Figure 2. A Schematic Diagram Illustrating the Preparation Process for Cashew Apple Powder (CAP) made from Fresh Cashew Apples. The Process Includes Grinding and Drying with a Vacuum Oven, Followed by Particle Size Reduction with a Ball Mill. The Schematic Diagram was Made from www.biorender.com with a Publication License, and Some Parts of this Figure were Drawn by the Author

2.4.5.2 Compressibility Index

The compressibility index of CAP was calculated based on bulk density (ρ_{bulk}) and tapped density (ρ_{tapped}), as described in USP general chapter <1174> on powder flow (United States Pharmacopeia (USP), 2024). The compressibility index (CI) was determined using Equation 4:

$$\text{Compressibility index, CI} = \frac{\rho_{tapped} - \rho_{bulk}}{\rho_{tapped}} \times 100 \quad (4)$$

2.4.5.3 Hausner's Ratio

This Hausner's ratio of the CAP was calculated from tapped density (ρ_{tapped})) and bulk density (ρ_{bulk}) according to general chapter <1174> powder flow using the following Equation 5 (United States Pharmacopeia (USP), 2024).

$$\text{Hausner's Ratio} = \frac{\rho_{tapped}}{\rho_{bulk}} \quad (5)$$

2.4.6 Particle Morphology by SEM

The morphology of the CAP was evaluated utilizing a scanning electron microscope (Zeiss Merlin FEG-SEM; Carl Zeiss, Oberkochen, Germany). Using a carbon ribbon as an electron conductor, the sample was dried on glass. The surfaces of the samples were covered with gold spray using a sputter coater. SEM imaging was performed at magnifications of 60× and 500×. Particle size was analyzed from the SEM micrographs using ImageJ software (US NIH, Bethesda, MD, USA).

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2.4.7 Compaction Properties

Tabletability profile: To evaluate the tabletability profile of CAP, the powder was compressed into tablets weighing 200 mg using a hydraulic press for an IR disk (Press200, Panchum Scientific Corp., Kaohsiung, Taiwan) with different compaction forces of low, medium, and high. The resulting tablets were measured for their thickness using a Vernier caliper (Mitutoyo, Japan), while weight was measured using an analytical balance (Mettler Toledo, Switzerland), and breaking force was calculated using a Monsanto-type hardness tester (Diligent, Thailand). The tensile strength ($\bar{\sigma}_t$) of each tablet was calculated using the Fell and Newton Equation (Equation 6), where F is the breaking force (N), while D and T are the diameter and thickness (mm) of the tablets, respectively (Kumari et al., 2024; Fell and Newton, 1970; Yohannes and Abebe, 2021).

$$\sigma_t = \frac{2F}{\pi DT} \tag{6}$$

The compaction pressure was calculated by dividing the compression force (N) by the surface of the tablet face Equation (7).

$$\text{Compaction pressure} = \frac{\text{Force}}{\text{Area}} \tag{7}$$

Subsequently, a tabletability profile was plotted as tensile strength (MPa) against the corresponding compaction pressure (MPa) (Kumari et al., 2024; Fell and Newton, 1970; Yohannes and Abebe, 2021).

Compactibility profile: This parameter was evaluated to determine how readily CAP undergoes volume reduction upon compaction. This was assessed by plotting the solid fraction as a function of tensile strength.

To assess compactibility, the apparent density of the tablets was calculated by dividing tablet mass by the tablet volume (determined from the tablet diameter and thickness). The solid fraction was calculated from Equation 8 (Kumari et al., 2024; Fell and Newton, 1970; Yohannes and Abebe, 2021).

$$\text{Solid Fraction} = \frac{\text{Tablet density}}{\text{True density}} \tag{8}$$

Compressibility profile: This parameter assesses how readily the material undergoes a change in volume when compressed into tablet form. The CAP was compressed, and the solid fraction was plotted against compaction pressure to obtain the profile (Kumari et al., 2024; Fell and Newton, 1970; Yohannes and Abebe, 2021).

2.5 Preparation of Simvastatin Tablets

Simvastatin tablets were prepared at a laboratory scale with a batch size of 1000 tablets (equivalent to 200 g of powder blend) for each formulation. Two distinct manufacturing processes were employed, including wet granulation for formulation F1-F2, and direct compression for formulation F3-F4. Table 1 displays the details of the excipient list for formulations F1-F4.

For simvastatin tablets prepared by wet granulation (formulation F1–F2), all intragranular ingredients (simvastatin, lactose monohydrate, or cashew apple powder, and croscarmellose sodium) were sieved through a #18 mesh sieve (1 mm aperture) to reduce particle agglomerates and ensure uniform mixing with other excipients. The sieved powders were accurately weighed and then blended thoroughly in a polyethylene (PE) bag for 10 minutes. A binder solution of PVP K30 was gradually added to the powder blend to form a wet mass with a mortar and pestle. This wet mass was passed through a #12 mesh sieve (1.25 mm aperture) to produce wet granules, which were subsequently dried in a hot-air oven (FFD Binder, Tuttlingen, Germany) at 60°C for 45 minutes. The dried granules were passed through a #18 mesh sieve to eliminate any large aggregates. For the final blending step, extragranular excipients, including croscarmellose sodium, were mixed with the dried granules for 5 minutes. Finally, magnesium stearate (which was pre-sieved through a # 40 mesh sieve) was added and blended for an additional 3 minutes.

For simvastatin tablets prepared by the direct compression method (formulation F3–F4). All ingredients (simvastatin and excipients), except for the lubricant, were first sieved through a mesh #18 and subsequently blended in a PE bag for 10 minutes. Magnesium stearate, previously passed through a 40–mesh sieve, was then added to the powder blend and mixed for an additional 3 minutes.

The final lubricated mixtures from both wet granulation and direct compression were pressed into tablets. An electric single-punch tableting machine (Charatchai Machinery Ltd., Bangkok, Thailand) equipped with an 8 mm diameter flat surface punch was utilized for the compression of all formulations.

2.6 Evaluation of Granules and Powder Blended Properties

2.6.1 Moisture Content

The moisture content of the dried granules (F1–F2), the final lubricated granules (F1–F2), and the direct compression powder blends (F3–F4) was determined using a moisture analyzer (model HR83, Mettler Toledo, Greifensee, Switzerland).

2.6.2 Flow Properties of Granules and Powder Blended

The flow properties of all simvastatin formulations (F1–F4) were evaluated by measuring the angle of repose, compressibility index, and Hausner's ratio, in accordance with (Equations 1 – 5 described in (Section 2.4.5).

2.6.3 Fourier-Transform Infrared Spectroscopy (FTIR)

FTIR spectroscopy was used to examine drug-excipient compatibility with an FTIR spectrometer (Bruker Corporation, Bremen, Germany). The analysis was conducted on pure simvastatin and the final formulations (F1–F4). For sample preparation, each material was mixed with KBr and compressed to obtain thin KBr disc using a hydraulic press (Press200, Panchum Scientific Corp., Kaohsiung, Taiwan). The spectra were then recorded in the range of 4000 to 400 cm^{-1} with a resolution of 4 cm^{-1} using 16 scans per sample.

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Table 1. Composition of Immediate-Release Simvastatin Tablet Formulations Prepared using Cashew Apple Powder as a Filler via Wet Granulation (F2) and Direct Compression (F4) Processes. Lactose Monohydrate (F1) and Spray-Dried Lactose (F3) were used as Reference Fillers

Ingredients	Formulation Code (Amount in mg/tablet)				Functions
	Wet Granulation		Direct Compression		
	F1	F2	F3	F4	
Simvastation	20	20	20	20	API
Lactose monohydrate	128	–	–	–	Filler
Spray-dried lactose	–	–	138	–	Direct compression filler
Cashew apple powder	–	128	–	138	Filler
PVP K30	10	10	–	–	Binder
Purified water*	0.1 mL	0.1 mL	–	–	Granulating solvent
Croscarmellose sodium	40	40	40	40	Superdisintegrant
Magnesium stearate	2	2	2	2	Lubricant
Total weight	200	200	200	200	

*It will evaporate during the manufacturing process

2.6.4 Differential Scanning Calorimetry (DSC)

The thermal behavior of pure simvastatin and the final formulations (F1-F4) was investigated using a DSC instrument (DSC 800, Perkin Elmer Inc., USA). For each analysis, a sample of approximately 4–5 mg was accurately weighed, hermetically sealed in an aluminum pan, and then heated from 50 to 200°C at a constant rate of 10°C/min. The analysis was conducted under a flowing nitrogen atmosphere (flow rate: 20 mL/min).

2.7 Evaluation of Tablet Properties

2.7.1 Appearance and Dimension

The appearance of the simvastatin tablets (F1–F4) was visually assessed during the tableting process for shape, color, and surface defects. Tablet diameter was measured using a Vernier caliper (Mitutoyo, Japan). For each formulation, the measurements were performed on six randomly selected tablets, and the results were expressed as the mean ± S.D.

2.7.2 Average Weight

The average weight of each formulation (F1–F4) was determined by individually weighing 20 randomly selected tablets using an analytical balance, with the results expressed as the mean ± S.D.

2.7.3 Hardness (Breaking Force)

Tablet hardness was measured using a tablet hardness tester (Pharma Test Model PTB-31, Ser. No. I-4390/B). The breaking force was recorded in Newtons (N) or kgf, and the results were reported as the mean ± S.D. of three replicate measurements.

2.7.4 Disintegration Time

The disintegration time of the tablets was evaluated using a disintegration tester (Model ZT31, Erweka, Hessen, Germany) in accordance with USP pharmacopoeial standards (United States Pharmacopeia (USP), 2024). The apparatus comprised a basket-rack assembly, a 1000 mL low-form beaker containing the immersion medium, and a thermostatic system to maintain the temperature. One tablet was placed in each of the six tubes of the basket. The basket was repeatedly raised and lowered in distilled water maintained at 37 ± 2°C. The wire mesh at the base of each tube ensured complete immersion of the tablets. The test was conducted for up to 30 minutes. The time required for all six tablets to completely disintegrate was recorded, and the entire test was performed in triplicate.

2.7.5 Friability

The tablet sample was weighing approximately 6.5 g and delicately dusted, weighed, and thereafter positioned into the drum of a friability tester (Model TA 120, Erweka, Hessen, Germany). The drum was turned at 25 ± 1 rpm for 4 minutes. The tablets were reweighed, and the percentage of weight reduction was determined. Tablets must be free from cracks, cleavage, or breaking, and the total weight loss must not exceed 1% (United States Pharmacopeia (USP), 2024). All tested formulations were assessed in triplicate.

2.8 Assay Content of Simvastatin by HPLC

The assay of simvastatin content in the tablet formulations was performed using HPLC in accordance with the official monograph for simvastatin tablets by the United States Pharmacopoeia (United States Pharmacopeia (USP), 2024). Briefly, twenty tablets were accurately weighed and finely powdered. A portion of the powder equivalent to 100 mg of simvastatin was transferred into a 100 mL volumetric flask. The drug powder was dissolved in a mixture of acetonitrile and 0.05 M glacial acetic acid (pH 4.0), followed by sonication for 10 minutes and diluted to obtain a final concentration of 100 μg/mL. A standard stock solution of simvastatin was prepared by accurately weighing 10 mg of simvastatin reference standard into a 10 mL volumetric flask and diluting to volume with a mix-

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ture of acetonitrile and 0.05 M glacial acetic acid solution (pH 4.0) to obtain a concentration of 1,000 μg/mL. Appropriate aliquots of the simvastatin standard stock solution were diluted in volumetric flasks with the mobile phase to create a simvastatin concentration in the range of 20 – 500 μg/mL. Before injection into the HPLC system, both the standard simvastatin and sample solutions were filtered through a 0.45 μm nylon membrane filter.

The quantification of simvastatin was performed using a Dionex Ultimate 3000 HPLC system (Thermo Scientific, Germany), which was equipped with an inline degasser, a temperature control device, an auto-sampler, and a UV/VIS absorbance detector. The Chromeleon operating software was used during the study. A C18 column (250×4.6 mm, 5 μm particle size) was used as the stationary phase. The mobile phase consisted of a 65:35 (v/v) mixture of acetonitrile and phosphate buffer (pH 4.5). The flow rate was set at 1.5 mL/min, and the injection volume of both standards and samples was 10 μL. The column temperature was maintained at 45°C. Detection was carried out at a wavelength of 238 nm using a UV/VIS detector. The total run time for each analysis was 10 minutes.

2.9 Dissolution Profiles

The dissolution profile of simvastatin tablets was conducted using a USP Apparatus II (paddle method) dissolution tester (Varian, Vanke VK7010, CA, USA), in accordance with the United States Pharmacopeia (United States Pharmacopeia (USP), 2024). The test was performed in 900 mL of a phosphate buffer solution, pH 7.0, containing 0.5% sodium dodecyl sulphate as the dissolution medium. The medium was maintained at 37 ± 0.5°C with a paddle rotation speed of 50 rpm. One tablet was placed in each dissolution vessel. At predetermined time intervals (0, 2, 5, 10, 15, 20, 30, 45, and 60 minutes), 5 mL aliquots were withdrawn and immediately replaced with an equal volume of pre-warmed fresh dissolution medium to maintain a constant volume and temperature. A total of twelve replicates were employed in the experiment. The collected samples were filtered using a 0.45-μm membrane filter, and the concentration of simvastatin in each aliquot was assessed using the validated HPLC method described earlier, with UV detection at 238 nm. To compare the dissolution profiles between formulations, the difference factor (f_1) and similarity factor (f_2) were calculated using Equations 9 and 10, respectively, as per the standard mathematical modeling approach.

$$f_1 = \left[\left\{ \frac{\sum_{t=1}^{n} |R_t - T_t|}{\sum_{t=1}^{n} R_t} \right\} \times 100 \right] \quad (9)$$

$$f_2 = 50 \times \log \left[\left\{ 1 + \frac{1}{n} \sum_{t=1}^{n} (R_t - T_t)^2 \right\}^{-0.5} \right] \times 100 \quad (10)$$

where n is the number of sampling time points, Rt and Tt are the percentages of drug dissolved at time t for the reference formulation (F1 for wet granulation or F3 for direct compression) and the test product (F2 for wet granulation or F4 for direct compression), respectively. For curves to be regarded as similar, their (f_1) values should be close to 0, and their f2 values should be close to 100. Typically, (f_1) values ranging from 0 to 15 and (f_2) values greater than or equal to 50 indicate that the two dissolution profiles are essentially the same or equivalent (U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), 1997).

2.10 Stability Studies

The stability of the optimized simvastatin tablets was evaluated following ICH guidelines for climatic zone IVb. The tablets were packaged in Alu–PVC blisters sealed with aluminum foil to protect them from moisture and light, after which they were stored under both accelerated (40 ± 2°C and 75 ± 5% relative humidity (RH)) and long-term (30 ± 2°C and 75 ± 5% RH) conditions representative of the climate in Thailand (Ghimire et al., 2020; González-González et al., 2022; Kopp, 2006). For this study, samples were withdrawn for analysis at 1 and 3 months from both storage conditions. At each time point, the tablets were determined the physical appearance changed, hardness, disintegration time, and simvastatin content (expressed as a % of the labeled amount, %LA) to assess the stability of the product over time.

2.11 Statistical Analysis

All results are shown as the mean ± S.D. Statistical comparisons between the means of samples were performed using two-sample t-tests in Microsoft Excel, which was used to compare the means of samples and considered statistically significant when P-values < 0.05.

3. RESULTS AND DISCUSSION

3.1 Development of CAP

Cashew apple fruit has been successfully processed into powder using various drying techniques such as freeze-drying (Rajkumar and Ganesan, 2021), an air-drying oven (Lagnika et al., 2019), and spray drying of cashew apple juice (Pereira et al., 2014; Rafeekher et al., 2015). The resulting powders have been investigated for use in bakery products, cereal-based extrudates, functional foods (Offia-Olua and Onwubiko, 2015; Prakoso and Mubarok, 2021; Preethi et al., 2021; Rajkumar and Ganesan, 2021).However, the potential of CAP as a pharmaceutical excipient remains largely unexplored. Given the high carbohydrate and sugar content of the cashew apple (Kannan et al., 2021; Walraven and Stark, 2024), this study aimed to investigate the feasibility of using CAP as a novel pharmaceutical diluent in tablet formulations. The CAP used in this study was produced by the vacuum drying of cashew apple pomace, followed by size reduction with a ball mill. These steps were found to influence the physicochemical characteristics relevant to its performance as a pharmaceutical diluent.

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The physical appearance of CAP is shown in Figures 3a and 3b. The vacuum-dried cashew apple pomace, prior to milling, appeared as brown, porous, and lightweight sheets (Figure 3a). After milling, the material was transformed into a free-flowing, fine brown powder (Figure 3b). The final CAP was light brown to dark brown in color, which may be attributed to the Maillard reaction of reducing sugars present in the cashew apple (Walraven and Stark, 2024). Scanning electron microscopy (SEM) revealed that the CAP particles have a porous and fibrous structure with irregular shapes, which is a characteristic of the grinding-based method Figures (3c and 3d). Furthermore, the fibrous characteristics of cellulose were observable at a higher magnification of 500×, as in Figure (3d), consistent with literature reports on nanocellulose that can be prepared from the cashew apple (Araújo et al., 2024b,a). Particle size distribution analysis based on SEM images Figure 3e indicated an average particle size of 249 μm with a broad distribution.

The dark brown coloration of CAP is a significant drawback, however, as it gives them a less conventional and more herbal-like appearance. Consequently, further optimization of the manufacturing process is required to yield a lighter-colored (white or off-white) powder that improves consumer acceptability and meets pharmaceutical appearance standards.

Alternative drying techniques such as freeze drying have been reported to reduce non-enzymatic browning and preserve the light color of fruit-derived powders (Rajkumar and Ganesan, 2021). Spray drying is another method used for drying cashew apple fruit juices, but it will produce water-soluble compounds such as sugar (Moraes et al., 2024). Additionally, pre-treatment strategies such as blanching, pH adjustment, or antioxidant incorporation (e.g., ascorbic acid) may further minimize browning during drying (Ratti, 2001).

3.2 Micromeritics Evaluation of CAP and Tablet Granules

The micromeritics properties of CAP, and the simvastatin powder blends and granules are summarized in Table 2. The average moisture content of CAP was 1.65 ± 0.25%, falling within the acceptable range of 1.0–2.5% w/w for pharmaceutical excipients, which is considered optimal for maintaining flowability, preventing microbial growth, and supporting powder compaction without causing sticking or capping during tableting (Ryckaert et al., 2021; Çelik, 2016). However, excessively low moisture may result in soft or fragile tablets due to insufficient plasticity, while excessive moisture can cause problems such as picking or poor ejection during tableting (Chattoraj et al., 2018; Veronica et al., 2024). Additionally, residual moisture plays a role in the binding mechanism during granulation, where it contributes to the formation of liquid or solid bridges that influence particle adhesion and final tablet strength (Simons et al., 2005). Similarly, the moisture content of the simvastatin formulations (F1–F4) ranged between 1.5–2.0%. Although the ideal moisture content may vary depending on the formulation and manufacturing method, maintaining granule moisture within a 1.00 to 2.50 %w/w range is generally acceptable.

The particle size is a critical parameter influencing the flowability, compressibility, and moisture behavior of pharmaceutical powders. Smaller particles may lead to poor flow due to increased cohesion, while larger particles flow better but can cause segregation when mixed with finer materials (Çelik, 2016). Finer powders exhibit better plastic deformation under pressure, resulting a stronger tablets but with an increasing risk of capping, whereas coarser particles are better in die filling. Smaller particles tend to absorb more moisture, affecting stability and binder performance.

The particle size of CAP determined by sieve analysis showed a median (D_{50}) of 282 ± 32 μm and a mean particle size of 265 ± 23 μm. The close alignment of mean and median (D_{50}) particle sizes suggests a relatively symmetrical distribution of particle size. Furthermore, the particle size range of CAP was comparable to that of the other excipients in the formulation, which is important to minimize the risk of segregation during granule storage and handling (Deng et al., 2021). Notably, the median particle size of CAP (282 ± 32 μm) falls within the recommended range of 150-400 μm for excipients used in direct compression and wet granulation, which promotes good flowability, uniform mixing, and effective compaction (Çelik, 2016; Shah et al., 2008).

The porosity of CAP reflects the proportion of void space within the powder structure. Porosity significantly impacts tablet performance, including the dissolution rate, disintegration time, and mechanical strength. Generally, higher porosity facilitates liquid penetration, which can accelerate tablet disintegration and enhance drug dissolution and bioavailability. However, excessive porosity may compromise tablet hardness and increase friability. In contrast, lower porosity tends to improve mechanical strength and slow drug release (Teixeira et al., 2020). The porosity of CAP was found to be 71.20%, indicating a highly porous structure. High porosity can facilitate liquid penetration, potentially accelerating the dissolution medium to readily penetrate the powder structure. This characteristic is likely to be beneficial for the disintegration behavior of CAP-containing tablets.

The CAP prepared in this study exhibited a relatively low bulk density of 0.405 g/mL. This is different from the CAP preparation done by Offia-Olua and Onwubiko (2015), which involved several steps. It was oven-dried and milled with a blender to obtain wheat grains, then washed, dried, and milled to obtain whole wheat flour, which had a bulk density of 0.630 g/mL due to multiple size reductions. The high-density powder is suitable for preparation as whole wheat flour for baking. The larger, porous particles of CAP obtained in this work are considered suitable for application as a pharmaceutical diluent.

The formulated granules (F1-F2) and powder blend (F3–F4) were characterized for their micromeritic properties, with the results presented in Table 2. The appearance of the formulations was dependent on the diluent and manufacturing method. The lactose-based formulations (F1 and F3) were white, in contrast to the brownish appearance of the formulations F2 and F4, which was attributed to the natural color of the CAP (Figure 4). Formulations prepared via wet granulation (F1

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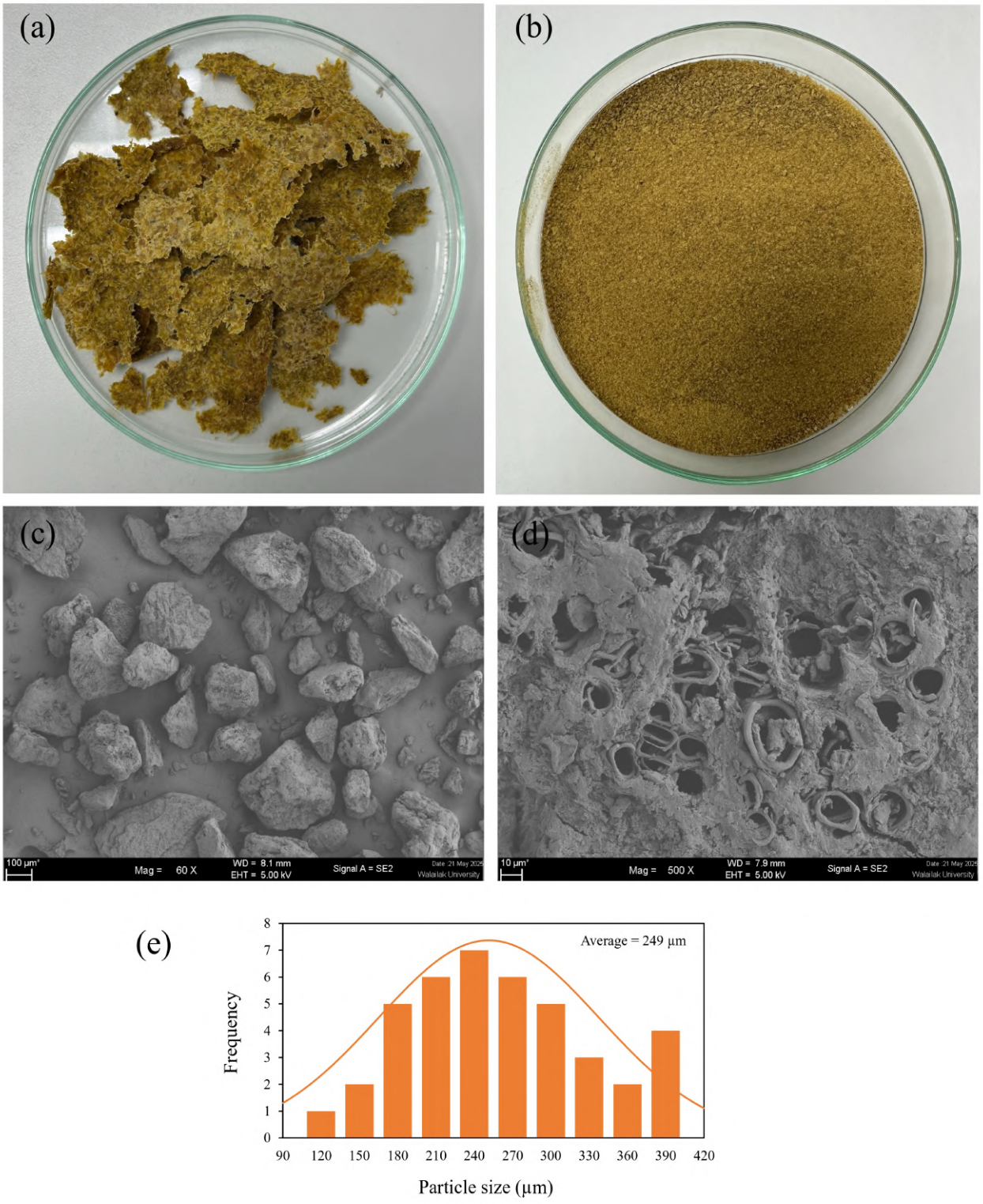

Figure 3. Appearance of Cashew Apple Fruit Powder (CAP) Obtained From the Grinding Process Followed by Ball Mill Reduction. The Appearance of Dried Cashew Apple Fruit After Vacuum Oven (a), and CAP After Particle Size Reduction with ball mill (b), SEM Images of CAP Showed Irregular Shapes with Porous Particles at a Magnitude of 60× and 500× (c and d, Respectively). The Histogram Shows the Particle Size Distribution of CAP as Determined From the SEM Image (e)

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Table 2. Micromeritic Results of Cashew Apple Pomace Powder (CAP) and the Simvastatin Granule and Powder Blend Formulations (mean ± S.D., n= 1 – 3)

Test	CAP	Simvastatin Granules and Powders			
		F1	F2	F3	F4
Moisture content (%)	1.65 ± 0.25	1.93 ± 0.43	1.87 ± 0.11	1.52 ± 0.23	1.66 ± 0.46
D_{50} (μm)	282 ± 32	–*	–*	–*	–*
True density (g/mL)	1.408	–*	–*	–*	–*
Tapped density (g/mL)	0.489	0.588	0.578	0.715	0.693
Bulk density (g/mL)	0.405	0.526	0.512	0.595	0.561
Porosity (%)	71.20	–*	–*	–*	–*
Angle of repose (°)	37.22	26.31	27.25	31.12	35.33
Compressibility index (%)	20.74	11.75	12.91	20.17	23.56
Hausner's ratio	1.21	1.12	1.13	1.20	1.23

* Not determined

and F2) consisted of visible agglomerated granules, whereas those prepared by direct compression (F3 and F4) retained a finer powder appearance Figure (4).

The flowability of CAP as a raw material and the formulated simvastatin granules or powder blend (F1–F4) was evaluated Table 2. CAP alone demonstrated fair flow properties, with an angle of repose of 37.22°, a compressibility index of 20.74%, and a Hausner's ratio of 1.21 (United States Pharmacopeia (USP), 2024). This is attributable to CAP characteristics such as fibrous morphology, high porosity, and irregular surface texture, which contribute to reduced flowability (Sinko, 2011).

Wet granulation is a common technique used to improve powder flow by increasing particle size (Vadaga et al., 2024). PVP K30, a commonly used binder, was incorporated into formulations F1 and F2 to facilitate wet granulation. During this process, an aqueous solution of PVP K30 initially forms temporary liquid bridges between powder particles. Upon drying, the solvent evaporates, causing the PVP K30 to solidify into a strong, polymeric bridge. These bridges are essential for strengthening the granules, improving their compressibility, and ensuring the final strength of the tablet. Both F1 (with lactose) and F2 (with CAP) exhibited markedly improved flow properties. The angle of repose values (26.31 for F1 and 27.25 for F2), compressibility index (11.75% and 12.91%), and Hausner's ratios (1.12 and 1.13) all fell within the range of excellent flowability. This suggests that the granulation process successfully transformed the free-flowing CAP into well-flowing granules. Importantly, the flow properties of the CAP-based formulation (F2) were comparable to the standard lactose-based formulation (F1).

In contrast, formulations prepared by direct compression exhibited lower flow performance. F3, containing spray-dried lactose specifically engineered for direct compression as the primary filler (69% w/w), displayed good flow, as reflected in

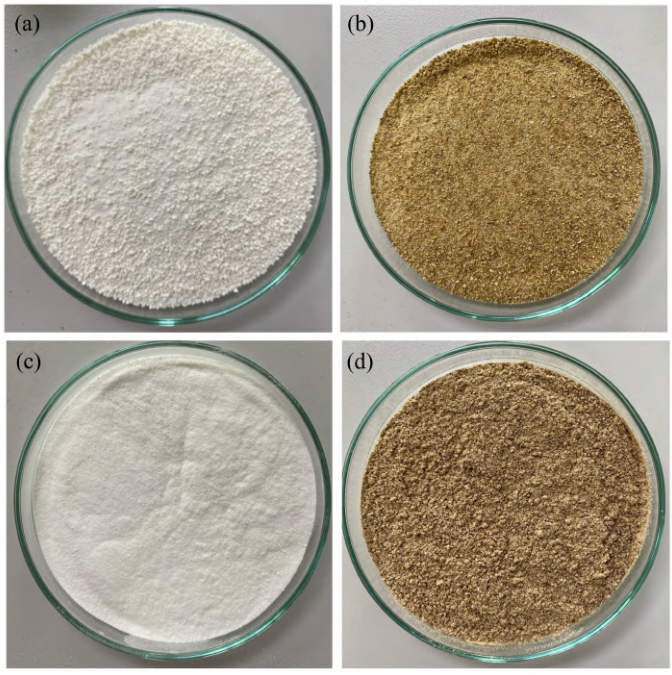

Figure 4. Appearance of Simvastatin 200 mg Granules Prepared by the Wet Granulation Process with Lactose Monohydrate Formulation F1 (a), Wet Granulation Process with Cashew Apple Powder (CAP) Formulation F2 (b), Appearance of Simvastatin 200 mg Powder Blend Prepared by the Direct Compression Process with Spray Dried Lactose Formulation F3 (c), Direct Compression Process with Cashew Apple Powder (CAP) Formulation F4 (d)

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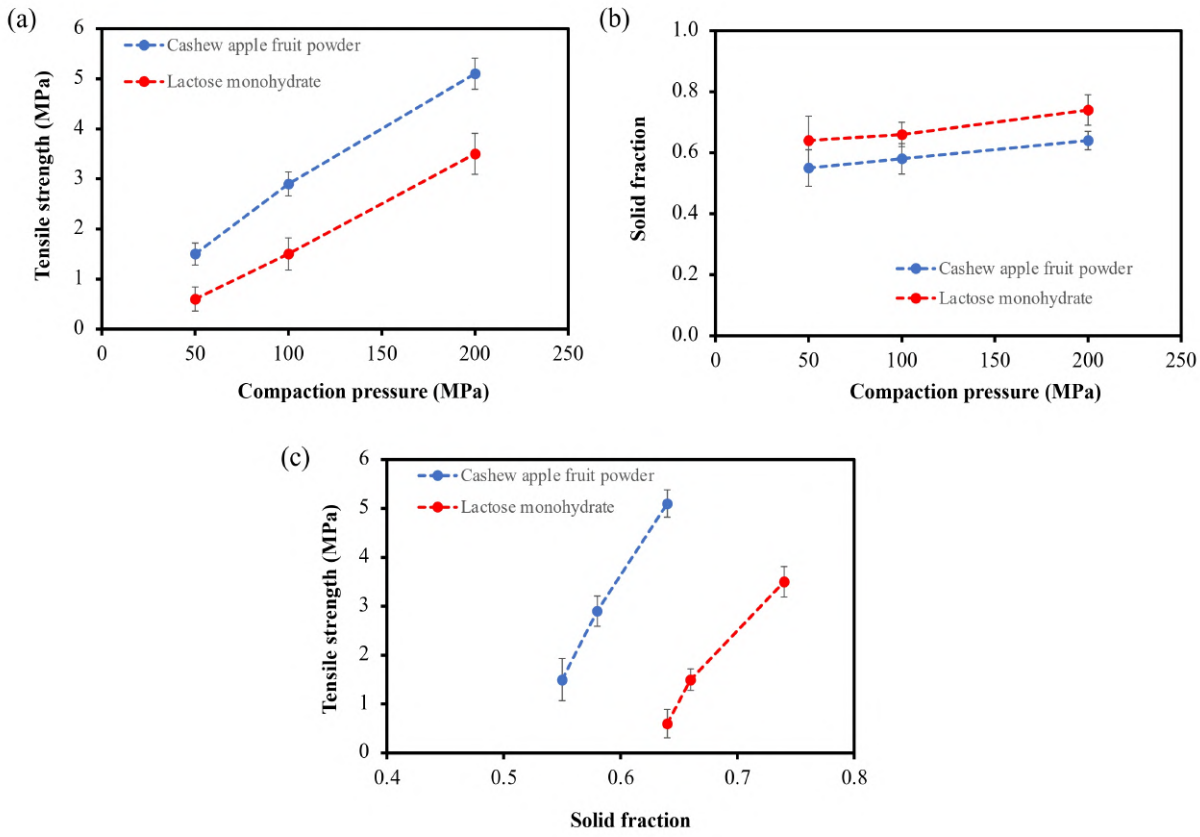

Figure 5. Tablet Compression Profiles of the Cashew Apple Powder (CAP) Compared with Lactose Monohydrate, Including Tabletability Profile (a), Compressibility Profile (b), and Compactibility Profile (c). Data Expressed in Mean ± S.D., n = 3

all flow parameters. In contrast, formulation F4, which used CAP as the primary filler, showed values for the angle of repose, compressibility index, and Hausner's ratio indicating poor flowability. This result confirms that the inherent fibrous and irregular characteristics of the CAP prepared in this study are unfavorable for the direct compression process.

3.3 Compaction Studies of CAP for Use as Tablet Excipients

The compaction profile of CAP is influenced by its micromeritic properties, including flowability, bulk density, tapped density, and true density. Tabletability, compressibility, and compactibility are three profiles that collectively describe the mechanical performance of powder during the tableting process and its ability to form robust tablets.

The tabletability profile of CAP compared with lactose monohydrate is illustrated in Figure 5a. Across the compaction pressure range of 50–200 MPa, CAP exhibited higher tensile strength than lactose monohydrate. This indicates that CAP possesses stronger tablet-forming properties, which may be attributed to its ability to undergo plastic deformation due to the presence of components such as starch, protein, fiber, pectin, and reducing sugars (Preethi et al., 2021; Rajkumar and Ganesan, 2021; Sucupira et al., 2020; Yapo and Koffi, 2013).

The compressibility profile of the materials describes the volume reduction of material during compression, represented by the relationship between compaction pressure and the solid fraction of the tablets Figure (5b). CAP showed a lower solid fraction at the equivalent pressure, suggesting a higher void volume than lactose monohydrate. This observation correlates with the lower density and more porous structure of CAP. In contrast, the lower compressibility of lactose monohydrate compared to CAP may be due to its higher particle density and lower powder void volume.

Compactibility refers to the ability of a powder to form a strong, solid compact when subjected to compression. The compactibility profile, which plots tensile strength versus solid fraction (Figure 5c), demonstrated that CAP achieved higher tensile strength than lactose monohydrate across comparable solid fractions. This property is closely related to the physical characteristics of the powder, including its compressibility, particle size and shape, flowability, bulk density, and surface properties. Understanding these characteristics is crucial for optimizing powder compaction processes, such as tablet manufacturing and formulation development (Leuenberger, 1982).

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3.4 Formulation Development of the Simvastatin Tablet by Using CAP

Simvastatin in 20 mg tablets were selected as a model drug to evaluate the performance of CAP as a novel pharmaceutical diluent in oral tablet formulations. Simvastatin is classified in BCS Class II due to its low solubility and high permeability (Mahboobian et al., 2022). For BCS Class II drugs, immediate-release formulations are desirable to facilitate rapid dissolution and absorption, thereby enhancing therapeutic efficacy. In this study, simvastatin tablets were prepared using both wet granulation and direct compression to assess the compatibility and performance of CAP in these standard manufacturing processes. Direct compression is suitable for active drugs with good flow and compaction properties, or for low-dose drugs when combined with well-engineered excipients that exhibit excellent flowability and compressibility. Thus, the purpose of this study was to assess CAP's qualities in tablet manufacturing utilizing both techniques. Compatibility was evaluated through chemical and thermal analyses using FTIR and DSC, respectively.

FTIR spectroscopy was employed to investigate the potential chemical interactions between simvastatin and the excipients Figure (6). The characteristic absorption peaks of simvastatin showed a strong peak at a wavenumber of 3550 cm^{-1}, representing the free –OH stretching vibration. Neighboring peaks at a wavenumber of 2968 cm^{-1} were attributed to methyl C–H stretching, while those at 2930 cm^{-1} indicated the ester and lactone (–COO–R), and those at 2872 cm^{-1} represented the aldehyde (–CO–R) functional group of the simvastatin structure. Notably, a prominent absorption band at a wavenumber of 1700 cm^{-1} is the –C=O stretching vibration of the ester and lactone, and a peak at 1268 cm^{-1} to the lactone –C–O–C stretching vibration. Furthermore, a distinct peak at 1055 cm^{-1} represents the C–O of a secondary alcohol stretching vibration (Pavia et al., 2001). The FTIR spectrum of simvastatin formulation F1–F4 showed complicated spectra due to the various excipients in the formulation. All the principal characteristic peaks of simvastatin were present and showed no obvious shift or disappearance. Although some C–H stretching peaks were obscured by spectral overlap, possibly due to the masking effect of a broad peak of –OH or an interaction at the methyl group with the excipients, either lactose or CAP. A summary of the spectral interpretation is provided in Table 3.

The DSC thermograms of pure simvastatin and the simvastatin formulations F1-F4 are presented in Figure 7. Pure simvastatin exhibited a sharp melting endothermic peak at approximately 142°C, which is consistent with the literature-reported melting point in the range of 139.5–140.5°C (Gu et al., 2018; Sopyan et al., 2024; SreeHarsha et al., 2019). In the formulations prepared by wet granulation (F1 and F2), the intensity of this peak was significantly reduced and slightly shifted to approximately 139°C. This change suggests a partial conversion of simvastatin from a crystalline to an amorphous or molecularly dispersed state, which is a result of the granulation process (Bhujbal et al., 2021).

Conversely, the direct compression formulations (F3 and F4) retained a distinct endothermic melting peak corresponding to simvastatin, although it was shifted to approximately 148°C. The slight shift in melting peak can be attributed to several factors, including non-isothermal heating conditions and the thermal dynamics of the heating process in the presence of the excipients in the formulation (Ghanbari et al., 2023).

Based on both FTIR and DSC analyses, the incorporation of CAP as a diluent did not induce any significant differences compared to lactose monohydrate in terms of the thermal behavior of chemical interactions in simvastatin. These findings strongly suggest that CAP does not adversely affect the stability of the active pharmaceutical ingredient and may serve as an alternative filler in tablet formulations.

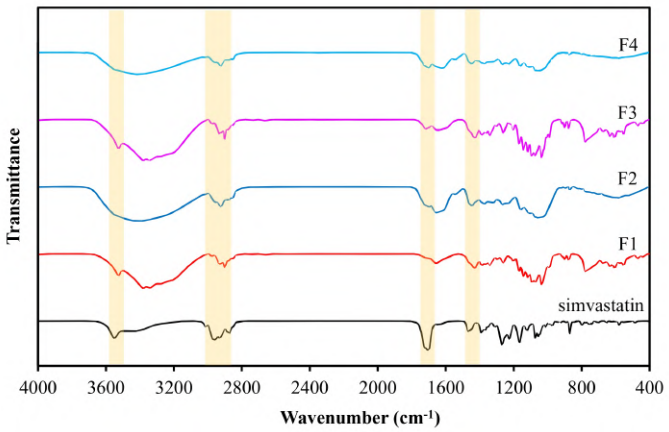

Figure 6. Fourier Transform Infrared Spectra of Simvastatin Raw Materials and Simvastatin Tablet Formulations (Formulation F1–F4)

3.5 Evaluation of the Physical Properties of Simvastatin Tablets

The physical properties of the simvastatin tablets (F1–F4) are summarized in Table 4. The most notable difference observed when using CAP as a pharmaceutical diluent (F2 and F4) was the tablet appearance, which ranged from light to dark brown. The brown color of the tablets is due to the high proportion of CAP (64–69%) in the formulation. Particularly, tablets prepared by wet granulation (F2) exhibited a darker brown color than those prepared by direct compression (F4), despite having a lower proportion of CAP (64%). This intensified browning may be due to the heat used during the drying process in wet granulation, which can accelerate Maillard reactions involving sugars and proteins naturally present in CAP. In addition, the water in the binder solution (wet granulation process) may increase the tablet hardness of CAP.

This coloration presents the main challenge for CAP's use, giving the tablets an "herbal-like" appearance that may affect patient acceptance and make it difficult to visually detect degradation during stability studies. However, this limitation can

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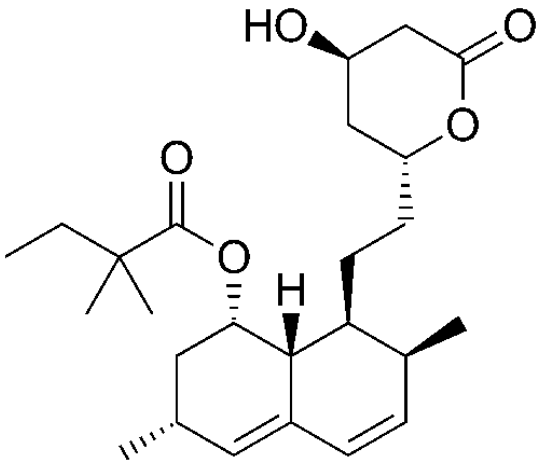
Table 3. FTIR Analysis Interpretation of Simvastatin and Simvastatin Formulation F1 – F4



Functional Group	Wavenumber (cm^{-1})				
	Simvastatin	F1	F2	F3	F4
Free –OH stretching	3550.48	3526.40	3411.88	3525.67	3415.71
Methyl C–H stretching	3011.89	2930.57	2922.79	2932.81	3013.06
Methyl C–H symmetric stretching	2968.32	2900.54	2853.93	2900.89	2923.72
–COO–R	2930.02	2930.57	2922.79	2932.81	2923.72
–CO–R	2872.76	2900.54	2853.93	2900.89	2853.45
Ester C=O stretching	1700.33	1656.75	1697.63	1717.66	1698.59
C–H bend	1390.29	1386.72	1372.05	1387.17	1371.96
Lactone –C–O–C stretching	1268.50	1261.25	1265.32	1260.88	1266.30
Secondary alcohol C–O stretching	1055.89	1072.77	1055.69	1035.90	1055.84

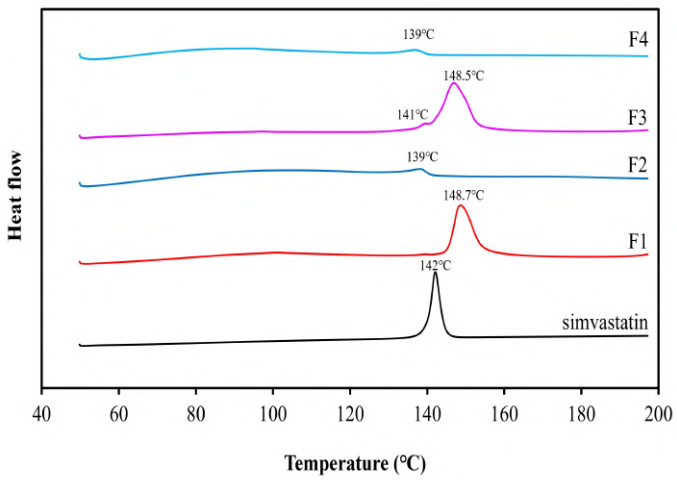


Figure 7. Differential Scanning Calorimetry (DSC) Thermograms of the Simvastatin Raw Materials and Simvastatin Formulation Tablets (F1–F4)

be addressed by applying appropriate colorants. The use of pharmaceutical-grade colorants is a widely accepted approach to enhance the visual appeal, mask undesirable natural hues, and improve product uniformity and consumer acceptance. In practice, colorants can be incorporated directly into the tablet core during powder blending or applied through film coating techniques. Commonly used agents such as titanium dioxide (white pigment) and iron oxide pigments (red, yellow, brown) are effective for masking uneven coloration from plant-derived excipients (Pérez-Ibarbia et al., 2016).

All formulations (F1–F4) had similar tablet dimensions in terms of diameter and thickness. The tablet diameter did not differ significantly ($P > 0.05$), as it is controlled by the die size. However, there was a significant difference in tablet thickness. Tablets containing lactose (F1 and F3) were found to be significantly thinner ($P < 0.05$) than those containing CAP (F2 and F4). Although CAP exhibited lower bulk and tapped density compared to lactose, tablets containing CAP (F2 and F4) were thicker than those containing lactose (F1 and F3). This may be attributed to the superior compactibility and plastic deformation behavior of CAP, allowing greater volume reduction during compression.

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Table 4. Physical Properties and Assay Content of Simvastatin Tablets (Data Expressed in Mean ± S.D.)

Test	Simvastatin Tablets			
	F1	F2	F3	F4
Appearance	Round, white, flat-faced tablet	Round, white to light brown color, flat-faced tablet	Round, white, flat-faced tablet	Round, white to light brown with brown spots, flat-faced tablet
				
Average weight (mg), *n*= 20	201.7 ± 2.5	202.2 ± 1.3	201.6 ± 2.1	206.2 ± 3.2
Diameter (mm), *n*= 10	8.00 ± 0.02	8.00 ± 0.01	8.00 ± 0.01	8.00 ± 0.01
Thickness (mm), *n*= 10	3.17 ± 0.15	3.24 ± 0.06	3.01 ± 0.04	3.52 ± 0.06
Hardness (kgf), *n*= 10	4.5 ± 0.3	6.2 ± 0.6	3.6 ± 0.5	4.1 ± 0.2
Disintegration time (min), *n*= 6	3.67 ± 0.25 (3 min 40 s ± 15 s)	2.50 ± 0.75 (2 min 30 s ± 45 s)	1.25 ± 0.33 (1 min 15 s ± 20 s)	0.83 ± 0.20 (0 min 50 s ± 12 s)
Friability (%), *n*= 1	0.13	0.65	0.41	0.86
Simvastatin content (% LA), *n*= 3	101.20 ± 0.50	101.22 ± 0.24	101.04 ± 2.20	102.65 ± 1.03

Table 5. Stability Data of Simvastatin Tablets Prepared by Cashew Apple Fruit Powder (Mean ± S.D., *n* = 6–20)

Formulation	Storage Condition	Time Interval	Weight (mg)	Hardness (kgf)	Disintegration Time (min)	Assay (%LA)
F2	Initial time	–	202.2 ± 1.3	6.2 ± 0.6	2.50 ± 0.75	101.22 ± 0.24
	30°C/75%RH	1 month	201.1 ± 0.2	6.5 ± 1.2	3.42 ± 0.50	–*
		3 months	200.2 ± 1.0	6.8 ± 0.5	4.12 ± 1.20	102.17 ± 0.23
	40°C/75%RH	1 month	201.1 ± 0.8	6.9 ± 0.7	5.30 ± 0.65	–*
		3 months	201.1 ± 0.4	7.4 ± 0.8	5.85 ± 1.22	99.56 ± 0.42
F4	Initial time	–	206.2 ± 3.2	4.1 ± 0.2	0.83 ± 0.20	102.65 ± 1.03
	30°C/75%RH	1 month	203.3 ± 2.1	4.2 ± 0.5	1.20 ± 0.25	–*
		3 months	201.2 ± 1.3	4.3 ± 0.8	1.05 ± 0.75	98.22 ± 1.86
	40°C/75%RH	1 month	205.1 ± 1.2	4.4 ± 0.3	1.00 ± 0.41	–*
		3 months	202.2 ± 0.8	4.2 ± 0.3	0.96 ± 0.23	100.33 ± 2.10

* Not determined in this interval

Interestingly, the disintegration times were shorter compared to their lactose–based formulation (F1 and F3), regardless of the method used, despite the higher hardness observed in CAP–based formulations (F2 and F4). This could be due to the multi-component nature of CAP, which contains naturally occurring disintegrant-like components such as fibers, sugars, and pectin, that facilitate water penetration and tablet breakup. However, these disintegrant-like components may contribute to reduced tablet robustness. However, rapidly disintegrating CAP base tablets may be affected as they possess a less cohesive internal structure, which may reduce their mechanical resistance to abrasion during friability testing. Nevertheless, the friability values for all formulations remained within the acceptable range of not exceeding 1% (United States Pharmacopeia

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(USP), 2024), indicating sufficient mechanical robustness. The assay for the drug content of simvastatin formulations was within the range of 101 – 102% of the labeled amount (LA), complying with the pharmacopoeial specification of 90 – 110% (United States Pharmacopeia (USP), 2024).

3.6 Dissolution Profiles of Simvastatin Tablets

Dissolution testing was performed by using a USP Apparatus II (paddle method). The dissolution medium used was a phosphate buffer solution, pH 7.0, containing 0.5% sodium dodecyl sulphate in accordance with the USP monograph for simvastatin tablets. This medium was used for testing as quality control and not for a bioequivalent test. Therefore, there was no need to study it in 4 media at pH values of 1.2, 3–6.5, and 6.8–7.5, with water as the guideline for bioequivalence. Sodium lauryl sulfate (sodium dodecyl sulfate) was included in the dissolution medium to significantly enhance the dissolution of the poorly soluble simvastatin or montelukast tablets (Alshora et al., 2022; Muenraya et al., 2024). The water solubility of simvastatin ranged from 0.0013 to 0.0015 mg/mL at 23°C (Serajuddin et al., 1991), and solubility in water and buffer was found to be 1.4 and 14.7 μg/mL, respectively at 37°C (Hashem et al., 2024). The pKa value of simvastatin in acidic conditions is 14.91 and 2.8 in basic conditions, indicating that its solubility decreases significantly and results in reduced solubility at low pH (Boovizhikannan et al., 2022)).

Figure 8 illustrates the dissolution patterns of simvastatin releases from the tablets. All simvastatin tablets of formulations (F1–F4) exhibited nearly complete drug release (100%) within 15 minutes. A notable difference was observed between the manufacturing methods. The direct compression formulations (F3 and F4) reached 100% release within 10 minutes, which was approximately 4–8% faster than the wet granulated tablets (F1, F2), for both the lactose-based and CAP-based formulations. The rapid disintegration of directly compressed tablets promotes a faster breakdown into primary particles, hence increasing the surface area to expose the medium and improve the dissolution rate. In contrast, the wet granulation process improves powder flow and compactibility, but it can result in a slower dissolution profile. This is because tablets made by wet granulation typically involve a two-step disintegration process, where the tablet first disintegrates into granules, followed by further disintegration into fine particles before the drug can dissolve. Therefore, the amount of disintegrant may need to be optimized if a faster dissolution rate is desired for immediate-release wet granulated formulations.

To assess the effect of CAP compared to standard diluent lactose, similarity (f_2) and difference (f_1) factors were calculated for both manufacturing methods. For wet granulation (F1 vs F2), (f_1) and (f_2) were 12.3 and 62.5, respectively. For direct compression (F3 vs F4), the (f_1) and (f_2) values were 8.2 and 81.4, respectively. The results of analysis of the difference factor (f_1) and similarity factor (f_2) showed that the use of CAP and lactose gave different dissolution profiles, both from wet granulation and direct compression preparations. These results indicate that CAP affects the dissolution profiles of simvastatin tablets. The effect of wet granulation is greater than direct compression because the granulation process disintegrates the tablet into granules, and then the small particles of granules disintegrate into smaller particles or powder, followed by the occurrence of dissolution. Due to the dissolution pattern of the simvastatin tablet, CAP can be applied for the preparation of other immediate-release tablets. However, if considered in terms of dissolution profiles within 30 minutes, the use of CAP or lactose as the diluent in this study did not affect the dissolution of simvastatin because both methods gave the same result, completely dissolving within 30 minutes. However, the formulation factors, such as type of binder, disintegrants, and lubricants, affect the dissolution. In addition, the drug properties, such as water solubility and particle size, also impact the dissolution (Chu et al., 2012).

Among all formulations, F4 exhibited the fastest dissolution rate due to the combination of the direct compression process and the inclusion of CAP as a diluent, which contributes a disintegrant-like behavior. However, the optimal formulation should be evaluated comprehensively, considering several factors such as tablet hardness, disintegration time, drug content, and drug stability. Based on these factors, formulation F2 demonstrated the most suitable performance, with acceptable simvastatin release and superior physical properties.

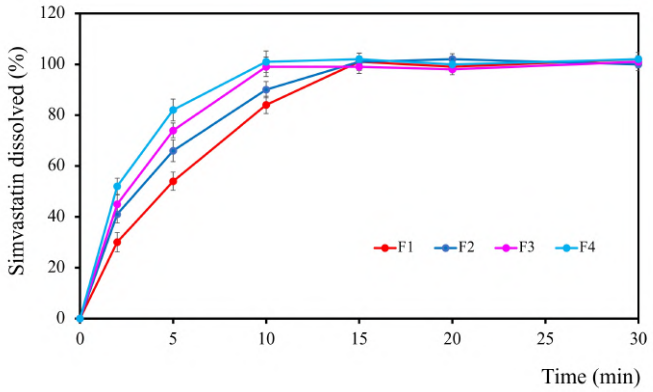

Figure 8. Dissolution Profiles of Simvastatin from Simvastatin Tablet Formulations F1–F4 in a Phosphate Buffer Solution pH 7.0 Containing 0.5% Sodium Dodecyl Sulphate. Data Expressed as Mean ± S.D., n = 12

3.7 Stability Results of Simvastatin Tablets

According to the USP, simvastatin tablets should be stored in tightly closed containers to protect them from moisture and light, which can adversely affect product stability. Previous studies have reported that generic simvastatin tablets, when stored, may exhibit reduced disintegration time, increased friability, and failure to meet USP dissolution criteria, although the assay content may remain within the acceptance range of 90–110 %LA (Yulianita et al., 2021). This is a result of the effect of moisture ingress during storage.

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In the present study, two simvastatin tablet formulations containing CAP, F2 (wet granulation) and F4 (direct compression), were packaged in PVC/Alu blister packaging and protected from light. The stability study was subjected to both accelerated conditions (40°C/75%RH) and long–term conditions (30°C/75%RH) for 3 months, in accordance with the guidelines for the ASEAN climatic zone of IVb (González-González et al., 2022; Kopp, 2006). The stability results are shown in Table 5.

After 3 months, the chemical and physical stability of the tablets was well maintained. The drug assay results for both F2 and F4 remained within ± 10% of the initial value and met the pharmacopoeial criteria. The results indicated that the temperature and humidity under the tested conditions did not adversely affect drug stability. Previous studies have demonstrated that improper storage conditions can lead to degradation of simvastatin in generic formulation (Yulianita et al., 2021). Therefore, the well–controlled environment is critical in maintaining the stability of the active ingredient. When stored under appropriate conditions, simvastatin remains stable and continues to meet the finished product specifications throughout the intended shelf–life.

In terms of appearance, no visible changes were observed in the tablets after storage. In addition, key parameters of the simvastatin tablets formulated with CAP, including weight variation, disintegration times, remained unchanged in both the wet granulation (F2) and direct compression (F4) formulations. However, a slight increase in tablet hardness was observed in the F2 formulation (wet granulation) under both 30°C/75%RH and 40°C/75%RH storage conditions. This may primarily be caused by moisture loss and subsequent recrystallization of water-soluble excipients or drugs within the tablet's void spaces. This recrystallization process strengthens the tablet structure, leading to an increase in hardness (Molokhia et al., 1982).

Overall, the results suggest that the use of CAP as a pharmaceutical excipient in tablet formulations does not adversely affect the physicochemical properties of the final product. Nevertheless, an extended stability study beyond the initial 3 months is required to confirm the long-term suitability of CAP for use in pharmaceutical products throughout their intended shelf life.

4. CONCLUSIONS

This investigation is the initial to document the potential of CAP as a pharmaceutical diluent for tablet applications. CAP was successfully developed and incorporated into simvastatin tablets using both wet granulation and direct compression manufacturing processes. The physical properties of CAP proved suitable for use as a diluent, offering strong compaction properties while enabling faster disintegration, which is ideal for immediate-release tablets. Stability testing demonstrated that tablets containing CAP remained stable, with no significant changes in hardness, disintegration time, or the chemical integrity of simvastatin. However, further advancements in quality control are essential to establish clear specifications and effectively implement CAP as a pharmaceutical filler or diluent in tablet formulations. Additional research is needed to identify factors influencing CAP production, such as the species and maturity of the cashew fruit at harvest, which affect its starch and sugar content. Moreover, the undesirable brown coloration of CAP may require additional processing steps for its removal or reduction. Ultimately, exploring new natural materials like CAP as alternatives for drug development-whether as active ingredients or excipients-can enhance the utilization of natural resources in pharmaceutical formulations.

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