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Formulation of Paracetamol Tablets using *Musa Paradisiaca L.* Extract as a disintegrant

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ABSTRACT

Abstract: Fruit juice (essence) has potential as a pharmaceutical excipient, functioning as a filler, disintegrant, or binder in tablet formulations. This study investigated the use of Kepok banana (Musa paradisiaca L.) fruit juice as a disintegrant in paracetamol tablets and evaluated the effect of different concentrations on tablet physical properties. Granules were evaluated for flow time, angle of repose, and compressibility index before tablet compression. All formulations met the required pre-formulation standards. The results showed that among the tested formulations, F4 exhibited the best overall tablet performance, with acceptable weight uniformity, hardness of 1.384 kg, friability of 19.69%, and a disintegration time of 1 min 23 s. These findings indicate that Kepok banana fruit juice has potential as a natural disintegrant in paracetamol tablet formulations.

Kata Kunci:

Jus Buah,
Musa Paradisiaca L,
Paracetamol,
Bahan Pengembang.

***Abstrak**: Ekstrak buah menunjukkan potensi sebagai eksipien farmasi, yang berfungsi sebagai bahan pengisi, penghancur (*disintegran*), atau pengikat dalam formulasi tablet. Penelitian ini mengkaji penggunaan ekstrak buah pisang Kepok (Musa paradisiaca L.) sebagai bahan penghancur dalam tablet parasetamol serta mengevaluasi pengaruh variasi konsentrasi terhadap sifat fisik tablet. Sebelum tahap pencetakan tablet, granul dievaluasi parameter waktu alir, sudut diam, dan indeks kompresibilitasnya. Seluruh formulasi memenuhi standar pra-formulasi yang dipersyaratkan. Hasil penelitian menunjukkan bahwa di antara formulasi yang diuji, F4 menghasilkan performa tablet terbaik secara keseluruhan, dengan keseragaman bobot yang dapat diterima, kekerasan 1,384 kg, kerapuhan 19,69%, dan waktu hancur 1 menit 23 detik. Temuan ini mengindikasikan bahwa ekstrak buah pisang Kepok memiliki potensi sebagai bahan penghancur alami dalam formulasi tablet parasetamol.*

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A. INTRODUCTION

Pharmaceutical dosage forms have undergone significant development alongside advances in pharmaceutical technology, resulting in products with improved quality, safety, and therapeutic effectiveness. Among the various dosage forms available, tablets remain the most widely used because of their convenience, stability, accurate dosing, ease of administration, and patient compliance (Berardi et al., 2021; Yee et al., 2024).

Excipients play essential roles in tablet formulations by functioning as fillers, binders, disintegrants, lubricants, and glidants. These materials facilitate the manufacturing process while improving tablet stability, mechanical strength, drug release, bioavailability, and overall product quality (Kapoor et al., 2025; Berardi et al., 2021). Despite their importance, many pharmaceutical excipients used in Indonesia are still imported, increasing production costs and creating dependence on foreign raw materials. Consequently, the exploration of locally available natural materials as alternative pharmaceutical excipients has become an important research priority (Kapoor et al., 2025).

Indonesia is one of the world's leading banana-producing countries, with Kepok banana (*Musa paradisiaca* L.) being one of the most abundant cultivars. The fruit is cultivated throughout the year, is relatively inexpensive, and contains a high amount of starch, making it a promising renewable resource for pharmaceutical applications. Banana starch has attracted increasing attention because of its biodegradability, biocompatibility, low toxicity, and favorable physicochemical properties that enable its use as a binder, filler, or disintegrant in tablet formulations (Dhull et al., 2021; Fauzi, 2025).

Previous studies have demonstrated that banana starch exhibits good swelling capacity, water absorption, and compatibility with pharmaceutical ingredients, indicating its suitability as a natural disintegrant. Furthermore, starch-based excipients have gained considerable interest as sustainable alternatives to synthetic excipients owing to their low cost, environmental friendliness, and satisfactory tablet performance (Khanam et al., 2021; Nabila & Karo-Karo, 2024).

Based on these considerations, this study aimed to investigate the utilization of Kepok banana (*Musa paradisiaca* L.) starch as a natural disintegrant in paracetamol tablets prepared by the wet granulation method. The influence of different starch concentrations on the physical characteristics of the tablets was also evaluated to determine its feasibility as a locally sourced pharmaceutical excipient.

B. METHOD

1. Study Design

This laboratory experimental study investigated the potential use of Kepok banana (*Musa paradisiaca* L.) starch as a natural disintegrant in paracetamol tablet formulations prepared by the wet granulation method. The study consisted of several stages, including sample preparation, starch extraction, starch characterization, tablet formulation, pre-compression evaluation of granules, and post-compression evaluation of tablets.

2. Sample Collection

Kepok bananas were collected using a purposive sampling method without comparison to samples from other geographical locations. Mature but unripe fruits with green peels were selected to ensure a high starch content suitable for pharmaceutical applications.

3. Starch Extraction

The banana fruits were peeled, washed, and soaked in water for approximately 5 min. The pulp was then cut into small cubes and blended with distilled water at a 1:1 (w/v) ratio until a homogeneous slurry was obtained. The slurry was filtered through a muslin cloth to separate the starch suspension from the fibrous residue. The remaining residue was repeatedly extracted with the same volume of distilled water until the filtrate became clear. The collected filtrate was allowed to stand for 12 h to facilitate starch sedimentation. After decanting the supernatant, the starch sediment was dried in a hot-air oven at 40°C for 12 h or until a constant weight was achieved (Musita Nanti, 2012).

4. Starch Characterization

The swelling capacity of the extracted starch was determined by dispersing 200 mg of starch in 10 mL of distilled water and liquid paraffin. After standing for 12 h, the sediment volume was recorded, and the swelling index was calculated according to the established procedure (Musita, 2012). Bulk density was determined by placing the starch into a 50-mL graduated cylinder, recording the initial volume, tapping the cylinder 15 times, and measuring the final volume. The bulk density was calculated as the ratio of starch mass to its occupied volume (Dalimunthe et al., 2019).

5. Tablet Preparation

Paracetamol tablets were prepared using the wet granulation technique. Kepok banana starch was incorporated as the disintegrant at concentrations of 5%, 10%, 15%, and 20% (w/w). Each tablet contained 250 mg of paracetamol as the active pharmaceutical ingredient, while gelatin (4%), magnesium stearate (2%), talc (1%), and lactose (q.s.) were used as the binder, lubricant, glidant, and filler, respectively.

6. Evaluation of Granules and Tablets

Prior to compression, the granules were evaluated for flow time, angle of repose, and compressibility index to determine their suitability for tableting. The tablets produced from the selected formulations were subsequently evaluated for weight uniformity, hardness, friability, and disintegration time according to the applicable pharmacopeial requirements.

C. HASIL DAN PEMBAHASAN

1. Isolation of Starch from Kepok Banana Fruit

In this study, the yield obtained from 2,000 g of Kepok banana using distilled water as the solvent was as follows: starch weight of 193.85 g. Thus, a yield of 9.69% was obtained.

Table 1. Macroscopic Characteristics of Kepok Banana (*Musa paradisiaca* L.) Starch

Sample	Parameter	Observation
Kepok banana (*Musa paradisiaca* L.) starch	Appearance	Fine powder
	Color	Off-white to light brown
	Odor	Odorless
	Taste	Tasteless

2. Starch Characterization

a. Swelling Index

The swelling index of Kepok banana (*Musa paradisiaca* L.) starch was determined by comparing the sediment volume in distilled water and liquid paraffin after 12 h of standing. The sediment volume measured **1.5 mL** in distilled water and **1.0 mL** in liquid paraffin. Based on these values, the swelling index of the starch was calculated to be **50%**.

The observed swelling index indicates that the extracted starch possesses a moderate capacity to absorb water and expand. This characteristic is particularly important for its potential application as a natural disintegrant in tablet formulations, as starch swelling facilitates tablet disintegration by promoting water penetration and the subsequent breakup of the tablet matrix. Therefore, Kepok banana starch demonstrates promising functionality as a pharmaceutical excipient for improving tablet disintegration.

b. Bulk Density

The bulk density of Kepok banana (*Musa paradisiaca* L.) starch was determined by measuring the ratio of starch mass to its occupied volume. The extracted starch had a mass of **28.5 g** and occupied a volume of **50 mL**, resulting in a bulk density of **0.57 g/mL**.

The measured bulk density indicates that the starch possesses satisfactory packing characteristics for pharmaceutical applications. Bulk density is an important physical property because it influences powder flowability, compressibility, die filling during tablet compression, and the uniformity of tablet weight. The value obtained suggests that Kepok banana starch has suitable physical characteristics for use as a pharmaceutical excipient in tablet formulations.

c. Pre-compression Evaluation of Granules

The pre-compression properties of the granules prepared with different concentrations of Kepok banana (*Musa paradisiaca* L.) starch are presented in **Table 2**.

Table 2. Pre-compression Evaluation of Granules Prepared with Different Concentrations of Kepok Banana (*Musa paradisiaca* L.) Starch

Formulation	Flow Time (s)	Angle of Repose (°)	Compressibility Index (%)
F1 (5%)	3.90	35	11.11
F2 (10%)	3.73	22	10.00
F3 (15%)	4.00	37	14.00
F4 (20%)	2.69	33	11.00
Acceptance criteria	< 10 s	20°–40°	< 20%

The pre-compression characteristics of pharmaceutical granules are critical determinants of tablet quality because they directly influence die filling, weight uniformity, mechanical strength, and the overall manufacturing process. In this study, granules containing different concentrations of Kepok banana (*Musa paradisiaca* L.) starch were evaluated through flow time, angle of repose, and compressibility index.

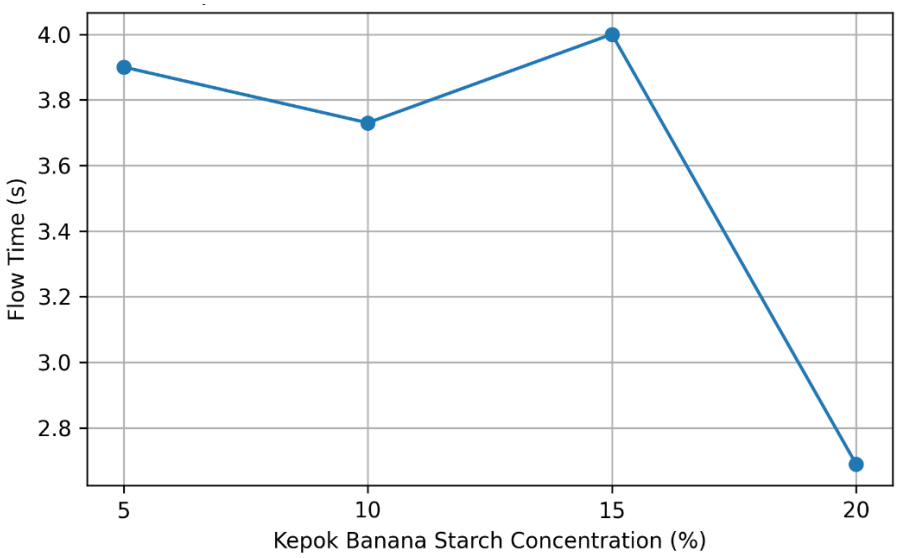


Figure 1. Effect of Kepok Banana Starch Concentration on Granule Flow Time

The flow time of the prepared granules ranged from **2.69 to 4.00 s**, with all formulations meeting the recommended acceptance criterion of less than 10 s. These findings indicate excellent granule flowability regardless of the starch concentration used. Among the formulations, **F4 (20% starch)** exhibited the shortest flow time (2.69 s), suggesting superior flow characteristics. Improved flowability at higher starch concentrations may be attributed to the formation of larger and more cohesive granules during wet granulation, which reduced interparticle friction and facilitated smoother movement through the funnel. Adequate powder flow is essential in pharmaceutical manufacturing because it ensures consistent die filling and minimizes tablet weight variation during compression (Tharanon et al., 2024).

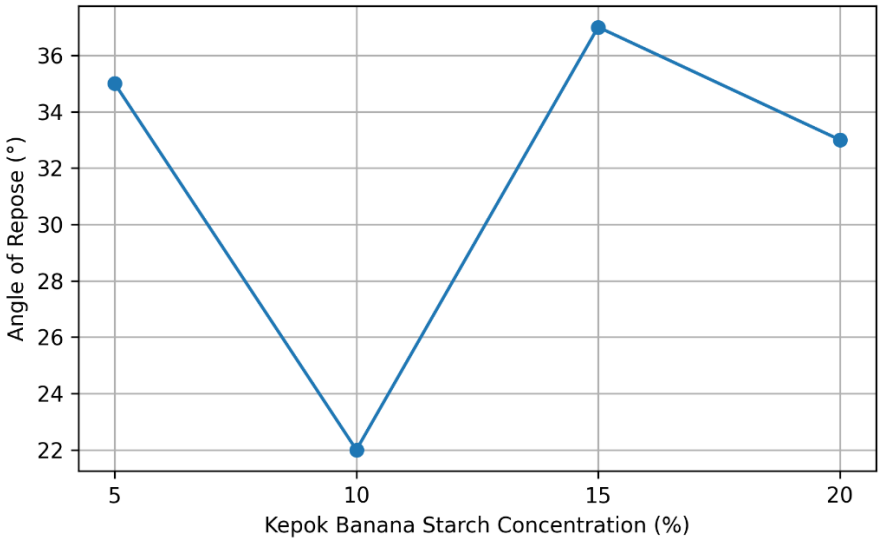


Figure 2. Effect of Kepok Banana Starch Concentration on Angle of Repose

The angle of repose values ranged from **22° to 37°**, indicating that all formulations possessed acceptable flow properties. According to pharmacopeial recommendations, materials with an angle of repose between **20° and 40°** generally exhibit good flowability, while lower values correspond to lower interparticle friction and better powder movement. Formulation **F2 (10% starch)** produced the lowest angle of repose (22°), indicating the most favorable flow behavior among the tested formulations. In contrast, F3 (15%) showed the highest angle of repose (37°), although this value remained within the acceptable range for pharmaceutical granules. These results demonstrate that the incorporation of Kepok banana starch did not adversely affect granule flowability and supports its suitability as a natural excipient in tablet formulations.

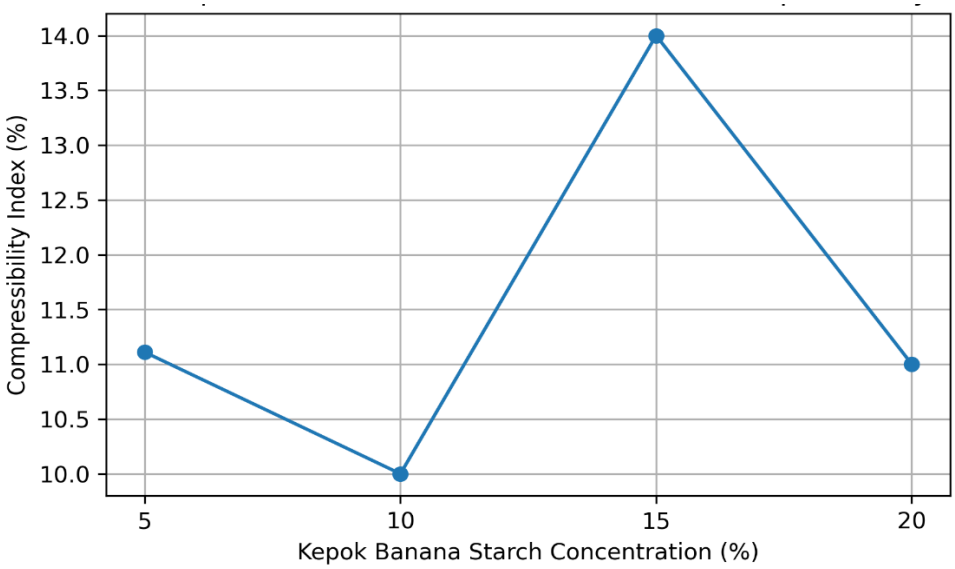


Figure 3. Effect of Kepok Banana Starch Concentration on Compressibility Index

The compressibility index values varied from **10.00% to 14.00%**, which are well below the pharmacopeial limit of 20%, indicating good packing ability and compressibility. A lower compressibility index generally reflects reduced cohesiveness, better flow characteristics, and improved compressibility during tablet manufacture. Among all formulations, **F2** exhibited the lowest compressibility index (10%), suggesting the most efficient packing behavior, whereas F3 showed the highest value (14%). Nevertheless, all formulations remained within the range classified as having good flowability, indicating that the extracted banana starch contributed positively to the physical quality of the granules. Similar observations have been reported in recent studies, which demonstrated that starch-based excipients provide satisfactory compressibility and can function effectively as natural disintegrants and fillers in tablet formulations.

Overall, the pre-compression evaluation demonstrated that all formulations fulfilled the standard requirements for pharmaceutical granules. Although **F2 (10% starch)** exhibited the most favorable angle of repose and compressibility index, **F4 (20% starch)** showed the fastest flow time. These findings indicate that Kepok banana starch possesses suitable physicochemical properties for application as a natural disintegrant in paracetamol tablets prepared by the wet granulation method. Furthermore, the results support the growing interest in starch derived from renewable plant sources as a sustainable alternative to conventional pharmaceutical excipients due to its biodegradability, biocompatibility, low cost, and satisfactory performance in solid dosage formulations.

D. CONCLUSIONS AND SUGGESTIONS

The results demonstrate that all granule formulations complied with the established acceptance criteria for flow time, angle of repose, and compressibility index. Flow times ranging from **2.69 to 4.00 s** indicate excellent flowability, which is essential for achieving uniform die filling during tablet compression. Likewise, the measured angles of repose (**22°–37°**) suggest good flow properties, as values between **20° and 40°** are generally considered acceptable for pharmaceutical granules.

The compressibility index ranged from **10.00% to 14.00%**, indicating good packing ability and compressibility. According to pharmaceutical standards, a compressibility index below **20%** reflects satisfactory flow characteristics and suitability for tablet production.

Among the formulations, **F2 (10% starch)** exhibited the lowest angle of repose (**22°**) and the lowest compressibility index (**10%**), indicating excellent flowability and packing behavior. In contrast, **F4 (20% starch)** showed the shortest flow time (**2.69 s**), suggesting the fastest powder flow. Overall, all formulations exhibited favorable pre-compression characteristics, indicating that Kepok banana starch can be successfully utilized as a natural disintegrant in wet-granulated paracetamol tablets.

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