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Physical characterization of paracetamol granule preparation using goroho banana starch as binder and disintegrant

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Abstract: The research aims to formulate Goroho banana starch (GBS) as a binding and disintegrating agent in paracetamol (PCT) granule preparations. PCT granules were made using GBS as a binding agent in 3 concentrations of 6, 8, and 10%, respectively. PCT granules using GBS as a disintegrating agent were made with three concentrations of 10, 15, and 20%, respectively. Paracetamol granules are made using the wet granulation method. Granules were evaluated using six parameters: flow rate, angle of repose, water content, bulk density, tapped density, and compressibility index. GBS as a binder showed good physical properties. F1 (6% GBS) showed a flow rate of 8.1 g/sec, an angle of repose of 22.9 degrees, a water content of 1.2%, and a compressibility index of 19.3%. F2 (8% GBS) shows a flow rate of 8.5 g/sec, an angle of repose of 18.5 degrees, a water content of 1.3%, and a compressibility index of 17.6%. F3 (10% GBS) shows a flow rate of 9.0 g/sec, an angle of repose of 21.5 degrees, a water content of 1.4%, and a compressibility index of 19.3%. 8% GBS showed the best physical properties as a binding agent for PCT granules. GBS as a disintegrating agent, shows excellent physical properties. F4 (10% GBS) shows a flow rate of 12.9 g/sec, an angle of repose of 17.0 degrees, a water content of 4.3%, and a compressibility index of 13.3%. F5 (15% GBS) shows a flow rate of 11.4 g/sec, an angle of repose of 18.0 degrees, a water content of 1.4%, and a compressibility index of 14.5%. F6 (20% GBS) shows a flow rate of 10.7 g/sec, an angle of repose of 23.0 degrees, a water content of 3.5%, and a compressibility index of 14.6%. 10% GBS showed the best physical properties as a disintegrants agent for PCT granules.

Keywords: binder; disintegrant; goroho banana; paracetamol granules; starch.

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Introduction

The development of pharmaceutical technology has been a dynamic and evolving process over the years. It involves the application of scientific and engineering principles to the design, discovery, development, and manufacturing of drugs. The pharmaceutical technology landscape is continually evolving, driven by scientific discoveries and technological innovations. These advancements contribute to the development of safer and more effective (Edy & Mansauda, 2020).

Excipients are inert substances added to pharmaceutical formulations alongside the active pharmaceutical ingredient (API) to facilitate the manufacturing process, enhance stability, improve bioavailability, and aid in patient administration. Excipients serve various functions in pharmaceutical formulations, contributing to the overall quality, stability, and acceptability of the products, such as filler, binder, disintegrant, and lubricant. While many excipients are synthetic, there is an increasing interest in using natural substances as excipients. Natural

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excipients can be derived from various sources, including plants, minerals, and animals (Saryanti et al., 2019; Tripathee et al., 2023).

Starch is a polymeric carbohydrate found in various plant sources such as potatoes, wheat, corn, and cassava. Starch is a natural ingredient often used as an excipient in manufacturing pharmaceutical preparations such as tablets (Ningsi, 2017). Excipients derived from starch are widely used in the pharmaceutical industry as fillers, disintegrants, and binders (Sulaiman et al., 2022). Starch is one of the most widely used pharmaceutical excipients because it is one of the few natural products that, with minimal processing, meet most of the requirements for excipients. It is nontoxic, odorless, inexpensive, widely available, and biocompatible (Kunle, 2020).

Another source of starch that can be used comes from bananas. Native banana starch has higher resistant starch content (65–98%) than other native starches such as aracca starch (17.5%), cassava starch (1.8%), cush-cush yam starch (55.8%), potato starch (48.5%), and taro starch (13.8%) (Marta et al., 2022). One of the bananas often found and consumed in North Sulawesi is the Goroho banana. According to Parumpa et al (2023), Goroho banana starch contains a nutritional value of 80.89% starch, 2.89% protein, 0.67% fat, and ±2% crude fiber. Goroho banana flour has an amylose content of 39.59% and an amylopectin of 31.19% (Taringan et al., 2019). Despite the potential benefits of natural excipients, there is a lack of research on the use of Goroho banana starch as an excipient in paracetamol granule formulation.

Granules are lumps or agglomerates that come from smaller particles made by granulation. Granulation is essential in tablet manufacturing, forming consistent, measurable granules that can be compressed into tablets. One granulation method that is often used in pharmaceutical formulations is wet granulation. This method is widely used in making paracetamol tablets (Elisabeth et al., 2018).

Paracetamol, also known as acetaminophen, is a commonly used analgesic and antipyretic drug. This drug is often used to treat mild to moderate pain, such as headaches, muscle pain, toothache, and fever. The disadvantage of paracetamol is its poor flow and compressibility properties, so tablet-making must be done using the wet granulation method (Özalp et al., 2020; Sugiyono et al., 2017). This research used Goroho banana starch as a binder and disintegrant in making paracetamol granules. Flow rate, angle of repose, moisture content, bulk density, tapped density, and compressibility index were evaluated.

Materials and Methods

Materials

Avicel Ph 101, distilled water, lactose, magnesium stearate, paracetamol (Anqiu Lu'an Pharmaceutical Co., Ltd., China), polyvinylpyrrolidone, talcum, and goroho banana (*Musa acuminata* AAA Group). Goroho banana was bought from Pasar Bobo, Manado City.

Preparation of goroho banana starch (GBS)

The Goroho bananas used in this research were unripe. Goroho banana flesh (3 kg) is washed using running water until clean and then grated until smooth. The finely ground fruit flesh is added to 6 litres of distilled water and filtered until the filtrate is obtained. The filtrate was decanted for 12 hours. The precipitate was filtered and then dried for 48 hours at 60°C using an oven. The dried starch is ground, and then the yield percentage is calculated.

Preparation of PCT Granules Using GBS as Binder

In tablet formulations, starch is used at a concentration of 3–20% (Rowe et al., 2009). Paracetamol granule formulations using GBS as a binder are presented in F1-F3 (n=3) with 6, 8, and 10% concentrations, respectively (see Table 1). GBS was suspended in 100 ml of distilled water and heated at 60˚C until a starch solution was formed. PCT, Avicel Ph 101, and lactose are mixed in mortar until homogeneous, and then the GBS solution is slowly added into the mixture while stirring until a wet mass is formed. The wet mass was sieved with a 14-mesh sieve and then dried at 60˚C for 60 minutes using an oven. The dry granules were sieved with a 16-mesh sieve. Magnesium stearate and talc are added to the granules and mixed for ±20 minutes.

Preparation of PCT Granules Using GBS as Disintegrant

Starch is one of the most commonly used tablet disintegrants at concentrations of 3–25% (Rowe et al., 2009). Paracetamol granules are made using GBS as a disintegrant, presented at F4-F6 (n=3) with concentrations of 10, 15, and 20%, respectively (see Table 1). PCT, GBS, and lactose are mixed in mortar until homogeneous. Polyvinylpyrrolidone (PVP) was slowly added while stirring until a wet mass was formed. The wet mass was sieved with a 14-mesh sieve and then dried at 60˚C for 60 minutes using an oven. The dry granules were sieved with a 16-mesh sieve. Magnesium stearate and talc are added to the granules and mixed until homogeneous.

PCT Granules Evaluations

Flow Rate

Twenty-five grams sample (n=3) was weighed and slowly poured into the funnel through the funnel wall. The funnel lid is opened slowly, and the sample is allowed to flow. The time required for the entire sample to pass through the funnel is calculated using a stopwatch. The flow rate is calculated using the following formula (Prajapati & Mishra, 2021):

$$\text{Flow rate (g/sec)} = \frac{\text{Granule weigth (gram)}}{\text{Flow time (second)}}$$

Table 1. PCT Granule Formulation with Various Concentration Ingredients

Ingredients (mg)	F1	F2	F3
Paracetamol	500	500	500
Goroho banana starch as binder	42	56	70
Goroho banana starch as disintegrant	-	-	-
Polyvinylpyrrolidone	-	-	-
Avicel Ph 101	56	56	56
Talcum	7	7	7
Magnesium stearate	7	7	7
Lactose	ad 700	ad 700	ad 700
Ingredients (mg)	**F4**	**F5**	**F6**
Paracetamol	500	500	500
Goroho banana starch as binder	-	-	-
Goroho banana starch as disintegrant	70	105	140
Polyvinylpyrrolidone	7	7	7
Avicel Ph 101	-	-	-
Talcum	7	7	7
Magnesium stearate	7	7	7
Lactose	ad 700	ad 700	ad 700

Table 2. Flowability Based on Flow Rate

Flow Rate (g/sec)	Type of Flow
> 10	Excellent
4-10	Good
1.6-4	Poor
< 1.6	Very poor

Angle of Repose

Twenty-five grams sample (n=3) was weighed and slowly poured into the funnel through the funnel wall. The funnel lid is opened slowly, and the sample is allowed to flow. The angle of repose is calculated using the following formula (Patel & Siddaiah, 2018):

$$\tan \alpha = \frac{h}{r}$$

h : height of sample heap (cm)
r : radius of sample heap (cm)

Table 3. Flowability Based on Angle of Repose

Angle of Repose (degrees)	Type of Flow
≤ 30	Excellent
31-35	Good
36-40	Fair
41-45	Passable
46-55	Poor
56-65	Very poor
≥ 66	Extremely poor

Moisture Content

Five grams sample (n=3) was weighed and then heated at 50˚C for 8 hours using an oven. Samples were weighed every hour until a constant weight was obtained. Moisture content is calculated using the following formula (Elisabeth et al., 2018):

$$\text{Moisture content (\%)} = \frac{w1 - w2}{w1} \times 100\%$$

w1: weight of sample before heating (gram)
w2: constant weight of sample after heating (gram)

Bulk Density

An empty 50 ml measuring cup is weighed. The sample (n=3) was put into a measuring cup to a volume of 50 ml and then weighed. Bulk density is calculated using the following formula (Sharma et al., 2021):

$$\text{Bulk density (g/ml)} = \frac{w1 - w2}{V}$$

w1: weight of measuring cylinder containing sample (gram)
w2: weight of empty measuring cylinder (gram)
V : volume of sample (ml)

Tapped Density

An empty measuring cup measuring 50 ml is weighed, and then the sample (n=3) is added to a volume of 50 ml. The measuring cup is tapped until a constant sample volume is obtained and weighed. The tapped density is calculated using the following formula (Vikas et al., 2018):

$$\text{Tapped density (g/ml)} = \frac{w1 - w2}{Vt}$$

w1: weight of measuring cylinder containing sample after tapped (gram)
w2: weight of empty measuring cylinder (gram)
Vt: tapped volume of sample (ml)

Compressibility Index

Bulk density and tapped density results are used to determine the sample compressibility index. The compressibility index is calculated using the following formula (Mirhosseini & Amid, 2013):

$$\text{Compressibility index (\%)} = \frac{\rho T - \rho B}{\rho T} \times 100\%$$

ρT : tapped density of sample (g/ml)
ρB : bulk density of sample (g/ml)

Table 4. Flowability Based on Compressibility Index

Compressibility Index (%)	Type of Flow
≤ 10	Excellent
11-15	Good
16-20	Fair
21-25	Passable
26-31	Poor
32-37	Very poor
≥ 38	Extremely poor

Result and Discussion

Goroho banana is a type of banana that is often found in Indonesia, especially in North Sulawesi Province. This banana is famous for its unique taste, sweet and slightly sour, and its small size compared to other banana varieties. Goroho bananas are often used in various regional dishes, including fried, grilled, or made into traditional Indonesian desserts (Suniati & Purnomo, 2019). Samples were obtained from Molas Village, Manado City, Indonesia. The starch content obtained from Goroho bananas was 9.06% (see **Table 5**). The separation process was carried out manually, causing the low starch yield. Separating the starch using a cotton cloth causes some of the starch to be carried away in the banana flesh (Suarni et al., 2013). Other factors that can influence the low starch yield include low amylose content (Harni et al., 2022), extraction methods (Pires et al., 2021), and soaking duration (Mojiono & Sholehah, 2020).

Table 5. Percentage Yield of GBS

Banana Flesh (gram)	Banana Starch (gram)	Yield (%)
3000	271.82	9.06

GBS is used as a binder and disintegrant in paracetamol granules. The use of GBS as a binding and disintegrating agent was made in 3 different concentrations (see **Table 1**). The concentrations of GBS as a binder were 6, 8, and 10%, while GBS as a disintegrant was 10, 15, and 20%, respectively. Granules are evaluated using six parameters: flow rate, angle of repose, moisture content, bulk density, tapped density, and compressibility index. The physical characteristics of PCT granules can be seen in **Table 6** and **Table 7**.

Table 6. Flow Properties of PCT Granules Using GBS as A Binder

Parameter	F1	F2	F3	Requirement
Flow rate (g/sec)	8.1 ± 1.08	8.5 ± 0.62	9.0 ± 0.53	See Table 2
Angle of repose (degrees)	22.9 ± 1.42	18.5 ± 1.04	21.5 ± 1.67	See Table 3
Moisture content (%)	1.2 ± 0.25	1.3 ± 0.58	1.4 ± 0.17	1-5
Compressibility index (%)	19.3 ± 3.06	17.6 ± 1.59	19.3 ± 1.15	See Table 4

Table 7. Flow properties of PCT granules using GBS as a disintegrant

Parameter	F4	F5	F6	Requirement
Flow rate (g/sec)	12.9 ± 0.92	11.4 ± 1.00	10.7 ± 0.35	See Table 2
Angle of repose (degrees)	17.0 ± 0.06	18.0 ± 1.10	23.0 ± 0.96	See Table 3
Moisture content (%)	4.3 ± 0.61	1.4 ± 0.67	3.5 ± 0.95	1-5
Compressibility index (%)	13.3 ± 1.10	14.5 ± 1.18	14.6 ± 1.15	See Table 4

Physical characterization of PCT granules

Starch is an ingredient often used as a binding agent in granule production, especially in the pharmaceutical and food industries. Starch is often used in solution or suspension form to combine active ingredients or other additives in the granulation process. The concentration, type of starch, and application technique will vary depending on the specific properties of the ingredients used and the final granulation goal (Dürig & Karan, 2019). In some cases, starch can be used as a disintegrating agent in pharmaceutical granulation. Disintegration is the process in which tablets disintegrate into smaller granules when exposed to fluids in the human digestive system, thereby facilitating the release of the active substances contained therein (I. G. N. A. D. Putra et al., 2018; O. N. Putra et al., 2022).

Flow Rate

As a binder, PCT granules (F1-F3) showed flow rates of 8.1, 8.5, and 9.0, respectively. The flow rate of the granule becomes better with increasing concentration of starch as binder. All formulas have good flowability. Overall, F3 showed the best results. As a disintegrant, PCT granules (F4-F6) showed flow rates of 12.9, 11.4, and 10.7, respectively. The flow rate of the granule becomes better with a reduced concentration of starch as a disintegrant. All formulas have excellent flowability. Overall, F4 showed the best results. Flow rate influences the process of uniform filling into the tablet machine mold holes by facilitating the movement of drug substance. (Cheiya et al., 2023).

Angle of Repose

As a binder, PCT granules (F1-F3) showed angles of repose of 22.9, 18.5, and 21.5, respectively. All formulas have excellent flowability. There is no effect of starch concentration as a binder on angle of repose of the granule. Overall, F2 showed the best results. As a disintegrant, PCT granules (F4-F6) showed angles of repose of 17.0, 18.0, and 23.0, respectively. The angle of repose of the granule increases as the concentration of starch as a disintegrant increases. All formulas have excellent flowability. Overall, F4 showed the best results. Smaller values make the granule flow properties better. As a result, tablets are easy to mold (Cheiya et al., 2023).

Moisture Content

As a binder, PCT granules (F1-F3) showed moisture contents of 1.2, 1.3, and 1.4, respectively. As a disintegrant, PCT granules (F4-F6) showed moisture content of 4.3, 1.4, and 3.5, respectively. Based on the results obtained, the moisture content of granules increased as the concentration of starch as a binder increased. While as a disintegrant, there is no effect of starch concentration on granule moisture content. Overall, all formulas met the moisture content requirement. Granules with low moisture content will be stable during storage. High moisture content causes the granule to be difficult to compress because the mass will be sticky on the molding machine. Meanwhile, if the moisture content is too low, it will cause the tablet to become brittle, because the binding force between particles in the tablet is low too. Therefore, moisture content will affect tablet hardness, tablet friability, and tablet disintegration (Cheiya et al., 2023).

Compressibility Index

As a binder, PCT granules (F1-F3) showed compressibility index of 19.3, 17.6, and 19.3, respectively. There is no effect of starch concentration as a binder on granule compressibility. All formulas have fair flowability. Overall, F2 showed the best results. As a disintegrant, PCT granules (F4-F6) showed compressibility index of 13.3, 14.5, and 14.6, respectively. Granule compressibility increases as the concentration of starch as a disintegrant increases. All formulas have good compressibility. Overall, F4 showed the best results. Granules with easy flowability, the interaction between particles is not significant so that the compressibility index will be smaller. Low compressibility will give good flowability (Wahyuni, 2016).

Conclusion

8% GBS (F2) demonstrated the best flowability as a binder for PCT granules, with a good flow rate, excellent angle of repose, good moisture content, and a fair compressibility index. As a disintegrant, 10% GBS (F4) showed the best performance, offering excellent flow rate, angle of repose, good moisture content, and compressibility index. These results demonstrate the potential of GBS as a natural and effective binder and disintegrant in pharmaceutical formulations. Future research can explore its performance in various drug formulations and its compatibility with other excipients.

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