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RESEARCH ARTICLE

Modification of purple sweet potato starch (*Ipomoea batatas L. Poir*) with pragelatination and acetylation methods as disintegrant of paracetamol tablets

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Abstract

Background: Starch of sweet potatoes is one of the ingredients that has many benefits, including in the pharmaceutical field, especially as a pharmaceutical excipient in pharmaceutical formulations. But it has poor flow properties. **Objective:** The objective of the study is to isolate, characterise, modify and formulate the starch of Purple sweet potatoes (*I. batatas L.Poir*) into tablet dosage forms. **Method:** purple sweet potato starch obtained from the isolation, then modified to improve its flow properties. Modifications made were by pregelatination and acetylation. after obtaining starch that meets the standards in the pharmacopoeia, then starch is used as a disintegrant in the formulation of paracetamol tablets with a concentration of 15%. **Result:** The physicochemical characteristics of starch isolated from purple sweet potatoes are considered to meet the requirements of pharmaceutical excipients required in the Handbook of Pharmaceutical Excipients sixth edition and the United States Pharmacopeia 32nd edition. **Conclusion:** The starch from purple sweet potato has the potential as an alternative disintegrant for tablet formulation, but the amount used needs to be reduced so as not to produce brittle tablets.

Introduction

Pharmaceutical companies in Indonesia still have to import about 96% of the excipients in formulating pharmaceutical preparations. This will increase the cost of production. Some objectives of adding excipients include protecting the active substance, increasing the stability of the active pharmaceutical ingredient, and increasing the safety and effectiveness of the preparation itself (Pawar, P.D.,2015).

One of the excipients that are often used in formulations as a binder or disintegrant in tablet preparations is starch. Starch is one of the carbohydrates stored in plants and can be found in many plant organs such as seeds, roots, fruits and tubers. It is widely used because it is easy to obtain, has inert properties, is cheap, and can be used as a filler, binder, disintegrant, and lubricant (Hu A. et al., 2015). Many plants in Indonesia contain starch and have great potential to be developed as excipients. One of them is the purple sweet potato (PSP).

PSP contains 25% amylose and 75% amylopectin which can absorb a large amount of water (Navarro *et al.*, 1996). Thus, it has the potential as a tablet disintegrant. Moreover, starch in its natural form (native starch) has poor compressibility, which makes it not suitable to be used as an additive in the manufacture of tablets using the wet granulation method (Rendowaty, 2018).

The poor flow and compressibility of starch can be improved by physical and chemical modification of

starch. Physical modification of starch can be done using the pregelatination method while chemical modification can be performed by the acetylation method.

In this study, PSP starch was modified using pregelatination and acetylation methods. Modified starch was evaluated according to the Pharmaceutical Grade standards required by the USP and the Handbook of Pharmaceutical Excipients. In this study, isolated purple sweet potato starch was used as a disintegrant in the manufacture of tablets with paracetamol as a model drug.

Method

Plant determination

Purple sweet potato (*Ipomoea batatas L. Poir*) of Ayamurasaki variety grown in Jenggawah – Jember, East Java and aged ± 120 days of the harvest was selected for the research. Determination of PSP was carried out at the Biology Laboratory of Ahmad Dahlan University.

Isolation procedure of PSP starch

Raw PSP was peeled, washed and then soaked in distilled water for one hour. The soaked PSP was then blended. The results in the form of mush were added with twice the amount of distilled water and then stirred until well-mixed and allowed to stand for two hours. The ingredients were squeezed using a cotton cloth until the filtrate was obtained. The filtrate obtained was precipitated for one day at room temperature. The resulting precipitate was dried in an oven at a temperature of 40° C for two to three hours (Rendowaty, 2018). The dried starch was then ground and sieved using an 80-mesh sieve.

Modification of PSP starch: pregelatination method

The starch paste is made with 42 g of PSP starch and 58 g of distilled water. This mixture was heated on a hotplate while stirring at 30 rpm at 52°C - 80°C for 30 minutes. After that, it was cooled and dried in an oven at 60°C for 24 hours. The results obtained were mashed and sieved with sieve no. mesh 100 (Hidayat et al., 2009).

Acetylation method

A total of 60 g of PSP starch was mixed with 180 mL of distilled water to form a starch suspension. The starch suspension was then added with 18 mL of 1% CH_3COOH, stirred for 45 minutes and then filtered. The residue obtained was then dried in an oven at 50°C for five hours (Azzahra, 2019).

Physical properties of PSP starch

Determination of compressive density

Ten grams of sample was put into a measuring cup, and the top surface of the powder was levelled. The tool stomped 500 times, and the volume of the powder was taken, then it stomped another 750 times and read the compressed volume (V1). After knowing the bulk volume and the compressed volume, the compressibility index was evaluated with the formula (Ohwoavworhua *et al.*, 2009). Compressibility (%) = (Bulk Volume - Compressed Volume) / (Compressed Volume) x 100%.

Determination of density

A dry, clean, and calibrated pycnometer was used by setting the pycnometer weight and paraffin weight. The test substance was added to the pycnometer, and paraffin was added to the pycnometer until the maximum volume. The density was obtained by dividing the weight of the substance by the volume occupied by the substance in the pycnometer (Farmakope Indonesia V, 2014).

Moisture determination

Placed on an aluminium plate, the sample was weighed as one gram. Samples were dried at 105° C using a moisture balance (United States Pharmacopeia 32nd, 2009).

Determination of flow rate and angle of repose

The starch powder was put into a flow time test funnel. The flow time, height, and diameter of the powder coming out of the funnel were recorded to determine its angle of repose using millimetre graph paper. An angle of repose between 20°- 40° and a flow time of more than ten grams per second indicates a good flow.

Tablet formulations

The starch from the isolation of PSP can be used as an excipient for tablet preparations. F1 contains 15% PSP starch pregelatination and F2 contains 15% PSP starch acetylation.

Evaluations of tablets

The compressed tablet formulation was compressed using a tablet machine with a tablet weight of 650 mg. The resulting tablets were evaluated for their

uniformity of weight, tablet hardness, disintegration time test, friability, and dissolution.

Result

Plant determination

The results of the determination showed that the plants examined were purple sweet potato species (*Ipomoea batata*s *L*.).

Isolation of PSP starch

From the isolation process, starch was obtained as 572g with a percentage yield of 11.44%. The obtained starch was then identified macroscopically indicating that it was in accordance with the literature, where the isolated starch was in the form of a light purple fine powder, odourless and tasteless. (Winata, Syukri & Chabib, 2019).

Modification of starch

Pragelatination

Modification of pregelatin has a very significant effect compared to without pregelatination. Based on a macroscopic comparison, there were differences in the degree of colour in starch. This is caused by the heating process in pregelatination that dissolves some chemical components in flour and starch cells such as sugar, amylose, and protein (Winata A, dkk., 2019).

Acetylation

In the acetylation method, a starch with a lighter colour and smaller granule size than the pregelatination process was obtained, which is due to the addition of CH3COOH in the starch modification process using the acetylation method. The higher the level of CH3COOH, the higher the level of amylose is higher.

Physical properties of PSP starch

Testing of perceived PSP starch includes examining according to the sixth edition of the Handbook of Pharmaceutical Excipients. From the physical test data, it can be seen that the PSP starch tested showed good results when compared with the requirements, where PSP starch had a fairly good flow rate and angle of repose. This data supports the use of starch as an excipient for tablets by direct pressing. If it is necessary to increase the flow rate and the angle of repose that does not affect the physical properties of the active substance at the time of tablet making (See Table I).

Table I: Physical properties of PSP starch

Parameters	PSP pragelatination	PSP acetylation	Standards of USP 32
Tapped density (g/cm^3)	0.019 ± 0.004	0.040 ± 0.004	0.69 – 0.77
True density (g/cm^3)	0.0355 ± 0.003	0.013 ± 0.031	1.478
Compressibility	12.73 ± 0.556	32.27 ± 0.667	< 30
Flow rate (g/s)	5.7 ± 0.234	6.59 ± 0.216	< 10
Angle of repose	29.08 ± 0.536	37.7 ± 0.190	25 – 30
Moisture content (%)	3.14 ± 0.085	4.23 ± 0.115	< 12

Tablet formulation

The tablet formulation in this study used paracetamol as the active ingredient and used 15% PSP starch as a disintegrant, Avicel as a filler, Mg Stearate as a lubricant and Glycerin as a binder.

Evaluation of paracetamol tablet

The results of the evaluation of paracetamol tablets, on the parameters of tablet hardness, weight uniformity test and disintegration time on both formulas met the requirements. However, on the tablet friability test parameters, both formulas did not meet the requirements. This is because the percentage of disintegrant added to the tablet formulation is too large. The results of the tablet evaluation can be seen in Table II.

Dissolution

Dissolution test results (%Q) on tablets with PSP pregelatinised starch dissolution of 83.57% in the 30th minute and the formula with PSP acetylated starch dissolution of 80.2% in the 30th minute so that both formulas meet the requirements in the Indonesian Pharmacopoeia IV edition which states that 80% of paracetamol should be in dissolute state at the 30th minute. (Farmakope Indonesia V, 2014). The results of the tablet dissolution can be seen in Figure 1.

Table II: Evaluation of Paracetamol tablet

Parameters	F1 (Pragelation)	F2 (Acetylation)	Standards of USP 32
Weight (mg)	632 ± 1.61	642 ± 1.81	--
Hardness (Kg/cm^2)	3.66 ± 0.319	3.48 ± 0.304	< 8
Disintegration times (minutes)	1.93 ± 0,350	1.28 ± 0.490	< 15
Friability (%)	2.61 ± 0,289	6.52 ± 0,101	1

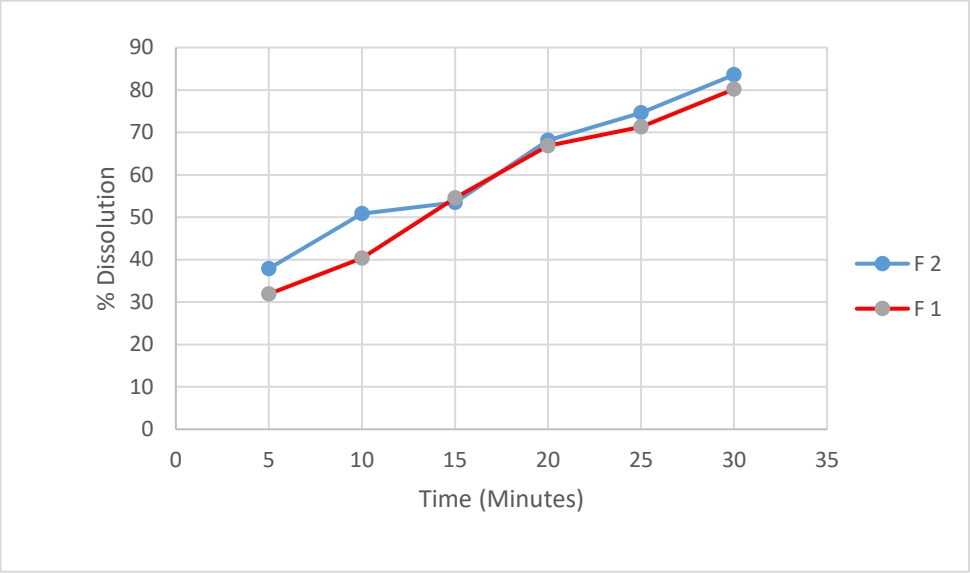

Figure 1: Dissolution profile of Paracematol tablets

Discussion

Brown pregelatinised starch was obtained in the early stages of the study, indicating a decrease in the amylose content of the purple sweet potato starch. When the starch is heated in water at the gelatinisation temperature, the heat energy causes the starch hydrogen bonds to weaken, making it easier for water to enter the granules and allow the exchange of amylose molecules with water (Azzahra, 2019). Compared to the pregelatinisation method, the acetylation method resulted in whiter starch, likely caused by the process of adding acetic acid (CH_3COOH). In 2007, a study reported that an increase in the amount of amylose in starch was caused by the breaking of the amylopectin branch chain at the α-1,6-glycosidic bond, resulting in a decrease in the number of amylopectin branched chains and an increase in amylose content (Wulan, Widyaningsih & Ekasari, 2007). The higher the acetic acid concentration, the higher the amylose levels.

The results of the characterisation of the two types of modified purple sweet potato starch, i.e., pregelatinised and acetylated, showed good flow properties, moisture content, and percentage of compressibility, indicating that using different techniques for starch modification (pregelatinisation and acetylation) did not significantly affect the characteristics of the modified starch obtained. The evaluation of tablets showed that Formula 3 was the best, with a modified starch concentration of 70 mg for a tablet formula weighing 650 mg. This composition met the requirements of hardness and disintegration time. However, the evaluation of tablet friability in all formulas showed results that did not meet the requirements. Friability is one of the methods used to measure the ability of tablets to withstand shock and abrasion during production, packing, and shipping without breaking or crumbling. This result indicates that the modified starch used does not have the ability to improve the friability of the tablets; hence, additional binders are needed to obtain a friability value that meets the requirements.

In the third formulation, all modified starches showed dissolution test results that met the requirements, likely because the concentration of the starch used as a disintegrant was higher than in formulas 1 and 2. This higher concentration of starch leads to a larger swelling power effect that could accelerate the disintegration time of the tablet, which, in turn,

increases the percentage of the active substance that dissolves in the test solution (Winata, Syukri & Chabib, 2019).

Conclusion

The starch from purple sweet potato has the potential as an alternative disintegrant for tablet formulation, but the amount used needs to be reduced so as not to produce brittle tablets.

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