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Research Article

# FORMULATION OF A FAST-DISINTEGRATING TABLET USING MALTODEXTRIN DE 10-15 AND PREGELATINIZATED CASSAVA STARCH AS EXPEDIENTS

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**ABSTRACT**

**Objective:** Fast-disintegrating tablets are a pharmaceutical preparation that is rapidly being developed because they can dissolve in the oral cavity without chewing and without additional water support. The type of dissolver is a crucial component in fast-disintegrating tablets. Maltodextrin and pregelatinized cassava starch (PPS) are excipients that can be used as dissolvers. This study aimed to formulate fast-disintegrating tablets using a combination of maltodextrin dextrose equivalent (DE) 10-15 and PPS in various concentrations as excipients.

**Methods:** The cassava starch classified as PPS was obtained. PPS was then mixed with maltodextrin DE 10-15 to create fast-disintegrating tablets using the wet granulation method.

**Results:** Tablet evaluation showed that formula F containing 40% maltodextrin DE 10-15 and 10% PPS was the most effective of the proposed fast-disintegrating tablets.

**Conclusions:** Formula F has a hardness of 3.39 kp, 0.74% friability, a wetting time of 7.87 seconds, and a dissolve time of 38.55 seconds.

**Keywords:** Maltodextrin dextrose equivalent 10-15, Fast-disintegrating tablets, Pregelatinized cassava starch.

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## INTRODUCTION

Today, many types of pharmaceuticals are being developed. Fast-dissolving tablets are an example of this development. This type of tablet is designed to instantly dissolve in the oral cavity when it comes in contact with saliva after it is placed on the tongue without chewing or without the help of water to release the drug [1,2]. This type of tablet has helped patients, including geriatric and pediatric patients, who have difficulty swallowing drugs. In addition, these tablets can also be used by patients with mental disorders, patients who frequently vomit, patients who cough during common cold and patients who have difficulty finding water when they travel [2]. The use of a dissolvent (disintegrants) is an important component in the production of fast-dissolving tablets. Maltodextrin and pregelatinized cassava starch (PPS) are examples of excipients that can serve as dissolvers. Maltodextrin is the product of partial starch hydrolysis containing a α-D-glucose unit attached to (1 → 4) glycoside with a dextrose equivalent (DE) value <20; it has the general formula: ([C6H10O5] nH2O) [3]. DE is the total amount of sugar obtained from the starch hydrolysis yield. PPS is a starch that has been physically modified by heating to gelatinization, followed by drying and smoothing [4]. The modified starch has good flowability and compressibility, so it can be used for direct induction [5].

Previous research has shown that maltodextrin DE 15-20 can be used as a dissolver due to its capillarity and porosity [6,7]. The present study used maltodextrin DE 10-15. Maltodextrin DE 10-15 was used as the dissolver because it has a smaller bulk density than maltodextrin DE 15-20, so it is expected to enable a tablet to dissolve more quickly since the type of DE being distributed in the tablet matrix will increase its capillarity action. Previous research has shown that PPS can be used as a single dissolver in fast-disintegrating tablets because of its ability to expand when it comes in contact with water [8]. In this study, maltodextrin DE 10-15 was combined with PPS as excipients in the fast-disintegrating tablet to determine their effectiveness as dissolvers. The tablets were made using the wet granulation method to create several fast-disintegrating tablet formulations using famotidine as a drug model. Furthermore, the resulting tablets were evaluated based on the requirements found in Pharmacopeia III and Pharmacopeia IV, and other literature, to determine the time it takes for each tablet to dissolve.

## METHODS

This research used the following materials: Famotidine tablets (Reddy's Laboratories, Hyderabad, India), cassava starch (PT Sungai Budi, Jakarta, Indonesia), maltodextrin DE 10-15 (Zhucheng Dongxiao Biotechnology, Shandong, China), aspartame (Vitasweet, Changzhou, China), mannitol (Qingdao Bright Moon Seaweed Group, Shandong, China), Avicel PH 102 (Gujarat Microwax Pvt., Ahmedabad, India), anhydrous lactose (Molkerei Meggle, Wasserburg, Germany), and 96% technical ethanol.

The following items were also used: AR 400 tablets (Erweka, Heusenstamm, Germany), sieves (Retsch GmbH & Co, Haan, Germany), TAR ferries (Erweka, Heusenstamm, Germany), a TBH 28 hardness tester (Erweka, Heusenstamm, Germany), a sliding range (Vernier Caliper) (Qingdao Wepro Tool, Shandong China), filter paper, an oven (Memmert, Schwabach, Germany), Petri dishes, a stopwatch, analytical scales Mettler Toledo AL-204 (Adam, Columbus, Ohio), a double drum drier (R. Simon Dryers, Nottingham, England), a disc mill, a light polarization microscope BH-2 PM Type 10A05 (Olympus, Center Valley, PA), and glassware. The preparation was initiated by converting cassava starch to PPS and then mixing it with maltodextrin DE 10-15, famotidine, and other excipients that were molded into seven formulas (Table 1) using the wet granulation method. After that, the following characteristics of the tablets were examined:

### Weight uniformity

A total of 20 tablets were weighed, one-by-one, and then the average weight was calculated. According to the 151-300 mg tablet weight uniformity requirement, no more than two tablets should have a deviation >7.5%, and no individual tablet should have a deviation >15% [9].

### Tablet hardness

Tablet hardness was measured using a TBH 28 hardness tester (Erweka, Heusenstamm, Germany). The harness requirement for fast-disintegrating tablets is that a tablet should dissolve in 1-3 kp [10].

**Tablet firmness**

Tablet firmness was measured using a TAR friability tester (Erweka, Heusenstamm, Germany). To meet the firmness requirement, the value of friability (% loss in weight) of tablet must be <1% [11].

**Wetting time**

Filter paper folded in half with a diameter of 6.5 cm was placed on a Petri dish containing 6 ml of Aquadest. A test tablet was placed in the middle of the filter paper that was soaked with Aquadest until the content of the tablet was evenly distributed. A stopwatch was used to calculate the time required for the water to diffuse from the filter paper that was moistened by the Aquadest into all parts of the tablet [12].

**Dissolve time**

A 10 cm diameter Petri dish was filled with 10 ml of Aquadest (pH=6.8). Each tablet was carefully placed into the middle of a Petri dish. A stopwatch was used to calculate the time it takes for a tablet to completely disintegrate into fine particles [12].

## RESULTS AND DISCUSSION

PPS is created by cooking cassava starch at 90°C. At that temperature, the starch will expand maximally [13]. The thickened mass is then dried using a double drum drier at 80°C until the viscous mass can be dried into white flakes. The flakes were then milled with a disc mill equipped with a 35-mesh sieve to obtain a powder that is not too fine. The PPS particle size should not be too fine so a fast dissolving time can be obtained. In this study, sieving produces a white powder that had the correct consistency. PPS was subsequently used as an excipient for the fast-disintegrating tablet. The fast-dissolving tablets were made using the wet granulation method; this enabled the tablets to have good flow rate and compressibility so that an effective tablet could be produced. The tablets produced from the seven formulas were generally rounded, flat, white, and odorless, and they had a sweet taste.

**Weight uniformity**

The desired weight of each tablet is 200 mg. The uniformity of the tablet weight is influenced by the flow properties. The weights obtained from the seven formulas were ranged from 200.06±2.21 mg to 202.42±2.25 mg (Table 2).

**Table 1: Formulation of the tablets**

| Material | Amount (%) | | | | | | |
|---|---|---|---|---|---|---|---|
| | A | B | C | D | E | F | G |
| Famotidine | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Maltodextrin DE 10-15 | 20 | 30 | 40 | 10 | - | 40 | 30 |
| PPS | 20 | 10 | - | 30 | 40 | 10 | 20 |
| Avicel pH 102 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| Anhydrate lactose | 19 | 19 | 19 | 19 | 19 | 9 | 8 |
| Mannitol | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Aspartame | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| Total | 100 | 100 | 100 | 100 | 100 | 100 | 100 |

DE: Dextrose equivalent, PPS: Pregelatinized cassava starch

**Table 2: Tablet size and weight uniformity results**

| Formula | Size uniformity | | Weight uniformity (g) |
|---|---|---|---|
| | Thickness (mm) | Diameter (mm) | |
| A | 4.32±0.07 | 8.10±0.00 | 202.18±2.39 |
| B | 4.33±0.06 | 8.10±0.00 | 201.48±2.20 |
| C | 4.34±0.06 | 8.10±0.00 | 202.42±2.25 |
| D | 4.17±0.06 | 8.10±0.00 | 200.70±2.26 |
| E | 4.02±0.06 | 8.10±0.00 | 201.37±2.25 |
| F | 4.47±0.06 | 8.10±0.00 | 200.85±2.30 |
| G | 4.43±0.06 | 8.10±0.00 | 200.06±2.21 |

**Tablet hardness**

Hardness is useful as a physical control method during the manufacturing process [11]. Formula F and formula G had the highest hardness: 3.39 kp. Formula E had the lowest hardness: 3.32 kp.

**Tablet firmness**

Tablet firmness (rigidity) is useful for determining the resistance of the tablets to shocks that occur during manufacturing, packaging, and distribution [11]. The rigidity of conventional tablets meets the requirement if the % loss in weight is <1% [11]. The friability test results are shown in Table 3; as seen, formulas B, C, F, and G meet the friability test requirements. Among those four formulas, formula C had the best rigidity (0.42%). Of the seven formulas, formula E had the worst rigidity (1.84%). The results showed that the use of PPS with a concentration >10% increased the firmness of the tablets, as seen in the friability test results for formulas A, D, and E. These three formulas were not good options for fast-disintegrating tablets because their friability value was >1%. However, this can be overcome by adding maltodextrin DE 10-15, as seen in formula G. Fast-disintegrating tablets, generally, have a high degree of friability; therefore, they are specially packaged so that each tablet is still intact and in good condition when it is distributed to patients [10].

**Wetting time**

The wetting time is closely related to the inner structure of the tablet and the hydrophilicity of the excipient [2]. The wetting time test results are shown in Table 3. Formula C had the fastest wetting time: 7.64 seconds. Formula E had the slowest wetting time: At least 298.25 seconds. The results showed that the higher the concentration of maltodextrin DE 10-15, the faster the wetting time. The rapid wetting time of maltodextrin DE 10-15 is due to its hydrophilicity, porosity, and capillarity which makes fluid (such as saliva) rapidly penetrate into the tablets [7]. The wetting time decreases with PPS. The wetting time of formula A is faster than the wetting time of formulas D and E. This result confirms that the higher the concentration of PPS the longer the wetting time.

**Dissolve time**

The dissolve time is the most important parameter of fast-disintegrating tablets. The method used to evaluate the dissolve time for fast-disintegrating tablets differs from the one used to evaluate conventional tablets. Therefore, modification of the dissolve time evaluation was done by comparing it to an oral condition [2]. The dissolve time requirement for fast-disintegrating tablets is <3 minutes [2]. The results of the dissolve time test are shown in Table 3. Formula D had the fastest dissolve time (24.49 seconds); the formula for that tablet contains 10% maltodextrin DE 10-15 and 30% PPS. Formula D dissolved faster than formula E, which does not contain maltodextrin DE 10-15. However, the dissolve time for formula E is still better than the dissolve times for the other formulas that use maltodextrin DE 10-15 with a concentration >10%. The large concentration of maltodextrin DE 10-15 in formula C resulted in a longer dissolve time for that tablet (69.67 seconds). This is because when maltodextrin is in a water-filled environment, it forms a gel layer around the tablet to prevent the water from penetrating into the tablet [7]. The dissolve time required for formula C can be solved by adding 10% PPS to the formula, as indicated in formula F where the dissolve time was 38.55 seconds. The dissolve time for formula G (35.77 seconds) was faster than the dissolve time for formula B (46.40 seconds); this further confirms that maltodextrin DE 10-15 has a longer disintegration time than PPS, but this is not necessarily the case with other forms of maltodextrin DE. Therefore, further research is needed to determine whether maltodextrin with a smaller or greater amount of DE will affect the tablet disintegration time. When the porosity and capillarity of maltodextrin are combined with PPS's expanding mechanisms, the tablets are able to more quickly dissolve. The order of the dissolve time for the tested tablets, from the fastest time to the slowest time is D<E<A<G<F<B<C.

## CONCLUSION

In this study, the best combination of maltodextrin DE 10-15 and PPS that can be used as fast-disintegrating tablet excipient was

**Table 3: Hardness, friability, wetting time, and tablet disintegration time**

| Formula | Hardness (kp) | Friability (%) | Wetting time (seconds) | Dissolve time (seconds) |
|---|---|---|---|---|
| A | 4.52±0.89 | 1.08±0.08 | 54.45±2.82 | 26.39±0.43 |
| B | 4.51±0.61 | 0.66±0.02 | 24.74±2.87 | 46.40±1.40 |
| C | 4.45±1.03 | 0.42±0.05 | 7.64±2.29 | 69.67±2.52 |
| D | 4.35±0.61 | 1.49±0.13 | 87.66±0.67 | 24.49±0.50 |
| E | 4.38±0.44 | 1.84±0.08 | 298.25±6.97 | 26.09±0.73 |
| $f(x)=a_0+\sum_{n=1}^{\infty}\left(a_n\cos\frac{n\pi x}{L}+b_n\sin\frac{n\pi x}{L}\right)$ | 4.72±0.88 | 0.74±0.22 | 6.51±0.89 | 38.55±0.83 |
| G | 4.21±0.33 | 0.78±0.01 | 35.57±1.98 | 36.76±1.19 |

found to be 40% maltodextrin DE 10-15 with 10% PPS. However, further research on fast-disintegrating tablets using other concentrations of maltodextrin DE is needed to determine if other combinations of these two excipients are effective for use in fast-dissolving tablets.

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