COMPARATIVE STUDY OF PRIMOJEL® 2%, 5%, & 8% TO PHYSICAL CHARACTERISTICS OF TABLET FROM DRIED EXTRACT Murraya paniculata (L.) Jack LEAVES

Uji perbandingan Primojel® 2%, 5%, & 8% terhadap karakteristik fisik tablet ekstrak kering daun Murraya paniculata (L.) Jack

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ABSTRACT
Comparative study of Primojel® 2%, 5% & 8% to physical characteristics of tablet from dried extract of Murraya paniculata (L.) Jack leaves has been investigated. Primojel® is one of the tablet excipients that acts as disintegrant. Dried extract Murraya paniculata (L.) Jack leaves was formulated with Primojel®, lactose, PVP K 30, magnesium stearate and silica coloidal; then pressed using direct compression method. Each formulae contained different concentration of Primojel® i.e : F1 = 2%, F2 = 5% & F3 = 8%. The results for all formulae conformed with the specifications. Statistical analysis (ANOVA & LSD on confidence level 5%) tend to showed significant differences on parameter disintegration, friability, hardness, and weight uniformity of tablet, but no significant differences on parameter dimension. Based on tablet disintegration, F3 could performed the best results.

Key words: Murraya paniculata, tablet, Primojel®, direct compression, disintegration, dried extract

INTRODUCTION
Disintegrating agents are substances routinely included in tablet formulations to promote moisture penetration and dispersion of the matrix of the dosage form in dissolution fluids. An oral solid dosage form should ideally disperse into the primary particles from which it was prepared. Although various compounds have been proposed and evaluated as disintegrants, relatively few are in common usage today. Tradition-
ally, starch has been the disintegrant of choice in tablet formulations where it is still widely used. However, starch is far from ideal. For instance, starch generally has to be present at concentration above 5% which could adversely affect compactibility, especially in direct compression (Swarbick, 2000).

In recent years, several new disintegrants have been developed. Often called super disintegrants, they can be used at lower levels than starch. Because they can be present in lower concentrations in the overall formulation than starch, any possible adverse effect on fluidity of compactibility would be minimized. Sodium starch glycolate is a super disintegrant made by cross-linking sodium carboxymethylstarch. Sodium starch glycolate are generally spherical, a characteristic which accounts for their good flowability. Sodium starch glycolate was popular in trade name as Primojel® (Swarbick, 2000).

Tablet formulation applied Murraya paniculata (L.) Jack leaves as antiinflammation (Sudibyo, 1998). In order to develop traditional medicine as a natural products into an accurate dose of application, careful consideration of formulation-related parameters is required.

MATERIALS AND METHODS

Preparation

Murraya paniculata (L.) Jack leaves was cleaned, cutted, milled. The extraction of leaves using decocta method. The extract was dried in oven 50°C for 10 hours.

Qualitative test of Dried Extract

Colour identification was done with acid resulting yellow-green colour.

Formulation

Formulation involve lactose, PVP K 30, silica coloidal, magnesium stearate and talc.

Quality Control of Powder (after formulation)

Powder were evaluated for moisture content, density, and compressibility.
1. Moisture content. The moisture content was determined using Sartorius moisture content tester.
2. Density. Density was determined i.e. true density and tapped density.
3. Compressibility. The compressibility of the granules was determined using tapped density and bulk density.

Preparation of Tablets

All powders were sieved and fractions corresponding to particle size range 100-315 μm were used for tablets preparations. Tablets were prepared weighing 400 mg and using flat face 11 mm punch. Tablet were prepared by direct compression method. The tablets were compressed using single compaction machine tablet (Erweka).

Evaluation of Tablet

Physical characteristics tablets tests include disintegration, friability, hardness, dimension and weight uniformity.
1. Tablet disintegration. For each formulation 12 tablets were tested using a Hanson-Research Q-21 (Germany).
2. Tablet friability. For each formulation 10 tablets were tested using a Erweka-type friabilator [Erweka D-63150 - Germany].
3. Tablet hardness. For each formulation 10
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Tablets were examined using a Monsanto hardness tester.

4. Tablet dimension. For each formulation 10 tablets were tested using a “jangka sorong”.

5. Weight uniformity of tablet.

Statistical Analysis

The difference of tablet physical characteristics contained different concentration of Primojel® done using ANOVA & LSD test with $\alpha = 5\%$.

RESULTS AND DISCUSSION

Qualitative Test of dried extract

Colour identification: reaction with acid yield yellow-greenish colour

Quality Control of Powder

Quality control of powder include moisture content, density and compressibility be shown on table 1.

<table>
<thead>
<tr>
<th>Replication</th>
<th>Moisture Content (%)</th>
<th>True density (g/mL)</th>
<th>Tapped density (g/mL)</th>
<th>Compressibility (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>2.041</td>
<td>0.702</td>
<td>0.897</td>
<td>21.739</td>
</tr>
<tr>
<td>II</td>
<td>2.041</td>
<td>0.702</td>
<td>0.897</td>
<td>21.739</td>
</tr>
<tr>
<td>III</td>
<td>2.041</td>
<td>0.670</td>
<td>0.885</td>
<td>24.294</td>
</tr>
</tbody>
</table>

Average ± SD 2.041 ± 0.000 0.691 ± 0.021 0.893 ± 0.011 22.591 ± 1.475

Evaluation of Tablet

Evaluation of tablet include disintegration, friability, hardness, dimension and weight uniformity. The result be shown on Table 2.

<table>
<thead>
<tr>
<th>Formula</th>
<th>Disintegration (minute)</th>
<th>Friability (%)</th>
<th>Hardness (kg)</th>
<th>Diameter (cm)</th>
<th>Thickness (cm)</th>
<th>Weight uniformity (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>8.859 ± 0.739</td>
<td>0.324 ±</td>
<td>4.300 ±</td>
<td>1.100 ±</td>
<td>0.394 ±</td>
<td>0.401 ±</td>
</tr>
<tr>
<td>F2</td>
<td>7.192 ± 0.359</td>
<td>0.222 ±</td>
<td>0.651 ±</td>
<td>0.000 ±</td>
<td>0.005 ±</td>
<td>0.002 ±</td>
</tr>
<tr>
<td>F3</td>
<td>5.958 ± 0.258</td>
<td>0.021 ±</td>
<td>5.927 ±</td>
<td>1.100 ±</td>
<td>0.392 ±</td>
<td>0.406 ±</td>
</tr>
</tbody>
</table>

Statistical Analysis result be shown on Table 3 and Table 4.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Sig.</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disintegration</td>
<td>0.000</td>
<td>Significant difference among F1, F2 and F3</td>
</tr>
<tr>
<td>Friability</td>
<td>0.000</td>
<td>Significant difference among F1, F2 and F3</td>
</tr>
<tr>
<td>Hardness</td>
<td>0.000</td>
<td>Significant difference among F1, F2 and F3</td>
</tr>
<tr>
<td>Dimension</td>
<td>0.638</td>
<td>No significant difference among F1, F2 and F3</td>
</tr>
<tr>
<td>Weight uniformity</td>
<td>0.000</td>
<td>Significant difference among F1, F2 and F3</td>
</tr>
</tbody>
</table>
Table 4. Statistical analysis using LSD

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disintegration</td>
<td>Significant difference among F1, F2 and F3</td>
</tr>
<tr>
<td>Friability</td>
<td>Significant difference between F1-F2, &amp; F2-F3</td>
</tr>
<tr>
<td></td>
<td>No significant difference between F1-F3</td>
</tr>
<tr>
<td>Hardness</td>
<td>Significant difference among F1, F2 and F3</td>
</tr>
<tr>
<td>Weight uniformity</td>
<td>Significant difference between F1-F2, &amp; F1-F3</td>
</tr>
<tr>
<td></td>
<td>No significant difference between F2-F3</td>
</tr>
</tbody>
</table>

Although disintegrants are important components in solid dosage forms, their mechanism of action has not been clearly elucidated. The mechanisms proposed in the past include water wicking, swelling, deformation recovery, repulsion, and heat of wetting. It seems likely that no single mechanism can explain the complex behavior of the disintegrants. However, each of these proposed mechanism provides some understanding of different aspects of disintegrant action (Swarbick, 2000).

Super disintegrants draw water into the matrix system at a faster rate and to a greater extent when compared to traditional starch. Kamp et al. (1987) utilizing a water-uptake measurement device, showed that tablets that demonstrate greater uptake volume and rate, such as those containing sodium starch glycolate, disintegrated more rapidly. Although the hydrophobic lubricant, magnesium stearate, seemed to negatively affect the wicking process, those containing sodium starch glycolate were less affected by the detrimental effect of mixing with the hydrophobic lubricant (Swarbick, 2000).

The effectiveness of superdisintegrants depend heavily upon the method of granulation and incorporation. Kamp et al. (1987) evaluated the method of some superdisintegrant include sodium starch glycolate in tablets. Whether the incorporation of the super disintegrant was intragranular, extragranular, or evenly distributed in both sites, they found little or no difference in disintegration time and crushing strength (hardness) of tablets (Swarbick, 2000).

Tablet production by direct compression has increased steadily over the years because it offers economic advantages through its elimination of the wet granulation and drying steps. The granulation technique that uses slugging or roller compaction is no longer a method of choice to produce compressed tablets. The elimination of the wet granulation step increases the stability of drugs that can degrade by moisture and/or heat. Another advantage of direct compression is that the tablets generally disintegrate into primary particles, rather than into granules. For the majority of tablet formulations, the addition of a disintegrant is necessary in order to obtain a fast tablet disintegration (Bolhuis, 2001).

The results for all formulae conformed with the specification. Therefore, as the percentage of Primojel® increase (F3 > F2 > F1), hardness of tablet also increases, resulting in stronger physical characteristics of tablet. At higher concentrations of Primojel®, the characteristics of disintegration getting better.
Statistical analysis (ANOVA & LSD on confidence level 5%) tend to showed significant differences on parameter disintegration, friability, hardness, and weight uniformity of tablet, but no significant differences on parameter dimension. Based on tablet desintegration, F3 could performed the best results.

CONCLUSIONS

The research yield conclusion:

1. *Murraya paniculata* (L.) Jack tablet dosage forms showed acceptable physical characteristics and conformed with the requirement.

2. The percentage of Primojel® increase (F3 > F2 > F1), hardness of tablet also increases, and the characteristics of disintegration getting better.

3. There is significant differences on parameter disintegration, friability, hardness, and weight uniformity of tablet, but no significant differences on parameter dimension.

4. Based on tablet desintegration, F3 could performed the best results.

REFERENCES


