COMPARATIVE EVALUATION OF POTATO STARCH AND BANANA POWDER AS DISINTEGRATING AGENTS IN ACECLOFENAC TABLET FORMULATION

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INTRODUCTION
Researches are being carried out to reduce the patient compliance and for an effective therapy. The most widely utilized route of administration is oral drug delivery among all the routes that have been explored for the systemic delivery of drugs. This is because that, the popularity involved in the case of administration and the traditional belief that by oral administration the drug is as well absorbed as the food stuffs are ingested daily[1]. Appropriate design and formulation of a dosage form need consideration in the physical, chemical and biologic characteristics of the drug substances. Excipients help the formulation design and perform a wide range of functions to obtain desired properties in the finished drug product. Excipients are the additives used to convert pharmacologically active compounds into pharmaceutical dosage forms suitable for administration to patients. Present day researches are looking for natural excipients as they believe that anything natural will be more safe and devoid of side effects. Advantage of natural excipients are low cost and natural origin free from side effects, biocompatibility & bioacceptance, renewable source, environment friendly processing, local availability, better patient tolerance as well as public acceptance, they comprise the natural economy by providing inexpensive formulation to people[2].

In the present context the focus was the study of natural excipients. For most tablets, the first important step is break down of tablets in to smaller particles or granules, a process is known as disintegration. Disintegration test is provided to determine whether tablet disintegrate within the prescribed time when placed in liquid medium as specific experimental condition. Starches are used extensively in pharmaceutical industries as disintegrants, binders and lubricants in tablet formulation. Starches are believed to extend its disintegrating property by absorption of moisture and spelling of the grain followed by rupture of tablet core[3]. Banana fruit is economically one of the most important fruit produced and consumed in the world. The soft and sweet fruit of this tropical plant is enjoyed by the people from around the world. The main objective of this study was to utilize banana powder [Musa acuminata] as a pharmaceutical excipient and evaluate its disintegrating properties in comparison with the other disintegrating agents. The dehydrated Banana powder is a natural commonly used as nutritional supplement as it contains many essential nutritional including minerals. It is considered to be good for treatment of gastric ulcer and diarrhea because they contain vitamin A[4].

MATERIALS AND METHODS

Materials
Aceclofenac was received as a gift sample from Macsur Pharma India Pvt Ltd, Puducherry, India. Dehydrated Banana powder (Banatone industries, Thiruvananthapuram), Lactose (Spectrum reagent & chemicals Pvt Ltd), Microcrystalline cellulose (Chemdyes co, Rajkot), Acacia (Nice chemicals Pvt Ltd), Talc (Spectrum reagent & chemicals Pvt Ltd), Magnesium stearate (Otto chemicals, Mumbai) were used as tablet excipients.

Methods
Extraction of Potato Starch
Potato was thoroughly washed and all foreign materials were removed. The potato was peeled, weighed and washed. The washed potato was pulverized using a blender. Enough quantity of water was added to the pulp which then passed through a sieve. The filtrate was allowed to settle and 0.1 N sodium hydroxide was added to separate the starch and proteinous materials as well as to neutralize the prevailing slight acidity. Excess sodium hydroxide was removed by washing several times with distilled water. The clear supernatant fluid was poured away while sedimented starch was collected on a tray and air-dried on a table at room temperature[5].

Characterization of Dehydrated banana powder and Potato starch [6,7]

Solubility Test
The solubility of the banana powder and potato starch in cold water was determined and the results recorded.

Iodine Test
1g of banana powder and potato starch was boiled with 15ml of water. After cooling to 1ml of the mucilage, 2drops of 0.1N iodine solution was added and the colour change noted.

Angle of repose
A 30 g sample was poured into a plugged glass funnel with the tip, 10 cm above the flat surface of the bench. The granules were allowed to flow freely through the orifice of the funnel to form a heap whose height and diameter were determined.

RESULTS

It was found that tablets with banana powder and potato starch disintegrate more rapidly than the tablets with microcrystalline cellulose. The prepared formulations were passed the evaluation test that is weight variation, hardness, friability and content uniformity. The mechanism of drug release from tablets was found to be non-Fikian, anomalous transport.

Conclusion
Results from various evaluations suggested that banana powder and potato starch could be used as disintegrants in tablet formulation.

Keywords: Potato starch, Banana powder, Natural excipients, Disintegrant, Aceclofenac.
The angle of repose was calculated using the equation below:
\[ \tan \theta = \frac{h}{r} \]
Where \( h \) is height and \( r \) is radius of circular heap.

**Bulk Density**
A 3g weight of each of the banana powder and potato starch to be used as carrier was weighted and poured into a 100ml measuring cylinder and the volume was recorded. The bulk density was then calculated.

Bulk Density (BD) = \( \frac{M}{V} \)

Where \( M \) is mass and \( V \) is volume.

**Tapped Density**
A 30g weight of each of the banana powder and potato starch was weighted and poured into a 100ml measuring cylinder and tapped on a hard surface 30 times from about 2cm height and the volume was recorded.

Tapped Density (TD) = \( \frac{M}{V} \)

Where \( M \) is mass and \( V \) is volume.

**Carr’s Index**
Carr’s Index (%) was determined using the following relationship

\[ C.I. = \frac{TD}{BD} \times 100 \]

**Hausner’s ratio**
Hausner’s ratio was determined using the following relationship

\[ H.R = TD/BD \]

Where TD is Tapped density, BD is Bulk density.

**Swelling capacity**
The tapped volume occupied by 10g of each banana powder and potato starch (\( V_d \)) in a 100ml measuring cylinder was noted. The powder was then dispersed in 35ml of distilled water and the volume made up to 100ml with more water. After 18 hours of standing, the volume of the sediment, (\( V_w \)) was estimated and the swelling capacity was computed as:

Swelling capacity = \( \frac{V_w}{V_d} \)

**Moisture Content**
A 3g weight of each banana powder and potato starch was heated at 1350°C using moisture analyzer (Sartorius, Germany); and the reading was recorded.

**Compatibility study**
Before formulation of a drug substance into a dosage form, it is essential that it should be chemically and physically characterized. Compatibility studies give the information needed to define the nature of the drug substances and provide a frame work for the drug combination with pharmaceutical excipients in the fabrication of a dosage form. One of the requirements for the selection of suitable excipients or carrier for pharmaceutical formulation is its compatibility. Therefore in the present work, a study was carried out by using Shimadzu FTIR spectrometer to find out if there is any possible chemical interaction between aceclofenac and excipients respectively. The samples were powdered and intimately mixed with dry powdered potassium bromide. The powdered mixture was taken in a diffuse reflectance sampler and the spectra recorded by scanning in the particular wavelength region (4000-400 cm\(^{-1}\)) using Shimadzu FTIR spectrometer. The IR spectrum of drug was compared with that of the physical mixture of the drug and excipients used to check for any possible drug-excipients interaction.

**Formulation of Aceclofenac Tablet**
Four different batches of tablets each containing 100mg of aceclofenac were formulated and evaluated. In all four batches the tablets were formulated employing aceclofenac alone and lactose as diluents and direct compression method. In all the batches acacia (2%) as binder, talc (2%) and magnesium stearate (2%) as lubricants were used. In formulation F1 Potato starch (5%), F2 banana powder & Potato starch (2.5% & 2.5%), F3 banana powder (5%) and F4 Microcrystalline cellulose [MCC] (5%) as disintegrant were used. In each batch 100 tablets were prepared.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/Tablet</td>
<td>F1</td>
</tr>
<tr>
<td>Aceclofenac</td>
<td>100</td>
</tr>
<tr>
<td>Lactose</td>
<td>291.6</td>
</tr>
<tr>
<td>Potato starch</td>
<td>22</td>
</tr>
<tr>
<td>Banana powder</td>
<td>-</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>-</td>
</tr>
<tr>
<td>Acacia</td>
<td>8.8</td>
</tr>
<tr>
<td>Talc</td>
<td>8.8</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>8.8</td>
</tr>
<tr>
<td>Total weight of tablet (mg)</td>
<td>440</td>
</tr>
</tbody>
</table>

**Evaluation of Tablets**[8,9,10]

**Weight variation**
The USP weight variation test was performed by taking 20 tablets from a batch. Then 20 tablet, were weighed and the average weight was taken. Then each tablet was weighed individually. The percentage deviation can be determined by using the following formula.

\[ \% \text{ Deviation} = \frac{\text{Average weight} - \text{Individual weight}}{X \times 100} \]

**Hardness Test**
Pfizer hardness tester was used for measuring the hardness of the formulated aceclofenac tablets. From each batch five tablets were taken at random and subjected to test. The mean of these five tablets were given in the table.

**Friability**
It is a measure of tablet strength. The friability was determined by using Roche Friabilator. 10 tablets were taken and their weight determined. Then they were placed in the friabilator and allowed to make 100 revolutions at 25rpm. The tablets were then dusted and reweighed. The percentage weight loss was calculated by using the following formula.

\[ F = 100 \times \left(1 - \frac{w}{w_0}\right) \]

Where, \( w_0 \) = Weight of tablets before friability
\( w \) = Weight of tablets after friability

**Drug content Uniformity**
The prepared tablets containing aceclofenac was tested for drug content uniformity. Tablets were dissolved in 100 ml of phosphate buffer (pH 6.8) in 100 ml volumetric flask which was previously clean and dry. This solution after suitable dilution was measured for absorbance at 274 nm in a UV-visible spectrophotometer.

**Disintegration Test**
Six tablets were taken in disintegration apparatus. Six glass tubes that are 3 inches long open at the top and held against a 10 mesh screen at the bottom end of the basket rack assembly. To test the disintegration time one tablet was placed in each tube, and the basket rack was positioned in a litre beaker of water at 37°C ± 2°C such that the tablets remain 2.5 cm from the bottom of the beaker. A standard motor driver device was used to move the basket assembly up and down through a distance of 5-6cm at a
frequency of 28-32 cycles per minute. To meet the USP standard all particles of tablet must pass through 10 mesh screen in the time specified.

**Dissolution**

Dissolution was carried out using USP dissolution apparatus II (paddle apparatus). Dissolution of tablets was carried out in 900ml dissolution medium. The dissolution medium for aceclofenac tablet was pH 6.8. The temperature of dissolution medium was maintained at 37°C ± 2°C. The agitation intensity was 100rpm. The samples of dissolution medium were withdrawn through a filter at different time intervals. Equal volume of fresh medium having same temperature was replaced at each time. The samples were suitably diluted and the amount of active ingredient was determined spectrophotometry with respect to the reported methods.

**Dissolution Kinetics**

To study the release kinetics, data obtained from in vitro drug release studies were plotted in various kinetic models: Zero order (cumulative amount of drug released vs time), First order (log cumulative percentage of drug remaining vs time), Hixson-Crowell (cube root of amount remained to be absorbed vs time) and Korsmeyer’s (log cumulative percentage of drug released vs log time).

**Stability studies**

To study the effect of temperature and humidity on the tablets, they were stored at 40°C and 75% RH in Stability chamber (LabTop Instruments Pvt.Ltd.). After three months disintegrating time, drug content and FTIR spectrum were recorded to observe any effect on the tablets by the exposure to humidity and temperature.

**RESULTS AND DISCUSSION**

**Compatibility study**

FTIR spectroscopy was performed to assess the compatibility of aceclofenac with excipients. Analysis of aceclofenac structure reveals that few intense peaks which are characteristic (3918.64, 3701.69, 3661.19, 3477.99, 3275.5, and 2916.16) of the drug, the similar peaks were observed in all formulations. The results clearly indicate no shifting of peaks was significantly found, indicating the stability of the drug during tablet formulation. Thus the IR study indicates stable nature of aceclofenac in the tablet formulations. This also confirmed that the drug and polymer does not interact.

**Table 2: It shows the physicochemical properties of starch powder.**

<table>
<thead>
<tr>
<th>Properties</th>
<th>Potato starch</th>
<th>Banana powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodine test</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>Solubility</td>
<td>Insoluble</td>
<td>Soluble</td>
</tr>
<tr>
<td>Angle of repose(0)</td>
<td>38.1±0.12</td>
<td>35.8±0.25</td>
</tr>
<tr>
<td>Bulk density (g/ml)</td>
<td>0.46±0.1</td>
<td>0.66±0.12</td>
</tr>
<tr>
<td>Tapped density (g/ml)</td>
<td>0.54±0.12</td>
<td>0.77±0.1</td>
</tr>
<tr>
<td>Carr’s index (%)</td>
<td>14.81±0.22</td>
<td>11.68±0.20</td>
</tr>
<tr>
<td>Hausner’s ratio</td>
<td>1.17±0.15</td>
<td>1.13±0.12</td>
</tr>
<tr>
<td>Melting point (°C)</td>
<td>72</td>
<td>78</td>
</tr>
</tbody>
</table>

Banana powder is soluble in water where Potato starch is practically insoluble in water. The powders also turn blue black on addition of iodine solution which confirmed the presence of starch. An angle of repose 35.03 and 38.13 were obtained for banana powder and potato starch respectively which all fall with the required range for pharmaceutical powders which is 25-450, that of the banana powder which is lower and indicates a better flow property. Angle of repose has been used to characterize the flow properties of powders, it also related to inter particulate friction or resistance to movement between particles.

**Table 3: It shows the physical evaluation of tablets**

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Hardness (kg/cm²)</th>
<th>Average Weight Variation (%)</th>
<th>Friability (%)</th>
<th>Drug Content (mg)</th>
<th>Disintegration Time (sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>5.6±0.12</td>
<td>2.5±0.13</td>
<td>0.48</td>
<td>98.64</td>
<td>44</td>
</tr>
<tr>
<td>F2</td>
<td>5.8±0.14</td>
<td>3.8±0.10</td>
<td>0.62</td>
<td>99.18</td>
<td>91</td>
</tr>
<tr>
<td>F3</td>
<td>5.7±0.12</td>
<td>2.8±0.25</td>
<td>0.52</td>
<td>98.74</td>
<td>51</td>
</tr>
<tr>
<td>F4</td>
<td>6.1±0.20</td>
<td>2.5±0.35</td>
<td>0.58</td>
<td>99.21</td>
<td>148</td>
</tr>
</tbody>
</table>

The hardness values ranged from 5.6 to 6.1 kg/cm² for all formulations (Table 3). The entire tablets passes weight variation test as the average % weight variation was the pharmacopoeial limit of 5% (Table 3). The friability values were found to be within the limit (Table 3). The drug content of aceclofenac determined at 274nm ranges from 98.64 to 99.21 and complies with IP standard. In the study, potato starch and banana powder was employed as disintegrant and its effect was compared with microcrystalline cellulose. Tablets produce from the potato starch and banana powder show a relative lower disintegration time compared to that of the microcrystalline cellulose (Table 3).

![Fig. 1: It shows the In vitro release profile of Aceclofenac Tablets.](image-url)
The dissolution process of a tablet depends upon the wetting followed by disintegration of the tablet. It was observed that the tablets containing banana powder and potato starch exhibited a higher percentage release in comparison with tablet containing microcrystalline cellulose. In vitro data obtained for tablets containing aceclofenac were used to determine the dissolution kinetics. The drug release data of aceclofenac were fitted to various kinetic models. The data were processed for regression analysis using MS-EXCEL statistical functions. Evaluation of release kinetics and application of best fit by correlation coefficient shows that the drug release following Higuchi square root kinetics. The release exponent 'n' calculated from the Korsemeyer-Peppas equation, shows that in all the batches, the 'n' values were between 0.45 and 1. It can be suggested that the release mechanism was non-Fickian, anomalous transport where release dependent on both drug diffusion as well as polymer relaxation.

Stability studies

The results of accelerated stability studies indicated that there was no significant change in the tablets. The drug content was found to be within 100±5% for all the formulations at the end of 90 days. FTIR analysis suggested that there was no significant degradation or changes taking place in the tablets during the study period.

CONCLUSION

The present study was aimed at evaluating the disintegration property of and compares it with other synthetic disintegrant in the preparation of orally disintegrating tablets. The study showed that the banana powder and potato starch have a better disintegrant property than the microcrystalline cellulose. It was concluded that banana powder and potato starch were having excellent superdisintegrant property which can be used as natural disintegrant in the tablet formulation.

ACKNOWLEDGEMENT

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REFERENCE