**International Journal of Pharmacy and Herbal Technology**

**e-ISSN:** 2583-8962 Vol. 2, Issue 4 (October – December, 2024) pp: (2846-2852)

# Formulation and In vitro Evaluation Fast Dissolving Tablet of Model Drug using Various Natural Super Disintegrants

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*Received Date: November 29, 2024; Published Date: 24 December,2024*

**Abstract**

*Fast dissolving tablets, or FDTs, have drawn a lot of attention because of how convenient and simple they are to use. Patients with dysphagia, the elderly, and children can especially benefit from FDTs. In order to improve disintegration and dissolving properties, the objective of this work was to construct and assess FDTs of a model medicine employing a variety of natural super disintegrants.*

*For fast-dissolving formulations, the model drug "Paracetamol" was selected because of its common therapeutic application. The drug-compatibility and disintegration efficiency of a variety of naturally occurring super disintegrants, including Guar gum, Banana powder, Mangifera indica gum, Agar and Arachis hypogaea shell powder.*

*Super disintegrants, other excipients, and the model medication were combined to create the tablets using the wet granulation process. In order to maximize the disintegration duration and dissolution profile, many formulations containing different concentrations of super disintegrants were created.*

*To evaluate factors such weight variation, hardness, friability, disintegration time, and drug release profile, the produced FDTs were evaluated in vitro. The outcomes showed that, in comparison to traditional formulations, the addition of natural super disintegrants greatly shortened the tablet's disintegration time.*

*Additionally, dissolving tests showed higher rates of drug release, proving that natural super disintegrants are useful for accelerating medication disintegration. All things considered, the created FDTs showed encouraging traits for quick medication delivery, indicating their possible use in enhancing patient adherence and treatment results.*

**Keywords** - Fast dissolving tablets, paracetamol, wet granulation technique.

## INTRODUCTION

Natural super disintegrants are substances or mixtures of substances that are added to drug formulations to help break up tablets and capsules into smaller particles. [1] Fast dissolving tablets (FDTs) have gained significant attention in the pharmaceutical industry due to their numerous advantages such as ease of administration, rapid onset of action, and improved patient compliance. Super disintegrants play a crucial role in the formulation of FDTs by facilitating rapid disintegration of the tablet matrix upon contact with saliva. [2,3]

Natural super disintegrants have gained attention in recent years due to their biocompatibility, sustainability, and cost-effectiveness. [4] Therefore, this study aims to explore various natural super disintegrants for the formulation of FDTs to enhance the dissolution rate and overall bioavailability of the drug. These natural ingredients are preferred in pharmaceutical formulations due to their biocompatibility, safety profile, and environmental friendliness. [5,6]

Fast-displacing tablets, or FDTs, have become a popular and patient-friendly dosage form. They are especially helpful for people who have trouble swallowing regular tablets or capsules. When these tablets come into touch with saliva, they dissolve quickly, which facilitates the drug's speedy dissolution and subsequent absorption in the oral cavity. The selection of disintegrants is one important factor affecting the FDTs' disintegration and dissolving characteristics. [7,8]

Super disintegrants are ingredients that are added to tablet formulations in order to facilitate quick dissolution and disintegration. Although synthetic super disintegrants have been widely used, due to their biocompatibility, safety, and environmental friendliness, there is growing interest in investigating natural alternatives. Plant-based compounds, which are natural super disintegrants, present a promising option with potential advantages. [9,10]

**Materials And Methods**

**Material**

Paracetamol (model drug)

Various natural super disintegrants (e.g., plant-based materials such as Gour gum, Banana powder, Mangifera indica gum, Agar, Arachis hypogaea shell powder.)

Maize starch (binder)

Magnesium stearate (lubricant)

Distilled water

Talc

**Methods**

The amounts indicated in Table 1 were followed in the preparation of the paracetamol fast-dissolving tablets. After thoroughly mixing each excipient, talc and magnesium stearate were added. Several parameters, as indicated in Table 2, were used to evaluate the created mixture. Following the mixed product evaluation, the tablets underwent wet granulation compression using a compression machine.[11]

| Sr. No. | Ingredients | Quantity/tablet (mg) | Quantity/ 50tablets (g) |
|---|---|---|---|
| **1** | Paracetamol | 500 | 5 |
| **2** | Disintegrant | ---------- | ---------- |
| **3** | Binder (maize starch) | q.s | q.s |
| **4** | Magnesium stearate | 1.30 | 0.016 |
| **5** | Talc | 13 | 0.16 |

***Table1*:** *Formulations Of fast dissolving tablets of paracetamol*

| Sr. No. | Disintegrants | Quantity/TABLET (mg) | | | |
|---|---|---|---|---|---|
| | | B1 | B2 | B3 | B4 |
| 1 | Gour gum | 10 | 15 | 20 | 25 |
| 2 | Banana powder | 10 | 20 | 30 | 40 |
| 3 | Mangifera indica gum | 10 | 20 | 30 | 40 |
| 4 | Agar | 10 | 20 | 30 | 40 |
| 5 | Arachis hypogaea shell powder | 10 | 20 | 30 | 40 |

***Table 2**: Quantity of Disintegrants in each batch*

**Procedure**

The fast-dissolving tablet of paracetamol were prepared by according to quantity shown in table 1 and 2.

**Granulation solution preparation**

To make the granulation solution, dissolve the binder(s) (pregelatinized starch, for example) in water or another appropriate solvent. Based on the intended tablet properties, the binder concentration in the mixture should be optimized. [12,13]

**Granulation**

In a suitable mixer, combine the paracetamol with the chosen natural super disintegrants and any additional excipients until the mixture is homogenous. Gradually incorporate the granulation solution into the powder mixture while stirring constantly until a moist mass of the required consistency is achieved. After the granules reach the appropriate size and consistency for compression, keep mixing. As needed, modify the granulation settings (such as the amount of granulation solution and mixing time). [14]

**Drying**

Utilizing appropriate equipment, dry the wet granules until the moisture content reaches the target level. A tablet's ideal moisture content is essential to avoid problems during compression. [15]

**Compression**

Compress the granules into tablets with an appropriate tablet press that includes a tablet punching machine for fast-dissolving tablets by wet granulation method. [16]

**Evaluation test**

***In-vitro* disintegration test**

Prepare a disintegration medium in accordance with the guidelines provided in the pharmacopeia or study protocol. Measure the weight and dimensions of the tablets to be tested and place one in each tube or basket of the disintegration apparatus. Submerge the tablets in the disintegration medium at the recommended temperature (usually 37°C). Turn on the apparatus in accordance with the predetermined conditions, which usually involve moving the tubes or baskets containing the tablets vertically. During the test, watch the tablets to see when they dissolve completely or break into small particles. Note the time it takes for each tablet to completely dissolve in order to assess the disintegration characteristics of the tablets.[17]

***In-vitro* dissolution test**

Prepare the dissolving media in accordance with the study protocol or the pharmacopeia's specifications. Usually, this entails creating buffers that mimic the pH levels of the gastrointestinal system. Based on the properties of the tablets being tested, select the suitable dissolving device. USP Apparatus 1 (basket apparatus) and USP Apparatus 2 (paddle apparatus)

are examples of common equipment. Weigh the tablets and take precise measurements of their size. Put one pill into every vessel for dissolving. At the designated temperature (typically 37°C), immerse the dissolution vessels holding the tablets in the dissolution medium. Follow the preset parameters when using the dissolving apparatus, such as the paddles' rotational speed or the basket apparatus's basket speed.[18]

**Weight Variation**

To guarantee uniformity, check for weight variations amongst tablets. To make sure the tablets are consistent, measure their thickness.[19]

**Testing for Hardnes**

Using a hardness tester, determine the hardness of tablets. This guarantees that the tablets have enough porosity to disintegrate while yet being able to tolerate handled without breaking.[20]

**Friability Examination**

To make sure the tablet doesn't break or lose too much bulk while being handled and transported, test their friability.[21]

## RESULT

**Evaluation of paracetamol fast dissolving tablets**

| Parameter | H1 | H2 | H3 | H4 |
|---|---|---|---|---|
| **Hardness** | 4.0 | 5.0 | 4.5 | 5.5 |
| **Friability (%)** | 0.54 | 0.61 | 0.55 | 0.48 |
| **Disintegration time (sec.)** | 52 | 50 | 56 | 42 |

***Table 3*: *Evaluation of fast dissolving tablets of paracetamol***

| Time(sec) | % of release Drug | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Gour gum | | | | Banana powder | | | |
| | H1 | H2 | H3 | H4 | H1 | H2 | H3 | H4 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 60 | 10.70 | 14.95 | 13.6 | 12.90 | 9.54 | 13.85 | 14.54 | 12.80 |
| 120 | 35.46 | 40.65 | 41.86 | 42.63 | 35.96 | 42.65 | 41.95 | 43.42 |
| 180 | 75.63 | 84.59 | 83.65 | 81.53 | 76.85 | 83.65 | 83.96 | 82.64 |
| 240 | 89.55 | 91.56 | 89.66 | 90.34 | 88.36 | 92.62 | 86.54 | 93.78 |
| 300 | 97.60 | 99.90 | 96.99 | 97.06 | 98.65 | 97.45 | 96.45 | 99.99 |
| Agar | | | | | Mangifera Indica gum | | | |
| | H1 | H2 | H3 | H4 | H1 | H2 | H3 | H4 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 60 | 10.87 | 14.98 | 13.66 | 15.99 | 10.74 | 13.36 | 14.23 | 12.75 |
| 120 | 34.66 | 41.69 | 42.89 | 43.43 | 35.56 | 42.25 | 43.65 | 44.42 |
| 180 | 76.53 | 82.39 | 84.25 | 82.53 | 76.65 | 86.55 | 83.66 | 84.24 |
| 240 | 88.65 | 92.36 | 88.36 | 91.36 | 88.46 | 94.65 | 85.54 | 91.28 |
| 300 | 97.49 | 99.436 | 96.88 | 98.06 | 96.65 | 99.45 | 94.45 | 96.99 |
| Arachis hypogaea shell powder | | | | | | | | |
| | H1 | H2 | H3 | H4 | | | | |
| 0 | 0 | 0 | 0 | 0 | | | | |
| 60 | 10.32 | 12.66 | 13.63 | 14.35 | | | | |
| 120 | 39.96 | 42.23 | 41.35 | 45.92 | | | | |
| 180 | 73.60 | 85.85 | 84.76 | 87.23 | | | | |
| 240 | 84.36 | 92.35 | 89.64 | 90.58 | | | | |
| 300 | 96.25 | 98.45 | 93.65 | 99.98 | | | | |

***Table 4*:** *Dissolution profile of fast dissolving tablets of paracetamol*

**Hardness**

The hardness was evenly maintained and was found within the range of 4.0 - 5.5 kg/cm2 for all batch (1 to 4).

**Friability**

For all formulations, the percentage of friability was less than 1%, and for formulations (B1-B4), the values range from 0.52 to 0.60 percent.

**Disintegration test (Time)**

The disintegration time decreases as the concentration of the disintegrants increases, and vice versa. Tablets from each batch disintegrate immediately. Table 3 displays disintegration time data. The formulation that contained exhibited fast disintegration. This is because the medium absorbs water quickly, causing swelling and a burst effect.

**Dissolution studies**

The dissolution profile of formulations (H1-H4) is illustrated in Table 4. As the concentration of disintegrants increased, the drug dissolving rate increased. More than 97.05-99.99% of the medication was released from the gaur gum disintegrants formulations (H1-H4) in 0, 60, 120, 180, 240, and 300 seconds, respectively. The dissolution profile of formulations H1-H4) is presented in Table 4. As the concentration of tablet, the disintegration time decreased and the medication dissolved faster. More than 97.59-98.56% of the medication was released from the banana powder formulations (H1-H4) in 0, 60, 120, 180, , 240, and 300 seconds, respectively. The concentration of disintegrants increased, the drug dissolving rate enhance. More than 97.05-99.99% of the medication was released from the agar disintegrants formulations (H1-H4)

in 0, 60, 120, 180, 240, and 300 seconds, respectively. As the concentration of disintegrants increased, the drug dissolving rate increased. More than 97.05-99.99% of the medication was released from the Mangifera indica gum disintegrants formulations (H1-H4) in 0, 60, 120, 180, 240, and 300 seconds, respectively. The concentration of disintegrants enhance, the drug dissolving rate increased. More than 97.05- 99.99% of the medicate(H1-H4) in 0, 60, 120, 180, 240, and 300 seconds, respectively. Under rapid temperature and humidity changes, the formulation remained stable.

**DISCUSSION**

When these tablets come into touch with saliva, they dissolve quickly, which facilitates the drug's speedy dissolution and subsequent absorption in the oral cavity. The selection of disintegrants is one important factor affecting the FDTs' disintegration and dissolving characteristics. Therefore, this study aims to explore various natural super disintegrants for the formulation of FDTs to enhance the dissolution rate and overall bioavailability of the drug. These natural ingredients are preferred in pharmaceutical formulations due to their biocompatibility, safety profile, and environmental friendliness.

**CONCLUSION**

Wet granulation technology was used to create fast-dissolving paracetamol tablets that were more palatable and improved patient compliance. Consequently, based on our findings, tablets with superior disintegrant qualities and dissolution profiles can be concluded. Therefore, it is possible to formulate fast-disintegrating tablets using natural disintegrants with success.

The creation and in vitro testing of paracetamol fast-dissolving tablets employing a variety of natural super disintegrants has yielded insightful information on formulation parameter optimization and the possibility of improving drug delivery systems. These results can be used to drive the design and manufacturing of fast-dissolving tablets with better performance and therapeutic results through more research and development. Gaur gum is found to be more effective than other natural super disintegrant.

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