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# Development and Evaluation of Mouth Dissolving Paracetamol Tablets for Improved Patient Compliance

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**Abstract:** Mouth dissolving tablets (MDTs) have gained important attention in recent years as a patient-friendly alternative to conventional oral dosage forms. Many patients, especially pediatrics, geriatrics individuals, and those suffering from swallowing difficulties, often face challenges while taking standard tablets. MDTs help overcome this problem by dissolving rapidly in the mouth without the need for water, thereby improving convenience and compliance. [2,6] Paracetamol is a widely used drug for relieving pain and reducing fever, making it a suitable candidate for such a formulation. [1]

The present study focused on developing and evaluating mouth dissolving tablets of paracetamol using different super-disintegrants. Tablets were prepared using the wet granulation method with crospovidone, croscarmellose sodium, and sodium starch glycolate at different concentrations. A novel co-processed excipient containing pregelatinized starch was also explored to enhance tablet performance. The prepared tablets were tested for various quality parameters including hardness, friability, drug content, disintegration time, wetting time, water absorption, and drug release behavior. [1,3]

All the formulations showed acceptable physical properties, with good strength and low friability. Drug content was found to be uniform across all batches. It was observed that tablets containing higher concentrations of super-disintegrants disintegrated more rapidly. Among all, formulations with crospovidone and croscarmellose sodium showed the fastest disintegration and better wetting properties. [1,7] Dissolution studies revealed that drug release increased with increasing concentration of super-disintegrants, and optimized formulations released more than 95% of the drug within 30 minutes, meeting pharmacopoeial requirements. [1,4]

Overall, the study demonstrates that fast dissolving tablets of paracetamol can be successfully developed with improved performance. The use of suitable super-disintegrants and co-processed excipients plays an important role in achieving rapid drug release and better patient acceptability.

**Keyword:** mouth dissolving tablet, super-disintegrant, rapid release, MDT, crospovidone, paracetamol

## Introduction

Oral administration remains the most commonly used route for drug delivery because it is simple, convenient, and widely accepted by patients. [6] Tablets and capsules are the most popular dosage forms; however, not all patients can easily swallow them. Children, elderly individuals, and patients with certain medical conditions such as dysphagia or nausea often find it difficult to take conventional tablets, which may result in poor compliance and ineffective therapy. [2,7]

To overcome these limitations, Mouth dissolving tablets (MDTs) have been introduced as an improved oral dosage form. These tablets are designed to break down quickly in the mouth without the need for water, making them easier to administer. [4] In addition to improving patient compliance, MDTs can provide a faster onset of action due to rapid disintegration and drug release, and in some cases may enhance bioavailability through pre-gastric absorption. [7]

Paracetamol is one of the most commonly used medications for treating pain and fever. Although it is available in various dosage forms, conventional tablets may not be suitable for all patients. [1] Therefore, developing a mouth dissolving tablet of paracetamol can enhance its ease of use and overall patient acceptance. The effectiveness of MDTs largely depends on the use of super-disintegrants, which help the tablet break apart quickly when it comes into contact with saliva. [3]

Commonly used super-disintegrants include crospovidone, croscarmellose sodium, and sodium starch glycolate. These agents improve the disintegration process by promoting water uptake and swelling. [6] In addition, recent advancements in formulation technology have introduced co-processed excipients that combine multiple functional properties, improving tablet performance, flowability, and mechanical strength. [7]

The present study aims to formulate and evaluate fast dissolving tablets of paracetamol using different superdisintegrants and a coprocessed excipient system. The goal is to develop a formulation that disintegrates rapidly, ensures efficient drug release, and enhances patient compliance.

## Materials and Methods

### Materials

Paracetamol was obtained as a gift sample from a pharmaceutical manufacturer. Super-disintegrants such as crospovidone, croscarmellose sodium, and sodium starch glycolate were procured from Ozone International Mumbai. Other excipients used in the formulation included lactose as a diluent, polyethylene glycol (PEG 1500), rice starch, talc, and magnesium stearate. All materials used in the study were of pharmacopoeial grade and used without further purification. [1,8]

### Preparation of Co-processed Excipient

A co-processed excipient consisting of pregelatinized starch, PEG 1500 was prepared in the laboratory. Rice starch was dispersed in water to form a uniform slurry. This slurry was gradually added to boiling water with continuous stirring to form a viscous mass. The mass was then treated with acetone to remove excess water and facilitate drying. The resulting product was filtered, dried at elevated temperature, and sieved to obtain uniform particle size. This co-processed excipient was used to improve the disintegration and flow properties of the formulation. [1,7]

**Formulation of Mouth Dissolving Tablets**

Mouth dissolving tablets of paracetamol were prepared using the wet granulation method. The required quantities of paracetamol, lactose, and binder were accurately weighed and mixed thoroughly. A sufficient quantity of water was added to form a wet mass, which was then passed through a sieve to produce granules. The wet granules were dried at controlled temperature and re-sieved to obtain uniform granule size.

After drying, the granules were blended with super-disintegrants (crospovidone, croscarmellose sodium, or sodium starch glycolate) at different concentrations (2%, 4%, and 5%). Lubricants such as talc and magnesium stearate were added and mixed uniformly. The final blend was compressed into tablets using a tablet compression machine with suitable punch size. [1,6]

**Evaluation of Tablets**

The prepared tablets were evaluated for various physicochemical properties as per standard procedures.

**1.Weight Variance:**

Twenty tablets from each batch were randomly selected and weighed individually. The average weight was calculated and compared with individual tablet weights to ensure uniformity. [8]

**2.Hardness:**

Tablet hardness was measured using a Monsanto hardness tester and expressed in kg/cm² to assess mechanical strength. [1]

**3.Friability:**

Friability was determined using a Roche friabilator. Tablets were rotated for a fixed number of revolutions, and percentage weight loss was calculated. A value below 1% was considered acceptable. [6]

**4. Drug Content:**

A sample of powdered tablets equivalent to a known amount of paracetamol was dissolved in phosphate buffer (pH 5.8), filtered, and analyzed using a UV spectrophotometer at an appropriate wavelength to determine drug content. [1,3]

**5. Disintegration time:**

The disintegration time was measured using a disintegration test apparatus with water as the medium. The time required for complete breakdown of the tablet was recorded. [4]

**6. Wetting time:**

Wetting time was determined by placing the tablet on a water-soaked tissue paper and recording the time required for water to reach the upper surface of the tablet. [1]

**7. Water Absorption Ratio:**

The water absorption ratio was calculated by measuring the weight of the tablet before and after complete wetting, indicating its ability to absorb moisture rapidly. [1]

**8.In Vitro Dissolution Studies:**

Dissolution studies were carried out using a USP dissolution apparatus (paddle method). The test was performed in phosphate buffer (pH 5.8) at 37 ± 1°C with constant stirring. Samples were withdrawn at predetermined time intervals, filtered, and analyzed spectrophotometrically. The percentage of drug released was calculated to study the release profile. [1,3]

Table 1: formulae for mouth dissolving tablets

| **Ingredients Mg/tab** | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** | **F7** | **F8** |
|---|---|---|---|---|---|---|---|---|
| **Drug** | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 |
| **mannitol** | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| **Sodium starch glycolate** | 90 | 90 | 90 | - | - | - | - | - |
| **Crosscaramelose sodium** | - | - | - | 90 | 90 | 90 | - | - |
| **crospovidone** | - | - | - | - | - | - | 90 | 90 |
| **Pre-gelatinized starch** | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| **Magnesium stearate** | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| **talc** | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| **Total Wt. (mg)** | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 |

Figure1: Calibration curve of paracetamol in PH 5.8 phosphate buffer

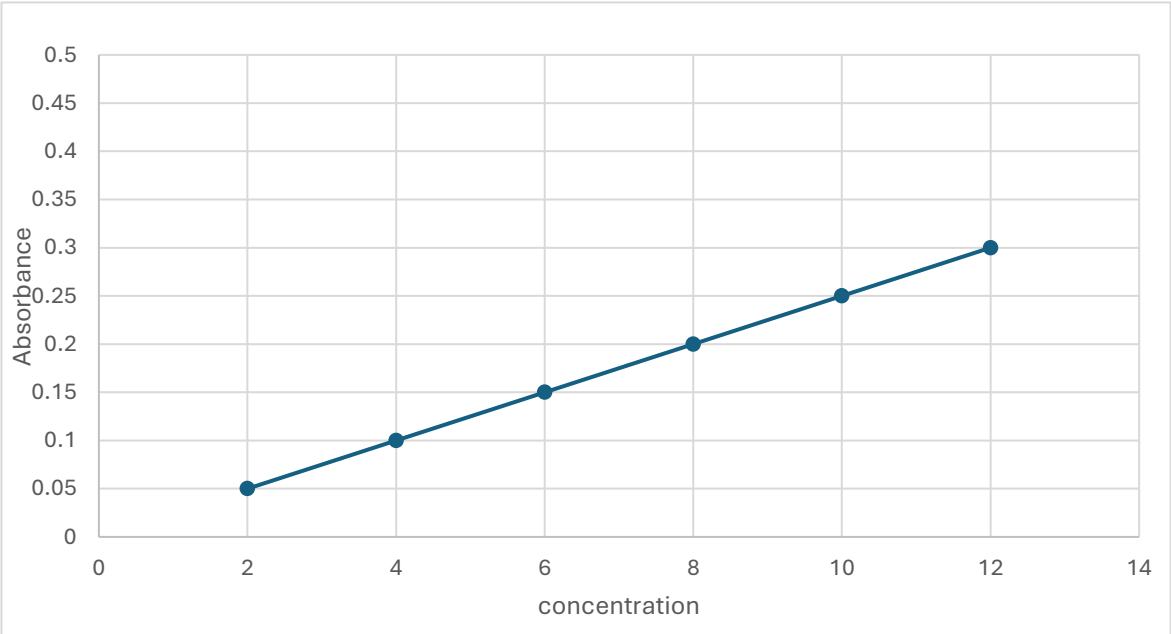

Table 2: Pre-compressional characteristics of powder blend

| formulation | Bulk density (gm / cc) | Tab density | % compressibility index | Hausners ratio | Angle of repose |
|---|---|---|---|---|---|
| F1 | 0.40 | 0.50 | 21.01 | 1.20 | 26.43 |
| F2 | 0.36 | 0.41 | 17.50 | 1.13 | 26.20 |
| F3 | 0.38 | 0.42 | 19.31 | 1.14 | 27.11 |
| F4 | 0.40 | 0.48 | 15.36 | 1.16 | 25.10 |
| F5 | 0.41 | 0.41 | 15.60 | 1.13 | 27.17 |
| F6 | 0.38 | 20.01 | 16.01 | 1.16 | 29.16 |
| F7 | 0.39 | 17.50 | 18.79 | 1.13 | 28.13 |
| F8 | 0.38 | 19.30 | 18.79 | 1.13 | 27.14 |

Table 3: Post-compressional characteristics of powder blend

| formulation | Mean wt±% variation | hardness kg / cm² | Friability (%) | Content uniformity (%) |
|---|---|---|---|---|
| F1 | 500±0.93 | 3.2±0.30 | 0.19±0.42 | 99.92±1.26 |
| F2 | 490.2±0.20 | 3.5±0.15 | 0.12±0.96 | 97.69±0.52 |
| F3 | 495.0±1.8 | 3.2±0.3 | 0.14±o.48 | 98.9±0.32 |
| F4 | 494.6±0.67 | 3.4±0.40 | 0.15±0.72 | 98.01±0.42 |
| F5 | 494.9±0.68 | 3.4±0.56 | 0.14±0.38 | 100.01±0.29 |
| F6 | 494.8±0.21 | 3.0±0.48 | 0.11±0.63 | 99.91±0.79 |
| F7 | 492.0.5±0.20 | 2.8±0.93 | 0.12±0.16 | 100.19±0.29 |
| F8 | 495.0±0.24 | 0.3±0.12 | 0.12±0.19 | 99.96±0.64 |

Table 4: in vitro disintegration data of MDTs

| Formulation | Disintegration time (sec) |
|---|---|
| F1 | 49 |
| F2 | 57 |
| F3 | 39 |
| F4 | 45 |
| F5 | 51 |
| F6 | 48 |
| F7 | 42 |
| F8 | 55 |

## Results and Discussion

The Mouth disintegrating tablets of paracetamol were successfully prepared using different super-disintegrants and a co-processed excipient. All formulations were evaluated for their physical properties, disintegration behavior, and drug release profile to assess their overall performance.

### Physical Evaluation of Tablets

All the prepared tablets showed uniform appearance and acceptable physical characteristics. The hardness of the tablets was found to be within a suitable range, indicating adequate mechanical strength to withstand handling and transportation. Friability values for all formulations were below 1%, which confirms good resistance to abrasion and mechanical stress. The weight variation test showed that all tablets complied with pharmacopoeial limits, ensuring dose uniformity. Drug content analysis revealed that the amount of paracetamol present in each

formulation was consistent and within acceptable limits, indicating proper mixing and uniform distribution of the drug. [1,8,9]

**Disintegration and Wetting Properties**

One of the key parameters for mouth dissolving tablets is rapid disintegration. In this study, all formulations disintegrated within a short period, confirming their suitability as MDTs. However, significant differences were observed depending on the type and concentration of super-disintegrant used. Tablets containing crospovidone and croscarmellose sodium showed faster disintegration compared to those prepared with sodium starch glycolate.

At higher concentrations (5%), crospovidone demonstrated the most rapid disintegration, followed closely by croscarmellose sodium. This behavior can be attributed to the high capillary activity and swelling properties of these super-disintegrants, which facilitate quick water uptake and tablet breakdown. Wetting time and water absorption studies also supported these findings, as formulations with faster disintegration exhibited shorter wetting times and higher water absorption ratios. [1,6,10]

**In Vitro Dissolution Studies**

Dissolution studies were carried out to evaluate the drug release profile of the prepared tablets. All formulations showed a rapid release of paracetamol, confirming the effectiveness of the mouth dissolving system. It was observed that the rate of drug release increased with an increase in the concentration of super-disintegrants.

Among all the formulations, tablets containing crospovidone exhibited the highest dissolution rate, followed by croscarmellose sodium, the co-processed excipient, and sodium starch glycolate. Optimized formulations released more than 95% of the drug within 30 minutes, which meets the official pharmacopoeial requirements. The enhanced dissolution can be attributed to faster disintegration, increased surface area, and improved wettability of the tablets. [1,3,8]

**Effect of Co-processed Excipient**

The co-processed excipient prepared using pre-gelatinized starch showed promising results. Although its performance was slightly lower compared to crospovidone and croscarmellose sodium, it still demonstrated satisfactory disintegration and dissolution behavior. This indicates that the co-processed excipient can serve as a potential alternative to conventional super-disintegrants in MDT formulations. [1,7]

**Overall Interpretation**

The study clearly indicates that the choice and concentration of super-disintegrants play a crucial role in determining the performance of mouth dissolving tablets. Crospovidone and croscarmellose sodium were found to be more effective in achieving rapid disintegration and enhanced drug release. Increasing the concentration of these agents improved the overall performance of the tablets. The results also suggest that MDT formulations can provide faster onset of action and improved patient compliance compared to conventional tablets.

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