

# Formulation and Evaluation of FDTs using *Aegle Marmelos* as a Natural Super-Disintegrants

Mayuri Patil<sup>1\*</sup>, Suvarna Shelke<sup>1</sup>, Dhanashri Bhangare<sup>1</sup>, Prajakta Shinde<sup>1</sup>, Dr. Manisha Gavit<sup>2</sup>, Dr. Rajesh Wankhede<sup>2</sup>

<sup>1</sup>Department of Pharmaceutics, SMBT College of Pharmacy, Nandi Hills, Dhamangaon, Nashik, Maharashtra

<sup>2</sup>Department of Dravyaguna, SMBT Ayurved College & Hospital, Nandi Hills, Dhamangaon, Nashik, Maharashtra

## Corresponding Author:

Mayuri Patil,

Department of Pharmaceutics, SMBT College of Pharmacy, Nandi Hills, Dhamangaon, Nashik, Maharashtra.


Email: [mayupatil2915@gmail.com](mailto:mayupatil2915@gmail.com)

ORCID: <https://orcid.org/0009-0000-8113-7807>



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## Abstract

The current study uses *Aegle marmelos* as a natural superdisintegrant in the formulation and assessment of fast-dissolving tablets (FDTs). FDTs improve patient compliance, beginning of action, and therapeutic efficacy since they dissolve quickly in the oral cavity without the need for water. Despite their widespread use, synthetic superdisintegrants like crospovidone and sodium starch glycolate have various drawbacks, such as increased expense, possible irritation, and environmental issues. As a result, interest in natural substitutes is growing.

The medicinal plant *Aegle marmelos* (Bael; Rutaceae) has good swelling and binding qualities and is rich in mucilage. In this work, the disintegration efficiency of tablet formulations containing mucilage derived from *Aegle marmelos* is assessed. Evaluation factors such disintegration time, hardness, friability, and weight fluctuation are measured for the manufactured tablets.

The goal of the project is to prove that *Aegle marmelos* is an efficient, affordable, and environmentally friendly superdisintegrant that can quickly disintegrate tablets with adequate mechanical strength and aid in the creation of sustainable pharmaceutical excipients.

## Keywords

*Aegle marmelos*, fast-dissolving tablets (FDTs), natural superdisintegrant, mucilage, tablet formulation, disintegration time.

## 1. INTRODUCTION

In order to improve patient compliance, therapeutic efficacy, and convenience, the pharmaceutical industry has concentrated on developing oral drug delivery systems in recent years. Fast Dissolving Tablets (FDTs), one of the novel dosage forms created, have drawn a lot of interest since they quickly dissolve in the mouth in a matter of seconds, removing the need for water and offering a quicker onset of action[1]. FDTs are solid dosage forms that dissolve or disintegrate in the mouth in a matter of seconds without the need for water, improving bioavailability and speeding up the commencement of action. Compared to liquid formulations, this dose form ensures correct administration and stability while offering a suitable substitute for patients who have trouble swallowing traditional tablets or capsules[2]

The selection of disintegrants, which are essential for encouraging quick tablet breakage upon contact with saliva, is crucial to the effectiveness of FDTs. The formulation of these tablets has been transformed by the addition of superdisintegrants, which are substances that promote immediate water absorption and swelling[3].

Natural polymers have drawn a lot of attention recently as superdisintegrants and binders in FDT formulations. Excellent swelling capacity, biodegradability, and biocompatibility have been established by natural materials including *Plantago ovata* (ispaghula husk), guar gum, okra gum, locust bean gum, and mucilages made from fenugreek or banana[4] These polymers support the increasing focus on safe and environmentally friendly excipients in pharmaceutical research in addition to improving tablet dissolving and disintegration. Additionally, natural polymers frequently have multiple functions, serving as stabilisers, disintegrants, and binders all at once, making formulation design easier[5], [6]

*Aegle marmelos*'s therapeutic qualities are attributed to a variety of bioactive substances, including marmelosin, tannins, phenols, alkaloids, and essential oils. In addition to its digestive and tonic properties, it has anti-inflammatory properties and is frequently used to treat dysentery, diarrhoea, stomach problems, constipation, and ulcers.[7]

This study used *Aegle marmelos* as a natural superdisintegrant to manufacture fast-dissolving Diclofenac sodium tablets utilising the direct compression method.

## 2. MATERIAL AND METHODOLOGY

Diclofenac sodium was used as the model drug for the formulation of fast-dissolving tablets, which was received as a gift sample from college. The raw plant materials *Aegle marmelos*, was collected from the Nashik region of Maharashtra. Other ingredient was obtained from pharmaceutical laboratory SMBT College of Pharmacy.

### 2.1 Extraction and isolation of *Aegle marmelos mucilage*

For the isolation of mucilage, the pulp was soaked in distilled water for 24 hours and then boiled for 1 hour to ensure complete extraction. The mixture was filtered through a muslin cloth to remove solid residues. An equal volume of acetone was then added to the filtrate to precipitate the mucilage. The obtained mucilage was separated, dried in an oven at 40–50°C, powdered (#60 mesh), weighed, and stored in an airtight container for further use[7].



Overnight-soaked  
Mucilage



Boiled for 1 hours



Precipitation of *Aegle marmelos* pulp



Mucilage obtained

after filtration

## 2.2 Preparation of Diclofenac sodium tablet by using *Aegle marmelos* powder.

The formulation of diclofenac sodium tablets was done by the direct compression method. The required quantity of the drug and the excipients were accurately measured and then passed through a sieve of #30 to obtain uniform particle sizes. The powders were mixed by the geometric mixing method for about 15 minutes to obtain uniform mixing. The magnesium stearate, which had been previously passed through a sieve of #60, was then mixed for an additional 5 minutes. The final mixing was then compressed to obtain tablets of 250 mg by the tablet compression method. The tablets were then evaluated for uniformity and physical appearance.

**Table 01: Formulation Table for preparation of Diclofenac sodium tablet**

Ingredients	Role	Quantity		
		F1 2%(mg)	F2 4%(mg)	F3 6%(mg)
Diclofenac sodium	Excipient	100	100	100
<i>Aegle marmelos</i> powder.	Natural Disintegrant	4.6	9.2	13.8
Lactose	Diluent	118.5	116.1	111.5
Talc	Glidant	4.6	4.6	4.6
Magnesium stearate	Lubricant	2.3	2.3	2.3
Total (mg)	-	250	250	250

### 3. RESULTS

**Table 02: Evaluation of Physicochemical characteristics of dried mucilage powder**

Parameter	Result
Organoleptic properties Color, Odor	Pale Brown color with characteristic odor
Solubility	Soluble in water
Swelling Index in Distilled water	38%
Loss on drying	4.4%
pH	6.5

**Table 03: Evaluation of Diclofenac sodium tablets**

Parameter	F1	F2	F3
Weight variation (mg)	250 ± 238	250 ± 245	250 ± 242
Hardness (kg/cm)	0.99-1.02	1.01-1.02	1.00-1.04
Friability (%)	0.38	0.6	0.20
Disintegration time (sec)	38	45	35
Thickness (mm)	4.09-4.19	4.12-4.18	4.12-4.17

#### 4. CONCLUSION

The current study shows that *Aegle marmelos* mucilage can be successfully used as a natural superdisintegrant in the creation of Diclofenac sodium tablets that dissolve quickly. All tablet formulations met established evaluation criteria, suggesting acceptable quality and performance, and the mucilage displayed appropriate physicochemical features. Higher mucilage levels improved tablet disintegration efficiency, and a concentration-dependent improvement in disintegration behaviour was noted.

The results provide credence to the potential for using *Aegle marmelos* as an alternative for sustainable, cost-effective, and biocompatible superdisintegrants. The study on oral medication delivery systems develops formulation methodologies for natural excipients.

Further investigations are warranted to assess long-term stability, in-vivo performance, and scalability of the formulation, as well as to explore its applicability with other therapeutic agents.

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