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Review Article

Fast Dissolving Tablets Using Natural Superdisintegrating Agents: A Review

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ABSTRACT

Fast dissolving tablets (FDTs) disintegrate in the mouth within seconds without water, and are useful for children, the elderly, bedridden patients and patients with nausea or vomiting, who find it difficult to swallow conventional tablets. The performance of an FDT depends mainly on the superdisintegrant. Synthetic superdisintegrants are effective but costly and are not always available locally, whereas plant mucilages from Isapgol (*Plantago ovata*), Linseed (*Linum usitatissimum*), Aliv (*Lepidium sativum*) and Fenu-greek (*Trigonella foenum-graecum*) are cheap, biodegradable and easily available, and have been reported to act as disintegrants and binders. The present review discusses the need for FDTs, their advantages and limitations, the technologies used for their preparation, the mechanisms of superdisintegrants, a comparison of synthetic superdisintegrants and natural mucilages, the isolation and characterisation of mucilage, the method of preparation of FDTs by direct compression, the tests used for evaluation, and the important reports on the subject. The review shows that natural mucilages are promising low-cost superdisintegrants, while comparative studies in the same formulation are still needed.

INTRODUCTION

The oral route is the most widely used route of drug administration because it is convenient, non-invasive, economical and well accepted by patients. However, swallowing a conventional tablet or capsule is difficult

for many people, including children, the elderly, bedridden patients, patients with nausea or persistent vomiting, and those who have no ready access to water. Difficulty in swallowing (dysphagia) often leads to missed doses and poor therapeutic outcomes.[1,2,3]

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Fast dissolving tablets (FDTs), also called orally disintegrating or mouth dissolving tablets, are placed on the tongue, where they disintegrate or dissolve in the saliva within seconds, without water and with little or no chewing; the resulting dispersion is then swallowed. The US FDA guidance describes an orally disintegrating tablet as one that disintegrates rapidly in the mouth, with a disintegration time of about 30 seconds or less. [4] An ideal FDT needs no water, disintegrates within seconds, leaves little or no residue, has a pleasant taste and mouthfeel, is strong enough to withstand handling

and can be made by a simple and economical method. [1,3,5]

The performance of an FDT depends mainly on the superdisintegrant. Synthetic superdisintegrants such as croscarmellose sodium, crospovidone and sodium starch glycolate are effective, but plant mucilages and gums are cheap, biodegradable, generally safe and easily available, and they have been studied as natural superdisintegrants and binders.[6,7,8]

Advantages and Limitations

Table: Advantages and Limitations of Fast Dissolving Tablets[1,3,5]

Sr. No.	Advantages	Limitations
1	No water needed; easy for children, elderly and bedridden patients	Mechanical strength is lower than that of conventional tablets; careful handling is needed
2	Rapid disintegration and possible quick onset of action	Many FDTs are hygroscopic and need moisture-protective packaging
3	Accurate dose compared with liquid dosage forms	Taste masking is needed for bitter drugs
4	Pleasant mouthfeel improves acceptance and compliance	High doses are difficult to accommodate
5	Can be made with conventional equipment by direct compression; reduced risk of choking	Excess disintegrant may cause grittiness or a sticky feel

Technologies for Fast Dissolving Tablets

Several technologies are used to prepare FDTs, and they differ in cost, tablet strength and the equipment

needed.[1,2,3] Freeze drying gives very fast dissolution but is costly and the product is fragile.[9] Direct compression is the simplest and most economical method.[3]

Table: Technologies Used for Fast Dissolving Tablets[2,3,9]

Sr. No.	Technology	Principle	Remarks
1	Freeze drying	Drug suspension in a matrix is frozen in blisters and the water is sublimed	Very fast dissolution; costly and fragile
2	Direct compression	Drug and excipients including a superdisintegrant are blended and compressed	Simplest and most economical
3	Tablet moulding	Moistened powder is moulded under low pressure and dried	Porous but weaker tablets
4	Sublimation	A volatile substance is compressed with the blend and then removed	Extra step; risk of residue
5	Spray drying	Porous powder is produced by spray drying and compressed	Needs special equipment

Superdisintegrants

A superdisintegrant acts by one or more mechanisms: swelling (particles absorb water and enlarge, breaking

the tablet structure), wicking or capillary action (water is drawn rapidly into the tablet through pores) and deformation recovery (particles deformed during compression return to their shape when wetted).[5,10,11]



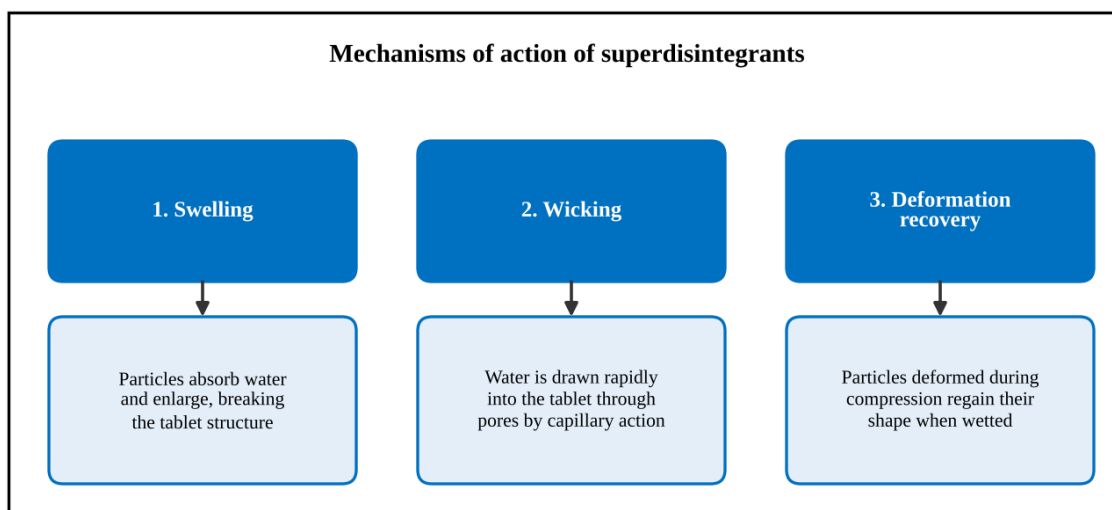


Figure 1: Mechanisms of Action of Superdisintegrants

Table: Comparison of Synthetic Superdisintegrants and Natural Mucilages[5,6,12]

Sr. No.	Feature	Synthetic superdisintegrants	Natural mucilages
1	Source	Chemically modified polymers	Seeds or husk of plants
2	Cost and availability	Higher cost; supplied by manufacturers	Low cost; locally available
3	Safety	Well established	Generally regarded as safe; need quality control
4	Biodegradability	Variable	Biodegradable
5	Consistency	High batch-to-batch consistency	May vary with source and extraction
6	Regulatory status	Pharmacopoeial excipients	Often non-official; need characterisation

Natural Mucilages as Superdisintegrants

Plant mucilages are hydrophilic polysaccharides, which hydrate and swell rapidly in water. Mucilages from the seeds or husk of Isapgol (*Plantago ovata*),

Linseed (*Linum usitatissimum*), Aliv or garden cress (*Lepidium sativum*) and Fenugreek (*Trigonella foenum-graecum*) have been reported as disintegrants and binders in tablets, and all four plants are easily available in Maharashtra.[7,8,13,14,15,16,17]

Table: Natural Sources of Mucilage Used in Fast Dissolving Tablets[6,7,8]

Sr. No.	Plant	Family	Part used	Main feature
1	Isapgol (<i>Plantago ovata</i>)	Plantaginaceae	Seed husk	Highly swelling polysaccharide mucilage
2	Linseed (<i>Linum usitatissimum</i>)	Linaceae	Seeds	Mucilage rich in polysaccharides; good swelling
3	Aliv, garden cress (<i>Lepidium sativum</i>)	Brassicaceae	Seeds	Mucilage swells rapidly in water
4	Fenugreek (<i>Trigonella foenum-graecum</i>)	Fabaceae	Seeds	Galactomannan-rich mucilage

Method of Isolation of Mucilage

The mucilage is generally isolated by extraction with water followed by precipitation with a non-solvent. [7,8,17] The steps are described below.

Step 1: Collection and Cleaning

The seeds or husk are purchased from a reliable source, authenticated and cleaned to remove foreign matter.

Step 2: Soaking and Heating

About 10 g of the material is soaked in 200 mL of distilled water for 12 to 24 hours and then heated gently on a water bath for about 30 minutes, so that the mucilage is released into the water.

Step 3: Separation of the Mucilage

The mass is squeezed through muslin cloth to separate the seeds or husk from the mucilage.

Step 4: Precipitation

The filtered mucilage is precipitated by adding about twice its volume of ethanol (or acetone), and the precipitate is separated and washed.

Step 5: Drying, Powdering and Storage

The precipitate is dried in a hot air oven at 45 to 50 °C, powdered, passed through sieve no. 80 and stored in a desiccator.

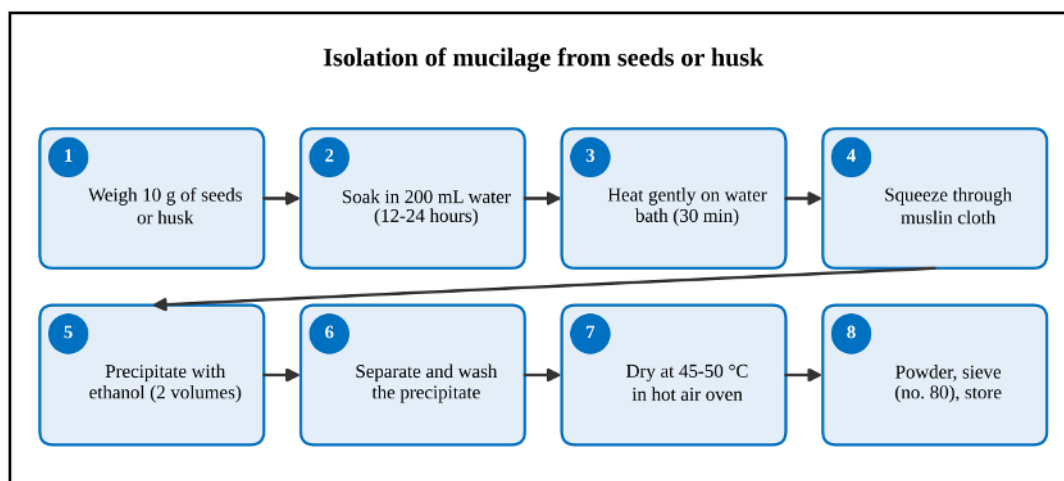


Figure 2: Isolation of Mucilage from Seeds or Husk

Characterisation of the Mucilage

Table: Tests for Characterisation of Isolated Mucilage[6,8,17]

Sr. No.	Test	Method
1	Percentage yield	Weight of dried mucilage divided by weight of starting material $\times 100$
2	Organoleptic properties and solubility	Colour, odour, taste; behaviour in water, ethanol, acetone and chloroform
3	pH	1% w/v dispersion measured with a pH meter
4	Loss on drying	Dried at 105 °C to constant weight
5	Swelling index	1 g powder in 100 mL water for 24 hours; volume of swollen mass noted
6	Micromeritic properties	Angle of repose, bulk and tapped density, Carr's index, Hausner's ratio
7	Chemical tests	Molisch test (carbohydrates), ruthenium red test (mucilage), tests for tannins, protein and starch

Method of Preparation of Fast Dissolving Tablets by Direct Compression

Direct compression is the simplest and most economical method, as it uses ordinary tablet-making equipment and needs no heat or solvent.[3,10] It also allows the effect of the superdisintegrant to be studied without interference from other process variables.

Step 1: Weighing and Sieving

The drug, superdisintegrant, diluents (mannitol, microcrystalline cellulose) and sweetener are weighed accurately and passed through sieve no. 60.

Step 2: Blending

The ingredients are blended thoroughly in a polybag or a blender, so that the drug and the disintegrant are distributed uniformly.



Step 3: Addition of Lubricant and Glidant

Magnesium stearate and talc are added last and mixed for 3 to 5 minutes, since longer mixing of the lubricant can weaken the tablet and slow its disintegration.[11]

Step 4: Compression

The blend is compressed on a single-punch or rotary tablet machine to the target weight, keeping the hardness the same in all batches, so that differences in disintegration can be attributed to the type and level of the disintegrant.

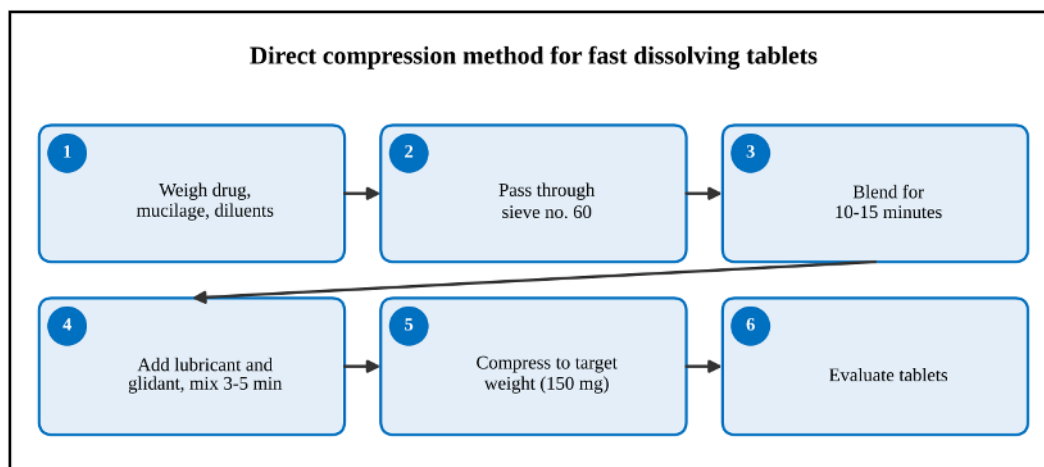


Figure 3: Direct Compression Method for Fast Dissolving Tablets

Table: Typical Composition of a Fast Dissolving Tablet[5,10,12]

Sr. No.	Component	Examples	Function
1	Active drug	Low-dose drug with suitable taste	Therapeutic action
2	Superdisintegrant	Natural mucilages; croscarmellose sodium, crospovidone, sodium starch glycolate	Rapid disintegration
3	Diluent	Mannitol, microcrystalline cellulose	Bulk, sweetness, binding
4	Sweetener and flavour	Aspartame, saccharin sodium; flavours	Taste masking
5	Lubricant and glidant	Magnesium stearate, talc	Flow and release from the die

Selection of the Drug

A drug for an FDT should be of low dose, stable, and have an acceptable taste or one that can be masked. Anti-emetic drugs such as ondansetron are often chosen as model drugs, since patients with nausea and

vomiting cannot easily swallow tablets with water and need a rapid onset.[1,2]

Evaluation of Fast Dissolving Tablets

The blend is evaluated before compression and the tablets after compression. The tests, methods and expected results are given below.[4,5,10]

Table: Evaluation of Fast Dissolving Tablets[4,5,10,11]

Sr. No.	Test	Method	Expected Result
1	Pre-compression properties	Angle of repose, bulk and tapped density, Carr's index, Hausner's ratio	Good flow and compressibility
2	Weight variation	Weigh 20 tablets individually	Within the pharmacopoeial limit
3	Thickness	Vernier calliper	Uniform
4	Hardness	Hardness tester	Enough for handling, but soft enough to disintegrate
5	Friability	Friabilator, 100 revolutions	Less than 1%



Sr. No.	Test	Method	Expected Result
6	Drug content	UV spectrophotometric assay	90 to 110% of label claim
7	Wetting time and water absorption ratio	Tablet on dye-wetted tissue paper; weight gain	Short wetting time; high water uptake
8	In vitro disintegration time	Disintegration apparatus at 37 ± 0.5 °C	About 30 seconds or less
9	In vitro dissolution	USP II paddle, 50 rpm, 900 mL medium at 37 ± 0.5 °C	Rapid release, comparable to the synthetic control
10	Stability	40 ± 2 °C and $75 \pm 5\%$ RH as per ICH Q1A(R2)[18]	No change in appearance, disintegration time and content

Review of Literature

Seager (1998) described the development of the Zydis fast-dissolving dosage form, one of the first commercial fast-dissolving products, which is prepared by freeze drying and dissolves almost instantly in the mouth.[9] **Habib et al. (2000)** reviewed fast-dissolve drug delivery systems and the technologies used to make them, their advantages and their limitations, such as taste, mechanical strength and moisture sensitivity.[1]

Fu et al. (2004) reviewed orally fast disintegrating tablets, covering the manufacturing technologies, taste masking and clinical studies, and pointed out that the choice of disintegrant strongly influences the disintegration time and mouthfeel.[2] **Bandari et al. (2008)** gave an overview of orodispersible tablets and highlighted direct compression as the simplest and most economical method, and **Bhowmik et al. (2009)** discussed the mechanisms of superdisintegrants and the quality-control tests.[3,5] The **US FDA guidance (2008)** describes the characteristics expected of an orally disintegrating tablet, including a disintegration time of about 30 seconds or less.[4]

Kulkarni et al. (2002) evaluated the binding property of mucilages of *Plantago ovata* and *Trigonella foenum-graecum* in tablets, and **Kumar et al. (2009)** isolated mucilage from fenugreek seeds and evaluated its disintegrant properties.[7,8] **Shirsand et al. (2009)** used *Plantago ovata* mucilage as a superdisintegrant in fast disintegrating tablets of prochlorperazine maleate, and reported that the batch with 8% mucilage dispersed in about 8 seconds and released the drug faster than the conventional tablet.[13]

Shrotriya et al. (2010) studied the disintegration properties of *Linum usitatissimum* mucilage in dispersible tablets of diltiazem hydrochloride, and reported that it was more efficient than starch.[14] **Inamdar et al. (2012)** described the isolation and evaluation of fenugreek and flaxseed mucilages as pharmaceutical binders.[17] **Goyal et al. (2013)** developed fast dissolving tablets of losartan potassium using mucilages of *Plantago ovata* and *Lepidium sativum*, and **Prajapati et al. (2014)** made fast-dissolving tablets of aceclofenac with natural superdisintegrants, including *Lepidium sativum* seed mucilage.[15,16]

Table: Summary of Studies on Natural Mucilages in Tablets[7,8,13,14,15,16,17]

Sr. No.	Source of mucilage	Study	Drug / system	Main point examined
1	Isapgol and Fenugreek	Kulkarni 2002	Tablet formulations	Binding property
2	Isapgol	Shirsand 2009	Prochlorperazine maleate FDT	Mucilage level, dispersion time, wetting time
3	Linseed	Shrotriya 2010	Diltiazem HCl dispersible tablet	Disintegration compared with starch
4	Fenugreek	Kumar 2009	Tablets	Disintegrant properties
5	Aliv and others	Prajapati 2014	Aceclofenac FDT	Natural superdisintegrants
6	Isapgol and Aliv	Goyal 2013	Losartan potassium FDT	Mucilage type and level (factorial design)
7	Fenugreek and Linseed	Inamdar 2012	Mucilages as binders	Isolation and properties

Research gap



Most studies examined one mucilage at a time, in different model drugs, at different concentrations and by different methods, so the natural agents cannot be compared directly. Few studies compare several seed mucilages with a synthetic superdisintegrant in the same formulation and under the same conditions. [13,14,15,16]

CONCLUSION

Fast dissolving tablets help patients who cannot swallow conventional tablets, and direct compression is a simple and economical way of making them. The superdisintegrant decides the disintegration time, and natural mucilages of Isapgol, Linseed, Aliv and Fenugreek are cheap, biodegradable, locally available alternatives to synthetic superdisintegrants, which have been reported to give rapid disintegration and quick drug release.

However, natural mucilages vary with their source and method of extraction, and are mostly non-official, so they need proper characterisation and quality control. Further work is required to compare the mucilages in the same formulation with a synthetic control, to study taste masking, toxicity and stability, and to confirm the performance in more model drugs and in vivo.

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