Section A-Research paper

Natural polymer used in mouth dissolving film

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Abstract: The Pharmaceutical Industry's key priorities are the Design And Development of Delicious Films. In The Case of Geriatric, Paediatric, and Patients Undergoing any Type of Protracted Therapy, Films are a Stable Alternative Medicine form that helps to overcome the Swallowing Disadvantage (Difficulties in Swallowing). Fast Mouth Dissolving Film is made using both Natural and Manmade Polymers. The Anglicised Name for the Natural Polymer, Trigonella Foenum-Graecum, is Fenugreek. It's Botanical Family is Fabaceae. Fenugreek has a Greater Quality of Protein than the Proteins found in other vegetables, Giving it Nutritional Benefits. The Nutritional Advantages of Fenugreek are Thoroughly Examined in the book Nutritional/Health Implications of Fenugreek Components. Fenugreek is a Well-Liked Flavour that is also used medicinally in India to Encourage Lactation as well as for Its Anti-Plasmodial, Anthelmintic, Anti-Diabetic, Anti-Bacterial, Immunological, Anti-Oxidant, Analgesic, And Anti-Inflammatory Effects. The Fenugreek seed mostly used in as a supplementary. It is traditionally used in home remedies. The Mouth dissolving film is also used as Fenugreek seed gum like as coating, as a plasticizer. fenugreek gum as a natural superdisintegrant showed better disintegrating property than the most widely used synthetic super disintegrants like the formulations of Fast dissolving Film.

Keywords: 'Mouth Dissolving Film,' 'Natural Polymer,' 'Fenugreek Seed,' 'Polymer, geriatric', and 'paediatric patients,' 'Nutritional value'.

Introduction:

1. Mouth dissolving films: [1,2,3,4,5,6,7]

Fast-dissolving films must ideally melt within three minutes. In the case of chronic illnesses such as cancer, heart disease, stroke, diabetes, rheumatoid arthritis, and mental illness, the rapidly films provide superior administration of medication. Melt-in-the-mouth film design and development are the main focuses of the pharmaceutical industry. The film is a medium for oral distribution in the oral cavity. The alternative and stable medication form is films, which assist to overcome the disadvantage of swallowing (difficulties in swallow) in the circumstance of geriatric, child, and patients undertaking any kind of prolonged therapy.

They should ideally be versatile and capable of dissolving in the shortest possible period of time. Incredibly simple administrations is used for melt-in-your-mouth films. Fast dissolving systems for drug delivery were originally created in the latter part of the 1970s to help immature and geriatric patients who already had trouble swallowing tablets and capsules.

Due to its low cost, the oral route of drug delivery is one of the most used. and simple to provide, which improves patient compliance in the juvenile and geriatric demographic, but it is still a difficult route because juvenile and elderly patients have problems eating. The usage of natural polymers for administering the medication into the buccal cavity has increased substantially in recent years among the many dosage forms.

When placed on the tongues, oral dispersing films (ODFs) immediately moisten by lapping up saliva after dissolving and/or disintegrating, delivering the active pharmaceutical ingredients from of the dosage form. Hydrophilic polymers are used to produce rapidly oral films, which rapidly disintegrate on the tongue or roof of the mouth and release the medication into the circulation when they interact with fluid. An unique alternative for the

traditional tablets, capsules, and fluids commonly found in conventional and over-the-counter medications is the fast-dissolving oral film.

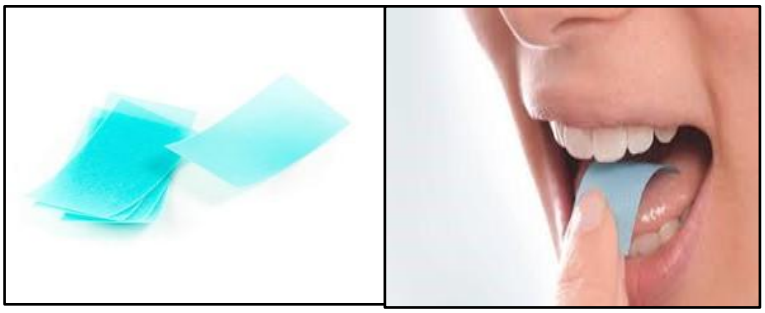

Figure. No. 1.Mouth Dissolving Film

1.1. Special features of fast dissolving films [8,9,10]

- Comes in a variety of sizes and forms.
- Film should be beautiful and thin.
- Unobstructive.
- Quick release
- Processes should be quick decomposition without water.

1.2. Orally fast-dissolving film requirements: [11,12]

- Feel good in the mouth
- Leave little to no aftertaste in the mouth after oral administration
- Show little susceptibility to environmental factors including humidity and temperature.

1.3.Drug candidates are chosen for oral fast-dissolving films based on the following requirements: [13,14,15]

- It must be able to penetrate oral mucosal tissue.
- The molecular weight of the medication should be low to moderate.
- The drug must be dependable and soluble in both saliva and water.

- At the pH of the cavity in the mouth, it should be completely unionised**.**

1.4.Ideal properties: [16, 17]

- The material used should be non-toxic, calming, and free of contaminants that can leach. Additionally, it ought to have good spreading and wetting properties.
- The polymer must possess strong enough tensile, peel, and shear characteristics.
- It ought to have a long shelf life.
- It shouldn't cause secondary infections in the oral or dental mucosa to spread or worsen.
- It should have a pleasant mouthfeel.

1.5.Applications: [17,18,19]

- It can also be utilised as a substrate for different barrier membranes that are employed in industries.
- Film forming systems used in the field of surgery.
- Film-forming polymers are employed to improve soil quality and raise soil temperature, both of which are beneficial for crop productivity.

2. Mouth Dissolving Film by Using Selection of Natural Polymer: [20.21,22,23,24]

The polymers utilised for the preparation of the oral film should be non-toxic and non-irritant, free of leachable impurities, not delay the film's time for disintegrating, tasteless, have good the wetting and spread ability characteristics, demonstrate sufficient peel, shear, and tensile strength, be easily accessible and not contribute to the occurrence of secondary infections in the oral mucosa or cavities regions. Since hydrophilic polymers have been shown to be biocompatible, they are generating considerable interest in biomedical and drug delivery applications. They can have custom architectures both at the molecular and device levels. Hydrophilic polymers have discovered significant uses in the healthcare field.

Today, fast mouth dissolving films can be constructed from polymers that are both synthetic and natural.

Classification of polymers used for MDF is as shown in figure,

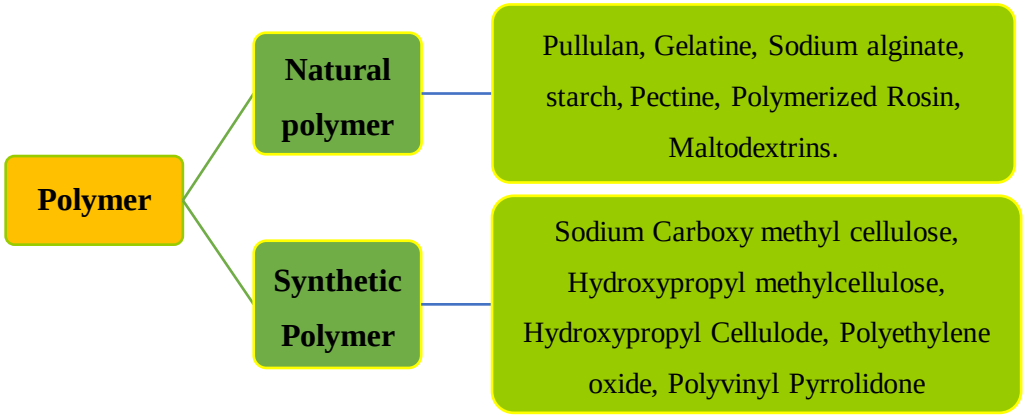

Figure. No. 2.Classification of polymers used for MDF

3. Natural Polymer of Fenugreek/ Methi: [25,26,27,28]

In Africa and India methi seeds it was first discovered. Fenugreek is the anglicized version, while synonym -Trigonella foenumgraecum, and family - Fabaceae, is the biological source. Chemically, the natural polymer galactomannans make up the fenugreek seed gum. A biological polymer is made up of many uniform tiny molecules coupled together in chains, such as fashions, to form larger, macroscale molecules. cellulose and starch are two examples of biological polymers. Fenugreek seeds and evergreens are used both as food and as medicinal, per a lengthy custom in human history. It has also been used to modify the texture of dietary elements, and additionally to heighten colour and flavour. Fenugreek seeds focus on providing therapeutic potential that include hypocholesterolaemia, lactation aid, antibiotic, gastric stimulant, and more, for hepatoprotective activity, anticancer, galactagogue, antidiabetic agent, and anorexia. It is known for having volatile chemicals, fibres, gum, and other substances. In addition, about 25% of the dietary fibre in fenugreek seeds modifies the food's texture. Due to its high fibre, protein, and gums content, it is currently utilised as an edible fixer, binder, and

emulsify. At an alkaline pH, the protein that's found in fenugreek seems to be less difficult to access. Fenugreek can alter how food is prepared and has an advantageous impact on digestion.

Figure. No. 3. Fenugreek Plant and Seed

Different amounts of fenugreek aqueous extract prevent clot formation and enlarge prothrombin time. It may possibly be utilised in the future as a supplementary anticoagulant drug in cardiovascular diseases and to avoid hypercoagulable conditions, subject to further interrogations on efficacy and safety.

3.1.Classifications of Natural Polymer:[29,30,31]

Classifications of Natural Polymer

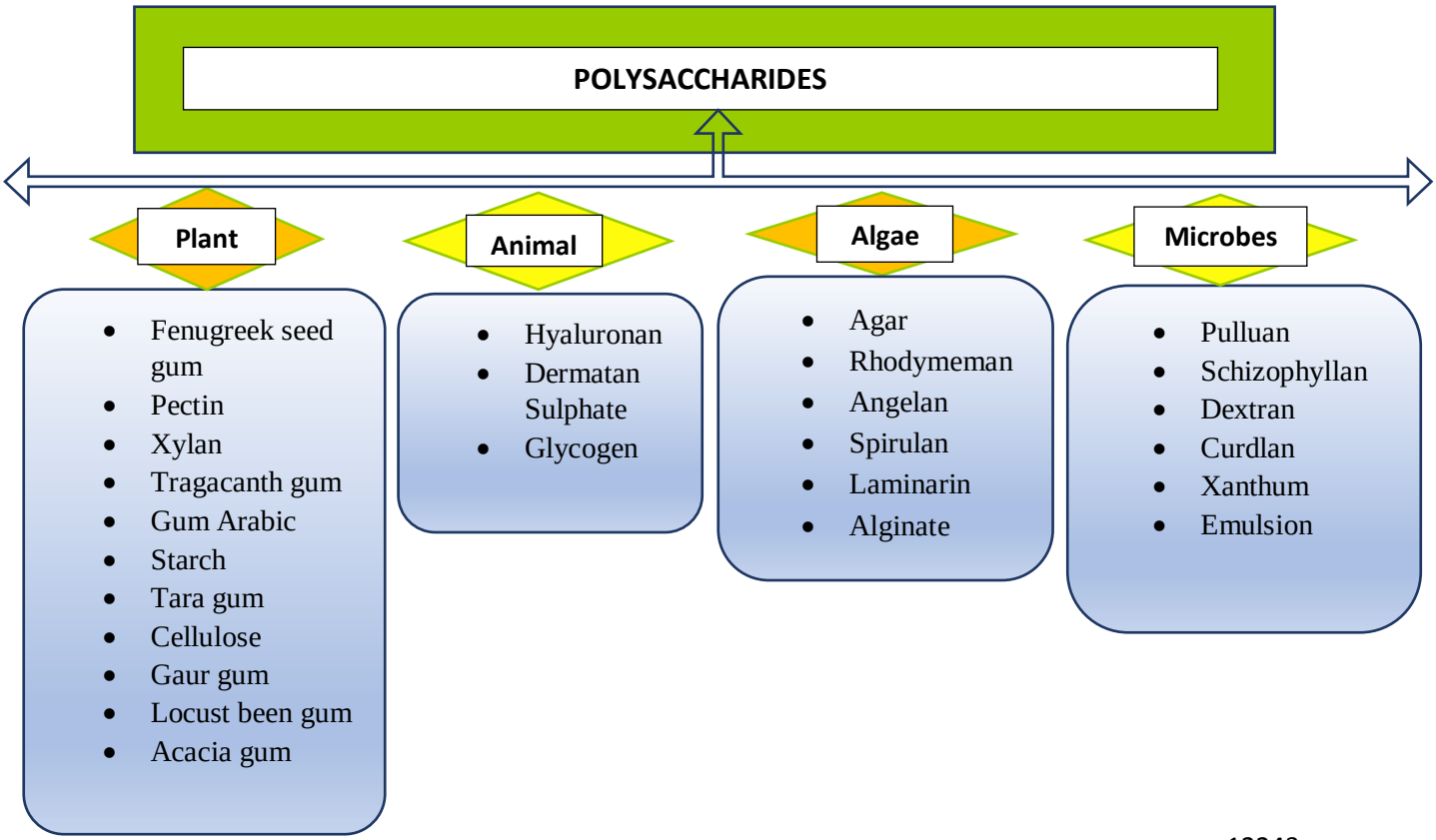

Figure No. 4. Classifications of Natural Polymer

4. Nutritional value of fenugreek: [32,33,34,35,36]

There are also trace levels of the sulphur-containing amino acids methionine and cysteine, which play important biological roles in the body. (2S, 3R, 4S) The free amino acid that is most frequently found in fenugreek is -4-hydroxyisoleucine. The non-protein amino acid 4-hydroxyisoleucine replaces about 80% of the amino acids in dried fenugreek seeds and multiplies fast throughout the stages of development. The proteins in fenugreek are of higher quality than those in other vegetables, based on a study. A study to compare fenugreek seeds' protein content to soy protein isolate. We discovered that compared to soy protein isolate, fenugreek seeds contain higher protein content and a superior amino acid profile.

Additionally, there were substantial quantities of aspartic and glutamate acids in fenugreek proteins. The findings indicate that fenugreek proteins can be utilised as a sustainable source of proteins in a variety of functional diets because they have more effectively denaturation conditions, foaming distinguishing characteristics, solubility, and the stability than soy proteins.

Table No.1 Minerals amount of fenugreek seed gum (mg/100 gramme) [36]

Minerals	Fenugreek seed extract (mg/gm)
Potassium(K)	603.0 ± 15.0
Magnesium	42.0 ±5.0
Calcium	75.0 ±9.0
Zinc (Zn)	2.1 ±0.2
Manganese	0.9 ±0.2
Iron (Fe)	25.8±1.2

Table No.2.Proximate chemical composition of the dried fenugreek seeds gum.[37]

Minerals	Percent (%)
Protein	28.55
Fiber	6.50
Fat	4.00
Carbohydrates	46.25
Ash	3
Moisture	4.00

5. The implications of fenugreek components on nutrition and health: [38,39,40,41,42,43,44,45]

Effects of diet on health a type of amino acid are 4-hydroxyisoleucine. Increases insulin levels during exercise Fibrous substances include galactomannans, non-starch polysaccharides, and soluble dietary fibre. Control of glucose absorption, food toxin binding, colon mucus layer protection, enhanced insulin secretion, intestinal water retention, and oxidising properties of acids and phenolics Vitamins and minerals, sometimes known as micronutrients Regulatory measures Flavonoids have oxidising properties. Protodioscin due to leukemic cells being blocked liver-protective, anti-cancer diosgenin. The compounds were also extracted from specific areas of the fenugreek plant along with isolates and the hydrolysates from the roots, leaves, and flowers. The majority of the flavonoids in fenugreek are discovered as glycosides because they have a difficult time conjugating with carbs via C- and O-glycosidic linkages. This information was made evident by the phytochemical examination of the plant. Fenugreek has a wide range of unique flavanol glycosides, such as apigenin-6-C-glucoside, vitexin-7-Oglucoside, and quercetin-3-O-rhamnoside (quercitrin) (isovitexin). Apigenin-8-C-glucoside (vitexin) and apigenin-6-C-glucoside (isovitexin) were found in fenugreek seeds. Additionally, is

flavonoid phytoalexin aglycones like medicarpin and maackiain have been reported to be present in this herb. These are referred to as "induced bioflavonoids," and it's likely that external factors such as bacterial metabolism control how they are produced.

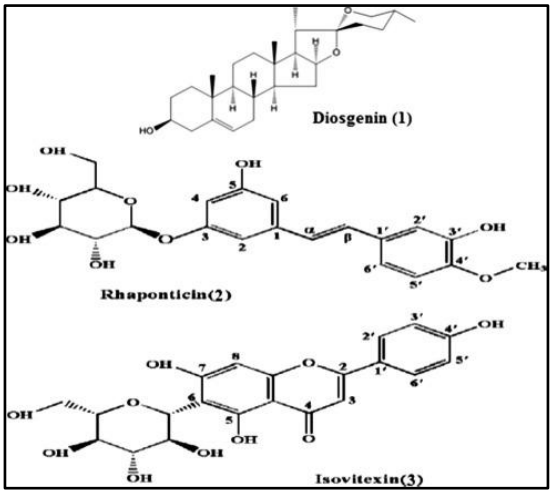

Figure No 5. The chemical structures of (1) Diosgenin (2) rhaponticin and (3) isovitexin.

Sapogenins, which are steroids, are among the chemical compounds found in fenugreek. Fenugreek's oily embryo contains a diosgenin component. Fenugreek contains two furastanol glycosides, also known as hederagin glycosides, which are F-ring opening precursors of diosgenin. Among the alkaloids present in stems are, nicotinic acid, trigocoumarin acid, trimethyl coumarin, and trigonelline. The mucilage of the seeds is one feature that stands out in particular. According to the stem has 28% mucilage, A volatile oil, two alkaloids, including trigonelline and choline, 5 percent of a fixed oil with a stronger aroma and a bitter taste, 22 percent proteins, and a yellow colouring agent are all present in the mixture. Fenugreek provides 58% carbs, 23-26 % protein, 6% fat, and around 25% of which are dietary fibre.

Approximately 19 mg of b-carotene and 220.97 mg of ascorbic acid are present per 100 g of fresh fenugreek leaves. On the other hand, it was discovered that ascorbic acid was decreased by 84.94% and 83.79%, respectively, when fenugreek leaves were dried in the sun and an oven. Vegetables in the meals are made up of fresh leaves. It emerged that fenugreek leaves

preserved nutrients more well. Fenugreek leaves should be blanched for a brief amount of time (about five minutes) or dried in an oven before being cooked in a pressure cooker. Fenugreek seeds are well known for their somewhat sweet and pleasant bitter flavour. Seeds are accessible.

A list of chemical components is shown in the table below,

Table No.3. Chemical structure Dietary benefits of fenugreek

	Chemical Structure	Vitamin Value (per 100 mg)
Protein & amino acid	Albumin	-
	Globulin	-
	Lecithin	Totally 24.4 g
	Lysin	-
	Histidine	-
	4- hydrooxyiosleucine	-
Vitamin	Vitamin A	1040 U
	Pyridoxine	0.6 mg
	Riboflavin	6 gm
	Nicotine acid	0.36 mg
	thiamine	1.1 mg
	Folate	0.41 mg

6. Historical Uses of Fenugreek seed:[46]

As a medicinal and culinary herb, fenugreek has a long history in the ancient world. Fenugreek was used in ancient Egypt for a number of purposes, including making incense and prepping corpses. The Latin term foenum graecum, meaning Greek hay, refers to the usage of it as cow feed by the Greeks and Romans. In ancient Rome, fenugreek was allegedly used to speed up labour and delivery. Traditional Chinese medicine uses fenugreek seeds as a tonic and treatment for oedema and leg weakness. In India, fenugreek is a taste that's also used medicinally to encourage breastfeeding.

7. Therapeutic Uses of Fenugreek: [47,48]

a. Anti-Plasmodic.

b. Antidiabetic.

c. Antibacterial.

d. Immunological.

e. Anthelmintic.

f. Hypolipidemic.

g. Antioxidant.

h. analgesic and Anti-inflammatory

a. Anti-Plasmodic activity: [49]

Administration of fenugreek enhances excretion of gastric acid and cholesterol from of the intestine. This could be a consequence of the creation of micelles that are too big is for digestive tract to absorb as a result of the interactions between bile acids and fenugreek saponins.as a result of the interactions between bile acids and fenugreek saponins. According to a different idea, the gum section of the seed, which is a good source of fibre and slows down the liver's production of cholesterol, is responsible for the seed's ability to lower cholesterol. Most likely, both mechanisms contribute to the final result.

b. Antidiabetic activity: [50,51]

- The dietary fibres in fenugreek seeds, which are abundant in galactomannan, may be the cause of their antidiabetic effects. Additionally, fenugreek has been linked to the amino acids 4-hydroxyisoleucine's insulinotropic and anti-diabetic properties. which contains it at a frequency of about 0.55%. It has been demonstrated through in vitro research that this amino acid efficiently stimulates cells. Other putative pathways include delayed stomach emptying and inhibition of glucose transport. Dialyzed

fenugreek seed extract has been shown in a study of alloxan-induced diabetic mice to have hypoglycaemic effect that is comparable to (1.5 U kg[(-1]) of insulin. Additionally, fenugreek seed extract improved the peritoneal glucose tolerance of normal mice.

c. Antibacterial activity: [52]

Fenugreek seed extracts were observed to be more potent against Staphylococcus aureus, Salmonella typhi, and Escherichia coli. Water was used to cook seeds to produce aqueous extracts**.**

d. Immunological activity: [53]

A study has shown that fenugreek seeds have strong antioxidant capabilities. Study examined at the ability of a polyphenol-rich extract from fenugreek seeds to inhibit hydrogen peroxide (H202)-induced oxidation in both diabetic as well as healthy human erythrocytes (RBCs)

e. Anthelmintic activity: [54]

Trigonella Foenum-graecum seeds exhibited strong and noticeable anthelmintic activity. Both water and alcoholic extracts have demonstrated some anthelmintic efficacy, but to a lesser degree. Thus, an effort has been undertaken to assess the anthelmintic activity of seeds on Pheritimapostuma adult micro - organisms.

f. Hypolipidemic activity:[55,56,57]

Fenugreek seeds may give protection against the rat breast cancer caused by 7,12-DMBA. The extract from fenugreek seeds significantly decreased the frequency of DMBA-induced mammary hyperplasia and strongly inhibited it at 200 mg/kg body mass. Apoptosis is another mechanism that epidemiological studies suggest may be responsible for the protective effect of fenugreek against breast cancer.

g. Antioxidant activity: [58]

(a) Allergies: Those who have a peanut allergy should use it carefully or altogether avoid it. Other than that, fenugreek is very safe.

(b) Side Effects:

1. Fenugreek may lower blood potassium levels. An allergic reaction is probably what causes numbness, facial swelling, breathing issues, and fainting.
2. Fenugreek could make bleeding more likely.
3. Some pregnant women may have uterine contractions, hypoglycaemia, and loose stools after consuming fenugreek.

h. Anti-inflammatory and analgesic activity: [59,60]

Comparing Trigonella foenum graecum (TFG) seeds to the Diclofenac potassium, a popular analgesic (DIP, 10 mg/kg, p.o.) in rats using the tail flick method. One hour before the onset of pain, TFG seed extracts in both aqueous and ethanol were given orally in doses of 50, 100, and 200 mg/kg.

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