IJPSM

Bhadoria Juhi *et al*, International Journal of Pharmaceutical Sciences & Medicine (IJPSM), Vol.7 Issue. 6, June- 2022, pg. 59-69

ISSN: 2519-9889
Impact Factor: 5.721

A Review on Orodispersible Tablet by Using *Hibiscus rosa sinesis* as Natural Superdisintegrant

Bhadoria Juhi; Likhariya Manoj
juhibhadoria980@gmail.com
Indore Mahavidyalaya, Indore (M.P)

DOI: 10.47760/ijpsm.2022.v07i06.003

ABSTRACT:
Oral delivery is current standard in the pharmaceutical industry wherever it is regarded as the safest, most suitable and most economical method of drug delivery. The oral cavity is an attractive site for the administration of drugs because of ease of administration. Oro-dispersible drug delivery system are Novel Drug Delivery techniques that make the tablets disintegrate in the mouth without chewing and water, and immediate release and enhanced bioavailability, with better patient compliance. Orodispersible tablets (ODTs), also known as fast melt, quick melts, fast disintegrating have the unique property of disintegrating in the mouth in seconds without chewing and the need of water. Recently, the European Pharmacopeia adopted the term Orodispersible tablet for a tablet that disperses or disintegrates within a minute or second in the mouth before swallowing. Natural polymers remain attractive primarily because they are natural products of plants, readily available, inexpensive, and capable of multitude of chemical modification. Leaves of Hibiscus rosa sinensis Linn (Family: Malvaceae) contains high proportion of mucilage which can be used as additives in pharmaceutical formulations. The investigation of polysaccharides isolated from leaves of Hibiscus rosa sinensis Linn mucilage as a superdisintegrant in the formulation development of Orodispersible Tablets.
Keywords: Orodispersible tablet, lipid-lowering agent, Superdisintegrant, Hibiscus rosa sinensis, Bioavailability, Solubility, Superdisintegrant.

ISSN: 2519-9889
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INTRODUCTION:

Orodispersible Tablet:

Oral delivery is current standard in the pharmaceutical industry wherever it is regarded as the safest, most suitable and most economical method of drug delivery.[1] The oral cavity is an attractive site for the administration of drugs because of ease of administration. [2]

Oro-dispersible drug delivery system are Novel Drug Delivery techniques that make the tablets disintegrate in the mouth without chewing and water, and immediate release and enhanced bioavailability, with better patient compliance. [3] Recently, the European Pharmacopeia adopted the term Orodispersible tablet for a tablet that disperses or disintegrates within a minute or second in the mouth before swallowing. [4]

United States Food and Drug Administration (FDA) defined Oro-dispersible tablet as "a solid dosage form containing medicinal substances or active ingredient which disintegrate or dissolve rapidly within seconds when placed upon the tongue. [5,6]

Oro-dispersible tablets have a quick dissolution and rapid absorption which provide rapid onset of action. Moreover, drug candidates that undergo pre-gastric absorption when formulated as ODTs may oral bioavailability of drug is enhanced by avoiding the hepatic first pass metabolism. It provides good stability, accurate dosing, easy of manufacturing. Oro-dispersible tablets are made by a direct compression method using super Disintegrate as an important component. [7,8]

Ideal properties of Oro-dispersible tablet: [9-11]

- It should be dissolve or disintegrate in the mouth or saliva within seconds.
- It should not require any liquid or water to show its action.
- It should have an acceptable taste masking property.
- It should leave no residue in mouth after the disintegration.
- It should exhibit low sensitivity to environmental conditions (temperature and humidity).
- More rapid drug absorption from the pre-gastric area i.e. mouth, pharynx and oesophagus

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- It may produce rapid onset of action.
- It should be cost effective.

Drug Selection Criteria of ODTs: [12]

- Able to saturate the oral mucosa.
- Have the ability to diffuse and partition into the epithelium of upper GIT.
- BCS class-II class drug is good candidate for ODTs.
- At least moderately non-ionized at oral cavity PH.
- Molecular weight below 500 Dalton.
- Low dose drugs mostly less than 50 mg.
- Should have good stability in saliva and water.
- Should have lower bio availability are good candidates for ODTs.
- Short half-life and frequent dosing drugs are unsuitable for ODTs.
- Very bitter taste and undesirable odor drugs are unsuitable for ODTs

Advantages of Oro-dispersible tablet: [13-15]

- Ease of Administration to the patient who cannot swallow then consequently improved patient compliance
- No need of water.
- Rapid dissolution, absorption of the drug and increase bioavailability
- Pregastric absorption of drug be able to enhance oral bioavailability of drug, and as a result of reduces dose administration.
- Good chemical stability as conventional oral solid dosage form.
- Decreased first pass metabolism.

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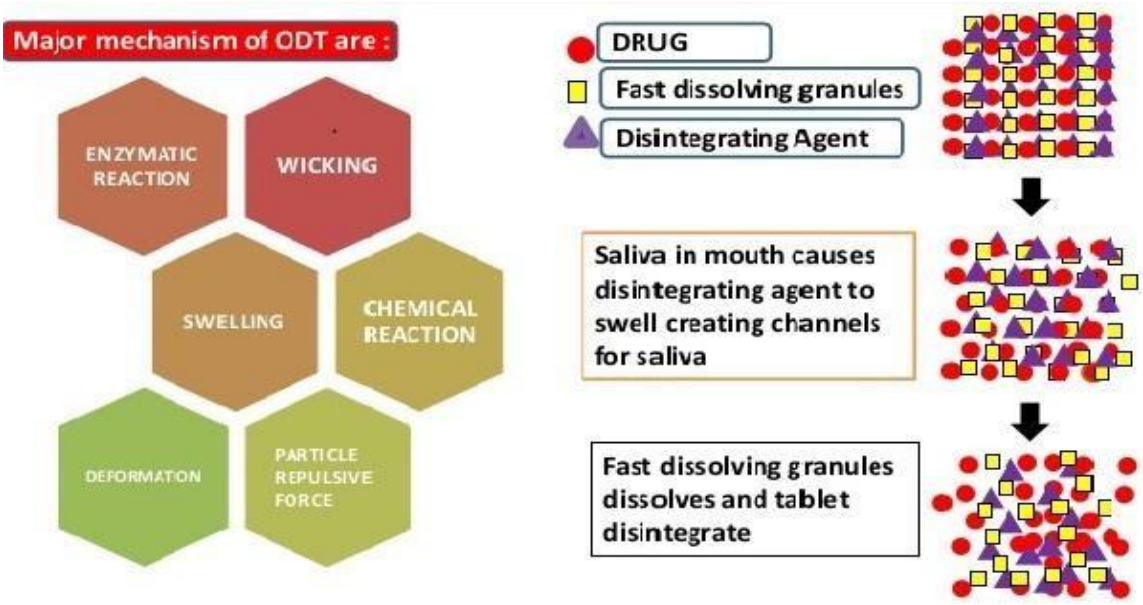
Mechanism of action of Oro-dispersible Tablet:

The Orodispersible tablet contain drug that are fast dissolving granules and disintegrating agents. The oral dispersible tablets come in contact with saliva in the mouth results, swelling of disintegrating agents that will create channels for saliva.



Types of Superdisintegrants

a. Natural Superdisintegrants.
b. Synthetic Superdisintegrants.

a. Natural Superdisintegrants:

These Super Disintegrate agents are natural in origin because they are comparatively cheaper, abundantly available, non-irritating and nontoxic in nature. The natural materials like gums and mucilage's have been extensively used in the field of drug delivery for their easy of availability, cost effectiveness, Eco friendliness, emollient and non-irritant nature, non-toxicity, there are several gums and mucilage's are available which have super-disintegranting activity. [19]

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Impact Factor: 5.721

b. Synthetic Superdisintegrants: [20]

Examples: Crosslinked Polyvinyl Pyrrolidone, Sodium Starch Glycolate, Croscarmellose Sodium, Chittin and Chitosan.

Table 1.1. Natural Superdisintegrants

Name of Natural Superdisintegrants	Part Used	Application
Isapghula Husk	Seeds	Binding, super disintegrating and sustaining properties.
Lepidium sativum	Seeds	Binding, superdisintegrating, gelling
Fenugreek(Trigonella Foenum-graceum)	Seeds	Binding, disintegrating properties
Cassia tora	Seeds	Binder, superdisintegranting
Locust Bean	Seeds	Thickening and gelling agent
Hibiscus Rosa Sinesis	Seeds	Binder, superdisintegranting

Mechanism of Superdisintegrants:

Fast Dissolving Tablet requires faster disintegration, that's why Super Disintegrate is needed in formulating ODT. Super Disintegrate used is the one that effective at low concentration and have greater disintegrating efficiency and they are more effective intra granularly. This Super Disintegrate act by swelling and due to swelling pressure exerted in the outer direction or radial direction, it causes tablet to burst or the accelerated absorption of water leading to an enormous increase in the volume of granules to promote disintegration.

1. By Swelling
2. Capillary action (wicking)
3. Deformation

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4. Combination action
5. Repulsion. [21]

Hibiscus Rosa Sinensis:

Hibiscus rosa-sinensis, known colloquially as Chinese hibiscus, China rose, Hawaiian hibiscus, rose mallow and shoe black plant, is a species of tropical hibiscus, a flowering plant in the Hibisceae tribe of the family Malvaceae, native to East Asia.

Phytography: It is also known as shoe flower. Hibiscus rosa-sinensis is a bushy, evergreen shrub or small tree growing 2.5–5 m (8–16 ft) tall and 1.5–3 m (5–10 ft) wide, with glossy leaves and solitary, brilliant red flowers in summer and autumn. The 5-petaled flowers are 10 cm (4 in) in diameter, with prominent orange-tipped red anthers.

The flowers of Hibiscus rosa-sinensis are edible and are used in salads in the Pacific Islands. The flower is additionally used in hair care as a preparation. It is also used to shine shoes in certain parts of India. It can also be used as a pH indicator. When used, the flower turns acidic solutions to a dark pink or magenta color and basic solutions to green.

Natural polymers remain attractive primarily because they are natural products of plants, readily available, inexpensive, and capable of multitude of chemical modification. Leaves of Hibiscus rosa- sinensis Linn (family: Malvaceae) contains high proportion of mucilage which can be used

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as additives in pharmaceutical formulations. The investigation of polysaccharides isolated from leaves of Hibiscus rosa-sinensis Linn mucilage as a Superdisintegrant in the formulation development of Oro-dispersible Tablets.

Pharmacological action:

- Helps lower LDL cholesterol: A study showed that having 1 gm of the leaf extract every day helped people control weight and lower LDL cholesterol levels given that they also followed a perfect diet and exercise plan for the same. Nothing works like magic, but this leaf extracts can help compliment your efforts.
- Polyphenols and flavonoids present in the leaves of Hibiscus Rosa Sinensis have been shown to alleviate chronic inflammation in the body and help treat IBS effectively. It is the flavonoids present in the leaves that are responsible for treating IBS.
- When applied to cuts and wounds hibiscus leaf extracts help wounds to heal faster. There are studies that indicate that hibiscus leaf extracts also help lower LDL cholesterol increase HDL cholesterol and lower blood pressure to prevent heart diseases.
- Hibiscus concentrate may affect digestion, averting heftiness and fat development in the liver. The tropical plant has even been utilized effectively as a major aspect of a natural concentrate blend to treat head lice.

Method of Preparation of Orodispersible Tablet and *Hibiscus rosa sinensis* mucilage:

There are several methods for the preparation of orodispersible tablets but the prepared products vary in their properties depending on the method of preparation. The properties in which they vary are mechanical strength of the tablets, swallowability, bioavailability, drug dissolution in saliva, stability, and to some extent taste. Various process of manufacturing of orodispersible tablets are molding, compaction, spray-drying, freeze-drying, and some special methods are melt granulation, phase transition, and sublimation.

1. Molding Methods
2. Compaction Methods

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3. Spray-Drying Methods
4. Freeze-Drying Methods

1. Molding Methods: Tablets formed by molding process are highly porous in structure, resulting in high rate of disintegration and dissolution. This process includes moistening, dissolving, or dispersing the drugs with a solvent then molding the moist mixture into tablets by applying lower pressure in compression molding, but always lower than the conventional tablet compression. The powder mixture may be sieved prior to the preparation in order to increase the dissolution.

2. Compaction Methods: Conventional methods for the preparation of tablets such as dry granulation, wet granulation, and direct compression are also exist for the preparation of orodispersible tablets. Some important super disintegrants, which are used during preparation of orodispersible tablets, are crosspovidone, crosscarmellose sodium, sodium alginate, acrylic acid derivatives. Even orodispersible tablets of Carbamazepine were prepared by this method having microcrystalline cellulose and crosspovidone (2%-10%). In all the cases it has been found that preparation by compression method along with addition of super disintegrants in correct concentration obey all the properties of orodispersible tablets.

3. Spray-Drying Methods: Orodispersible tablets are made up of hydrolyzed or unhydrolyzed gelatin as supporting agent for matrix, mannitol as bulk agent, and sodium starch glycolate or croscarmellose sodium as disintegrating agent. Sometimes in order to improve the disintegration and dissolution, citric acid and sodium bicarbonate are used. Finally, the formulation is spray-dried in a spray drier. Orodispersible tablets prepared through this method are disintegrated in less than 20s.

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Impact Factor: 5.721

4. Freeze-Drying Methods: This is a very popular process for the preparation of orodispersible tablets. Tablets prepared by this process have low mechanical strength, poor stability at higher temperature and humidity, but glossy amorphous structure resulting in highly porous, lightweight product. There are various patents on this particular technology.

Extraction of *Hibiscus rosa-senensis* leaves mucilage:

Hibiscus rosa sinensis (China rose) was procured from the local area of Greater Noida, India. Collected leaves was carefully washed and dried under shade for 24 h and then further dried in oven at 30-40°C. Size was reduced with the help of grinder. Powdered leaves were passed through sieve no. #22 and then used for further evaluation.

Extraction of mucilage includes 2 steps:

Step 1: Extraction of Mucilage: Powdered leaves of Hibiscus rosa sinensis were used for the extraction of mucilage. The powdered leaves placed in 1000ml beaker containing 500ml of distilled water and allowed it to boil for at least 3-4 h with continuous stirring and heating at 60°C of sufficient release of mucilage in water. Concentrated solution was then filtered through muslin cloth in order to separate marc from the filtrate and refrigerated for cooling (3-4°C).

Step 2: Isolation of Mucilage: To the extract of mucilage in acetone was added to the quantity of three times the volume of filtrate for precipitation of mucilage to occur. The precipitated mucilage was washed with acetone and then collected through filtration by muslin cloth. Mucilage was further dried in hot air oven at temperature less than 40°C. The obtained dried mucilage was grinded and passed through sieve #80 and finally stored in air tight container.

Characterization of prepared mucilage powder: [22]

Organoleptic Characterization of Isolated Mucilage: The extracted mucilage was characterized for various parameters like color, odor, taste, texture and fracture etc.

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CONCLUSION:

In the present review, the effect of Hibiscus rosa sinensis as a superdisintegrant in Orodispersible tablet was studied. Various studies found that the Hibiscus rosa sinesis mucilage powder can be used as the super-disintegrants in the formulation at different concentrations. As the concentration of superdisintegrant hibiscus rosa sinesis mucilage powder has significant effect on disintegration characteristics as well as drug release. But the higher concentration of mucilage had negative impact on drug release & disintegration time.

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