IJNRD.ORG ISSN : 2456-4184
INTERNATIONAL JOURNAL OF NOVEL RESEARCH AND DEVELOPMENT (IJNRD) | IJNRD.ORG
An International Open Access, Peer-reviewed, Refereed Journal

FAST-DISSOLVING TABLET USING NATURAL SUPER DISINTEGRANTS AN OVERVIEW

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ABSTRACT-

Fast-disintegrating tablets (FDTs) have become increasingly popular over the past decade and have become a rapidly growing segment in the pharmaceutical industry. Oral administration of drugs continues to be the preferred route of administration for various drugs. Recent technological developments prompted the scientist to develop his FDT to improve patient compliance and comfort. Once placed in the mouth, these tablets dissolve or disintegrate in the mouth, allowing easy administration of the pharmaceutically active ingredients without the need for additional water. Several FDT techniques have been developed due to the popularity and availability of this formulation. FDDS, a fast disintegrating drug delivery system, combines the advantages of both liquid and traditional tablet formulations while offering advantages over both traditional dosage forms. They combine the ease of ingestion of tablet formulations with the convenience of liquid forms. FDDS allows for much more precise dosing than leading oral rehydration fluids. Aphasic, geriatric, pediatric, traveling or psychotic patients will benefit from this portion of the formulation. Those who are unable or unwilling to take conventional oral formulations. Fast-dissolving tablets (FDTs), which dissolve in the mouth without chewing and require additional water consumption, have received a lot of press over the past decade. The term orodispersible tablet was recently coined by the European Pharmacopoeia to describe tablets that dissolve within 3 minutes before being swallowed or disintegrating in the mouth.

Keywords- Fast Disintegrating Tablets (FDA), Natural Supper Disintegrants, Formulation processes

INTRODUCTION-

Rapidly disintegrating tablets (FDT) are gaining popularity as a new drug delivery technology. These dosage forms dissolve or disintegrate within 1 minute without water or chewing when in contact with saliva in the oral

cavity. The basic technique in the development of FDT is to use materials such as carboxymethyl cellulose, sodium starch glycolate and polyvinylpyrrolidone, which break down the tablet immediately after it is placed on the tongue and release the drug into saliva [1].

Emits to FDT is useful for administering medication to children and the elderly. Fast Disintegrating Drug Delivery System "FDDS" combines the advantages of both liquid and traditional tablet formulations while offering advantages over both traditional dosage forms. They combine the ease of taking tablet formulations with the convenience of liquid forms. FDDS allows for much more precise dosing than the leading oral liquid replacements. Aphasic, geriatric, pediatric, traveling or psychotic patients will benefit from this portion of the formulation [2].

Those who are unable or unwilling to take conventional oral formulations. Fast-dissolving tablets (FDTs), which dissolve in the mouth without chewing and require additional water consumption, have received a lot of press over the past decade. The term orodispersible tablet was recently coined by the European Pharmacopoeia to describe tablets that dissolve or dissolve in the mouth within 3 minutes before swallowing. Patients can easily ingest such tablets as they break up into smaller granules or dissolve on the tongue from a hard, solid, gel-like structure [3].

It can take a few seconds to almost a minute before the proper FDT is resolved. Neuroleptic, cardiovascular, analgesic, and antiallergic drugs are all good candidates for this system.When the tablet is placed on the tongue, it quickly disintegrates, releasing the drug to disperse or dissolve in saliva. As a result, the drug has a faster acting and higher bioavailability than traditional tablet formulations [4].

FDT is manufactured using different techniques based on improving tablet porosity by adding super-disintegrants or water-soluble excipients. Rapidly dissolving tablets are an emerging trend for new drug delivery systems and have been in increasing demand over the past decades. Superdisintegrants are used in orally disintegrating tablets to improve the disintegration and potency of solid dosage forms [5].

This is achieved by shortening the disintegration time and increasing the dissolution rate of the drug. Disintegrants are substances used in formulations to help break tablets (and capsule "hit") into smaller pieces in an aqueous environment, thereby increasing the available surface area and allowing the active ingredients to break down. promotes the rapid release of Natural superdisintegrants, which are natural products of plants, are readily available, inexpensive, biocompatible, and capable of various chemical modifications, still play an attractive role in orally disintegrating tablets [6].

Increase. In recent years, several new materials known as superexplosives have been developed. Natural super-disintegrants are derived from natural sources and have many advantages: cheap, non-toxic, biodegradable, environmentally friendly, no side effects, renewable, and nutraceutical. , natural polymers are more effective and safer than synthetic polymers [7].

IDEAL PROPERTIES & MERITS OF FAST-DISSOLVING TABLETS

If you put it in your mouth, it should decompose within seconds. No water is required to dissolve. Because they are unit dosage forms, precise dosing must be possible. Rapid dissolution and absorption in the oral cavity. Tablets

are manufactured on conventional low-cost equipment. Insensitive to environmental conditions such as humidity and temperature. They should be indestructible and retain their hardness [8].

Fast Dissolving Tablets (FDT) are solid unit dosage forms that allow for precise dosing and high drug loading. It is also an ideal alternative to traditional tablets as well as an ideal dosing method for geriatric and pediatric patients. Since the patient ingests it, it has a fast-acting effect, and when it comes into contact with saliva, it begins to dissolve, is rapidly absorbed in the oral cavity, and dissolves quickly to provide a fast-acting effect. Pre-gastric absorption alters drug bioavailability, requiring lower doses, altering patient compliance, and altering clinical reporting. Quick-dissolving tablets do not require water to swallow and can be taken anytime, anywhere. A convenient option for mobile patients and hard-working people who do not have ready access to water. Therefore, patient compliance is altered [9].

DIFFERENT NATURAL SUPPER DISINTEGRANTS USED IN THE FORMULATION-

Mucilage of Lepidum Sativum (Asaliyo)-

Lepidum sativum (Family: Brassicaceae), commonly known as short-necked clams, has long been used as a herbal medicine in India. It is readily available in local markets and has a very low cost. The parts used are leaves, roots, oil, seeds, etc. The seeds contain a large amount of mucilage containing dimeric imidazole alkaloids lepidine B, C, D, E, and F and two new monomeric imidazole alkaloids, semilepidinosides A and B [10].

Lepidium Sativum slime has various properties such as binding, dissolving and gelling. Therefore, in one study, mucilage was isolated from seeds and used to develop fast-dissolving tablets. It was found that the superdisintegrant obtained from Lepidium sativum slime had good physicochemical properties and the swelling index of slime and skin obtained from Lepidium sativum was 27 and 25 respectively [11].

The swelling factor is associated with rapid water absorption during tablet disintegration, and rapid swelling leads to rapid tablet disintegration. As stated in the official statement, the LOD values are within the given limits. The compression index and angle of repose values show that the slime and shell powder have moderate compressibility and good flow properties. Different batches were formulated using different ratios of drug, mucilage and hulls of Lepidium sativum seeds by direct compression technique. Other excipients such as sucrose, microcrystalline cellulose, talc and magnesium stearate are incorporated into the formulation [12].

Coarse microcrystalline cellulose (PH102) was chosen as the diluent because it facilitates the flow properties of the mixture from the hopper. Fast-dissolving aceclofenac tablets were prepared using Lepidum sativum mucus, formulation D5 was selected by the design expert software, and DT of 15.5 seconds, WT of 18.94 seconds, and in-had in vitro drug release (100%) was obtained in 15 minutes. It turns out that you can [13].

Locust bean

Locust bean gum, also known as locust bean gum, is a galactomannan gum extract obtained from the seeds of the locust bean tree (Ceretonia siliqua) found mainly in the Mediterranean region. It is widely used in the food industry as a thickening and gelling agent. It has been. It is also reported to have properties of increasing stickiness and solubility. Malik K et al. Nimesulide in the melt was formulated and evaluated using locust bean gum as a super disintegrant. Locust bean gum was evaluated for powder flow properties, swelling index and loss on drying

and was found to exhibit excellent powder flow properties with a swelling index of 20 seconds. This indicates that locust bean gum is quite suitable for use as a super-disintegrant for fast-dissolving tablets. The manufactured tablets were compared with standard super-disintegrants. H. Croscarmellose sodium evaluated. A tablet containing 10% locust bean gum as a super disintegrant had a disintegration time of 13 seconds [14].

Isapghula Husk (Plantago ovata)-

Pantago ovata belongs to the Plantago family. The seeds and psyllium husk are valuable sources of dietary fiber and mucilage from this plant. Psyllium husk is used as a laxative, lowers the glycemic index, and is being developed in controlled release formulations by the pharmaceutical industry. Flea seed shells absorb moisture so quickly that they weigh up to 10 times. Hydrocolloids make up 10-30% of the psyllium husk [15].

These are water-soluble polysaccharides that form a layer of slime when exposed to water. During hydrolysis, the mucus is split, yielding various polysaccharides such as xylose, arabinose, galacturonic acid, rhamnose and galactose. These compounds are responsible for the explosive properties of psyllium husk and can be used as natural explosives in pharmaceutical manufacturing. found slime to be effective as a super-disintegrant at low concentrations. Isapghula Husk (Plantago ovata) Pantago ovata belongs to the Plantago family [16].

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The decaying properties of Plantago ovata slime were demonstrated by Prajapati et al. We prepared dispersible tablets of nimesulide using wet granulation technology and found slime to be effective as a super-disintegrant at low concentrations. Furthermore, the results showed that the disintegration properties of isabgol mucus were comparable to his Ac-DiSol and superior to sodium starch glycolate [18].

Gellangum [19, 20]-

Gellan gum is a biodegradable linear anionic polysaccharide polymer derived from Pseudomonos elodea, composed of repeating linear tetrasaccharide structures. The effectiveness of gellan gum and gum as superdisintegrants is compared to conventional disintegrants such as dry cornstarch, Explotab, Avicel (pH 102), Ac-disol and Kollidon CL.

Due to the instant swelling properties of gellan gum in contact with water and its high hydrophilicity, tablet disintegration occurs, and when the gellan gum concentration in the formulation is 4% by weight, complete tablet disintegration is achieved within 4 minutes. Percentage of drug dissolved within 23 minutes was observed. Ac-di-sol and Kollidone CL show very similar decay patterns and dissolution rates in vitro. The same potency

formulation using Explotab shows 90% drug release at 36 minutes and strength at 220 minutes. Therefore, the conclusion of the study was that gellan gum proved to be a super disintegrant.

Soy polysaccharide [21, 22]-

High fiber soy polysaccharide materials generally contain high molecular weight carbohydrate polymers found primarily in soybeans, such as arabinose, galactose, xylose, and mannose. It is usually used as an umbrella term to describe fibrous carbohydrate materials derived from the structural components of soybean cell membranes, including soybean flakes, meal, or grist.Sildenafil citrate (SC) is used as a model drug. was conducted to study the disintegration effect of soybean polysaccharides using Sublingual formulations containing super-disintegrating ingredients (Embosome or Explotab) were acceptable, with short wetting times ranging from 25 to 40 seconds, high water absorption ranging from 41 to 60, and short wet times ranging from 55 to 74 seconds. In vitro dispersal time.

Mango peel [23, 24]-

Pectin mucilage and pectin are most commonly used as adjuvants in the manufacture of various pharmaceutical dosage forms. They have various pharmaceutical properties, including binding, disintegrating, suspending, emulsifying, and maintaining properties in various ratios. In some pharmaceutical dosage forms, synthetic polymers used as excipients suffer from several drawbacks such as high cost, toxicity, non-biodegradability, and environmental pollution caused during synthesis. Natural slime, pectin and pulp are preferred over semi-synthetic and synthetic materials because they are non-toxic, low cost, free available, emollient and non-irritating. Contains tannins namely protocatechuic acid, quinic acid and catechins.

Gaur gum [25, 26]-

Consisting of a linear chain of β-(1→4) linked D-mannose units, D-galactose is linked to all other mannose units via α-(1→6) linkages to form short side chains. Although not self-gelling, guar gum has a high low-shear viscosity. Because it is non-ionic, it is not affected by ionic strength or pH. Guar gum is a non-ionic polysaccharide extracted from Siam seeds. opsis tetragonolobus, legume family. It consists of a linear chain of -D-mannopyranosyl units with -D-galactopyranosyl units linked by bonds. In pharmacy, guar gum is used in solid dosage forms as a binder and disintegrant.

Table number- Natural polymers used in fast dissolving tablets [27-30]

Natural polymer	Marketed drug	Disintegration time
Chitin and chitosan	Cinnarizine	60 sec
Gum karaya Amlodipine	Granisetron hydrochloride	17.10 sec
Soy polysaccharide	Lornoxicam	12 sec
Locust bean gum	Nimesulide	13 sec
Mangifera indica gum	Metformin HCL, paracetamol	3–8 min

MECHANISM OF ACTION OF SUPER DISINTEGRANTS [31-35]-

Swelling-

Swelling is a well-established mechanism and necessarily the first step in tablet disintegration. Certain explosives (e.g. starch) produce an explosive effect in the process. Tablets with high porosity have poor disintegration due to lack of sufficient swelling power. Disintegrant particles swell when in contact with water, which can overcome the stickiness of other pharmaceutical ingredients present in the tablet and break the tablet. Non-swelling disintegrants work through a mechanism of porosity and capillary action. The porosity of the tablet provides pathways for liquids to penetrate the tablet. When the tablet is placed in a suitable aqueous medium, the medium permeates the tablet and replaces the air adsorbed on the particles, weakening the intermolecular bonds and breaking the tablet into small pieces. Water absorption by tablets depends on the hydrophilicity of the drug/excipients and the compression conditions. Liquid is drawn or "sucked" into this pathway by capillary action, breaking the bonds between the particles and breaking the tablet apart. These types of disintegrants require maintenance of a porous structure and low interfacial tension with aqueous liquids and aid disintegration by creating a hydrophilic network around the drug particles.

Combination Action-

In this mechanism, the combination of both wicking and swelling action to disintegration

Heat of wetting-

When the exothermic disintegrant is wetted, air expansion in the capillaries creates localized stresses that accelerate tablet disintegration. This mechanism of action explains the action of some explosives, but not most modern explosives.

Deformation-

The disintegrated particles deform during tablet compression and these deformed particles return to their normal structure upon contact with water. The ability to swell during deformation increased and the tablet burst. In the case of starch (potato starch, cornstarch, etc.), it is thought to be elastic in nature, but due to the high compression force during tableting, the granules deformed by pressure return to their original shape upon compression. Removed. When these tablets are exposed to an aqueous environment, the energy potential of the deformed starch granules is released, causing disintegration.

Enzymatic action-

Endogenous enzymes also act as disintegrants. These enzymes act on the binding action of binders and aid in their breakdown. Expansion creates outward pressure that causes the tablet to break or burst. Accelerated water uptake results in a significant increase in granule volume to facilitate disintegration. H. Expansion creates outward pressure, breaking the tablet and increasing water absorption.

Electrostatic Repulsion-

This is another disintegration mechanism that attempts to explain the swelling of tablets made with non-swelling disintegrants. Guyot-Hermann proposed an interparticle repulsion theory based on the observation that non-swollen particles also cause tablet disintegration. Electrical repulsion between particles is the mechanism of collapse, which requires water. Due to its affinity with the starch surface, water penetrates between the starch granules, breaking hydrogen bonds and other forces that hold the tablet together.

Chemical Reaction (Acid Base Reaction)-

The release of carbon dioxide in the tablet when wet due to the interaction of tartaric and citric acids (acids) with alkali metal carbonates or bicarbonates (bases) in the presence of water breaks the tablet. The tablet disintegrates due to pressure build up inside the tablet. This effervescent blend is used when pharmacists need to prescribe very fast-dissolving or fast-disintegrating tablets. Strict environmental controls are required during the manufacture of these tablets as these disintegrants are very sensitive to slight changes in humidity levels and temperature. The effervescent mixture can be added just before compression or added in two separate parts during compounding

FORMULATION PROCESSES FOR MAKING FAST-DISSOLVING TABLETS-

Freeze Drying Freeze-drying [36, 37] –

Technique is used in order to improve the dissolution rate and oral bioavailability of drugs with poor solubility and high permeability (biopharmaceutic classification system Class II drugs). Freeze drying (Lyophilization) is a process in which water is sublimated from the product after freezing. This process can be performed in many ways to achieve the same end product, i.e., I) drug is physically trapped in a water-soluble matrix (water-soluble mixture of saccharide and polymer, formulated to provide rapid dispersion, and physical strength), which is freeze dried to produce a product that dissolves rapidly when placed in mouth.

For such types of formulations, a chemically stable and water-insoluble drug with particle size less than 50 µm are required Formation of porous solid form obtained by freezing an aqueous dispersion or solution of the active containing matrix by removing the water using an excess of alcohol (solvent extraction) and for that, the active should be insoluble in the extraction of solvent with the advantage that the thermolabile drugs can be formulated at non-elevated temperature, thereby eliminating adverse thermal effects, and stored in a dry state with few shelf-life stability problems.

solid form lyophilization of an oil-in-water emulsion (porous solid galenic form) is placed directly in the blister alveolus. The major drawbacks of these dosage forms are their lack of physical stability and limited ability to incorporate high concentrations of active ingredients in standard blister packs, in addition to expensive manufacturing processes.

Granulation Methods

Wet granulation [38, 39]

Wet granulation is the process of adding a liquid to a powder in a container with some kind of agitator that creates agglomerates or granules. Wet granulation is commonly used to improve the tableting process by producing a

product (granules) with improved flowability, uniformity, and compressibility compared to the original drug-containing powder blend. tablet manufacturing process. There are many methods used to manufacture granules in the pharmaceutical industry. However, the most common is high shear. Like most pharmaceutical processes, wet granulation is complex and many factors, such as the binders used and processing conditions, affect the physical properties of the resulting granules.

Dry granulation [40]

Slugging can be used to form granules when tablet ingredients are sensitive to moisture or cannot withstand high temperatures during drying, and when tablet ingredients have sufficient inherent binding or cohesive properties. This process is called dry granulation, pre-compaction, or double compaction.

Spray drying [41]

Spray drying was used to prepare the microspheres. Spray drying is widely used in pharmaceutical processing because it requires only a one-step process and is easy to control and scale up. Spray drying is widely used in the pharmaceutical and biochemical fields and the final particle size is controlled by many factors, including the size of the nozzle used in the process. This method yields fine powders with high porosity. Allen and Wang used this method to prepare his FDT. The FDT formulation consisted of hydrolyzed/non-hydrolyzed gelatin as matrix proppant, mannitol as bulking agent, and sodium starch glycolate and croscarmellose sodium as disintegrants. Disintegration and dissolution were further improved by adding effervescent ingredients. H. Citric acid (acid) and sodium bicarbonate (base). The formulation was spray dried to obtain a porous powder. An FDT generated this way is decomposed into < 20 seconds.

Flash heat process [42]

Flash flow processing can be accomplished in a number of ways. Flash heat and flash shear are two very popular methods. In the flash heat process, the raw material is sufficiently heated that a portion of the raw material is forced to move against the rest of the mass at sub-particle level, turning the provided head. The centrifugal force generated in the spinner head causes the flowing material to be thrown outward from the head, changing its structure and reforming. The force required to separate and eject the fluid ingredients is the centrifugal force generated by the spinner head. A preferred apparatus for carrying out the rapid heating method is a "cotton candy" type machine. Sucrose (78.25%), sorbitol (11.0%), xylitol (10.0%) and Tween 80 (0.75%), ibuprofen, cymitedin, vitamin C, calcium carbonate/vitamin D, or paracetamol were used in the manufacture used in FDT It has been.

FUTURE RESEARCH TRENDS IN FAST-DISINTEGRATING TABLETS [43-47]

FDT's products and technologies face various challenges as shown in the table. These challenges are related to new technologies and products. As these technologies mature and new products are developed, some of these challenges will be addressed by various companies. Several techniques have been used to achieve rapid distribution and drug delivery to the oral cavity. The four of his FDT technologies discussed in this chapter include WOWTAB®, Zydis®, OraSolv®, and Shearform™. Formulation considerations, including drug, excipient,

packaging, and manufacturing process selection, were contrasted for these different FDT techniques. Each FDT technique has its own strengths and weaknesses, but what they all have in common is rapid disintegration and convenient dosing for the patient. Specific in vitro and in vivo test methods are required to investigate the performance of these products. FDT's technology and products face many challenges as they are relatively new to the market, but these technologies are evolving rapidly to meet future challenges and patient and medical needs. Continuously improved to keep up with changes. Overall, FDT products have great commercial potential that is expected to materialize over the next decade.

Table number- Orally disintegrating tablet products available in Indian market [48-50]

Brand name	Active ingredient	Company
Domray MD	Domperidone	Ray Remedies
Vomidon MD	Domperidone	Olcare Lab
Manza RDT	Olanzapine	Mano Pharma (Orchid)
Doloroff	Rofecoxib	Indoco
Zofex-25 MD	Rofecoxib	Zota Pharma
Topmide	Nimesulide	Antigen Health Care
Mosid MT	Mosapride	Torrent

CONCLUSION-

This article provided a review of the various types of superexplosives currently available. Advances in the formulation of fast-dissolving tablets have made it possible to formulate these tablets with reduced amounts of many types of super-disintegrants. Approximately one-third of patients require rapid therapeutic effects of drugs. This review describes various formulations and techniques developed to achieve rapid dissolution/dispersion of tablets in the oral cavity. In particular, this review details FDT techniques based on freeze-drying, molding, sublimation, and compression, as well as approaches to improve his FDT properties, such as spray-drying and the use of disintegrants. In addition, taste masking technology.

ACKNOWLEDGMENT-

The authors express their sincere gratitude to Parikrama College of Pharmacy, Kashti, Shrigondha, Our, University Libraries, and all other sources for their cooperation and advice in writing this review.

CONFLICT OF INTERESTS-

Nil

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