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Review Article

Super Disintegrants in Development of Orally Disintegrant Tablet

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ABSTRACT

Over the past few decades, there has been a growing demand for oral disintegrating tablets, a developing trend in innovative drug delivery systems. Because of its simplicity of use and improved patient compliance, particularly for elderly and pediatric patients, the field is expanding quickly within the pharmaceutical industry. ODTs are solid unit dose forms that dissolve quickly in the mouth without the need for water or chewing. Several excipients can be added to a dosage form to provide this kind of feature; the disintegrant being the most important adjuvant. A number of more contemporary substances called as superdisintegrants have been created in recent years. To create effective mouth-dissolving tablets and get around the drawbacks of traditional tablet dosage forms, a variety of superdisintegrant categories including synthetic, semi-synthetic, natural, and co-processed blends—have been used. The goal of this article is to describe the many types of superdisintegrants and their functions in drug release and tablet disintegration. These ingredients are employed in formulations to deliver drugs in a safer, more efficient manner while maintaining patient compliance. The efficiency of co-processed excipient blends, natural superdisintegrants derived from various plant sources, and various synthetic superdisintegrants are the main topics of this review.

INTRODUCTION

The most popular and practical method is oral administration, which has excellent stability and a compact package size [1]. A significant portion of patients take the conventionally formulated tablets, but some patients such as individuals who are young, old, bedridden, mentally ill, or uncooperative still have trouble swallowing them because of various systemic abnormalities. It was determined that 50% of patients experience these outcomes, leading to an elevated rate of non-compliance and ineffective treatment. For these unique patient groups, a novel dosage form orally dispersible tablets has been created for the oral administration of medications. Orally dispersible tablets are advanced solid dosage forms that enable solid medications to dissolve or disintegrate

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quickly, displaying them as a suspension or solution prior to delivery.

The following ODTs are also well-known under a number of other names, including rapimelts, porous tablets, fast dissolving tablets, fast disintegrating tablets, mouth dissolving tablets, and fast dissolving tablets. "Dispersible tablet" refers to a "uncovered tablet for buccal cavity, where it spreads before ingestion," In accordance to the European Pharmacopeia[2].

Tablets that dissolve quickly are getting increasingly popular as Novel medication delivery methods. These dosage forms don't require water or chewing because they dissolve or disintegrate in the oral cavity in a matter of seconds. Patients with dysphagia, the elderlyEveryone, including children, can benefit from these, which will increase patient compliance. However, because of its ease of use, adaptability, patient acceptability, and simplicity, oral dosage continues to be the recommended method of administration for many types of medications. Fast-dissolving medication formulations have been created recently to address issues with swallowing. Saliva quickly penetrates the oral cavity when these tablets are inserted inside, causing the pills to dissolve quickly [3].

Requirements of FDTs for an ideal preparation

- Without the need for water, it dissolves or disintegrates in the mouth in a matter of seconds.
- Has a low molecular weight.
- To react rapidly by penetrating the tissue of the oral cavity.
- Ability to break down and permeate into the upper gastrointestinal tract's epithelial membrane (log P>1 or2).
- It has the ability to mask flavor.
- The tablet is just the right amount of hard and loose.
- It has a pleasant mouthfeel.
- When used orally, it leaves no residue behind.
- Temperature and humidity are not major environmental determinants for it.
- Using standard manufacturing and packaging tools to create affordable tablets [4].

Methods of Formulation for Fast-Dissolving Tablets:

Fast dissolving tablets can be developed using a different kinds of techniques and methods, and the resulting FDTs have a range of characteristics, including

- Tablets' mechanical strength
- Mouthfeel and taste
- The ability to swallow
- Salivary drug dissolution
- Bioavailability
- Stability

Freeze-drying, direct compression, molding, the cotton candy process, spray drying, nanonization, mass extrusion, sublimation and compaction are few of the methods used to create ODTs. The simplest and the most cheapest technique of manufacturing tablets is direct compression. Due to the posibility of better excipients, particularly superdisintegrants and sugar-based excipients, this technology can now be used to prepare ODT [5].

SUPERDISINTEGRANTS

Tablet disintegration is a key step in achieving rapid drug release. Availability of the medicine indicates the significance it is for a tablet to dissolve quickly in order to provide unhindered drug dissolving behaviour. Drug formulations that include disintegrants substances or combinations of substances increase the dispersion or breakage breaking down tablets and capsules into tiny particles for quicker dissolving. A class of

substances known as disintegrants causes a disruptive change in the tablet when it comes into contact with water. These materials may swell, hydrate, alter in volume, or undergo a chemical reaction. It should break up the pill into the compacted granules and the powder particles that were used to make the granules [6].In order to increase the available surface area and facilitate a quicker release of the drug substance, superdisintegrants are agents added to tablet and some encapsulated formulations that encourage the tablet and capsule "slugs" to break up into smaller fragments in an aqueous environment. They facilitate the tablet matrix's dispersion and moisture penetration.

Numerous physical characteristics of superdisintegrants influence the rate at which dosage forms disintegrate.

They are as follows:

- The proportion of disintegrants in the mixture
- The proportion of disintegrants utilized
- Compatibility with additional excipients
- Surfactants are present
- The pills' hardness
- Characteristics of Drugs substances
- Types of adding and mixing [7].

More focus has been given in recent years on creating oral disintegrating tablets that are meant to dissolve and/or disintegrate quickly in the mouth, in addition to fast dissolving and/or disintegrating tablets that are swallowed. Compared to disintegrants with higher mechanical strength and disintegration efficiency, the superdisintegrants work better at low concentrations. It is used sparingly in tablets, usually 1–10% by weight in relation to the dosage unit's total weight. 10 - 40 grams of water or aqueous media are absorbed by one gram of superdisintegrants. It causes stress after absorption, which leads to the disintegration of the entire tablet structure [8].

SUPERDISINTEGRANTS' ADVANTAGES

- Disintegration does not result in lump production.
- Compatible with a wide range of medicinal agents and excipients.
- Effective in hydrophilic or hydrophobic compositions.
- Provides the tablet with great mechanical strength, simplifying shipping and packing.
- Even if there are a number of superdisintegrants that show superior disintegration, researchers are continually looking for novel disintegrants and experimenting with modified natural materials [9].
- Rapid disintegration is a result of exceptional wetting ability.
- It doesn't stick to punches and dies.
- At lesser quantities, it is effective.
- Minimal effect on flowability and compatibility.
- It works better when used intragranularly.
- Some may produce slight in vitro binding to cationic medicines since they are
- anionic.
- Biodegradable [10].

SUPERDISINTEGRANTS' DISADVANTAGES

- Costly
- Time-consuming and delicate
- Highly sensitive and hygroscopic [9].

SELECTION CRITERIA FOR SUPERDISINTEGRANTS

Superdisintegrants largely influence the rate of disintegration, but when taken in large quantities,

they can also alter the hardness, mouthfeel, and friability of the tablet. When choosing superdisintegrants for a particular formulation, there are a number of optimal aspects to take into account, including:

- The tablet will quickly dissolve when it comes into contact with saliva in the mouth or oral cavity.
- Be sufficiently compact to make tablets that are less likely to break.
- Small particle sizes are preferred in order to give patients pleasing mouth feelings.
- Flow is significant because it enhances the overall flow properties of the blend [11].

METHODS OF INCORPORATING DISINTEGRANTS INTO TABLET

Internal Addition

Before soaking the powder with the granulating fluid, the disintegrant is mixed with other excipients in the wet granulation process. In this way, the granules incorporate the disintegrant. Prior to crushing the powder between the rollers, the disintegrant is mixed with other excipients in the dry granulation process. The effects of adding croscarmellose sodium, a disintegrant, intragranularly, extragranularly, or uniformly between the two phases of a tablet in which a poorly soluble medication made up at least 92.5% of the formulation were demonstrated in a computer-optimized experiment. When the super disintegrant is added intragranularly, tablets with the same total concentration of crosscarmellose sodium dissolve more quickly, according to the results of an analysis using a general quadratic response surface model. The disintegrant inclusion method has little effect on tablet friability.

External Addition

The superdisintegrant is added to the granules during dry mixing before compression in both the wet and dry granulation methods. The impact of adding superdisintegrants (crospovidone, sodium starch glycolate, and croscarmellose sodium) on dissolution of three model medications with different levels of water solubility (carbamazepine, acetaminophen and cetrizine HCl) from their corresponding tablet formulation was examined. It has been demonstrated that Regardless of the solubility of the primary tablet ingredient, crospovidone is useful in enhancing the medications' dissolving in the greater granular mode of addition, which appears to be the ideal method of inclusion.

Internal and External Addition

The disintegrant is separated into two portions in this manner. Before granule formation, one component is added (intra), and the remaining portion is mixed with granules (extra) before compression. This approach might work better. When using both intragranular and extragranular methods, the medication component is released into solution when the extragranular portion breaks the tablet into granules and the intragranular portion further disintegrates the granules. However, because the intra-granular disintegrant is subjected to wetting and drying (as part of the granulation process), which lowers the disintegrant's activity, it is often less effective than the extra-granular portion in wet granulation procedures. Because the intragranular disintegrant is not exposed to wetting and drying throughout a compaction process, it often maintains good disintegration activity [12].

MECHANISM OF SUPERDISINTEGRANTS

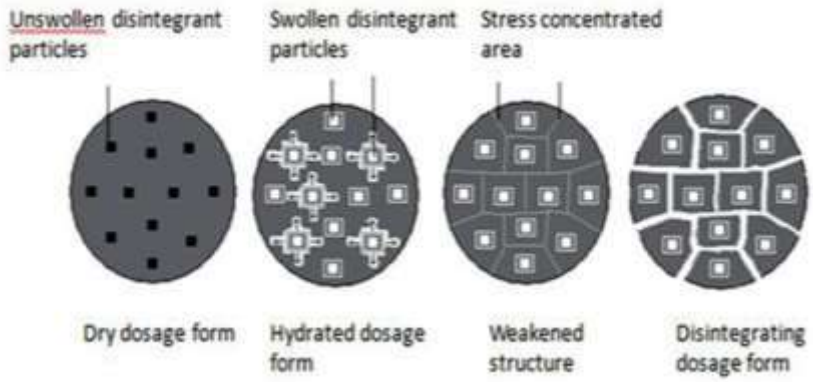

Fig. 1: Disintegration Mechanism of Superdisintegrant Materials

- Swelling.
- Porosity and capillary action (wicking).
- Combination action.
- Heat of wetting.
- Deformation.
- Enzymatic reaction.
- Due to disintegrating particle/particle repulsive forces.
- Electrostatic repulsion [13].

SWELLING

When superdisintegrants come into contact with a suitable medium, their common mode of action is swelling, which causes the tablets to dissolve. Water penetration and subsequent enlargement of the disintegrant particle are the main steps in the mechanism that cause the tablet to break down [14].

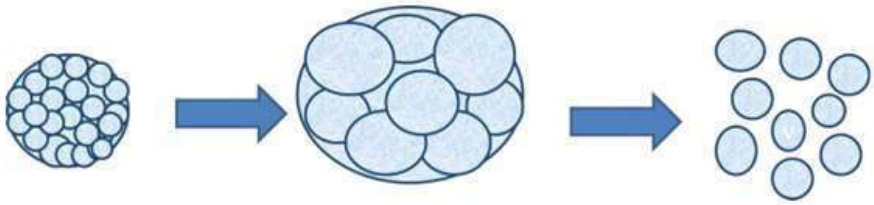

Fig. 2: Disintegration of Tablets by Swelling Mechanism

CAPILLARY ACTION

Disintegration via capillary action is the initial step. The tablet breaks down into fine particles when it is immersed in an appropriate aqueous medium or solution because the air adsorbed on the particles is replaced by the medium as it enters the tablet, weakening the intermolecular bond. Water uptake is influenced by the drug's and excipients' hydrophilicity as well as the parameters of the tableting process. These kinds of disintegrants, which facilitate disintegration by creating a hydrophilic network around the drug particle, must maintain a porous structure and low interfacial tension towards aqueous fluid. disintegrating chemicals that do not swell are utilized to create porosity and capillary action mechanisms. Fluid can enter through the channels made by the tablet's porosity. Particles are broken apart, porosity is increased, and pathways into the tablet are created by low cohesion and compressibility. capillary action causes the liquid to be pushed up or "wicked" into these channels, rupturing the particle bond and shattering the tablet, as shown in figure [15].

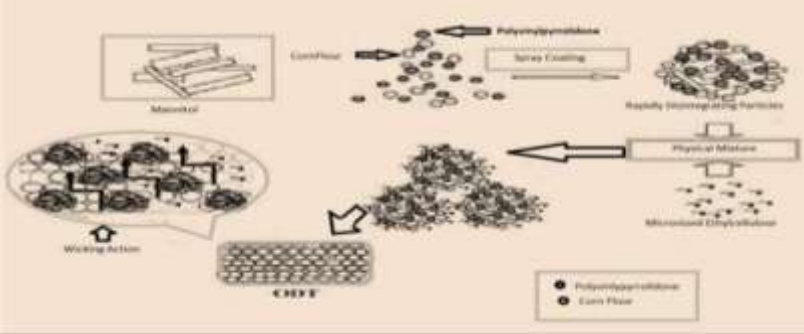

Fig. 3: Disintegration of Tablets by Capillary Action Mechanism

COMBINATION ACTION

The swelling mechanism and type wicking work together to break down the tablets [13].

HEAT OF WETTING

Tablet disintegration is aided by the localized tension caused by capillary air expansion that occurs when exothermic disintegrants get wet. However, this explanation only covers a small number of disintegrant types and is unable to explain how the majority of modern disintegrating agents work [16].

DEFORMATION

It is a process by which previously elastic starches, like corn or potato starch, turn plastic when subjected to high compaction pressure during tableting. These pills disintegrate when they come into contact with water because it activates the starch granules' potential energy [17].

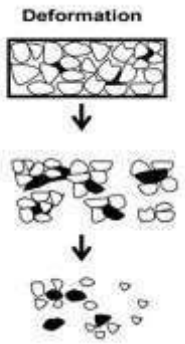

Fig. 3: Disintegration of Tablets by Deformation Mechanism

Enzymatic reaction: In this case, the body's natural enzymes serve as disintegrants. These enzymes aid in disintegration by destroying the binder's binding activity [18].

DUE TO DISINTEGRATING PARTICLE / PARTICLE REPULSIVE FORCE

Another aspect of the disintegration process aims to explain why tablets containing non-swallowable disintegrants swell. Guyot-Hermann's particle repulsion theory was founded on the discovery that non-swelling particles also contribute to tablet disintegration.

Water is necessary for disintegration, which is caused by electric repulsive interactions between particles. Researchers discovered that wicking takes priority over repulsion. The majority of disintegrants are thought to function through many mechanisms [19].

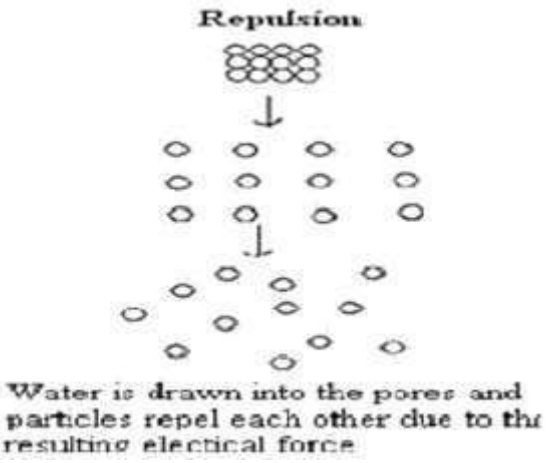

Fig. 4: Disintegration of Tablets By Repulsion Mechanism

ELECTROSTATIC REPULSION

Another factor contributing to tablet disintegration is non-swelling particles. Because disintegration processes depend on electrostatic repulsive interactions between particles, water is required. Wicking is more important than repelling, according to research findings [13].

TYPES OF SUPER DISINTEGRANTS

1. Synthetic
2. Natural
3. Co processed

Synthetic Superdisintegrants:

These disintegrants are the most widely used in oral disintegrating tablets because they enhance the rate and degree of tablet disintegration, which in turn promotes tablet dissolving.

Advantages:

1. Effective at low dosages
2. Improved intragranular
3. Less impact on flowability and compressibility

Limitations:

1. Moisture sensitivity

Crospovidone:

It is also known as polyvinyl pyrrolidone, polyplasdone, and cross-linked povidone. These are artificial N-vinyl-2-pyrrolidone homopolymers that are cross-linked and insoluble. Acids, chloroform, 95% ethanol, ketones, methanol, and water all readily dissolve it.Crospovidone provides quick disintegration through a number of methods. Swelling is not the only mechanism for tablet disintegration, even though crosspovidone polymers swell by 95% to 120% when they come into contact with water. Through capillary action, their porous particle shape quickly absorbs water (wicking). Additionally, tablets are quite compressible after compaction. Crospovidone is utilized as a super disintegrant in direct compression, wet granulation, and dry granulation processes at low concentrations (2–5%). Because its micrograded particles disseminate it equally, the formulation containing this super disintegrant had a concentration of 1% to 3%. Through volume expansion and hydrostatic stresses, it rapidly disintegrates and wicks saliva. It is typically thought of as a non-irritating and non-toxic excipient [20].

Croscarmellose sodium:

Two common superdintegrants used in FDTs are crospovidone and croscarmellose sodium. They break down quite effectively. The tablets are broken down and croscarmellose sodium swells substantially when it comes into contact with water. Furthermore, even at low levels of extra- and intra-particulate matter, its polymeric fabric structure encourages water wicking. Croscarmellose sodium is thought to rapidly expand and wick when exposed to water, facilitating disintegration. Wicking is a "whipping" motion that instantly replaces material-air and material-material contact with the material-water interface, assisting in maintaining capillary flow. When CCS is used at high concentrations, longer disintegration times have been observed. The most likely cause of such is Partial gelling, which could function as a viscous wall and prevent water from entering the tablet.

Sodium Starch Glycolate

Pharmaceutical solid dose forms use SSG, a cross-linked synthetic potato starch, as a disintegrant. Chemically, SSG is known as a carboxymethyl

ether derivative of starch, where sodium serves as the salt. Two chemical changes were done to starch in order to produce SSG: cross-linking and substitution, which reduced gel formation and improved solubility in water. The product is marketed by a few manufacturers under the names Primogel, Explotab, and Vivastar. Potato starch and sodium chloroacetate are reacted to provide the components for sodium starch glycolate and Explotab. It's unclear, though, if the potato starch cross-links prior to or during replacement. Because Vivastar P employs the starch alcohol group after replacement and the Na carboxylate moieties, the material is cross-linked. Primogel is the sodium salt version of carboxymethyl ether. Corn, wheat, rice, or potatoes are the sources of starch glycolates. White to off-white, tasteless, odorless, and just slightly free-flowing, sodium starch is a powder. Primogel is used as an excipient to help dissolve tablets or capsules. Primogel's rapid absorption of water results in swelling, which accelerates the breakdown of tablets and granules. It has three functions: suspending, dissolving, and gelling. Without a disintegrant, tablets might not dissolve completely, which could have an impact on the amount of active ingredient that is absorbed. Numerous manufacturers sell the material under various brand names, such as Vivastar, Primogel, and Explotab [21].

NATURAL SUPERDISINTEGRANTS:

A number of compounds are derived from natural sources. Natural polymers are becoming more and more popular these days due to their advantages over synthetic ones. The primary benefits of natural agents are their availability, non-irritating nature, nontoxicity, affordability, ease of chemical modification, etc. Because of the drug's specific distribution in the GIT, or stomach, these agents are typically employed in floating systems. Our natural resources provide a variety of superdisintegrants [22].

Advantages

- Biodegradable disintegrants in nature: are the biodegradable in nature, because it is obtained from natural resources.
- Lower cost: Compared to synthetic materials, the production costs are lower.
- Greater availability: Pharmaceutical excipients like gum and mucilages will be produced in greater quantities in regions with a diverse plant population.
- Biocompatible: These materials are composed of repeated sugar polysaccharides.
- Good acceptance by public: the chances of getting adverse effects are less [23].

Commonly used natural superdisintegrants

Agar:

It has a mucilage-like taste and can be yellowish, grey, or colorless. It comes in the form of dried gelatinous material that is extracted from many species, including Pterocladia (red algae), Gelidium amassii, and Gracilaria. Polysaccharides like agarose and agaropectin make up agar. The former is what gives gel its strength, and a high gel strength allows it to be used as a disintegrant in the creation of tablets that dissolve when taken orally [24].

Pectin from mango peel:

Pectin, which is a hydrophilic colloid made up of a group of heteropolysaccharides. Even though the pectin cannot be used to anticipate superdisintegrant behaviour, but its high swelling index and biological fluid solubility, makes it to be used to produce orodispersible tablets [25].

Chitin and chitosan

Both chitin and chitosan are present in crab and shrimp shells. It contains an amino group that is covalently bound to the acetyl group, unlike chitosan. Chitin, a structural element of crustacean exoskeletons (crabs and shrimp), and fungus cell wallsis deacetylated to create chitosan. Chitosan appears to be better. It works well as a super disintegrant in tablets and is comparable to maize starch as a disintegrating agent [26][27].

Soy polysaccharide:

Another naturally occurring superdisintegrant is soy polysaccharide. The source of it is soy beans. It is made up of high molecular weight polymers of carbohydrates, including mannose, arabinose, galactose, and xylose. It functions as a superdisintegrant when tablets are compressed directly [28].

Guar gum:

Guar gum is derived from Cyamopsis tetragonolobus endosperms, which are members of the Leguminosae family. It is composed of mannan and galactan units joined by glycoside bonds. It can be employed as a disintegrant, binder, stabilizing, thickening, and suspending agent, among other things, in the pharmaceutical industry [29].

Mangifera indica gum:

Mango gum, also known as Mangifera indica, is a member of the Anacardiaceae family. The powder has an appearance of being white to off-white. It can be employed as an emulsifying, suspending, binding, and disintegrating agent [30].

Gum karaya:

It is the exudate that is extracted from trees that are part of the genus Sterculia. It is composed of the following polysaccharides: galacturonic acid, rhamnose, and galactose. Gum karaya's low cost, biocompatibility, and other qualities make it a viable substitute for other superdisintegrants [31].

Locust bean gum (carob gum):

It is a gum that is made from Ceratonia siliqua seeds. It can be applied as a bio-adhesive, thickening, and gelling agent. It resembles an odorless, yellowish-white powder [32].

Mucilage of fenugreek seeds:

The plant Trigonella foenum-graceum is a member of the Leguminosae family. The seeds' mucilage will create a sticky mass when they are exposed to water. Compared to the commonly used superdisintegrant Ac-di-sol, it demonstrated better dissolving properties[33].

Plantago ovata mucilage:

It is a member of the Plantaginaceae family. This is frequently used to create fast-dissolving tablets as a superdisintegrant. Mucilage makes up the largest percentage of seeds and the husk. Hydrocolloids make roughly 10–30% of the husk. The dissolving qualities are caused by the polysaccharide’s xylose, galacturonic acid, galactose, rhamnose, and arabinose [34].

Mucilage of Hibiscus rosa Sinensis:

It is a member of the Malvaceae family and goes by several names, including Chinese hibiscus, shoe flower plant, and China rose. Mucilage is employed with thickeners, disintegrants, suspending agents, and water-retention agents. Mucilage, which contains L-rhamnose, D-galactose, D-galacturonic acid, and other substances, is found in its leaves [35].

Dehydrated banana powder:

This powder is made from an assortment of bananas called ethan and nenthran. It is a member of the Musaceae family. It is a wonderful source of energy because of its high carbohydrate content [36].

CO PROCESSED SUPER DISINTEGRANTS

This is predicated on the innovative idea that two to three excipients interact at the particle level with the dual goals of enhancing functionality growth and concealing an individual's undesirable characteristics. Excipient granules with better qualities are created when excipients are co-processed. In contrast to physical combinations of elements, such as enhanced compressibility and flow characteristics. Improved dilution reduced lubricant sensitivity and maybe complete homogeneity.

There are numerous co-processed superdisintegrates available.

- Ludipress
- Starlac
- Starcap 1500
- Ran explo-c
- Ran explo-s
- Pan excea
- Ludiflash [37].

Table: List of marketed fast dissolving tablets [38].

Brand name	Active ingredient	Application
Citalopram® ODT	Citalopram	Antidepressant
Claritin®, RediTabs®	Loratadine	Antihistamine
DuraSolv®, Alavert®	Loratadine	Allergy
Excedrin® QuickTabs	Acetaminophen	Pain reliever
Feldene® Melt	Piroxicam	Rheumatoid arthritis
Gaster D®	Famotidine	Antiulcer
Imodium Instant Melts®	Loperamide HCL	Antidiarrhoeal
Kemstro™	Baclofen	Antispastic, analgesic
Klonopin®	Clonazepam	Anticonvulsant
Maxalt® -MLT	Rizatriptan benzoate	Migraine
Metozolv ODT®	Metoclopramide	Antiemetic, Gastroprokinetic agent
Nasea OD®	RamosetronHCl	Antiemetic
Nimulid MD®	Nimesulide	Pain reliever
NuLev®	Hyoscyaminesulfate	Antiulcer
Pepeid® ODT	Famotidine	Antiulcer
Propulsid® Quicksolv®	Cisapride Monohydrate	Gastrointestinal prokinetic agent
Relivia®	Tramadol Hydochloride	Pain reliever
Remeron® Soltab®	Mirtazapine	Antidepression
Resperdal®, M-TabTM®	Resperidone	Schizophrenia
Tempra®Quiclets	Acetaminophen	Analgesic
Vimovo®	Naproxen	NSAID
Vometa® FT	Domperidone	Antiemetic, Prokinetic agent
ZelaparTM	Selegiline	Parkinson's disease
Zofran® ODT	Ondansetron	Antiemetic
Zomig® ZMT	Zolmitriptan	Migraine
Zyprexia®	Olanzapine	Antipsychotic

CONCLUSION:

The fast dissolving drug delivery system has emerged as a key component of current research due to the growing demand for innovative drug delivery. Researchers are experimenting with modified natural products such as formalin casein, chitin, chitosan, polymerized agar acrylamide, xylan, smecta, key-jo-clay, crosslinked carboxymethyl guar, mango peel pectin, cassia tora, cassia nodosa, and modified tapioca starch, among others, in an effort to find newer disintegrating agents despite the abundance of superdisintegrants. Because they don't have a propensity to swell, studies have indicated that water insoluble superdisintegrants have superior disintegration properties compared to somewhat water soluble agents. Because of the creation of a viscous barrier, superdisintegrants that have a tendency to swell exhibit a minor slowing of the disintegration property. Thus, there will be ongoing interest in the creation of oral disintegrating tablets based on natural polymers in the upcoming age. Future developments in drug delivery system innovation will keep combining several technical fields and formulation elements to produce new technologies.

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