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Review

Review of Fast-dissolving Tablets: A noble approach

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Abstract:
Fast disintegrating tablets (FDTs) have received ever-increasing demand during the last decade, and the field has become a rapidly growing area in the pharmaceutical industry. Oral drug delivery remains the preferred route for administration of various drugs. The popularity and usefulness of the formulation resulted in development of several FDT technologies. FDTs are solid unit dosage forms, which disintegrate or dissolve rapidly in the mouth without chewing and water. FDTs or orally disintegrating tablets provide an advantage particularly for pediatric and geriatric populations who have difficulty in swallowing conventional tablets and capsules. This review describes various formulations and technologies developed to achieve fast dissolution/dispersion of tablets in the oral cavity. In particular, this review describes in detail FDT technologies based on lyophilization, molding, sublimation, and compaction, as well as approaches to enhancing the FDT properties, such as spray drying and use of disintegrants.
Keywords: Fast dissolving tablets, freeze drying, Swallowing.

Oral drug delivery

Oral delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, most convenient and an economical method of drug delivery having the highest patient compliance.[1] During the past four decades, the pharmaceutical industry has invested vast amounts of time and money in the study of tablet compaction. The expenditure is quite reasonable when one considers how valuable tablets, as a dosage form, are to the industry. Because oral dosage forms can be self-administered by the patient, they are obviously more profitable to manufacture than parentral dosage forms that must be administered, in most cases, by trained personnel.[2]

Advantages of tablets

- The oral route represents a convenient and safe way of drug administration.
- The preparation procedure enables accurate dosing of the drug.
- Tablets are convenient to handle and can be prepared in a versatile way with respect to their use and to the delivery of the drug.
- Tablets can be mass produced, with robust and rugged quality-controlled production procedures giving an elegant preparation of consistent quality.
- Tablets are the manufacturer's dosage form of choice because of their relatively low cost of manufacture, package and shipment, increased stability, and virtual tamper resistance.[3]

Disadvantage of tablets

The disadvantages of tablets are dysphasia or difficulty in swallowing is seen to affect nearly 35% of the population. This disorder is also associated with number of medical conditions including stroke, Parkinson's disease, head and neck radiation therapy and other neurological disorders including cerebral palsy. Many elder persons will have difficulty in taking conventional dosage forms because of hand tremors and dysphasia. Others who may experience problems

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in swallowing are the mentally ill, developmentally disabled uncooperative patients, reduced liquid intake plan, and nausea. In some cases such as motion sickness, sudden episode of allergic attack or coughing and unavailability of water for swallowing tablets may become difficult.[4] However, geriatric and pediatric patients experience difficulty in swallowing conventional tablets which leads to poor patient compliance. To overcome this weakness, scientists have developed innovative drug delivery systems known as fast dissolving tablets.[5]

Fast dissolving drug delivery system

United States Food and drug administration (FDA) defined fast dissolving tablet (FDT) as "a solid dosage form containing medicinal substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed up on the tongue". Fast dissolving tablets are also known as mouth dissolving tablets, melt-in-mouth tablets, orodispersible tablets, rapid melts, porous tablets and quick dissolving tablets. Fast dissolving tablets dissolve or disintegrate in the oral cavity without the need of water.[6] Their characteristic advantages such as administration without water, anywhere, anytime lead to their suitability to geriatric and pediatric patients. They are also suitable for the mentally ill, the bedridden, and patients who do not have easy access to water. The benefits, in terms of patient compliance, rapid onset of action, increased bioavailability and good stability make these tablets popular as a dosage form of choice in the current market.[7]

Criteria for fast dissolving drug delivery system

The tablets should-

1. Not require water to swallow but it should dissolve or disintegrate in the mouth in few seconds.
2. Be compatible with taste masking.
3. Be portable without fragility concern.
4. Have a pleasant mouth feel.
5. Leave minimum or no residue in the mouth after oral administration.
6. Exhibit low sensitive to environmental condition as temperature and humidity.[8]

Characteristics of fast dissolving delivery systems

1. Ease of administration
2. Hygroscopicity
3. Taste of the medicament
4. Friability
5. Mouth feel

1. Ease of administration:

Fast Dissolving Delivery Systems are easy to administer and handle, hence leads to better patient compliance. Usually, elderly people experience difficulty in swallowing the conventional dosage forms (tablets, capsules, solutions and suspensions) because of tremors of extremities and dysphasia. Fast dissolving delivery systems may offer a solution for these problems.

2. Hygroscopicity:

Several fast dissolving dosage forms are hygroscopic and cannot maintain physical integrity under normal condition from humidity which calls for specialized product packaging.

3. Taste of the medicament:

Mouth dissolving delivery systems usually contain the medicament in taste masked form. Taste-masking is of critical importance in the formulation of an acceptable FDTs. Traditional tablet formulations generally do not address the issue of taste masking, because it is assumed that the dosage form will not dissolve until itpasses the oral cavity. Many oral suspensions, syrups and chewable tablets simply contain flavours, sugars and other sweeteners to complement the bitter taste of the drug. Current methods of taste masking in fast dissolving/disintegrating tablets include sweeteners and flavours however; these are not a sufficient means for taste- masking many bitter drugs.

4. **Friability:**

In order to allow fast dissolving tablets to dissolve in the mouth, they are made of either soft moulded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle which are difficult to handle, often requiring specialized peel-off blister packaging.

5. **Mouth feel:**

Mouth feel is critical and patients should receive a product that feels pleasant. Any large particles from the disintegrating tablet that are insoluble or slowly soluble in saliva would lead to an unpleasant gritty feeling. This can be overcome by keeping the majority of the particles below the detectable size limit. In some cases, certain flavours can imbibe an improved mouth feel perception, resulting in a product that is perceived as being less gritty, even if the only change is the flavour. Effervescence can be

added to aid disintegration and improve mouth feel by reducing the "dryness" of a product.[9]

Salient features of fast dissolving drug delivery system:

1. Ease of Administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and patient who refuse to swallow such as pediatric, geriatric & psychiatric patients.
2. No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have immediate access to water.
3. Rapid dissolution and absorption of the drug, which will produce quick onset of action.
4. Some drugs are absorbed from the mouth, pharynx and oesophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is increased.
5. Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
6. Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
7. The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
8. New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
9. Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra-rapid onset of action required.
10. An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
11. Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.[8]

Mechanism: Bioavailability of a drug depends on absorption of the drug, which is affected by solubility of the drug in gastrointestinal fluid and permeability of the drug across gastrointestinal membrane. The solubility of a drug mainly depends on physiochemical properties of the drug. The rate of drug dissolution is greatly influenced by disintegration of the tablet. Disintegrants are important excipient of the tablet formulation they are always added to tablet to induce breakup of tablet when they are in contact with aqueous fluid and this process of deaggregation of constituent particles before the drug dissolution occurs, is known as disintegration process and excipients which induce this process are known as disintegrants. The objectives behind addition of disintegrants are to increase surface area of the tablet fragments and to overcome cohesive forces that keep particles together.[10]

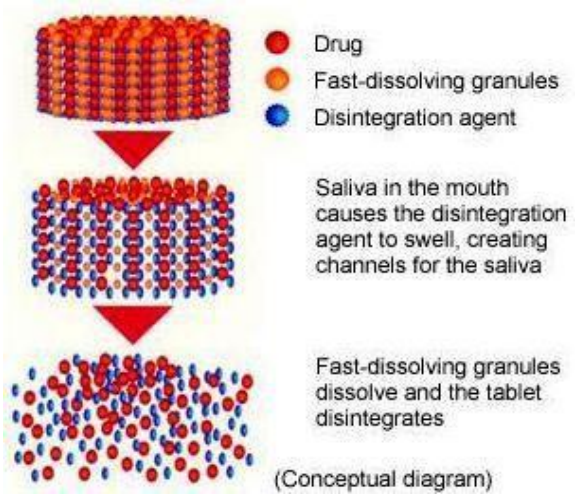

Fig.2: Mechanism of fast dissolving tablets

Advantages of fast dissolving tablets

1. Quick onset of action and improved bioavailability.
2. Useful for patients who cannot swallow the dosage forms and for pediatric, geriatric and mentally retard patients.
3. Improved patient compliance.
4. Frequently administered when water is not available.
5. Accurate dose can be given as compared to oral liquids.
6. Pleasant mouth feel of the tablet helps to change the perception of medication as bitter pill particularly in pediatric patients.
7. Stability of drug is improved as compared to oral dosage forms like suspensions.
8. Disintegrates rapidly which may result in rapid release of drugs.

9. High production capacity as compared to suspensions.[11]

Limitations

1. The tablets usually have insufficient mechanical strength. Hence, careful handling is required
2. The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.[12]
3. Drugs with relatively larger doses are difficult to formulate into MDT e.g. antibiotics like ciprofloxacin with adult dose tablet containing about 500 mg of the drug.
4. Patients who concurrently take anticholinergics medications may not be the best candidates for MDT.[13]
5. MDT requires special packaging for proper storage and safety of product.[14]

Selection of FDT drug candidates:

Several factors must be considered while selecting drug candidates for delivery as FDT dosage forms.

1. The drugs which have significantly different pharmacokinetic profiles compared with the same dose administered in a conventional dosage form. E.g., Selegiline, Apomorphine, Buspirone etc.
2. The drugs that produce a significant amount of toxic metabolites mediated by first pass liver metabolism and gastric metabolism and for drugs that have a substantial fraction of absorption in the oral cavity and segments of the pre-gastric GIT.
3. Drugs having ability to diffuse and partition into the epithelium of the upper GIT
4. Patients with Sjögren's syndrome or dryness of the mouth due to decreased saliva production may not be good candidates for FDT formulations.
5. Drugs with a short half-life and frequent dosing.
6. Drugs which are very bitter or otherwise unacceptable taste because taste masking cannot be achieved.
7. Drugs which require controlled or sustained release are unsuitable candidates of fast dissolving oral dosage forms.
8. Pharmaceutical Companies have formulated FDT for various categories of drugs such as neuroleptics, cardiovascular agents, analgesics, antiallergic, antiepileptic, anxiolytics, sedatives, hypnotics, diuretics, anti-asthmatic agents, anti-parkinsonism agents, anti-bacterial agents and drugs used for erectile dysfunction.[15]

Conventional techniques for preparing fast dissolving tablets

Many techniques have been reported for the formulation of fast dissolving tablets.

1. Freeze drying / Lyophilization
2. Tablet Molding
3. Spray drying
4. Sublimation
5. Mass extrusion
6. Direct compression
    1. Superdisintegrants. ii. Sugar based excipients

1. Freeze drying / Lyophilization

Freeze drying is the process in which water is sublimed from the product after it is frozen. This technique creates an amorphous porous structure that can dissolve rapidly. A typical procedure involved in the manufacturing of ODT using this technique is mentioned here. The active drug is dissolved or dispersed in an aqueous solution of a carrier/polymer. The mixture is done by weight and poured in the walls of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion. Then the frozen blister packs are placed in refrigerated cabinets to continue the freeze-drying. After freeze-drying the aluminum foil backing is applied on a blister-sealing machine. Finally the blisters are packaged and shipped. The freeze-drying technique has demonstrated improved absorption and increase in bioavailability. The major disadvantages of lyophillization technique are that it is expensive and time consuming; fragility makes conventional packaging unsuitable for these products and poor stability under stressed conditions.

2. Tablet Molding:

Molding process is of two types i.e. solvent method and heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). The solvent is then removed by air-drying. The tablets manufactured in this manner are less compact than compressed tablets and posses a porous structure that hastens dissolution. The heat molding process involves preparation of a suspension that contains a

drug, agar and sugar (e.g. Mannitol or lactose), and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 30 °C under vacuum. The mechanical strength of molded tablets is a matter of great concern. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Taste masking is an added problem to this technology.

The taste masked drug particles were prepared by spray congealing a molten mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol and an active ingredient into a lactose based tablet triturate form. Compared to the lyophillization technique, tablets produced by the molding technique are easier to scale up for industrial manufacture.

3. Spray Drying:

In this technique, gelatin can be used as a supporting agent and as a matrix, mannitol as a bulking agent and sodium starch glycolate or crosscarmellose sodium or crospovidone are used as superdisintegrants. Tablets manufactured from the spray- dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium. The formulation contained bulking agent like mannitol and lactose, a superdisintegrants like sodium starch glycolate & crosscarmellose sodium and acidic ingredient (citric acid) and/or alkaline ingredients (E.g. sodium bicarbonate). This spray-dried powder, which compressed into tablets showed rapid disintegration and enhanced dissolution.

4. Sublimation:

To generate a porous matrix, volatile ingredients are incorporated in the formulation that is later subjected to a process of sublimation. Highly volatile ingredients like ammoniumbicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane and phthalic anhydride may be compressed along with other excipients into a tablet. This volatile material is then removed by sublimation leaving behind a highly porous matrix. Tablets manufactured by this technique have reported to usually disintegrate in 10-20 sec. Even solvents like cyclohexane; benzene can be used as pore forming agents.

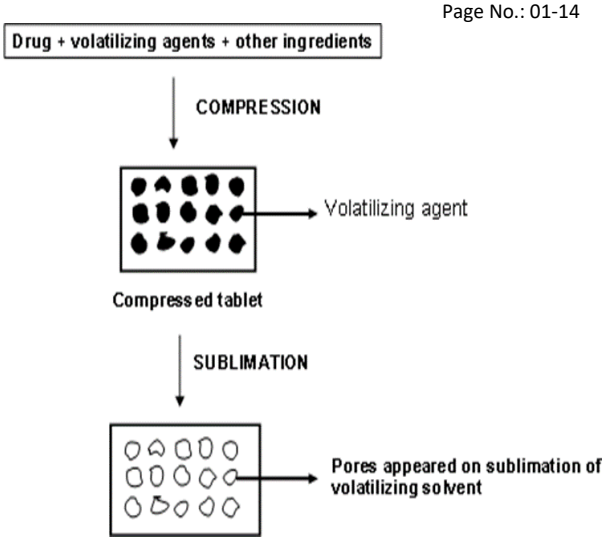

Fig.3: Schematic representation of sublimation technique

5. Mass-Extrusion:

This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol and methanol and subsequent expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablet. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking.

6. Direct Compression:

It is the simplest and most cost effective tablet manufacturing technique. This technique can now be applied to preparation of ODT because of the availability of improved excipients especially superdisintegrants and sugar based excipients.

a. Super disintegrants:

In many orally disintegrating tablet technologies based on direct compression, the addition of super disintegrants principally affects the rate of disintegration and hence the dissolution. The presence of other formulation ingredients such as water- soluble excipients and effervescent agents further hastens the process of disintegration.

b. Sugar Based Excipients:

This is another approach to manufacture ODT by direct compression. The use of sugar-based excipients especially bulking agents like dextrose, fructose, isomalt, lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol, which display high aqueous solubility and sweetness, and hence impart taste masking property and a pleasing

mouth feel. Mizumito et al have classified sugar-based excipients into two types on the basis of molding and dissolution rate.

Type 1 Saccharides (lactose and mannitol) exhibit low mouldability but high dissolution rate.

Type 2 Saccharides (maltose and maltilol) exhibit high mouldability and low dissolution rate.[16]

Patented technologies for FDTs Zydus Technology

Zydus, the best known of the fast-dissolving/disintegrating tablet preparations was the first marketed new technology tablet. The tablet dissolves in the mouth within seconds after placement on the tongue. A Zydus tablet is produced by lyophilizing or freeze-drying the drug in a matrix usually consisting of gelatin. The product is very lightweight and fragile and must be dispensed in a special blister pack. Patients should be advised not to push the tablets through the foil film, but instead peel the film back to release the tablet. The Zydus product is made to dissolve on the tongue in 2 to 3 seconds. The Zydus formulation is also self-preserving because the final water concentration in the freeze-dried product is too low to allow for microbial growth.

Durasolv Technology

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of a drug, fillers and a lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be packed into conventional packaging system like blisters. Durasolv is an appropriate technology for products requiring low amounts of active ingredients.

Orasolv Technology

Orasolv Technology has been developed by CIMA labs. In this system active medicament is taste masked. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce the tablets. The tablets produced are soft and friable and packaged in specially designed pick and place system.

FlashDose Technology

Flash dose technology has been patented by Fuisz. Nurofen meltlet, a new form of ibuprofen as melt-in-mouth tablets, prepared using flash dose technology is the first commercial product launched by Biovail Corporation. Flash dose tablets consist of self-binding shear form matrix termed as “floss”. Shear form matrices are prepared by flash heat processing.

Wowtab Technology

Wowtab technology is patented by Yamanouchi pharmaceutical co. WOW means “Without Water”. In this process, combination of low mouldability saccharides and high mouldability saccharides were used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide and granulated with a high mouldability saccharide and compressed into tablet.

Flashtab Technology

Prographarm laboratories have patented the Flashtab technology. Tablets prepared by this system consist of an active ingredient in the form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like coacervation, micro encapsulation, and extrusion spheronisation. All the processing utilized conventional tableting technology.[17]

OraQuick Technology

The OraQuick fast-dissolving/disintegrating tablet formulation utilizes a patented taste masking technology. KV pharmaceutical claims its microsphere technology, known as Micro mask, has superior mouth feel over taste masking alternatives. The taste masking process does not utilize solvents of any kind, and therefore leads to faster and more efficient production. Also, lower heat of production than alternative fast dissolving/disintegrating technologies makes OraQuick appropriate for heat-sensitive drugs. KV pharmaceutical also claims that the matrix that surrounds and protects the drug powder in microencapsulated particles is more pliable, meaning tablets can be compressed to achieve significant mechanical strength without disrupting taste masking.

Quick -Dis Technology

Lavipharm laboratories Inc. (Lavipharm) have invented an ideal intraoral fast- dissolving drug delivery system, which satisfies the unmet needs of the market. The novel intraoral drug delivery system, trademarked Quick-Dis™, is Lavipharm’s proprietary patented technology and is a thin, flexible, and quick-dissolving film. The film is placed on the top or the floor of the tongue. It is retained at the site of

application and rapidly releases the active agent for local and/or systemic absorption. The Quick-Dis™ drug delivery system can be provided in various packaging configurations, ranging from unit-dose pouches to multiple-dose blister packages.

Ziplets/Advatab

This technology is patented by Passano con barnago, Italy. It utilizes water- insoluble ingredient combined with one or more effective disintegrants to produce ODT with improved mechanical strength and optimal disintegration time at low compression force. This technology handles high drug loading and coated drug particles and does not require special packaging, so they can be packed in push through blisters or bottles.

Lyoc

Lyoc technology is patented by Pharmalyco. Oil in water emulsion is prepared and placed directly into blister cavities followed by freeze-drying. Nonhomogeneity during freeze-drying is avoided by incorporating inert filler to increase the viscosity finally the sedimentation. High proportion of filler reduces porosity of tablets due to which disintegration is lowered.

Pharmaburst technology

SPI Pharma, New Castle, patents this technology. It utilizes the co-processed excipients to develop ODT, which dissolves within 30-40 s. This technology involves dry blending of drug, flavor, and lubricant followed by compression into tablets. Tablets obtained have sufficient strength so they can be packed in blister and bottles.

Frosta Technology

Akina patents this technology. It utilizes the concept of formulating plastic granules and compressing them at low pressure to produce strong tablets with high porosity. Plastic granules composed of porous and plastic material, water penetration enhancer, and binder. The tablets obtained have excellent hardness and rapid disintegration time ranging from 15 to 30 sec depending on size of tablet.

Nano crystal Technology

This is patented by Elan, King of Prussia. Nanocrystal technology includes lyophilization of colloidal dispersions of drug substance and water-soluble ingredients filled in to blister pockets. This method avoids manufacturing process such as granulation, blending, and tableting, which is more advantageous for highly potent and hazardous.[18]

Direct compression, over and above eliminates exposure of heat and moisture during processing and is a more economical process. However, the majority of active pharmaceutical ingredients exhibit poor compressibility. Therefore, the addition of directly compressible adjuvant is mandatory. Ideal directly compressible adjuvant must exhibit good flow ability and compatibility. No single adjuvant is likely to possess all the ideal characteristics. For this reason, the current trend in industry is to use multifunctional co processed excipients. Nowadays co-processing is the one of the most widely explored and commercially utilized method for the preparation of directly compressible adjuvants. It can be defined as combining two or more established excipients by an appropriate process. Co-processing is based on the novel concept of two or more excipients interacting at the sub particle level, the objective of which is to provide a synergy of functionality improvement as well as masking the undesirable properties of individual.[19]

Major challenge for tablets manufacturing comes from the flow properties of the materials to be compressed. Most of the formulations (>70%) contain excipients at higher concentration than active drug. In recent years drug formulation scientists have recognized that single-component excipients do not always provide the requisite performance to allow certain active pharmaceutical ingredients to be formulated or manufactured adequately. Hence, there is a need to have excipients with multiple characteristics built into them such as better flow, low/no moisture sensitivity, superior compressibility and rapid disintegration ability. Excipients with improved functionality can be obtained by developing new chemical excipients, new grade of existing materials and new combination of existing materials. New combinations of existing excipients are an interesting option for improving excipients functionality because all formulations contain multiple excipients. One such approach for improving the functionality of excipients is co processing of two or more excipients.[20]

Excipients used in fast dissolving drug delivery systems

Super disintegrants: Crosspovidone, Microcrystalline cellulose, sodium starch glycolate, sodium carboxy methyl cellulose, pregelatinized starch, calcium carboxy methyl cellulose, and modified corn starch. Sodium starch glycolate has

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good flowability than crosscarmellose sodium. Crospovidone is fibrous nature and highly compactable.

Flavours: Peppermint flavour, cooling flavour, flavour oils and flavouring aromatic oil, peppermint oil, clove oil, bay oil, anise oil, eucalyptus oil thyme oil, oil of bitter almonds. Flavouring agents include, vanilla, citrus oils, fruit essences.

Sweeteners: Aspartame, Sugar's derivatives

Fillers: Directly compressible spray dried Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate, calcium sulphate, pregelatinized starch, magnesium trisilicate, aluminum hydroxide.

Surface active agents: sodiumdoecylsulfate, sodiumlauryl sulphate, polyoxymethylene sorbitan fatty acid esters (Tweens), sorbitan fatty acid esters (Spans), polyoxymethylene stearates.

Colour: Sunset yellow, Amaranth etc.

Lubricants: Stearic acid, Magnesium stearate, Zinc state, calcium state, talc, polyethylene glycol, liquid paraffin, colloidal silicon dioxide.[10]

Co-processing is defined as combining 2 or more established excipients by an appropriate process. Co-processing of excipient could lead to formation of excipients with superior properties compared with the simple physical mixture of their components or with individual components. A large number of co processed diluents are commercially available. The representative examples are Ludipress, Cellactose, and Starlac.

The use of co-processing is a totally unexplored avenue in disintegrants. The widely used superdisintegrants are sodium starch glycolate, Crospovidone, and crosscarmellose sodium. Like diluents, each superdisintegrants has strengths and weaknesses. In the present investigation, the preparation and evaluation of coprocessed disintegrant containing crospovidone and sodium starch glycolate was explored.

The reasons for the selection of crospovidone are as follows: better compressibility compared with other superdisintegrants, high capillary activity, pronounced hydration capacity, and little tendency to form gels. Moreover, the rate and extent of liquid uptake and swelling of crospovidone (Polyplasdone XL 10) are not reduced in 0.1N hydrochloric acid when compared with aqueous medium. The aqueous medium (water) represents disintegration medium and 0.1 N HCl represents gastric environment. Sodium starch glycolate was chosen because of its high swelling capacity. Moreover, the disintegrant efficiency of sodium starch glycolate is unimpaired by the presence of hydrophobic excipients such as lubricants. Sodium starch glycolate exhibits good flow (angle of repose G36º). The bulk density of crospovidone and sodium starch glycolate is 0.4 and 0.756 g/cm^3, respectively. Hence, if a physical mixture of superdisintegrants is used in high-speed tableting, the problem of segregation of the disintegrants may be encountered. One of the reasons for preparing the co processed superdisintegrants was to avoid the problem of segregation. A blend of swelling and wicking types of excipient may also prove to be efficient because the medium (usually water) required for swelling will be brought into the tablet more easily if a wicking (hydrophilic) type of superdisintegrants is also present.[21]

Mechanism of superdisintegrants

There are major mechanisms for tablets disintegration as follows

1. Swelling
2. Porosity and capillary action (Wicking)
3. Due to disintegrating particle/particle repulsive forces
4. Due to deformation
5. Heat of wetting
6. Chemical reaction (Acid-Base reaction)
7. By enzymatic reaction

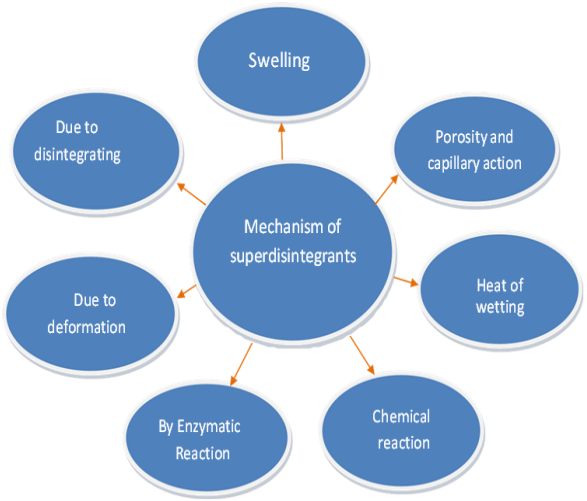

Fig.5: Schematic representation of these is mechanisms of super disintegrants

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1. Swelling:

Perhaps the most widely accepted general mechanism of action for tablet disintegration is swelling. Tablets with high porosity show poor disintegration due to lack of adequate swelling force. On the other hand, sufficient swelling force is exerted in the tablet with low porosity. It is worthwhile to note that if the packing fraction is very high, fluid is unable to penetrate in the tablet and disintegration is again slows down.

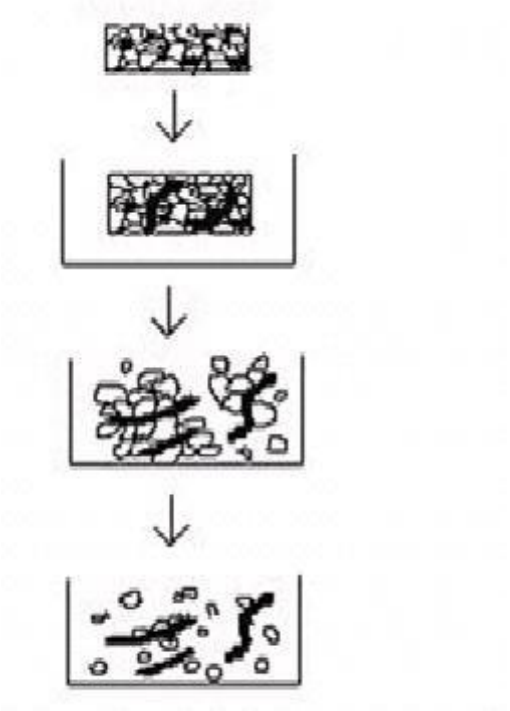

Fig.6: Schematic representation of swelling mechanism, in which water is pulled by disintegrant and reduced the physical bonding force between particles.

2. Porosity and capillary action (Wicking):

Disintegration by capillary action is always the first step. When we put the tablet into suitable aqueous medium, the medium penetrates into the tablet and replaces the air adsorbed on the particles, which weakens the intermolecular bond and breaks the tablet into fine particles. Water uptake by tablet depends upon hydrophilicity of the drug/excipient and on tabletting conditions. For these types of disintegrants maintenance of porous structure and low interfacial tension towards aqueous fluid is necessary which helps in disintegration by creating a hydrophilic network around the drug particles.

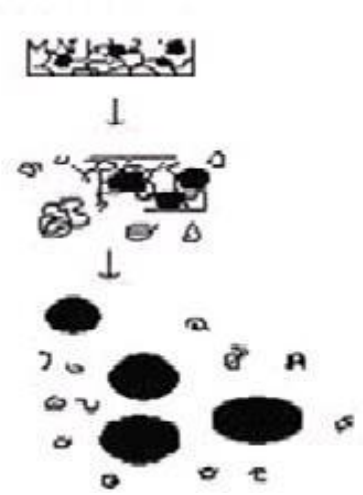

Fig.7: Schematic representation of wicking mechanism, in which Particles swell and break up the matrix.

3. Due to disintegrating particle/particle repulsive forces

Another mechanism of disintegrate attempts to explain the swelling of tablet made with 'nonswellable' disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that nonswelling particle also cause disintegration of tablets. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it. Researchers found that repulsion is secondary to wicking.

Fig. 8: Schematic representation of Due to disintegrating particle Particles swell to pre compression size and break up matrix

4. Due to deformation

During tablet compression, disintegrated particles get deformed and these deformed particles get into their normal structure when they come in contact with aqueous media or water. Occasionally, the swelling capacity of starch was improved when granules were

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extensively deformed during compression. This increase in size of the deformed particles produces a breakup of the tablet. This may be a mechanism of starch and has only recently begun to be studied.

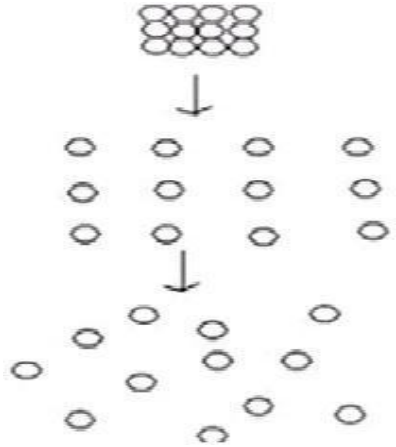

Fig. 9: Schematic representation of Due to deformation, in which water is drawn into pores and particles repel each other because of resulting electrical force.

5. Heat of wetting

When disintegrants with exothermic properties get wetted, localized stress is created due to capillary air expansion, which aids in disintegration of tablet. This explanation, however, is limited to only a few types of disintegrants and cannot describe the action of most modern disintegrating agents.

6. Chemical reaction (Acid-Base reaction)

The tablet is quickly broken apart by internal liberation of CO2 in water due to interaction between tartaric acid and citric acid (acids) with alkali metal carbonates or bicarbonates (bases) in presence of water. The tablet disintegrates due to generation of pressure within the tablet. Due to liberation in CO2 gas, the dissolution of active pharmaceutical ingredients in water as well as taste masking effect is enhanced. As these disintegrants are highly sensitive to small changes in humidity level and temperature, strict control of environment is required during preparation of the tablets. The effervescent blend is either added immediately prior to compression or can be added in two separate fractions of formulation.

7. By enzymatic reaction

Enzymes present in the body also act as disintegrants. These enzymes dearth the binding action of binder and helps in disintegration. Due to swelling, pressure is exerted in the outer direction that causes the tablet to burst or the accelerated absorption of water leads to an enormous increase in the volume of granules to promote disintegration. Some examples of disintegrating enzymes are presented in (**Table 1) along** with the binders against which these are active.

Table 1: Disintegrating enzymes and binders

ENZYME	BINDER
Amylase	Starch
Protease	Gelatin
Cellulose	Cellulose derivatives
Invertase	Sucrose

It is believed that no single mechanism is responsible for the action of most disintegrants. But rather, it is more likely the result of inter-relationships between these major mechanisms.[22]

FAST DISSOLVING TABLET

Fast dissolving tablets are also known as mouth-dissolving tablets, melt-in mouth tablets, Orodispersible tablets, rapimelts, porous tablets, quick dissolving tablet. Fast dissolving tablets dissolve or disintegrate in the oral cavity without the need of water. Most fast-dissolving tablets must include substances to mask the bitter taste of the active ingredient. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients. It has been concluded that faster the dissolution, faster the absorption (only the unionized form of drug) and onset of action. Some drugs are absorbed from the oral cavity, pharynx and esophagus as the saliva passes down into the stomach. Thus, the bioavailability of drug is significantly more than those observed from conventional tablets dosage form. The time for disintegration of fast disintegrating tablets is generally considered to be less than one minute 6 - 9.

Fast dissolving technology offers following advantages:

- No water needed
- No chewing needed
- Better taste
- Improved stability
- Suitable for controlled as well as fast release actives
- Allows high drug loading.
- Ability to provide advantages of liquid medication in the form of solid preparation.

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- Adaptable and amenable to existing processing and packaging machinery.
- Cost- effective.
- Improved compliance.

SALIENT FEATURES OF FDTs

- Does not require water for oral administration
- Have sufficient strength to withstand the rigors of the manufacturing process and post manufacturing handling
- Allow high drug loading
- Insensitive to environmental conditions such as humidity and temperature
- Adaptable and amenable to existing processing and packaging machineries
- Cost effective.
- Have a pleasant mouth feel
- Ease of administration for patients who are mentally ill, disabled and uncooperative.
- Requires no water.
- Quick disintegration and dissolution of the dosage form.
- Overcomes unacceptable taste of the drugs.
- Can be designed to leave minimal or no residue in the mouth after administration and also to provide a pleasant mouth feel.
- Allows high drug loading.
- Ability to provide advantages of liquid medication in the form of solid preparation. Adaptable and amenable to existing processing and packaging machinery.

SIGNIFICANCE OF ORAL DISINTEGRATING TABLETS:

Oral Disintegrating Tablets offer dual advantages of solid dosage forms and liquid dosage forms along with special features which include:

- **Accurate dosing:** Being unit solid dosage forms, provide luxury of accurate dosing, easy Portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients.
- **Enhanced bioavailability:** Bioavailability of drugs is enhanced due to absorption from mouth, pharynx and oesophagus.
- **Rapid action:** Fast onset of therapeutic action as tablet gets disintegrated rapidly along with quick dissolution and absorption in oral cavity.
- **Patient compliance:** No need of water to swallow the dosage form. Hence, it is convenient for patient who are travelling and do not have immediate access to water.
- **Ease of administration:** Convenient to administer specially for geriatric, paediatric, mentally disabled and bed ridden patients who have difficulty in swallowing.
- **Obstruction free:** No risk of suffocation in airways due to physical obstruction when swallowed, thus providing improved safety and compliance.
- **Enhanced palatability:** Good mouths feel, especially for paediatric patients as taste masking technique is used to avoid the bitter taste of drug.
- **Simple packaging:** No specific packaging required. It can be packaged in push through blisters.
- **Business Avenue:** Provide new business opportunities in the form of product differentiation, line extension, uniqueness and life cycle management.
- **Cost effective:** Conventional processing and packaging equipment allow the manufacturing Fast dissolving dosage forms are suitable for those patients (particularly pediatric and geriatric patients) who are not able to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following of tablets at low cost.

THE NEED FOR DEVELOPMENT OF FDTs:

Patient Factors:

- patient's incompliance due to fear of choking patients who have difficulty in swallowing or chewing solid dosage forms
- very elderly patients of depression who may not be able to swallow the solid dosage forms
- an eight-year-old patient with allergies desires a more convenient dosage form than antihistamine syrup
- a middle-aged patient undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2- blocker
- a schizophrenic patient who may try to hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic

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- a patient with persistent nausea, who may be journey, or has little or no access to water.

Effectiveness Factors:

Dispersion in saliva in oral cavity causes pre-gastric absorption of drug which dissolves. Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre-gastric absorption avoids first pass hepatic metabolism which increase the bioavailability. Furthermore, safety profiles may be improved for drugs that produce significant amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism and for drugs that have a substantial fraction of absorption in the oral cavity and pre-gastric segments of GIT.

MECHANISMS OF FDTs:

FDTs involve the following mechanisms to achieve the desired fast dissolving characteristics

1. Water must quickly enter into the tablet matrix to cause rapid disintegration and instantaneous dissolution of the tablet.

2. Incorporation of an appropriate disintegrating agent or highly water-soluble excipients in the tablet formulation.

3. There are some under mentioned mechanisms by which the tablet is broken down into the smaller particles and then subsequently result a solution or suspension of the drug.

The mechanisms are-

- ✓ High swellability of disintegration
- ✓ Chemical reaction
- ✓ Capillary action

FORMULATION ASPECTS OF FDTs

Important ingredients that are used in the formulation of FDTs should allow quick release of the drug, resulting in faster dissolution. This includes both the pharmacologically active ingredients (drug) and the excipients (additives).

Selection of drug candidate: Several factors may be considered while selecting an appropriate drug candidate for development of orally disintegrating tablets. The ultimate characteristics of a drug for dissolution in mouth and pregastric absorption from fast dissolving tablets include:

1. Free from bitter taste
2. Dose lower than 20mg
3. Small to moderate molecular weight
4. Good solubility in water and saliva
5. Partially unionized at oral cavity pH
6. Ability to diffuse and partition in to the epithelium of upper GIT (log >1,or preferably>2)
7. Ability to permeate oral mucosal tissue.

CHARACTERISTICS OF FAST DISSOLVING DELIVERY SYSTEM

Ease of administration: Fast Dissolving Delivery Systems are easy to administer and handle hence, leads to better patient compliance. Usually, elderly people experience difficulty in swallowing the conventional dosage forms (tablets, capsules, solutions and suspensions) because of tremors of extremities and dysphasia.

Taste of the medicament: As most drugs are unpalatable, mouth dissolving delivery systems usually contain the medicament in taste masked form. Delivery systems dissolve or disintegrate in patient's mouth, thus releasing the active ingredients which come in contact with the taste bud and hence, masking of the drugs becomes critical to patient compliance

Hygroscopicity: Several fast-dissolving dosage forms are hygroscopic and cannot maintain physical integrity under normal condition from humidity which called for special packaging.

Friability: In order to allow fast dissolving tablets to dissolve in the mouth, they are made of either very porous and soft-molded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle which are difficult to handle, often requiring specialized peel-off blister packaging

Mouth feel: Mouth feel is critical, and patients should receive a product that feels pleasant. Any large particles from the disintegrating tablet that are insoluble or slowly soluble in saliva would lead to an unpleasant gritty feeling. This can be overcome by keeping the majority of the particles below the detectable size limit. In some cases, certain flavours can imbibe an improved mouth feel perception, resulting in a product that is perceived as being less gritty, even if the only change is the flavour. Effervescence can be added to aid disintegration and improve mouth feel by reducing the "dryness" of a product.

LIMITATIONS:

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required during manufacturing process.

- The tablets may leave unpleasant taste and/or grittiness in oral cavity if not formulated properly.
- Drugs with larger doses are difficult to formulate into FDT e.g., rifampin (600 mg), ethambutol (1000mg) etc.

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