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A Systematic Overview On: Orodispersible Tablets

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ABSTRACT
The most common and preferred route of drug administration is through the oral route. Orodispersible tablets are gaining importance among novel oral drug-delivery system as they have improved patient compliance and have some additional advantages compared to other oral formulation. Over the past three decades, orodispersible tablets (ODTs) have gained considerable attention as a preferred alternative to conventional tablets and capsules due to better improved solubility and stability. Usually, elderly people experience difficulty in swallowing the conventional dosage forms like tablets, capsules, solutions and suspensions because of tremors of extremities and dysphagia. They are also solid unit dosage forms, which disintegrate in the mouth within a minute in the presence of saliva due to super disintegrants in the formulation. Thus this type of drug delivery helps a proper peroral administration in pediatric and geriatric population where swallowing is a matter of trouble. In some cases such as motion sickness, sudden episodes of allergic attack or coughing, and an unavailability of water, swallowing conventional tablets may be difficult. ODTs systems may offer a solution for these problems. Advancements in the technology arena for manufacturing these systems includes the use of freeze drying, cotton candy, melt extrusion, sublimation, direct compression besides the classical wet granulation processes. This has encnouraged both academia and industry to generate new orally disintegrating formulations and technological approaches in this field. This article attempts at discussing the ideal characteristics, advantages and disadvantages, formulation aspects, formulation technologies.

Key Words : Orodispersible tablets, Dysphagia, Disintegration, Cotton candy

I. INTRODUCTION

1.1Oral drug delivery system:

The oral route is the preferred route of administration of therapeutic agents because of accurate dosage, low cost therapy, self- medication, noninvasive method and ease of administration leading to high level of patient compliance. The most popular dosage forms are being conventional tablets and hard gelatin capsules. One important drawback of such dosage forms is 'Dysphagia' or difficulty in swallowing for many patients; almost 50% of the population is affected by such problem, hence high incidence of non- compliance and ineffective therapy. Recently, fast disintegrating drug delivery systems have started gaining popularity and acceptance as new drug delivery systems, because they are easy to administer and lead to better patient compliance. In some cases such as motion sickness, sudden episodes of allergic attacks or coughing and unavailability of water, swallowing conventional tablets may be difficult. Particularly the difficulty is experienced by pediatric and geriatric patients. To overcome such a problems, fast disintegrating tablets or orally disintegrating tablets have emerged as an alternative dosage form.[1]

Orodispersible tablets [ODTs] are "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue". Orodispersible tablets are also known as 'fast dissolving', 'mouth dissolving', 'rapid-dissolve', 'quick disintegrating', 'fast disintegrating', 'rapimelt', 'fast melts', orally disintegrating', 'melt- in- mouth', 'quick dissolving', 'porous tablets', 'EFVDAS' or 'effervescent drug absorption system. Orodispersible tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperse in the saliva. When faster the drug into solution, quicker the absorption and onset of clinical effects. Some drugs are absorbed from mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form. The advantage of mouth dissolving dosage forms are increasingly being recognized in both, industry and academics. The basic approach in development of ODT is the

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use of superdisintegrants like cross linked polyvinylpyrollidone (crospovidone), cross linked carboxymethyl cellulose(croscarmellose), sodium starch glycolate(primogel, explotab) etc. which provide instantaneous disintegration of tablet after putting on tongue, their by release the drug in the saliva. The bioavailability of some drug may be increased due to absorption of drug in oral cavity and also due to pre-gastric absorption of saliva containing dispersed drugs that pass down into the stomach[2]

1.12 Criteria's of drug selection for preparation of orodispersible tablet

a) 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.

b) 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.

c) Drugs having ability to diffuse and partition into the epithelium of the upper GIT (log P > 1, or preferable > 2); and those able to permeate oral mucosal tissue are considered ideal for FDT formulations.

d) Patients who concurrently take anticholinergic medications may not be the best candidates for these drugs.

e) Patients with Sjögren's syndrome or dryness of the mouth due to decreased saliva production may not be good candidates for FDT formulations.

f) Drugs with a short half-life and frequent dosing.

g) Drugs which are very bitter or otherwise unacceptable taste because taste masking cannot be achieved.

h) Drugs which require controlled or sustained release are unsuitable candidates of fast dissolving oral dosage forms.

i) Pharmaceutical Companies have formulated FDT for various categories of drugs such as neuroleptics, cardiovascular agents, analgesics, antiallergic, antiepileptics, anxiolytics, sedatives, hypnotics, diuretics, anti-parkinsonism agents, anti-bacterial agents and drugs used for erectile dysfunction.

1.13 The need for development of orodispersible tablet:

i. Patient factors:

Fast disintegrating dosage forms are particularly suitable for patients, who for one reason or the other; find it inconvenient to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following:

- Geriatric patients suffering from hand tremors and dysphasia condition.
- Central nervous system and internal muscles of pediatric patients are not developed completely so they are unable to swallow easily.
- Patients who travel suffering from motion sickness and diarrhea that do not have easy access to water.
- Patients with persistent nausea for a long period of time are unable to swallow. Especially cancer patients after taking their chemotherapy are too nauseous to swallow the H2 blockers.
- Bedridden patients, mentally challenged patients and psychiatric patients.

ii. Effectiveness factor:

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 man drugs. Any pregastric absorption avoids first pass hepatic metabolism which increase the bioavailability. Furthermore, safety profiles may be improved for drugs that produce significant amounts of toxic metabolite 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.[3]

1.14 Challenges in formulation ODT:

i. Palatability:

Most orally disintegrating drug delivery systems disintegrate or dissolve in patient's oral cavity, thus releasing the active ingredients which come in contact with the taste buds; hence, taste-masking of the drugs becomes critical to patient compliance.

ii. Mechanical strength:

In order to allow ODTs to disintegrate in the mouth, they are made with very low compression force, which makes the tablets friable and/or brittle, difficult to handle, and often requiring specialized peel-off blister packing that may increase the cost.

iii. Hygroscopicity:

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Several ODTs are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized product packaging.

iv. Amount of drug:

For lyophilized dosage forms, the drug dose must be lower than 400 mg for insoluble drugs and less than 60 mg for soluble drugs.

v. Aqueous solubility:

Water-soluble drugs form eutectic mixtures, which result in freezing-point depression and theformation of a glassy solid that may collapse upon drying because of loss of supportingstructure during the sublimation process.

vi. Size of tablet:It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve.[4]

1.15 Requirements of fast disintegrating tablets:

The tablets should

- Not require water to swallo w and should dissolve or disintegrate in the mouth within a few seconds.
- Allow high drug loading.
- Be compatible with taste masking and other excipients.
- Have a pleasing mouth feel.
- Leave minimal or no residue in the mouth after oral administration.
- Have sufficient strength to withstand the rigors of the manufacturing process and post manufacturing handling.
- Exhibit low sensitivity to environmental conditions such as humidity and temperature.
- Allow the manufacture of tablets using conventional processing and packaging equipments at low cost. [5]

1.16 Advantages of fast disintegrating tablets:

FDTs 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 esophagus.
- 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 patients who are traveling and do not have immediate access to water.
- Ease of administration: Convenient to administer specially for geriatric, pediatric , 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 mouth feel, especially for pediatric 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 e xtension, uniqueness and life cycle management.
- Cost effective : Conventional processing and packaging equipments allow the manufacturing of tablets at low cost.

1.17 Limitations of Mouth Dissolving Tablets:

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.[6,7]

1.2 Super disintegrants:

In recent years, several newer agents have been developed known as“Superdisintegrants”. A “Superdisintegrants” is an excipient, which is added to tablet or capsule blend to aid in the breakup of the compacted mass, when put into a fluid environment. This is especially important for immediate release product where rapid release of the product is required.

These newer substances are more effective at lower concentrations with greater disintegrating efficiency and mechanical strength.The use of superdisintegrants is the basic approach in the development of fast disintegrating tablets (FDTs). Superdisintegrants plays a major role in the dissolution and disintegration of the tablets. It is

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essential to choose an optimum concentration of superdisintegrants so as to ensure rapid disintegration and high dissolution rates of tablets. Superdisintegrants provide rapid disintegration due to combined effect of swelling and water absorption by the formulation. Due to swelling of superdisintegrants, the wetted surface of the carrier increases, this promotes the wettability and dispersibility of the system, thus enhancing the disintegration and dissolution.

The optimum concentration of the superdisintegrant can be selected according to the critical concentration of the disintegrant. Below this concentration, the tablet disintegration time is inversely proportional to the concentration of the superdisintegrant, where as above this concentration the disintegration time remains almost constant or even increases.

Common superdisintegrants used in formulation are croscarmellose sodium (Vivasol, Ac-Di-Sol), crospovidone (Polyplasdone), carmellose (NS-300), carmellose calcium (ECG-505), sodium starch glycolate (SSG) etc. Recently few ion exchange resins (e.g. Indion 414) are found to have superdisintegrant property and are widely used in pharmaceutical industry.

1.21 Mechanism of action of super disintegrants[9,10]

The tablet breaks to primary particles by one or more of the mechanisms listed below:

(a) Porosity and capillary action (Wicking):

Capillary action (figure 3) is always the first step in tablet disintegration. Suitable aqueous medium into which tablet is placed, penetrates into the tablet and replaces the air adsorbed on the particles there by weakens the intermolecular bond and breaks the tablet into fine particles. Water uptake by tablet depends upon hydrophilicity of the drug /excipients and on tableting 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.

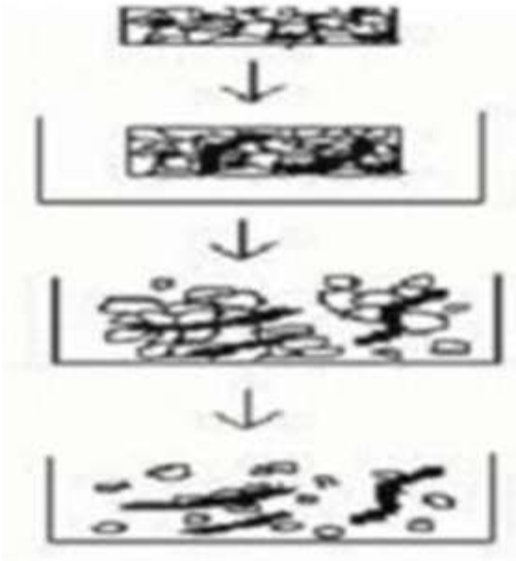

Figure 1: Porosity and capillary action (Wicking)

(b) Swelling:

The general mechanism of act ion for tablet disintegration is swelling (Figure 4).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 to penetrate in the tablet and disintegration is again slows down.

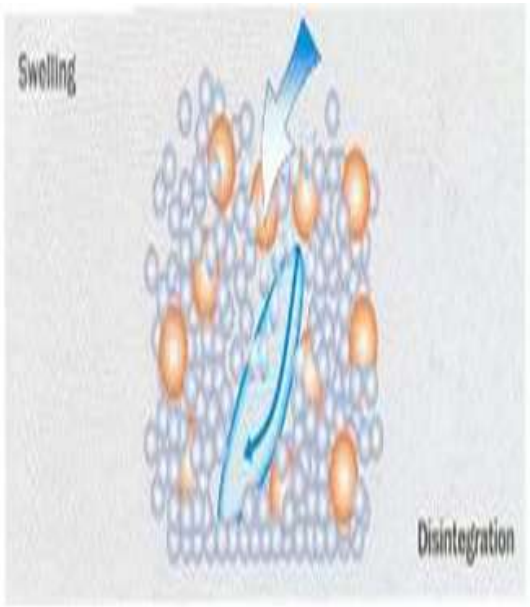

Figure 2: Swelling

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(c) Due to disintegrating particle/ particle repulsive forces:

Another mechanism of disintegrating attempts to explain the swelling of tablet made with "non swellable" disintegrants. Guyot- Hermann has proposed a particle repulsion theory (figure 5) based on the observation that non swelling 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.

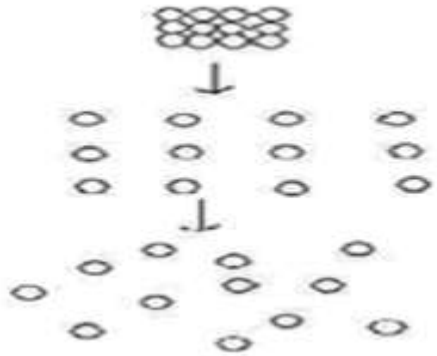

Figure 3: Repulsion Theory

(d) Due to deformation :(Elastic recovery)

Most materials, which undergo a plastic deformat ion during compression, try to return to their initial shape as soon as possible (stored potential energy). In the tablet matrix, there is no means to recover the former shape. But as soon as water penetrates into the tablet matrix and the forces, which keep the partic les together, are diminished, those particles
have the ability to expand back.

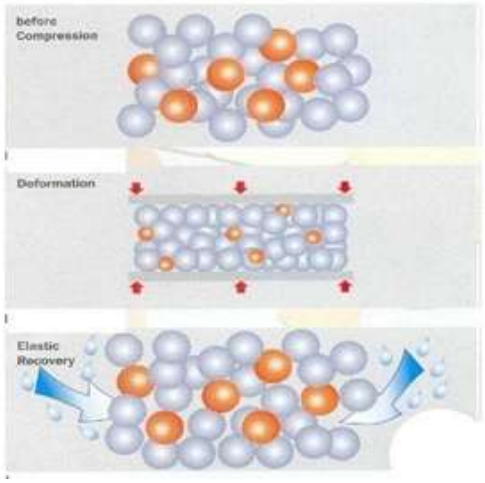

Figure 6: Elastic Recovery

In figure 6 elastic partic les are shown before compression (red). After comp ression, these particles are plastically deformed. After penetration of water into the tablet, these particles return back to their initial shape.

(e) By enzymatic reaction:

Here, enzymes present in the body act as disintegrants. These enzymes destroy the binding action of binder and helps in disintegration. Actually due to swelling, pressure exerted in the outer direction or radial direction, it causes tablet to burst or the accelerated absorption of water leading to an enormous increase in the volume of granules to promote disintegration.[7]

1.3 Techniques for Preparing Orodispersible Tablets[8] :

Many techniques have been reported for the formulation of Fast dissolving tablets or
Orodispersible tablets.

1) Freeze drying / lyophilization
2) Tablet Moulding
3) Spray drying
4) Sublimation
5) Direct compression
6) Mass extrusion
7) Cotton candy process
8) Phase transition process
9) Melt granulation

1)Freeze-Drying or 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

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packaging unsuitable for these products and poor stability under stressed conditions.

2)Tablet Molding:

Molding process is of two types i.e. solvent methodand 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 30^0C 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 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 superdisintegrant like sodium starch glycolate & croscarmellose 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 ammonium bicarbonate, 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.

5) Direct Compression:

Direct compression represents the simplest and mostcost 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) Superdisintegrants: In many orally disintegrating tablet technologies based on direct compression, the addition of superdisintegrants 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 mouthfeel. 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.

6) 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 tocoat granules for bitter drugs and thereby achieve taste masking.

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7) Cotton Candy Process:

This process utilizes a unique spinning mechanism to produce floss-like crystalline structure. Cotton candy process involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is partially recrystallized to improve flow property and compressibility. This candy floss matrix is then milled and blended with active ingredients and excipients and subsequently compressed to orally disintegrating tablet. This process can accommodate larger drug doses and offers improved mechanical strength. However, high process temperature limits the use of this process.

8) Melt granulation:

Melt granulation technique is a process by which pharmaceutical powders are efficiently agglomerated by a meltable binder. The advantage of this technique compared to a conventional granulation is that no water or organic solvents is needed. Because there is no drying step, the process is less time consuming and uses less energy than wet granulation. It is a useful technique to enhance the dissolution rate of poorly water-soluble drugs, such as griseofulvin. This approach to prepare FDT with sufficient mechanical integrity, involves the use of a hydrophilic waxy binder. Superpolystate© is a waxy material with a melting point of 33-37 °C and HLB value of 9. So it will not only act as a binder and increase the physical resistance of tablets but will also help the disintegration of the tablets as it melts in the mouth and solubilizes rapidly leaving no residues.

9) Phase transition process:

The combination of low and high melting point sugar alcohols, as well as a phase transition in the manufacturing process, is important for making orally disintegrating tablets without any special apparatus. Here, tablet produced by compressing the powder containing two sugar alcohols of high and low melting point and subsequently heating at temperature between their two melting points. Orally disintegrating tablets were produced by compressing powdercontaining erythritol (melting point: 122 °C) and xylitol (melting point: 93-95 °C), and then heating at about 93 °C for 15 min. After heating, the median pore size of the tablets was increased and tablet hardness was also increased. The increase of tablet hardness with heating and storage did not depend on the crystal state of the lower melting point sugar alcohol.[11,12]

1.4 Important Patented Technologies for Orodispersible Tablets:

1)Zydis Technology :

Zydis formulation is a unique freeze dried tablet in which drug is physically entrapped or dissolved within the matrix of fast dissolving carrier material. When zydis units are put into the mouth, the freeze-dried structure disintegrates instantaneously and does not require water to aid swallowing. The zydis matrix is composed of many material designed to achieve a number of objectives. To impart strength and resilience during handling, polymers such as gelatin, dextran or alginates are incorporated. These form a glossy amorphous structure, which imparts strength. To obtain crystallinity, elegance and hardness, saccharides such as mannitol or sorbitol are incorporated. Water is used in the manufacturing process to ensure production of porous units to achieve rapid disintegration while various gums are used to prevent sedimentation of dispersed drug particles in the manufacturing process. Collapse protectants such as glycine prevent the shrinkage of zydis units during freeze-drying process or long-term storage. Zydis products are packed in blister packs to protect the formulation from moisture in the environment.

2)Durasolv Technology:

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

3)Orasolv Technology:

CIMA labs have developed Orasolv Technology. 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.

4)Flash Dose Technology :

Flash dose technology has been patented by fuisz. Nurofen meltlet, a new form of ibuprofen

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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.

5)Wow tab Technology:

Wow tab technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide (eg. lactose, glucose, and mannitol) and granulated with a high mouldability saccharide (eg. Maltose, oligosaccharides) and compressed into tablet.

6)Flash tab Technology:

Prographarm laboratories have patented the Flash tab technology. Tablet prepared by this system consists 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 tabletting technology.

II. CONCLUSION:

Orodispersible tablets have potential advantages over conventional solid dosage form. This drug delivery is one of the great inventions of all the novel drug-delivery systems. They have improved patient compliance, convenience, bioavailability, and rapid onset of action. Many drugs can be incorporated in ODT especially unpalatable drugs. ODTs may disintegrate in moist condition and thus there is always a probability of deteriora-tion of the prepared tablets. So packaging of the formulations should be considered with highest care. Moreover drugs those require sustained release are not good candidate to be formulated as ODTs. These disadvantages may limit the preparation of ODTs in some cases.

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