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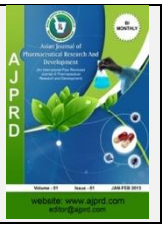

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Review Article

Fast Dissolving Tablets A Review

Ankit Sen*, Rajendra Pal Singh Rathore

Bhupal Nobles' Institute of Pharmaceutical sciences, Udaipur, Rajasthan, India

A B S T R A C T

Fast dissolving tablets emerge as one of the popular and widely accepted dosage forms, especially for pediatric patients because of incomplete development of the muscular and nervous system and a case of geriatric patients suffering from Parkinson's disorder or hand tremors. Few solid dosage forms like capsules and tablets are present days facing the problems like difficulty in swallowing (dysphagia), resulting in many incidences of non-compliance and making the therapy ineffective. Oral dosage form and oral route are the most preferred route of administration for various drugs have limitations like first-pass metabolism, psychiatric patients, bedridden and uncooperative patients. FDTs are disintegrating or dissolve quickly in the saliva without a need of water. Fast dissolving tablets are designed to dissolve in saliva remarkably faster, within a few seconds (less than 60 seconds), and those are real fast-dissolving tablets. FDTs formulations contain super disintegrants to enhance the disintegration rate of a tablet in the buccal cavity. FDTs have advantages such as easy portability and manufacturing, accurate dosing, good chemical and physical stability and an ideal alternative for geriatric and pediatric patients. FDTs have disintegrated quickly, absorb faster so, in vitro drug release time improve and this property of drugs (dosage form) enhanced bioavailability. 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. In addition, taste-masking technologies, experimental measurements of disintegration times, and dissolution are also discussed.

Keywords: Fast dissolving tablets, FDTs, Superdisintegrants, Mouth dissolving tablets.

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*Address for Correspondence:

Ankit Sen, Bhupal Nobles' Institute of Pharmaceutical sciences

INTRODUCTION

Fast dissolving tablets are known as mouth-dissolving tablets, melt-in mouth tablets, Oro dispersible tablets, rapimelts, porous tablets, fast dissolving etc. They disintegrate instantly releasing the drug that dissolve or disperses within the saliva. According to European assemblage, the ODT should disperse/disintegrate in but 3 minutes. the fundamental approach in development of FDT is that the use of superdisintegrants like cross connected carboxymethylcellulose (croscarmellose), sodium starch glycolate (primogel, explotab), polyvinylpyrollidone (polyplasdone) etc, which give instant disintegration of tablet once putting on tongue, there by release the drug in spittle. Another methodology is increasing pore structure of the tablets by freeze drying and vacuum-drying. The bioavailability of some medication conjointly is also increased because of absorption of drug in oral cavity and also because of pre gastric absorption of saliva containing distributed medication that pass down into the stomach.[1]

The oral route of administration is the most preferred route due to its many advantages like ease of administration, accurate dosage, self medication, pain avoidance, versatility and patient compliance. [2] The most popular dosage forms being tablets and capsules, one important drawback of these dosage forms however is the difficulty to swallow.

The conventional dosage forms have wide acceptance up to 50-60% of total dosage forms. Tablet continues to be preferred standard dosage forms existing these days because of simple self-administration, compact in nature, simple to manufacture and it will be delivered in correct dose. One

major drawback of solid dosage forms is the problem in swallowing or chewing in some patients particularly geriatric patients. The matter of swallowing is development in elderly patient due to fear of choking, dysphasia and in early people due to underdeveloped muscular and nervous systems and in schizophrenic patients that results in poor patient compliance. Difficulties in swallowing of tablet and capsule also are occurring once water isn't accessible, in symptom, coughing throughout the cold, allergic condition and bronchial infection. Approximately one-third of the population (mainly medicine and geriatric) has swallowing difficulties, leading to poor compliance with oral pill drug medical care that results in reduced overall medical care effectiveness. Some tablets are designed to dissolve in saliva remarkably quick, at intervals a number of seconds, and are true fast-dissolving tablets. Others contain agents to enhance the speed of tablet disintegration within the oral cavity, and are a lot of befittingly termed fast-disintegrating tablets, as they will take up to a moment to utterly disintegrate. Oral delivery is presently the gold standard within the pharmaceutical trade wherever it's considered the safest, most convenient and most economical methodology of drug delivery having the very best patient compliance quick or mouth dissolving tablets are developed for paediatric, geriatric, and bedfast patients and for active patients UN agency are busy and movement and should not have access to water. Several old persons can have difficulties in taking typical oral indefinite quantity forms (viz., solutions, suspensions, tablets, and capsules) because of hand tremors and disorder. Alternative teams which will expertise issues using typical oral indefinite quantity forms embody the unstable, the disabled, and patients UN agency are uncooperative, on reduced liquid-intake plans, or are nauseated.[2-5]

A fast dissolving tablet is defined as a solid dosage form that may disintegrates into smaller granules that slowly dissolve within the mouth. The disintegration time for quick dissolving tablet varies from many seconds to over a minute depending on the formulation and the size of the tablet. A quick disintegrating or dissolving system or tablet is outlined as a solid dosage form that may disintegrate or dissolve at intervals 30 seconds, within the mouth leading to a solution or suspension while not administration of water. The quick disintegrating tablets are similar with quick dissolving tablets; soften in mouth tablets, rapimelts, Porous tablets, Orodispersible, fast dissolving or rapidly disintegrating tablets.

Ideal Characteristics of Fast Dissolving Delivery System[6]

Mouth-feel

Mouth-feel is critical, and patients ought to receive a product that feels pleasant. Any large particles from the disintegrating pill that are insoluble or slowly soluble in secretion would result in an unpleasant gritty feeling. This could be overcome by keeping the bulk of the particles below the detectable size limit. In some cases, certain flavors will an improved mouth-feel perception, leading to a product that's perceived as being less gritty, even if the sole change is that the flavor. Effervescence is adscititious to assist disintegration and improve mouth-feel by reducing the “dryness” of a product.

Hygroscopicity

Several quick dissolving dose forms are absorptive and can't maintain physical integrity beneath normal conditions of temperature and humidness. They have protection from humidness that calls for specialized product packaging.

Friability

In order to permit quick dissolving tablets to dissolve within the mouth, they're made of either terribly porous or soft wrought matrices or compressed into tablets with terribly low compression force, that makes the tablets friable and/or brittle that are difficult to handle, usually requiring specialized peel off blister packing.

To overcome this downside, some companies introduced additional strong kinds of quick dissolving tablets, like Wowtab by Yamanouchi Shadlee and meninges Solve by CIMA labs. Excipients balance the properties of the actives in fast-melting tablets. This demands an intensive understanding of the chemistry of those Excipients to prevent interaction with the actives. Determinative the cost of those ingredients is another issue that must be addressed by formulators.

The role of excipients is very important within the formulation of fast-melting tablets. These inactive food-grade ingredients, when incorporated within the formulation, impart the specified organoleptic properties and products effectiveness. Excipients are general and may be used for a broad vary of actives, except some actives that need masking agents.

The Additional Advantages of FDT7

- Superior taste of the tablets helps to change the basic views of medications as the "Bitter pill" particularly for pediatric patients.
- Rapid drug therapy intervention is possible.
- More rapid drug absorption through pre-gastric absorption from the mouth, pharynx and esophagus.
- Free of the risk of suffocation due to physical obstruction when swallowed, thus offering improved safety.

Characteristics of ideal fast dissolving tablets

- They should not require water for administration yet dissolve or disintegrate in the mouth with in a few seconds.
- They should have pleasing mouth feel.
- They should allow high drug loading.
- They should leave minimal or no residue in the mouth after oral administration.
- They should be compatible with taste masking.
- They should be portable without fragility concerns.
- They should be manufactured using conventional tablet processing and packaging equipment at low costs.
- They should exhibit low sensitivity to environmental conditions such as humidity and temperature.

Desired Criteria for Fast Dissolving Drug Delivery System (FDDS): [7]

FAST DISSOLVING TABLET SHOULD

- Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- Be compatible with taste masking.
- Have a pleasing mouth feel.
- Leave minimal or no residue in the mouth after oral administration.
- Exhibit low sensitivity to environmental conditions as humidity and temperature.
- Allow the manufacture of tablet using conventional processing and packaging equipment at low cost.

Salient Features of Fast Dissolving Drug Delivery System (FDDS) : [9]

- Ease of administration to pediatric, geriatric and psychiatric patients who refuse to swallow a tablet.
- 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.
- Good mouth feel property of MDDS helps to change the basic impression of medication as 'Bitter pill' particularly for pediatric patients
- Rapid dissolution and absorption of drug, which may produce rapid onset of action.
- Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach, which enhances the bioavailability of drugs.
- Ability to provide advantage of liquid medication in the form of solid preparation.
- Pregastric absorption can result in improved bioavailability and as a result of reduced dosage improved clinical performance through a reduction of unwanted effects.

Target Drugs[10-13]

- Migraine drugs
- CV drugs (angina, stroke, hypertension etc)
- Respiratory drugs (anti-asthmetic, systemic antihistamine, throat, cold and cough problems)
- Anticancer drug
- CNS drugs (sedatives antiemetics, antisychoticdrug, antimaniac drugs)

Synonyms of Fast dissolving/Disintegrating Tablets (FDTs)[14]

- Melt in mouth tablets
- Fast dissolving/Disintegrating tablets
- Rapidly dissolving/Disintigrating tablets
- Rapid melt tablets
- Fast melt tablets
- Fast dispersion tablets
- Mouth dissolving tablets
- Saliva soluble tablets
- Orally disintegrating tablets
- Orally dissolving tablets
- Rapid suspension tablets

CHALLENGES TO DEVELOP FAST DISSOLVING TABLETS

- Rapid disintegration of tablet
- Avoid increase in tablet size
- Have sufficient mechanical strength
- Minimum or no residue in mouth
- Protection from moisture
- Not affected by drug properties

Drug Used in Fast Dissolving Drug Delivery System:[15-18]

Analgesic Andante-Inflammatory Agents: Mefenamic acid, Ibuprofen, Proxicam.

- **Anti-Bacterial Agents:** Erythromycin, Tetracycline, Doxycycline, and Rifambicin.
- **Anti-Fungal Agents:** Griseofulvin, Miconazole.
- **Anti-Malarial Agents:** Chlorquine, Amodiaquine.
- **Anti-Gout Agents:** Allopurinol, Probenecid
- .**Anti-Hypertensive Agents:** Amlodipine, Nefidipine.
- **Anti-Coagulant Agents:** Tolbutamide, Glipizide.
- **Anti-Protozoal Agents:** Benznidazole, Tinidazole.
- **Anti-Thyroid Agent:** Carbimazole.
- **Cardiac Inotropic Agents:** Digitoxin, Digoxins.
- **Gastro Intestinal Agents:** Omeprazole, Ranitidine,

Techniques for Preparing Fast Dissolving Tablets:[19-22]

- Conventional tabletingn methods with slight modifications.
- Freeze drying
- Molding
- Spray drying
- Sublimation
- Sugar based excipients Three-dimensional printing Technology
- Effervescent tablets
- Extrusion method.

Techniques for Preparing Mouth Dissolving Tablets:[23-24]

Freeze Drying : [1, 2, 5, 11]

A process, which involves sublimation of water from the product after freezing, is called freeze-drying. Freeze-dried forms offer more rapid dissolution than other available solid products as process imparts glossy amorphous structure to the bulking agent and some times to the drugs.

A tablet that rapidly disintegrates in aqueous solution includes a partially collapsed matrix network that has been vacuum dried above the collapse temperature of the matrix. The matrix is partially dried below the equilibrium freezing point of the matrix. Vacuum drying of the tablet above its collapse temperature instead of freeze drying below its collapse temperature provides a process for producing tablets with enhanced structural integrity, while rapidly disintegrating in normal amounts of saliva.

However, the use of freeze-drying is limited due to high cost of the equipment and processing. Other major disadvantages of the final dosage forms include lack of physical resistance in standard blister packs.

Moulding : [1, 2, 3, 5, 9]

Mouldability is defined as the capacity of the compound to get moulded or compressed. Low mouldability means that the compound show reduced compressibility by tablet and rapid dissolution while high moulding compounds show excellent compressibility and slow dissolution.

Tablets produced by moulding are solid dispersions. Physical forms of the drug in the tablets depend whether and to what extent it dissolves in the molten carrier. The drug can exist as discrete particles or micro particles dispersed in the matrix. It can dissolve totally in the molten carrier to form solid solution or dissolve partially in the molten carrier and the remaining particles stay undissolved and dispersed in the matrix. Disintegration time, drug dissolution rate and mouth feel will depend on the type of dispersion or dissolution. Moulded tablets disintegrate more rapidly and offer improved taste because the dispersion matrix is, in general, made from water-soluble sugars.[25]

Types of Moulded Tablets:

I. Compression Moulding:

Compressed moulded tablets are prepared from soluble ingredients by compressing a powder mixture previously moistened with solvent (usually water or ethanol) into mould plates to form wetted mass.

II. Heat Moulding:

In this, moulded form have been prepared directly from the molten matrix in which drug is dissolved or dispersed.

III. No-Vacuum Lyophilization:

Moulded form prepared by no-vacuum evaporation method involves evaporation of solvent from the suspension at standard pressure.

T. Makino, et al have developed compression moulded mixtures containing drug and combination of starches and sugars with surface that have been wetted with suitable amount of water. The wetted mass is compression moulded and dried porous tablets with sufficient mechanical strength have been obtained.

Moulded tablets typically do not possess great mechanical strength. Erosion and breakage of the moulded tablet often occur during handling and opening of blister packs

Sublimation : [1, 2, 3, 5, 9]

Compressed tablets composed of highly water-insoluble excipients do not dissolve rapidly in the water because of its low porosity, so porous tablets that exhibit good mechanical strength and dissolve quickly is the best remedy for above problem.

Heinemann and Rose et. al. have produced porous tablet by addition of inert solid ingredients such as urea, urethane, ammonium bicarbonate, camphor, naphthalene with other tablet excipients and the blend was compressed into tablet. Then, volatile material from compressed tablet is removed by sublimation so as to impart porosity to the tablet.

A method of producing fast dissolving tablet using water as the pore forming material has been described by Makino, et al. Koizumi, et al have developed a new method of preparing high porosity tablet that dissolve rapidly -within 10-20 seconds and exhibit sufficient mechanical strength using mannitol with camphor, a subliming material.[26]

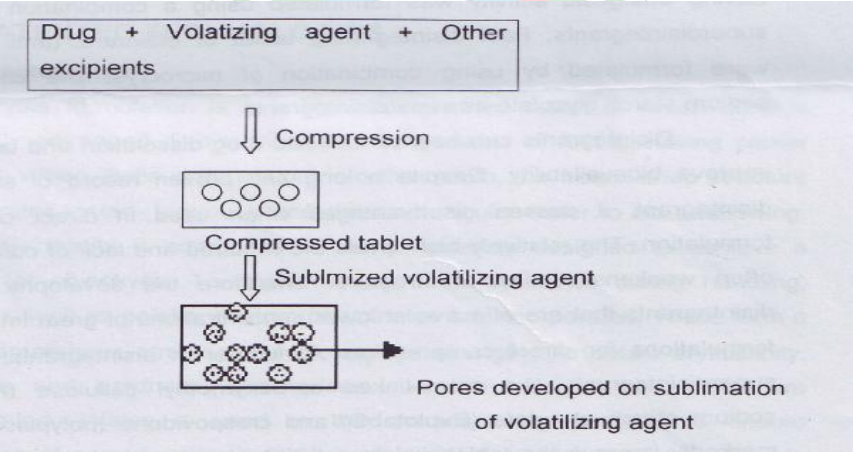

Figure 1: Sulimation process

Spray Drying: [27]

As the processing solvent is evaporated rapidly during spray drying, it gives highly porous and fine powders. Allen and Wang have employed spray-drying technique to prepare fast dissolving tablets. They developed formulation by using mannitol as bulking agent, hydrolyzed and non-hydrolyzed gelatin as support matrix, sodium starch glycolate as disintegrant and acidic material (citric acid) and /or alkali material (ex. $NaHCO_3$) to enhance disintegration and dissolution. When immersed in an aqueous medium the tablets compressed from spray -dried powder, disintegrated within 20 seconds.

Mass-Extrusion: [2, 5]

In this technology the active blend is softened by using the solvent mixture of water soluble polyethylene glycol, methanol and then softened mass is expulsed through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablets. The dried cylinder can also be used to coat granules of bitter tasting drugs in order to mask their bitter taste.

Direct Compression: [2, 5]

Direct compression is the easiest way to manufacture tablets. It can be done with conventional equipment, commonly available excipients and a limited number of processing steps. It also allows to accommodate high doses , and final weight of tablet can easily exceed that of the other production methods.

Directly compressed tablet's disintegration and solubilization depends on various factors such as single or combined action of disintegrants, water-soluble excipients and effervescent agent. Disintegrant efficacy is based on force equivalent concept, which is the combined measurement of swelling force development and amount of water absorption and defines the capability of disintegrant to transform absorbed water into swelling force. Disintegrant efficacy is strongly affected by tablet size and hardness. Large and hard tablet require more disintegration time. As consequences, products with optimal disintegration properties often have medium to small size and high friability and low hardness. The tablet with high friability and low hardness has less physical resistance, which cause breakage of tablet edges during the opening of blister alveolus.[23]

Mouth dissolving tablet prepared by direct compression method involves use of superdisintegrant. Superdisintegrant are the agent, which are completely effective in very low concentration (2-5%). So to ensure a high disintegration rate of MDDS, choice of suitable type and an optimal amount of disintegrant is important. Other formulation components such as water-soluble excipients or effervescent agents can further enhance dissolution or disintegration properties but main drawback of using effervescent excipients is their highly hygroscopic nature.The simultaneous presence of disintegrant with a high swelling force called disintegrating agent and substances with low swelling force (starch, cellulose and direct compression sugar) defined as "swelling agent" was claimed to be a key factor for rapid disintegration of tablet, which also offers physical resistance.[24]

Patented Technologies for Mouth Dissolving Tablets:

1. Zydis Technology : [1, 2, 4, 7, 9, 10]

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. OraSolv Technology: [2, 7, 9]

Ora Solv is first fast dissolving/disintegrating dosage form of 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. The taste-masking associated with the OraSolv formulation is two-fold. The unpleasant flavor of a drug is not merely counteracted by sweeteners or flavors; both coating the drug powder and effervescence are means of taste-masking in OraSolv. This technology is frequently used to develop over-the-counter formulations. The major disadvantage of the OraSolv formulations is its mechanical strength.

3. Dura Solv Technology : [2, 7]

Dura Solv is CIMA's second-generation fast-dissolving/disintegrating tablet formulation. 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.

One disadvantage of DuraSolv is that the technology is not compatible with larger doses of active ingredients, because the formulation is subjected to such high pressures on compaction. Unlike OraSolv, the structural integrity of any taste masking may be compromised with high drug doses. The drug powder coating in DuraSolv may become fractured during compaction, exposing the bitter-tasting drug to a patient's taste buds. Therefore, the DuraSolv technology is best suited for formulations including relatively small doses of active compound.

4. WOWTAB Technology: [1, 2, 7, 9]

WOWTAB 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, mannitol) and granulated with a high mouldability saccharide (eg. Maltose, oligosaccharides) and compressed into tablet.

5. Flash Dose Technology : [1, 2, 7]

FlashDose 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.

6. FlashTab Technology: [1, 2, 7]

Prographarm laboratories have patented the FlashTab 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.

7. OraQuick Technology: [7]

The Ora Quick fast-dissolving/disintegrating tablet formulation utilizes a patented taste masking technology. KV Pharmaceutical claims its microsphere technology, known as MicroMask, 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. OraQuick claims quick dissolution in a matter of seconds, with good taste-masking. There are no products using the OraQuick technology currently on the market, but KV Pharmaceutical has products in development such as analgesics, scheduled drugs, cough and cold, psychotropics, and anti-infectives.

Mechanism of action of disintegrants [24-28]

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

a) By capillary action

b) By swelling

c) Because of heat of wetting

d) Due to release of gases

e) By enzymatic action

f) Due to disintegrating particle/particle repulsive forces

g) Due to deformation.

Marketed Preparation of Melt-in-Mouth Tablets:[25]

The current pharmaceutical market for mouth dissolving tablets is on increasing trend. Because of strong patient demand, several products have been commercialized.

Table 1: Examples of Marketed Preparation of Melt-in-Mouth Tablet

Name of the Product	Manufacturer and Country	Remark
Imodium Lingual	R. P. Scherer corp., USA	Fast Dissolving Formulation of Imodium
Pecidin Rapitab	Mktd. by Merck and co., USA	Quick Releasing Anti Ulcer Preparation of Pepcid
Mosid –MT	Torrent Pharmaceuticals, India	Mouth Melt Tablet of Mosapride Citrate
Claritin Reditabs	Mktd. By Schering plough Corp., USA	Immediate dissolving Formulation of Claritin
Nimulid –MD	Panacea Biotech, India	Mouth Dissolving Tablet of Nimesulide
Zyrof Meltab	Zydus Cadila, India	Melt In Mouth Tablet of Rofecoxib

PACKAGING

Packaging special care is required during manufacturing and storage to protect the dosage of other fast dissolving dosage forms. Quick dispersing and dissolving oral delivery system can be packaged using various option, such as single pouch, blister card with multiple unit dispenser, depending on the application and marketing objectives.

CONCLUSION

Fast dissolving tablets are innovative dosage forms developed and specially designed to overcome some of the problems that seen in conventional solid dosage form i.e. difficulty in swallowing of the tablet in geriatric and pediatric patients. Fast dissolving tablets are designed to dissolve or disintegrate quickly in the saliva generally within less than 60 seconds (range of 5-60 seconds). Fast dissolving tablets have better patient compliance and acceptance may improve biopharmaceutical properties, bioavailability improved efficacy, convenience, and better safety compared with conventional oral dosage forms. The popularity of FDTs has increased fabulously over the last decade. FDTs need to be formulated for psychotic patients, bedridden, geriatric, pediatric patients, for those patients who may not have access to water, patients who are busy in traveling. FDTs formulations formulated by some of these conventional and patent technologies and FDTs have sufficient mechanical strength.

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