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Review on Fast Disintegrating Tablet

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ABSTRACT

A fast-dissolving tablet is a solid dosage form that contains medication that, when placed on the tongue, usually dissolves quickly in less than three seconds. Fast-dissolving tablets dissolve more quickly and start working faster. A tablet that dissolves quickly increases bioavailability and initiates oral absorption. There are numerous technologies available today for producing tablets that dissolve quickly, including direct compression, spray drying, tablet moulding, sublimation, freeze drying, and others. This review provides a brief overview of the benefits, requirements, procedures, excipient standards, patented technologies, assessment, workings, and composition of fast-dissolving tablets.

INTRODUCTION:

The most popular dosage forms for solid oral administration are tablets and capsules. However, some disadvantages of those dosage forms include poor patient compliance due to elderly, pediatric, and mentally ill patient not having access to water and having trouble swallowing conventional tablets. The creation of Fast Dissolution Tablets (FDT) holds the potential to solve the issue.[1-4]

In order to provide pediatric and elderly patients with an alternative to conventional dosage forms, fast-dissolving drug delivery systems were originally created in the late 1970s. Fast-dissolving tablets are made to dissolve or break down quickly in saliva, typically in less than 60 seconds.[5]

USFDA defined fast dissolving tablet as a "solid dosage form containing a medical substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed upon the tongue." According to European Pharmacopoeia "The FDT should disintegrate in less than 3 min." [6-7]

Certain medications may have a higher bioavailability due to oral drug absorption or pregastric drug absorption from saliva that travels down into the stomach. It is often advised to utilize these kinds of formulations for medications used in emergencies. FDT is also known as rapimelts, porous tablets, fast dissolving tablets, orally disintegrating tablets, orodispersible tablets, and quick disintegrating tablets.[8–10]

ADVANTAGES OF FDT:

1. Simplicity of administration for elderly, young, mentally challenged, and bedridden patients who struggle to take the tablet.

2. There is no chance of a dosage form obstruction, which is advantageous for patients who are traveling and do not have access to water.

3. Being a unit solid dosage form offers the conveniences of precise dosage, simple manufacture and transportation, strong chemical and physical stability, and a great substitute for elderly and pediatric patients.

4. These dosage forms provide better patient compliance because there is no chance of suffocating from a physical blockage when ingested.

5. Bioavailability of drugs is enhanced due to absorption from mouth, pharynx and oesophagus.

6. Rapid drug therapy intervention is possible.

7. No specific packaging is required. It can be packaged in push through blisters.

8. Provide new business opportunities in the form of product differentiation, patent life extension, uniqueness, line extension and life cycle management and exclusivity of product promotion.[11-15]

NEED FOR DEVELOPMENT OF FDT:

1. Patient factors – Geriatric people are primarily affected by disorders such as hand tremors and dysphagia. Children who are unable to swallow comfortably because their central nervous system and internal muscles have not fully grown. Patients traveling with motion sickness and diarrhea who do not have easy access to water. Fast-dissolving tablets are ideal for the patients listed above.

2. Effectiveness factor – These formulations make a big claim about increased bioavailability and speedier onset of action. In circumstances where the medicine dissolves fast, dispersion in saliva in the oral cavity induces pre-gastric absorption from some formulation ions. Many medications are absorbed in the buccal, pharyngeal, and stomach regions. Any pre-gastric absorption avoids first pass metabolism and can be very beneficial in medications that are metabolized in the liver.[16]

MECHANISM OF FDT:

Newer agent dubbed "super disintegrants" have been produced in recent years. These more recent materials have higher mechanical strength and disintegration efficiency, making them more effective at lower concentrations. This worry proposes a number of mechanisms, including repulsion, swelling, deformation recovery, and water wicking. Every one of these suggested mechanisms offers some insight into various facets of disintegrants' actions.[17–22]

1. Swelling –

Although water penetration is a necessary first step for disintegration, swelling is probably the most widely accepted mechanism of action for tablet disintegrants. For swelling to be effective as a mechanism of disintegration, there must be a superstructure against which disintegrants swells. Swelling of the disintegrants against the matrix leads to development of

a swelling force. 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 slowed down.[3, 24, 25, 26]

2. Water wicking –

The ability of disintegrants to draw water into the porous network of tablet is essential for effective disintegration. When we put the tablet into suitable dissolution medium, the medium penetrates into tablet and replaces air adsorbed on the particles, which weakens intermolecular bond and break the tablet into particles. Water uptake by tablet depends upon hydrophobicity of drug, excipients and on manufacturing 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 particles. This process is also considered as capillary action method.[24, 26, 27, 28]

3. Particle repulsive forces–

This is another mechanism of disintegration that attempts to explain the swelling of tablet made with non-swellable disintegrants. Guyot-Hermann proposed a particle-particle repulsion theory to explain the observation that particles which do not swell extensively such as starch, could still disintegrates tablets. According to this theory, water penetrates into tablet through hydrophilic pores and a continuous starch network is created that can convey water from one particle to the next, imparting a significant hydrostatic pressure. The water then penetrates between starch grains because of its affinity for starch surfaces, thereby breaking hydrogen bonds and other forces holding the tablet together. The electric repulsive forces between particles are the mechanism of disintegration and water is required for this purpose.[26, 29]

4. 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. Occasionally, the swelling capacity of starch was improved when granules were extensively deformed during compression. This increase in size of the deformed particles produces a breakup of the tablet.[23, 26, 27]

CHALLENGES OF FAST DISSOLVING TABLET: [30, 31, 32]

Challenges	Explanation
Mechanical strength and disintegration time	FDTs are formulated to obtain disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge. Many FDTs are fragile and there are many chances that such fragile tablet will break during packing, transport or handling by the patients. It is very natural that increasing the mechanical strength will delay the disintegration time.
Taste masking	Many drugs are bitter in taste. So effective taste masking of the bitter drugs must be done so that the taste of the drug is not felt in the oral cavity.
Mouth feel	Tablet should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the tablet should be as small as possible. Tablet should leave minimal or no residue in mouth after oral administration.
Sensitivity to environment	Tablet generally should exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in a tablet are meant to dissolve in minimum quantity of water.
Palatability	As most drugs are unpalatable, tablets should contain the medicament in a taste-masked form.
Mechanical strength	In order to allow ODTs to disintegrate in the oral cavity, they are made of either very porous and soft-moulded matrices or compressed into tablets 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 add to the cost.
Hygroscopic property	Several orally disintegrating dosage forms 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.
Aqueous solubility	Water-soluble drugs pose various formulation challenges because they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation.
Size of table	It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was one larger than 8 mm. Fast Disintegration FDTs should disintegrate in the mouth.
Fast Disintegration	FDTs should disintegrate in the mouth without additional water or with a very small amount (e.g., 1–2 mL) of water.

TECHNIQUES OF PREPERATION OF FDT:

1. Freeze drying/ Lyophilization

2. Direct compression

3. Sublimation

4. Moulding

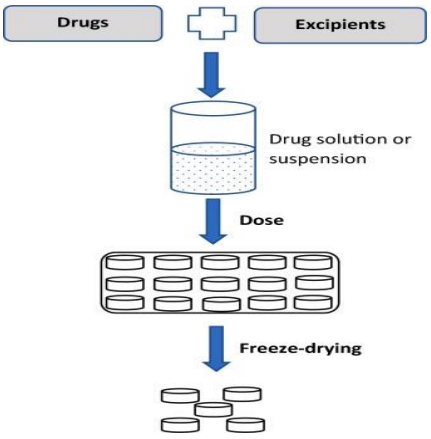
5. Mass extrusion

6. Cotton candy process

7. Spray drying

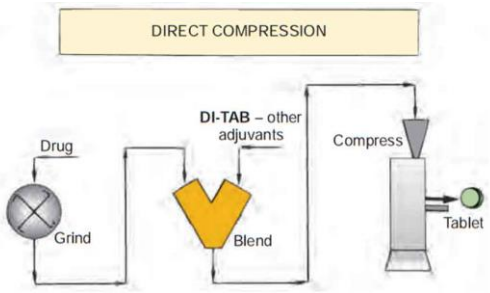
1. Freeze drying/ Lyophilization:

It is a pharmaceutical procedure that allows the drying of heat sensitive drugs and biological at low temperature with the aid of using the utility of vacuum to get rid of water with the useful resource of the use of sublimation. Drugs are dissolved or dispersed in aqueous medium of a carrier, transferred to preformed blister packs and subjected to nitrogen flush to freeze out, then positioned within side the fridge to finish the procedure. Characteristics of lyophilisation strategies are, they own excessive porosity and unique surface area, and get dissolve swiftly in mouth imparting excessive drug bioavailability. The major drawback is excessive cost, time-consuming method and fragility, making traditional packing beside the point for packing this dosage form and stability problems beneath neath stress condition.[33]



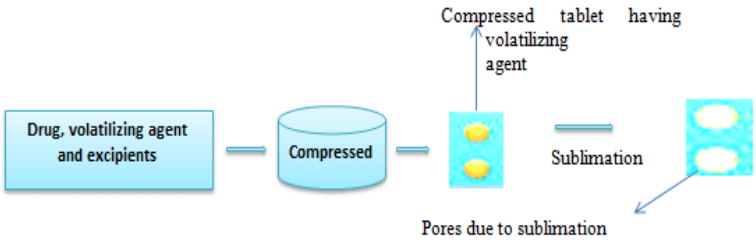
2. Direct compression:

This is one of the popular techniques used for preparation of fast dissolving dosage forms. In this technique, tablets are prepared directly by compression of mixture of drug and excipients without any preliminary treatment. The basic principle involves addition of superdisintegrant and water soluble excipients. This technique involve use of superdisintegrant in optimum concentration so as to achieve rapid disintegration along with good mouth feel. The mixture which is to be compressed must have good flow properties. Few drugs can be directly compressible into tablets of acceptable quality. Tablet disintegration time can be optimized by using an effective concentration of superdisintegrant. It is considered as the best method to prepare orally disintegrating dosage forms since the prepared tablets provides higher disintegration due to absence of binder and low moisture content. Various advantages of this method include easy implementation, use of conventional equipment along with commonly available excipients, limited number of processing steps and cost effectiveness.[34, 35]



3. Sublimation:

Sublimation has been used to produce FDTs with high porosity. A porous matrix is formed by compressing the volatile ingredients along with other excipients into tablets, which are finally subjected to a process of sublimation. Inert solid ingredients with high volatility (e.g., ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hexamethylenetetramine, naphthalene, phthalic anhydride, urea and urethane) have been used for this purpose. Solvents such as cyclohexane and benzene were also suggested for generating the porosity in the matrix.[36]



4. Moulding:

Tablets are designed using hydrophilic ingredients, with the aim to get maximum drug dissolution. Powder mass is wetted with hydro alcoholic solvent and compressed into a dosage form. The solvent system is then allowed to evaporate. Taste of drug particles is developed by spray congealing the molten mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol with an active ingredient into lactose based tablet triturate. Characteristics of moulding method are, very porous as solvents are removed by drying leaving porous mass which promotes rapid dissolution.[34]

5. Mass extrusion:

In this the blended substances are softened via way of means of water-soluble component i.e., polyethylene glycol, the use of methanol as solvent, passing through an extruder to form thin cylinders. Which in addition get sliced with a heated blade to form small tablets. Characteristics of this technique is those products can be used to mask sour tasting drugs making small granules thus consequently, improving oral bioavailability.[30, 31]

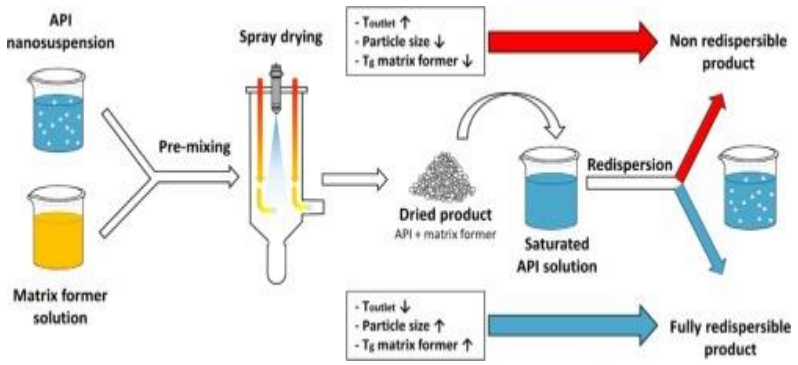
6. Cotton candy process:

In order to make an orally disintegrating tablet with greater mechanical strength and the ability to hold larger pharmaceutical dosages, the candy floss matrix is crushed and mixed with active ingredients as well as excipients. When flash melting and spinning are done at the same time, a polysaccharide or saccharide matrix is created. The partially re-crystallized matrix's flow and compressibility have both improved.[32]

7. Spray drying:

In this technique, gelatin is used as a matrix and a supporting agent, mannitol as a a bulking agent, and super disintegrant like crosscarmellose or sodium starch glycolate or crospovidone. The Tablets manufactured from the spray dried powder containing bulking

agent, superdisintegrant and acidic ingredient (citric acid) and/or alkaline ingredients (e.g. sodium bicarbonate) have been reported to disintegrate in within 20 seconds in aqueous medium. This spray-dried powder, compressed into tablets showed quick disintegration and improved dissolution. [31, 32, 33]



EXCIPIENTS CRITERIA:

Excipients used in FDTs contain at least one superdisintegrant, a diluent, a lubricant and optionally a swelling agent, a permeabilizing agent, sweeteners and flavourings.

Name of the Excipients	% used
Super disintegrants	1-15%
Binders	5-10%
Antistatic agent	0-10%
Diluents	0-85%

1. List of Super disintegrants: [8, 37]

These super disintegrants act by swelling and due to swelling pressure exerted in the outer direction or radial direction, it causes the tablet to burst or the accelerated absorption of water leading to an enormous increase in the volume of granules to promote disintegration.

Name of super disintegrant	Mechanism of action	Specific properties
1. Croscarmellose sodium	Swells 4–8 folds in<10 s. Swelling and wicking action.	Effective in low concentration (0.5 2.0%), high swelling capacity, cross-linking of the carboxyl ester groups.
2. Crospovidone	Combination of swelling and wicking action. Swells 7–12 folds in<30 s.	The effective concentration is 1–3%. Rapidly disperses and swells in water, available in micronized grades.
3. Cross linked alginic acid	Hydrophilic colloidal substance which has high sorption capacity.	The combination of swelling and wicking action causes disintegration.
4. Gellan gum	Strong swelling properties upon contact with water.	Anionic polysaccharide of linear tetra saccharides, good super disintegrants property similar to the modified starch and celluloses.
5. Sodium starch glycolate	Strong swelling properties upon contact with water. Swells 7–12 folds in<30s.	Rapid absorption of water results in swelling up to 6%, high concentration causes gelling.
6. Soy polysaccharide	Rapid dissolving.	Does not contain starch or sugar so can be used in products meant for diabetics.
7. Xanthan gum	Extensive swelling properties for faster disintegration.	High hydrophilicity and low gelling tendency.

2. Binders

Polyvinyl pyrrolidone (PVP), Polyvinyl alcohol (PVA), Hydroxypropyl methylcellulose (HPMC).

3. Fillers

Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate, calcium sulphate, pre-gelatinized starch, magnesium trisilicate, and aluminium hydroxide are all spray-dried and directly compressible.

4. Lubricants

Magnesium stearate, zinc oxide, calcium oxide, talc, polyethylene glycol, liquid paraffin, magnesium lauryl sulphate, colloidal silicon dioxide.

5. Sweeteners

Aspartame, Sugar's derivatives.

PATENTED TECHNOLOGY: [38, 43]

1. Zydis technology
2. Orasolv technology
3. Durasolv technology
4. Wowtab technology
5. Flashtab technology
6. Oraquick technology
7. Nanocrystal technology
8. Quicksolv
9. Frosta technology
10. Dispersible tablet technology

1. Zydis technology

Zydis technology is the first mouth dissolving dosage form in the market. It is a unique freeze dried tablet in which the active drug is incorporated in a water soluble matrix, which is then transformed in to blister pockets and freeze dried to remove water by sublimation. When zydis units are put into the mouth, the freeze dried structure disintegrates instantaneously and does not require water to aid swallowing.

2. Orasolv technology

This includes use of effervescent disintegrating agents compressed with low pressure to produce the FDTs. This evolution of carbon dioxide from the tablet produces fizzing sensations, which is a positive organoleptic property. Concentration of effervescent mixture usually employed is 20-25% of tablet weight. As tablets are prepared at low compression force, they are soft and fragile in nature. This initiated to develop pakslov, a special packing to protect tablets from breaking during storage of transport. Paksolv is a dome-shaped blister

package, which prevents vertical movement of tablet within the depression. Paksolv offers moisture, light and child resistance packing.

3. 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 packaged into conventional packaging system like blisters. Durasolv is an appropriate technology for products requiring low amounts of active ingredients.

4. Wowtab technology

Yamanauchi pharmaceutical company patented this technology. 'wow' means 'without water'. The active ingredients may constitute upto 50% w/w of the tablet In this technique, saccharides of both low and high mouldability are used to prepare the granules. Mouldability is the capacity of a compound to be compressed. The Wowtab product dissolves quickly in 15 s or less. Wowtab product can be packed in both into conventional bottle and blister packs.

5. Flashtab technology

This technology includes granulation of recipients by wet or dry granulation method and followed by compressing into tablets. Excipients used in this technology are of two types. Disintegrating agents include reticulated polyvinylpyrrolidine or carboxy methylcellulose. Swelling agents include carboxy methylcellulose, starch, modified starch, microcrystalline cellulose, carboxy methylated starch, etc. These tablets have satisfactory physical resistance. Disintegration time is within 1min.

6. Oraquick technology

KV Pharmaceutical claims its micro sphere 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 Oraquick claims quick dissolution in a matter of seconds, with good taste masking.

7. Nanocrystal technology

Nano Crystal Fast dissolving technology provides for:

- Pharmacokinetic benefits of orally administered nano particles (<2 microns) in the form of a rapidly disintegrating tablet matrix.
- Product differentiation is based upon a combination of proprietary & patent-protected technology elements.
- Cost-effective manufacturing processes that utilize conventional, scalable unit operations.
- Exceptional durability, enabling the use of conventional packaging equipment & formats (bottles &/or blisters).
- Wide range of doses (up to 200mg of API per unit).
- Use of conventional, compendial inactive components.
- Employment of non-moisture sensitive in actives.

8. Quicksolv

In Quicksolv porous solid dosage forms are obtained by freezing an aqueous solution of the drug-containing matrix and then drying it by removing the water using excess of alcohol by solvent extraction. The final form disintegrates rapidly, but is limited to low drug content and can be used only for those drugs that are insoluble in the extraction solvent. The ideal drug characteristics required for this technology are relative low aqueous solubility, fine particle size <50 μm, and good aqueous stability in the suspension.

9. Frosta technology

It utilizes the concept of formulating plastic granules and compressing at low pressure to produce strong tablets with high porosity. Plastic granules are composed of porous and plastic material, water penetration enhancer and binder. The process involves usually mixing the porous plastic material with water penetration enhancer and followed by granulating with binder. The tablets obtained have excellent hardness and rapid disintegration time ranging from 15 to 30s depending on size of tablet. Filler reduces the porosity of tablets due to which disintegration is lowered.

10. Dispersible tablet technology

Lek in Yugoslavia was issued patents for dispersible tablets of dihydroergotoxine and cimet idine, which were claimed to disintegrate in less than 1 minute when in contact with water at room temperature. Dihydroergotoxine is poorly soluble in water in the free base form. An improved dissolution rate of dihydroergotamine methanesulphonate was observed with dispersible tablets containing 0.8-10%, preferably about 4% by weight, of an organic acids. One of the essential excipients in the cimetidine formulate ion was a disintegrating agent. It provides rapid swelling and/or good wetting capability to the tablets and thereby a quick disintegration.

EVALUATION PARAMETERS: [44]

1) Physical appearance

Physical appearance of tablets is determined by visual identity which involves the measurement of number of factors such as tablet size, shape, color, odour, taste, surface texture and any identification marks present on the tablet.

2) Weight variation test

The weight variation test is performed by taking 20 tablets from each formulation and weighing the individual tablets by using electronic balance. Their average weight was calculated as,

$$\% \text{ Weight variation} = (WA - WI) \times 100 / WI$$

Where,

WI = Individual weight of the tablets

WA = Average weight of the tablet

3) Thickness

Thickness of the tablet was determined using vernier callipers. Five tablets from each batch were used, and an average value was determined.

4) % Friability

Friability of the tablets was determined in a Roche friabilator. Ten tablets were weighed initially(W1) and placed in the friabilator that revolves at a speed of 25rpm, dropping those tablets at a distance of six inches height with each revolution and rotated in the friabilator for

100 revolutions. After completion of rotations, the tablets were dedusted and weighed (W2). The percent loss in weight is calculated by using the formula:

% Friability= (Initial weight- Final weight)/ Initial weight × 100

5) Content uniformity

The test for uniformity of content is based on the assay of the individual contents of active substances to determine whether the individual contents are within limits set with reference to the average content of the sample.

Method: 30 tablets are kept aside and 10 tablets are assayed. 9 tablets should have %limit of 85-115% if more than 1 tablet has 85-115% then, 20 tablets are assayed not more than one tablet should have 75-125%.

6) In-vitro disintegration studies

In-vitro disintegration time was performed by apparatus specified in USP. The water was used as disintegration medium, and the temperature was maintained at and the time in seconds taken for the complete disintegration of the tablet, with no palpable mass remaining in the apparatus, was measured in seconds.

7) In-vitro dissolution studies

In-vitro dissolution study was performed by using USP type- II dissolution test apparatus (paddle type) at 75rpm. 900ml of buffer medium was used as the dissolution medium which was maintained at 37±0.5degree centrigrade. Aliquots of dissolution medium (5ml) were withdrawn at specific time intervals and were filtered. The amount of drug dissolved was determined by UV spectrophotometer by measuring the absorbance of sample.

MARKETED PRODUCTS OF FDT: [45]

Brand name	Active ingredient	Application	Company
1. Feldene Melt^{R}	Piroxicam	NSAIDs	Pfizer
2. Maxalt –MLT	Rizatritpan benzoate	Migrane	Merck
3. Pepeid^{R} ODT	Femotidene	Anti-ulcer	Merck
4. Zyperxa^{R}	Olazepine	Psychotropic	Eli Lilly
5. Zofran^{R} ODT	Olandansetron	Antiemetic	Galaxo Smith kline
6. Resperdal^{R} M-TabTM	Resperidone	Schizophrenia	Janssen
7. ZubrinTM (Pet drug)	Tepoxelin	Canine NSAIDs	Scherig corporation
8. ZelaparTM	Selegiline	Parkinsons disease	Elanl Amarin corporation
9. Klonopin^{R} wafer	Clonazepam	Sedation	Roche
10. Imodium Istant Melts	Loperamide HCL	Antidiarrheal	Janssen

CONCLUSION:

Improved patient compliance, efficacy, and biopharmaceutical characteristics have been demonstrated with fast dissolving drug delivery systems. FDT concept evolved to overcome some of the problems that existed in conventional solid dosage form i.e. difficulty in swallowing of tablet in pediatric and geriatric patients. FDTs is fast disintegration, dissolution in the mouth of the drug in presence of saliva. FDTs is a growing technology, offering considerable benefits for lifecycle management development timelines, patient convenience and market share. The newer technologies utilized for the formulation of the FDTs that provide more effective dosage forms with more advantages and minimal disadvantages. FDT in the near future is expected to grow at a great and rapid pace, owing to the advancement in the scientific research and discovery of new excipients, resulting in a future-ready, combative area of pharmaceutical drug delivery systems.

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