A SHORT REVIEW ON “A NOVEL APPROACH IN ORAL FAST DISSOLVING DRUG DELIVERY SYSTEM”

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ABSTRACT

Fast dissolving tablets are disintegrating or dissolve quickly in the saliva without water. Some tablets are designed to dissolve in saliva extremely fast, within a few seconds. Others containing agents to enhance the rate of tablet disintegration in the oral cavity and more appropriately termed as fast-disintegrating tablets, as they may take up to a minute to completely disintegrate. Oral delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, most convenient and most economical method of drug delivery. This tablet format is designed to allow administration of an oral solid dose form in the absence of water or fluid intake. Such tablets readily dissolve or disintegrate in the saliva within few seconds. Fast or mouth dissolving tablets have been formulated for pediatric, geriatric, and bedridden patients and for active patients who are busy and traveling and may not have access to water. Such formulations provide an opportunity for product line extension in the many elderly persons will have difficulties in taking conventional oral dosage forms (viz., solutions, suspensions, tablets, and capsules) because of hand tremors and dysphagia. Swallowing problems also are common in young individuals because of their underdeveloped muscular and nervous systems. Other groups that may experience problems using conventional oral dosage forms include the mentally ill, the developmentally disabled, and patients who are uncooperative, on reduced liquid-intake plans, or are nauseated. 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.

Key words: Mouth dissolving, Superdisintegrants, Lyophilization, Direct compression, Fast dissolving tablet.

INTRODUCTION

Drug delivery systems are becoming increasingly sophisticated as pharmaceutical scientists acquire a better understanding of the physicochemical and biochemical parameters pertinent to their performance. Over the past three decades, mouth
disintegrating tablets (ODTs) have gained considerable attention as a preferred alternative to conventional tablets and capsules due to better patient compliance. Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self medication, pain avoidance and most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules; one important drawback of this dosage forms for some patients, is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic condition and bronchitis. For these reason, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Or dispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. Fast dissolving tablets are known as mouth-dissolving tablets, melt-in mouth tablets, Oro-dispersible tablets, rapimelts, porous tablets, quick dissolving etc. Fast dissolving tablets are those when put on tongue disintegrate directly releasing the drug which dissolve or disperses in the saliva5. faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the 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 academics7. Their growing significance was underlined recently when European pharmacopoeia adopted the term “Oro-dispersible tablet” as a tablet that to be placed in the mouth where it disperses quickly before swallowing [1].

MECHANISM OF SUPER-DISINTEGRANTS

There are four major mechanisms for tablet disintegration as follows
Swelling

Although not all effective disintegrants swell in contact with water, swelling is believed to be a mechanism in which the disintegrating effect expressed by certain disintegrating agents (such as starch). By swelling in contact with water, the adhesiveness of other ingredients in a tablet is overcome causing the tablet to fall apart.

Porosity and Capillary Action (Wicking)

Effective disintegrants that do not swell are believed to impart their disintegrating action through porosity and capillary action. Tablet porosity provides pathways for the penetration of fluid into tablets. The disintegrant particles (with low cohesiveness & compressibility) themselves act to enhance porosity and provide these pathways into the tablet. Liquid is drained up or “wicked” into these pathways through capillary action and ruptures inter particulate bonds causing the tablet to break apart.

Deformation
Starch grains are generally thought to be “elastic” in nature meaning that grains that are collapsed under pressure will return to their original shape when that pressure is removed. But, with the compression forces involved in tableting, these grains are believed to be collapsed more permanently and are said to be “energy rich” with this energy being released upon exposure to water. In other words, the ability for starch to swell is higher in “energy rich” starch grains than it is for starch grains that have not been collapsed under pressure.

Due to disintegrating particle/particle repulsive forces

Mechanism of disintegration attempts to explain the swelling of tablet made with ‘non swellable’ disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that non swelling particle also cause disintegration of tablets. The electric repulsive forces produces between particles and water is required for the mechanism of disintegration. Researchers found that repulsion is secondary to wicking[8]. 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.
TECHNOLOGIES FOR PREPARING FAST DISSOLVING TABLETS :-

The fast dissolving property of the tablet is attributable to a quick access of water into the tablet matrix resulting in its rapid disintegration. Hence, the basic approaches to developing fast dissolving tablets include maximizing the porous structure of the tablet matrix, incorporating the suitable disintegrating agent, and using highly water soluble excipients in the formulation. Various technologies used in the manufacture of Fast dissolving tablets.

**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 develop the poorly water-soluble drugs dissolution rate, such as griseofulvin\[16\]. This approach to prepare FDT with sufficient mechanical integrity, involves the use of a hydrophilic waxy binder (Superpolystate©, PEG – 6 – stearate). Superpolystate© is a waxy material with a melting point of 33–37°C and a...
HLB value of 9. So it will not only act as a binder and increase the physical resistance of tablets but also help the disintegration of the tablets as it melts in the mouth and solublises quickly leaving no residues\cite{3}.

Phase transition process

It is accomplished that not only combination of low and high melting point sugar alcohols, but also a phase transition in the manufacturing process. These are important for making FDTs without any special apparatus. FDT were produced by compressing powder containing 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\cite{23}.

Sublimation

The key to fast disintegration for mouth dissolving tablets is the presence of a porous structure in the tablet matrix. Conventional compressed tablets that contain highly water soluble ingredients are not to dissolve quickly because of low porosity of the matrix. Hence, to generate porous matrix, volatile ingredient are used that are later subjected to a process of sublimation. In studies conducted inert solid ingredients that displayed high volatility (e.g., ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hexamethonium tetramine, naphthalene, phthalic anhydride, urea, and urethane) were compressed along with other excipients into a tablet. The volatile material was then removed by sublimation, leaving behind a porous matrix. Solvents such as cyclohexane and benzene were also suggested for the generation of porosity in the matrix. Applied sublimation technology to manufacture tablets that rapidly dissolve in saliva. Mannitol is used as a matrix former, and camphor was used as a sublimating agent. The tablets dissolved in 10-20 seconds and displayed satisfactory handling properties\cite{18,20,22}. This method using water as pore-forming material. A mixture of drug and carbohydrate (e.g.
erythritol, glucose, sucrose, xylitol). The water was then removed, yielding highly porous tablets with satisfactory mechanical strength and a high dissolution rate.

Three-dimensional Printing (3DP)

Three-dimensional printing (3DP) is a rapid prototyping (RP) technology. Prototyping involves constructing specific layers that uses powder processing and liquid binding materials. A novel fast dissolving drug delivery device (DDD) with loose powders in it was fabricated using the three dimensional printing (3DP) process. Based on computer-aided design models, the DDD containing the drug acetaminophen were prepared automatically by 3DP system\textsuperscript{[28]}. It was found that proper hardness of rapidly disintegrating oral tablets can be prepared using TAG. The rapid disintegration of the TAG tablets seemed due to the quick water penetration into the tablet resulting from the large pore size and large overall pore volume\textsuperscript{[19]}.

Mass Extrusion

This technology involves softening of the active blend using the solvent mixture of water soluble polyethylene glycol and methanol and expulsion of softened mass through the extruder or syringe to get a cylindrical shaped extrude which are finally cut into even segments using heated blade to form tablets. This process can also be used to coat granules of bitter drugs to mask their taste\textsuperscript{[7]}.

Spray drying

Spray drying is a process by which highly porous, fine powders can be produced. Spray dryers are invariably used in the pharmaceutical industry to produce highly porous powders. The formulations that were produced contained unhydrolyzed and hydrolyzed gelatine as a supporting agent, mannitol as a bulking agent, and sodium starch glycolate or crosscarmellose as a disintegrant. Disintegration and dissolution was further enhanced by adding an acid (e.g., citric acid) or an alkali (e.g., sodium bicarbonate). The formulation was spray dried to yield a porous powder. Tablets manufactured from this powder disintegrated in less than 20 second in an aqueous medium\textsuperscript{[20,22]}.

Tablet Molding
Molding process is of two type’s 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 300°C under vacuum. The mechanical strength of molded tablets is a matter of great concern. Mechanical strength increase by addition of binder. 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 active ingredient into a lactose based tablet triturate form. Compared to the lyophillization technique, tablets formed by the molding technique are easier to scale up for industrial manufacture[9].

Lyophilization or Freeze-Drying

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 quickly. 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 established improved absorption and increase in bioavailability. The major disadvantages of lyophilization technique are that it is costly and time consuming; fragility makes conventional packaging unsuitable for these products and poor stability under stressed conditions[21,5].
Direct compression
It is the simple way to manufacture tablets. Conventional equipment, generally available excipients and a limited number of processing steps are involved in direct compression. Also high doses can be accommodated and final weight of tablet can easily improve on that of other production methods. This technique can now be applied to fast dissolving tablets because of the availability of improved tablet excipients, especially tablet disintegrants and sugar-based excipients. Addition of disintegrants in fast dissolving tablets leads to quick disintegration of tablets and hence improve dissolution. In many fast dissolving tablet technologies based on direct compression, the disintegrants principally affect the rate of disintegration and hence the dissolution. The introduction of superdisintegrants and a better understanding of their properties have increased the popularity of this technology. Tablet disintegration time can be optimized by occupied the disintegrants. Below significant concentration, tablet disintegration time is inversely proportional to disintegrants concentration. Above the critical concentration level, however, disintegration time remains approximately constant or even increases\[20\].

Microcrystalline cellulose, cross-linked carboxymethyl cellulose sodium, cross-linked polyvinylpyrrolidone and partially substituted hydroxypropyl cellulose, though water insoluble, absorb water and swell due to capillary action and are considered as effective disintegrants in the preparation of first dissolving tablets. Generally microcrystalline cellulose (MCC) and low substituted hydroxypropyl cellulose (HPC) used to manufacture rapidly disintegrating tablets. The ratios of MCC to HPC varied from 8:2 to 9:1. Ito and Sugihan investigated applying agar powder as a disintegrants because the powder absorbs water and swells considerably without forming a gel at physiological temperatures. Fast dissolving of tablets can also be achieved by incorporating effervescent, disintegrating agents, which generates carbon dioxide. This phenomenon also resulted in partial taste masking of unacceptable taste of the drug. The major drawback of effervescent excipients is their hygroscopicity (i.e., the ability to absorb atmospheric moisture). Hence, their manufacture requires control of humidity conditions and protection of the final product.
This is reflected by the overall cost of the product. Another approach to fast dissolving tablets by direct compression is the use of sugar based excipients (e.g., dextrose, fructose, isomalt, maltitol, maltose, mannitol, sorbitol, starch hydrolyse, polydextrose, and xylitol), which display high aqueous solubility and sweetness, and hence, impart taste masking and a pleasing mouth feel\cite{2}.

OraSolv and DuraSolv Technology

OraSolv technology (Cima Labs) produces tablets by low compression pressure. It uses an effervescent disintegrant that releases gas upon contact with water. The widely used effervescent disintegration pairs usually include an acid source and a carbonate source. The acid sources include citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, and succinic acids. The carbonate sources include sodium bicarbonate, sodium carbonate, potassium bicarbonate, and potassium carbonate. The carbon dioxide evolved from the reaction may provide some “fizzing” sensation, which is a positive organoleptic sensation. The amount of effervescent agent is in general about 20–25% of the total weight of the tablet. Because of the soft and fragile nature of OraSolv tablets, a special packaging system, known as PakSolv, was developed to protect the tablets from breaking during transport and storage\cite{23}. PakSolv is a “dome-shaped” blister package that prevents the vertical movement of the tablet within the depressions, because the diameter of the lower portion of the field is too narrow to accommodate the tablet. PakSolv also offers light, moisture, and child resistance. As a second-generation technology, the DuraSolvR technology was developed by Ciba to provide stronger tablets for packaging in blisters or bottles\cite{5}. The key ingredients in this formulation are non-direct compression filler and lubricant. The particle size of the non-direct compression filler is preferably between about 20 and 65 μm, while for direct compressible fillers at least 85% of the particles are over 100 μm in size. These non-direct compression fillers, such as dextrose, mannitol, sorbitol, lactose, and sucrose, have the advantage of quick dissolution and avoid some of the gritty or sandy texture usually present in direct compressible versions of the sugar. The amount of non direct compression filler is usually about 60–95% of the total tablet
weight. The tablets have low friability, which is about 2% or less when tested according to the USP, and the hardness of the tablets is at least about 15–20 N. The disintegration time is less than 60 seconds. It is interesting to note that in comparison with the conventional tablet formulations, higher amounts of hydrophobic lubricants, such as magnesium stearate, can be added to the formulation with non-direct compression fillers as the main component. About 1–2.5% of lubricant can be added to the formulation, compared with 0.2–1% of lubricant in conventional tablets. The lubricant blending times can also be increased to 10–25 minutes or longer. Relatively modest compressive force is needed to compress the formulation. This method can produce tablets by the direct compression method and use conventional tableting methodologies and conventional package equipment. Thus, the production cost is significantly decreased\cite{25}.

**WOWTABR Technology**

WOWTABR technology employs a combination of low and high-moldability saccharides to produce fast-dissolving tablets using conventional granulation and tableting techniques. According to the patent, saccharides were divided into two groups: those with high moldability and those with low moldability. Low moldability saccharides produce tablets with hardness between 0 and 2 kg, when 150 mg of such a saccharide is compressed under pressure of 10–50 kg/cm² using a die 8 mm in diameter. The typical low moldability saccharides include lactose, mannitol, glucose, sucrose and xylitol. High-moldability saccharides produce tablets with hardness above 2 kg when prepared under the identical conditions. The typical high-moldability saccharides are maltose, maltitol, sorbitol, and oligosaccharides. When tablets are made by compressing a saccharide having low moldability or high moldability alone, the desired properties of adequate hardness and quick disintegration in the mouth cannot be achieved simultaneously. Moreover, if saccharides having low moldability and high moldability are mixed (physical mixture) before tableting, quick disintegration and dissolution in the mouth cannot be
obtained. As clearly indicated in the patents, there is no single saccharide that can make
tablets having both high strength and fast disintegration properties. For this reason, a
saccharide having low moldability was granulated with a saccharide having high
moldability as a binder. The low-moldability saccharides were used as the main
component. The tablets show an sufficient hardness and fast disintegration and
dissolution when put in the mouth\(^{[27]}\).

Flashtab Technology

Flashtab technology (Ethypharm, France) produces tablets by compression of granular
excipients. This technology uses almost the same excipients as do conventional
compressed tablets. Excipients used in this technology comprise two groups
disintegrating agents, such as carboxymethylcellulose or insoluble reticulated
polyvinylpyrrolidone; and swelling agents, such as carboxymethylcellulose, starch,
modified starch, carboxymethylated starch, microcrystalline cellulose, and possibly
directly compressible sugars. The mixture of excipients is prepared by either dry or wet
granulation methods. The produced tablets are known to have satisfactory physical
resistance and disintegrate in the mouth within 1 minute\(^{[13]}\).

AdvaTab Technology

AdvaTab technology (Eurand) produces FDT tablets based on a proprietary tablet
composition that was designed and patented by Kyowa Hakko Kogyo (Tokyo, Japan) in
which the lubrication is dispensed onto each tablet by using a spray during the production
process. Traditional tablets are produced using an internal lubrication system, which
disperses lubricant on the inside and the surface of the tablets. This method can decrease
tablet mechanical strength. AdvaTab is produced using 10–30 times less hydrophobic
lubricant and can be 30–0% stronger than conventional tablets. As a result, the tablets are
hard and durable yet do not impede liquid entry upon contact with saliva. AdvaTab can
handle high drug loading and coated drug particles. Importantly, the technology does not
require specialty packaging and, as a result, can be packaged in both standard bottles and
push-through blisters\(^{[21]}\).
Dispersible Tablet Technology

The dispersible tablets of dihydroergotoxine and cimetidine, which were claimed to disintegrate in less than 1 minute when in contact with water at room temperature. Dihydroergotoxine is weakly soluble in water in the free base form. An improved dissolution rate of dihydroergotoxine methanesulphonate was observed with dispersible tablets containing 0.8–10%, preferably about 4% by weight, of an organic acid. One of the essential excipients in the cimetidine formulation was a disintegrating agent. It provides rapid swelling and/or good wetting capability to the tablets and thereby a quick disintegration. The disintegrating agents include starch or modified starches, microcrystalline cellulose, alginic acid, cross-linked sodium carboxymethyl cellulose, and cyclodextrin polymers. A combination of two or more disintegrating agents produced better disintegration results [1].

Pharmaburst Technology

Pharmaburst technology uses off-the-shelf coprocessed excipients to build an FDT that, depending on the type of active and loading (up to 700mg), dissolves within 30–40 seconds. The quantity of Pharmaburst™ required in the formulation of tablet. It is necessary to carry out initial studies on a formulation by varying the amount of Pharmaburst™ from 50 to 80%, depending on the desired mouth feel and disintegration time. The process involves a dry blend of a drug, flavor and lubricant that are compressed into tablets on an average tablet press with stock tooling. The manufacture process can be carried out under normal temperature and humanity conditions. The tablets can be packaged in blister packs or bottle [12].

OraQuick technology

The OraQuick fast dissolving/disintegrating tablet formulation utilizes a patented taste masking technology. KV Pharmaceutical claims its microsphere technology, known as MicroMask, has superior mouthfeel 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. K V Pharmaceutical also claims that the matrix that surrounds and protects the drug powder in microencapsulated particles is more elastic, meaning tablets can be compressed to achieve significant mechanical strength without troublemaking 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\cite{10}.

**Quick –Dis technology**

Lavipharm Laboratories Inc. (Lavipharm) has invented an ideal intra-oral fast dissolving drug delivery system. The novel intra oral drug delivery system, trademarked Quick Dis\textsuperscript{TM}, is Lavipharm’s proprietary patented technology is not only thin, flexible but also 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\textsuperscript{TM} drug delivery system can be provided in a variety of packaging configurations, ranging from unit dose pouches to multiple dose blister packages. The disintegration time was defined as the time at which the film begins to break when brought into contact with water. It is only 5 to 10 seconds for the Quick Dis\textsuperscript{TM} film with a thickness of 2 mm. The dissolving time was defined as the time at which not less than 80\% of the tested film is dissolved in aqueous media. It is around 30 seconds for Quick Dis\textsuperscript{TM} film with a thickness of 2 mm. The typical release profile of an active ingredient exhibited by drug delivery system is 50\% released within 30 seconds and 95\% within 1 minute\cite{15}.

**Nanocrystal technology**

For fast dissolving tablets, Elan’s proprietary Nanocrystal technology can enable formulation and improve compound activity and final product characteristics. Decreasing particle size increases the surface area, which leads to an increase in dissolution rate. This can be accomplished predictably and efficiently using Nanocrystal technology.
Nanocrystal particles are small particles of drug substance, typically less than 1000 nanometers (nm) in diameter, which are produced by milling the drug substance using a proprietary wet milling technique\cite{26}.

NanoCrystal

Fast dissolving technology provides for\cite{1}:

1. Pharmacokinetic benefits of orally administered nanoparticles (<2 microns) in the form of a rapidly disintegrating tablet matrix
2. Product differentiation based upon a combination of proprietary and patent protected technology elements.
3. It is cheapest preparation.
4. It is not time consuming process.
5. Wide range of doses (up to 200mg of API per unit).
7. Nanocrystal colloidal dispersions of drug substance are combined with water soluble GRAS (Generally Regarded as Safe) ingredients, filled into blisters, and lyophilized.
8. The resultant wafers are remarkably robust, yet dissolve in very small quantities of water in seconds. This approach is especially attractive when working with highly potent or hazardous materials because it avoids manufacturing operations (e.g., granulation, blending, and tableting) that generate large quantities of aerosolized powder and present much higher risk of exposure.
9. The freeze drying approach also enables small quantities of drug to be converted into FDT dosage forms because manufacturing losses are negligible.

Zydis technology

Zydis is a freeze dried oral solid dosage form that can be administered without water and it dissolves immediately on the tongue in less than 3 seconds. The drug is physically trapped in a water soluble matrix, and then freeze dried to produce a product that rapidly dissolves. The matrix usually contain excipients like polymers (e.g., gelatine, alginates, and dextrin) to provide strength and rigidity to tablets; polysaccharides (e.g., mannitol and
sorbitol) to impart crystallinity and hardness to the matrix and to improve palatability; collapse protectants (e.g., glycin) to prevent the product from shrinking in its packaging during manufacturing or storage; flocculating agents to provide uniform distribution of drug particles; preservatives (e.g., parabens) to prevent microbial growth; permeation enhancers to improve transmucosal permeability; pH adjusters to optimize chemical stability; flavours and sweeteners to improve patient compliance and water to ensure formation of porous units. Thirteen products are currently available based on zydis technology. In the worldwide market, zydis formulations are also available for oxazepam, lorazepam, loperamide, perindopril and enalapril\[4\].

Frosta technology

This technology is patented by Frosta technology utilizes the core concept of formulating plastic granules and compressing at low pressure to produce strong tablets with high porosity. The process involves mixing the porous plastic material with water penetration enhancer and followed by granulating with binder. The technology can be used for almost any drugs including aspirin, loratidine, caffeine, and folic acid, vitamins and dietary supplements. Melting time varies from several seconds to about 10 seconds depending on the formulation\[19\].

CONCLUSION

It is developing a novel, cost effective one step FDDT manufacturing process using conventional tabletting technology for the production of robust tablets suitable for conventional packaging. This proprietary technology is applicable to a wide range of therapeutic agents including generics, thereby adding value, i.e. 'supergenerics' for veterinary or human application. There is a clear opportunity for new enhanced oral products arising within this market segment. Approximately one-third of the population, primarily the geriatric and pediatric populations, has swallowing difficulties, resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness. A new tablet dosage format, the fast dissolving tablet has been developed which offers the combined advantages of ease of dosing and convenience of dosing in the
absence of water or fluid. These tablets are designed to dissolve or disintegrate rapidly in the saliva within few seconds (range of 5-50 seconds). Due to the constraints of the current FDDT technologies as highlighted above, there is an unmet need for improved manufacturing processes for fast dissolving tablets that are mechanically strong, allowing ease of handling and packaging and with production costs similar to that of conventional tablets. To fulfill these medical needs, formulators have devoted considerable effort to developing a novel type of tablet dosage form for oral administration, one that disintegrates and dissolves rapidly in saliva without the need for drinking water. The development of a fast-dissolving tablet also provides an opportunity for a line extension in the marketplace. A wide range of drugs can be considered candidates for this dosage form. Pharmaceutical marketing is another reason for the increase in available fast dissolving/disintegrating products. As a drug entity nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form. A new dosage form allows a manufacturer to extend market exclusivity, while offering its patient population a more convenient dosage form or dosing course of therapy. In this regard, fastdissolving/disintegrating tablet formulations are similar to many sustained release formulations that are now commonly available. Although the cost to manufacture these specialized dosage forms exceeds that of traditional tablets, this additional cost is not being passed on to the consumer.

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