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Fast dissolving tablet: An study on novel drug delivery system (A review)

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Abstract
The convenience of administration and improved patient compliance are important in the design of oral drug delivery system which remains the preferred route of drug delivery in spite of various disadvantages. One such problem can be solved in the novel drug delivery system by formulating "mouth dissolving tablets" (MDTs) which disintegrates or dissolves rapidly without water within few seconds in the mouth due to the action of superdisintegrants or maximizing pore structure in the formulation. Fast dissolving tablets are one of them. FDT have benefits such as accurate dosing, easy portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients. FDTs have disintegrated quickly, absorb faster so, *in vitro* drug release time improve and this property of drugs (dosage form) enhanced bioavailability. FDT formulations have the advantage of both conventional tablet formulation and liquid dosage forms. There are several technologies that are conventional or patented based on spray drying, cotton candy process, sublimation, melt granulation, direct compression freezes drying/Lyophilization, phase transition process, mass extrusion, etc. have been developed for manufacturing of FDTs. In this review contain brief information about FDTs including definition, advantages, needs or requirements of FDTs, salient features of FDTs, limitations, marketed formulations of fast dissolving tablets, etc.

Keywords: fast dissolving tablets, superdisintegrants, direct compression, sublimation

Introduction

Patient compliance is one of the most important aspects in the pharmacy practice. Now days, pharmacy companies are coming up with development of new drug delivery systems to ensure the delivery of the drugs to the patients efficiently and with fewer side effects. Solid dosage forms are popular because of ease of administration, accurate dosage, self medication, pain avoidance and most importantly the patient compliance. The oral route of administration is considered as the most widely accepted route because of its convenience of self-medication, compaction, ease of manufacturing, ease of administration, accurate dose, safest and economical route. It is the duty of the health care provider to administer bitter drugs orally with acceptable level of palatability especially with pediatric and geriatric patients. The most evident drawback of the commonly used oral dosage forms like tablets and capsules is swallowing, particularly in case of pediatric and geriatric patients. To fulfill these medical needs, pharmaceutical technologists have developed a novel oral dosage forms known as orally disintegrating tablets (ODTs) or Fast disintegrating tablets (FDTs) or mouth melting tablets (MMTs) or mouth dissolving tablets (MDTs) which disintegrate rapidly in saliva, usually in a matter of seconds, without the need to take water. Drug dissolution and absorption as well as onset of clinical effect and drug bioavailability may be significantly greater than those observed from conventional dosage forms. When such tablets are placed in oral cavity, saliva quickly penetrates into the pores to cause rapid tablet disintegration.

Drug delivery systems (DDS) are a strategic tool for expanding markets, extending product life cycles and generating opportunities. Oral administration is the most popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly, patient compliance. Also solid oral delivery systems do not require sterile conditions and are therefore, less expensive to manufacture. Patient compliance, high-precision dosing, and manufacturing efficiency make tablets the solid dosage form of choice. Excipients and equipments choices will be significantly affected should solid dosage form technologies change in response to the unprecedented shifts in the drug discovery such as genomics. Injections generally are not favored for use by patients unless facilitated by sophisticated auto injectors. Inhalation is one good alternative system to deliver these drugs, but the increased research into biopharmaceuticals so far has generate predominantly chemical entities with low molecular weights. The development of enhanced oral protein delivery technology by Fast dissolving Tablets which may release these drugs in the mouth are very promising for the delivery of high molecular weight protein and peptide. The oral route remains the perfect route for the administration of therapeutic agents because the low cost of therapy, manufacturing and ease of administration lead to high levels of patient compliance [1].

Advantages of FDTS

- Easy administration for patients how are mentally ill, disabled and uncooperative.
- No water needed.
- Can design to live minimal or no residue in mouth.
- It provided a pleasant mouth feel.
- No chewing needed.

- Better taste obtained by taste masking
- Improved stability, low sensitivity environmental condition [2].

Disadvantage
- Drugs with relatively largely doses difficult to formulate into FDT e.g. antibiotic.
- Patients who concurrently take anti cholinergic medication may not be the best candidate for FDTs.
- Patient with shogren's syndrome of dryness of mouth due to decrease saliva production may not be good candidate for this tablet formulation.

Limitations of FDTS
- Patients who concurrently take anti-cholinergic medications may not be the best candidates for FDTs.
- Tablets usually have insufficient mechanical strength. Hence, it requires careful packaging and handling.
- Tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.
- They are more susceptible to degradation by humidity and temperature [1].

Ideal properties of FDTS
- Not require water or other liquid to swallow
- Easily dissolve or disintegrate in saliva within a few seconds.
- Have a pleasing taste.
- Leave negligible or no residue in the mouth when administered.
- Be portable and easy to transport.
- Be able to be manufactured in a simple conventional manner within low cost.
- Be less sensitive to environmental conditions like temperature, humidity etc. [1].

Need for development of FDTS
The need for development of FDTS includes following factors:

1. 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:
- Patients who are unwilling to take solid preparation due to fear of choking.
- An eight-year old with allergies who desires a more convenient dosage form than antihistamine syrup.
- Pediatric and geriatric patients who have difficulty in swallowing or chewing solid dosage forms.
- A middle-aged woman undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2-blocker.

2. Effectiveness Factor
Increased bioavailability and faster onset of action are a major claim of these formulations. Dispersion in saliva in oral cavity causes pregastric absorption from some formulations in those cases where drug dissolves quickly. Buckle, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pregastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo a great deal of hepatic metabolism.

3. Manufacturing and marketing factors
As a drug 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, unique product differentiation, value-added product line extension, and extend patent protection, while offering its patient population a more convenient dosage form. This leads to increased revenue, while also targeting underserved and undertreated patient populations [2].

Formulation aspects in developing FDTS
Orally disintegrating tablets are formulated by utilizing several processes, which differ in their methodologies and the FDTs formed vary in various properties such as:
1. Mechanical strength of tablets
2. Taste and mouth feel
3. Swallow ability
4. Drug dissolution in saliva
5. Bioavailability
6. Stability [3]

Excipient used in fast dissolving tablets
Excipients balance the properties of the actives in fast melting tablets. This demands a thorough understanding of the chemistry of these excipients to prevent interaction with the actives. Determining the cost of these ingredients is another issue that needs to be addressed by formulators. The role of excipients is important in the formulation of fast dissolving tablets. These inactive food-grade ingredients, when incorporated in the formulation, impart the desired organoleptic properties and product efficacy. Excipients are general and can be used for a broad range of actives, except some actives that require masking agents.

Superdisintegrants
Disintegrates are substances routinely included in tablet formulations and in some hard shell capsule formulations to promote moisture penetration and dispersion of the matrix of dosage form in dissolution fluids. An oral solid dosage form should ideally disperse into the primary particles from which it was prepared. Superdisintegrants are generally used at a low concentration, typically 1-10% by weight relative to total weight of dosage unit. Generally employed superdisintegrants are croscarmellose sodium (Ac-Di-Sol), Crospovidone (CP), sodium starch glycolate (SSG) etc. which represent example of crosslinked cellulose, crosslinked polymer and cross linked starch respectively. Selection of appropriate formulation excipients and manufacturing technology is necessary for obtaining the optimized design features of orally disintegrating dosage forms. Ideally, superdisintegrants should cause the tablet to disrupt, not only into the granules from which it was compressed but also into powder particles from which the granules were prepared [4].

Table 1: List of superdisintegrants

Superdisintegrants	Example	Mechanism action	Special comment
Croscarmellose ® Ac-di-sol® Nymce ZSX® Primellose®Solutab® Vivasol® L-HPC	Crosslinked Cellulose	-swells 4-8 folds in <10 second. -swelling and –wicking both.	Swells in two dimension. -direct composition or granulation. -starch free.
Crosspovidone® Crosspovidone M® Kollidon® polyplasdone®	Crosslinked PVP	-swells very little and returns to original size after compression but act by capilliary action.	Water insoluble and spongy in nature so get porous tablet.
Sodium starch glycolate Explotab® Primolgel®	Crosslinked Starch	-swells 7-17 fold in <30 second	Swells in three dimenions and high level serve as sustain Release matrix
Alginic acid NF Satialgine®	Crosslinked Alginnic acid	-rapid swelling in aqueous medium or wicking action.	Promote disintragartion in both dry wet granulation
Soy polysaccharides Emcosoy®	Natural super Disintegrants		-does not contain any sstarch or sugar. used in nutritional product.
Calcium silicate		-wicking action	Highly porous, optimum concentration is between 20-40%.

Selection of superdisintegrants

Although superdisintegrants primarily affect the rate of disintegration, but when used at high levels they can also affect mouth feel, tablet hardness and friability. Hence, various ideal factors to be considered while selecting an appropriate superdisintegrants for a particular formulation should:

- Produce rapid disintegration, when tablet comes in contact with saliva in the mouth/oral cavity.
- Be compactable enough to produce less friable tablets.
- Produce good mouth feel to the patients. Thus, small particle size is preferred to achieve patient compliance.
- Have good flow, since it improves the flow characteristics of total blend. Mechanism ells but does not gel even after long exposure.

Bulking Materials

Contributes functions of a diluents, filler and cost reducer. Bulking agents improve the textural characteristics that in turn enhance the disintegration in the mouth, besides adding bulk also reduces the concentration of the active in the composition. The recommended bulking agents for this delivery system should be more sugar-based such as mannitol, polydextrose, lactitol, DCL (direct compressible lactose) and starch hydrolysate for higher aqueous solubility and good sensory perception.

Lubricants

Lubricants, though not essential excipients, can further assist in making these tablets more palatable after they disintegrate in the mouth. Lubricants remove grittiness and assist in the drug transport mechanism from the mouth down into the stomach.

Flavors and Sweeteners

Flavors and taste-masking agents make the products more palatable and pleasing for patients. The addition of these ingredients assists in overcoming bitterness and undesirable tastes of some active ingredients. Both natural and synthetic flavours can be used to improve the Organoleptic characteristic of fast-melting tablets. Formulators can choose from a wide range of sweeteners including sugar, dextrose and fructose, as well as non-nutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols and sucralose. The addition of sweeteners contributes a pleasant taste as well as bulk to the composition.

Mechanisms of tablet disintegration

- By capillary action (Wicking)
- By swelling
- Because of heat of wetting
- Due to release of gases
- By enzymatic action
- Due to disintegrating particle/particle repulsive forces
- Due to deformation [5].

Techniques for preparing fast dissolving tablets

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

1. Freeze drying/lyophilization
2. Tablet Moulding
3. Spray drying
4. Sublimation
5. Direct compression
6. Mass extrusion

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.

2. Tablet Molding

Molding process is of two types i.e. solvent method and heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). The solvent is then removed by air-drying. The tablets manufactured in this manner are less compact than compressed tablets and posses a porous structure that hastens dissolution. The heat molding process involves preparation of a suspension that contains a drug, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 30○C under vacuum. The mechanical strength of molded tablets is a matter of great concern. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Taste masking is an added problem to this technology.

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

(a) 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 excipient

This is another approach to manufacture ODT by direct compression. The use of sugar based Excipients especially bulking agents like dextrose, fructose, is malt, lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol, which display high aqueous solubility and sweetness, and hence impart taste masking property and a pleasing mouth feel. Mizumito *et al* have classified sugar-based excipients into two types on the basis of molding and dissolution rate.

Type 1 saccharides (lactose and mannitol) exhibit low mould ability but high dissolution rate.

Type 2 saccharides (maltose and maltilol) exhibit high mould ability 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 to coat granules for bitter drugs and thereby achieve taste masking.

7. Cotton candy process

This process is so named as it utilizes an inimitable spinning mechanism to produce floss like crystalline structure, which mimics cotton candy. This technique involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is partially recrystallized to have better flow properties and compressibility. This matrix is milled and blended with active ingredients as well as excipients and subsequently compressed to FDTs.

8. Phase Transition

A novel method to prepare FDTs with sufficient hardness by involving the phase transition of sugar alcohol. In this technique, FDTs are produced by compressing and subsequently heating tablets that contain two sugar alcohols, one with high and other with a low melting point [4, 6, 8, 9].

Evaluation of mouth dissolving tablet

MDTs formulations have to be evaluated for the following evaluation test:

1. Size and Shape

The size and shape of the tablet can be dimensionally described, monitored and controlled.

2. Tablet thickness

Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Some filling equipment utilizes the uniform thickness of the

tablets as counting mechanism. Ten tablets were taken and their thickness was recorded using micrometer.

3. Uniformity of weight

I.P. procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weigh of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity.

Table 2

Average weight of Tablets (mg)	Maximum percentage difference allowed
130 or less	10
130-324	7.5
More than 324	5

4. Tablet hardness

Hardness of tablet is defined as the force applied across the diameter of the tablet in the order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. Hardness of the tablet of each formulation was determined using Monsanto Hardness tester.

5. Friability

It is measured of mechanical strength of tablets. Roche friabilator was used to determine the friability by following procedure. A pre weighed tablet was placed in the friabilator. Friabilator consist of a plastic-chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets were rotated in the friabilator for at least 4 minutes. At the end of test tablets were dusted and reweighed, the loss in the weight of tablet is the measure of friability and is expressed in percentage as;

%Friability = loss in weight / Initial weight x 100

6. *In-vivo* Disintegration test

The test was carried out on 6 tablets using the apparatus specified in I.P.-1996 distilled water at 37°C ± 2°C was used as a disintegration media and the time in second is taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds.

7. Wetting time

The method reported by Yunixia *et al*., was followed to measure tablet wetting time. A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in a small Petridish (ID =6.5 cm) containing 6 ml of Sorenson's buffer pH 6.8. A tablet was put on the paper, and the time for complete wetting was measured. Three trials for each batch and the standard deviation were also determined.

8. *In vitro* dispersion time

In vitro dispersion time was measured by dropping a tablet in a beaker containing 50 ml of Sorenson's buffer pH 6.8.Three tablets from each formulation were randomly selected and *in vitro* dispersion time was performed [4, 7].

Important patented technologies for fast dissolving 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.

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 tableting equipment and have good rigidity. These can be packaged into conventional packaging system like blisters. Durasolv is anappropriate 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 produce dare soft and friable.

4. Flash dose technology

Flash dose technology has been patented by fuisz. Nurofen meltlet, a new form of ibuprofen as melt in mouth tablets prepared using flash dose technology is the first commercial product launched by biovail corporation. Flash dose tablets consist of self-binding shear form matrixtermed 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 mould ability saccharides and high mould ability saccharide is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mould ability saccharide (e.g. lactose, glucose, and mannitol) and granulated with a high mould ability saccharide (e.g. Maltose, oligosaccharides) and compressed into table.

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 maybe prepared by using the conventional techniques like coacervation, micro encapsulation and extrusion spheronisation. All the processing utilized conventional tableting technology [7, 8, 10].

Table 3: List of commercially available fast dissolving tablets

Trade Name	Active Drug	Manufacturer
Felden fast melt	Piroxicam	Pfiser Inc., NY, USA
Claritin redi Tab	Loratidine	Schering plough Corp., USA
Maxalt MLT	Rizatriptan	Merck and Co., NJ, USA
Zyprexia	Olanzapine	Eli lilly, Indianapolis, USA
Pepcid RPD	Famotidine	Merck and Co., NJ, USA
Zofran ODT	Ondansetron	Glaxo Wellcome, Middlesex, UK
Zoming-ZMT	Zolmitriptan	AstraZeneca, Wilmington, USA
Zeplar TM	Selegilline	Amarin Corp., London, UK
Tempra Quiclets	Acetaminophen	Bristol myers Squibb, NY, USA
Febrectol	Paracetamol	Prographarm, Chateauneuf, France
Nimulid MDT	Nimesulide	Panacea Biotech, New Delhi, India
Torrox MT	Rofecoxib	Torrent pharmaceuticals, India
Olanex instab	Olanzapine	Ranbaxy lab. Ltd. New-Delhi, India
Romilast	Montelukast	Ranbaxy lab. Ltd. New-Delhi, India
Benadryl Fastmelt	Diphenhydramine	Warner Lambert, NY, USA

Future Prospects

There are several biopharmaceutical advantages such as improved efficiency over conventional dosage forms for Fast disintegrating tablets. For example, they require smaller amounts of active ingredient to be effective, improve absorption profiles, and offer better drug bioavailability than regular tablets and capsules. There are still many aspects to improve in the FDT formulations. The disintegration times of most FDTs on the market are acceptable i.e., less than 60 seconds but certainly there is a room for improvement. Because the disintegration time is related to other formulation variables, a balance has to be maintained between shortening the disintegration time and other tablet properties. The tablet hardness, friability, and stability can be further improved to such a level that multi-tablet packaging in conventional bottles becomes a norm. The future of FDTs lies in the development of FDTs with controlled release properties. Despite advances in the FDT technologies, formulation of hydrophobic drugs is still a challenge, especially when the amount of drug is high. The low dose drugs, such as Loratadine with 10 mg dose, pose little problem, but as the dose increases, the formulation sacrifices its fast disintegrating property. A new technology is being developed to incorporate higher doses of hydrophobic drugs without affecting the fast disintegrating property too severely. If one FDT can deliver drugs with short half-lives for 12-24 hours, it would be a quantum improvement in the FDT technology. The added convenience and compliance of such formulations would be enormous An FDT formulation that would require fewer excipients than the drug itself would be a break through. While the problems to be solved are not easy, the history suggests that it is just a matter of time before they are solved. The safety and efficacy profile of drugs in orodispersible tablet is same like their conventional tablet dosage form. Based on conventional techniques, new techniques are developed like Zydis, Wow Tab, Flash tab technology and many more, which leads to getting a patent and new mark [11, 12].

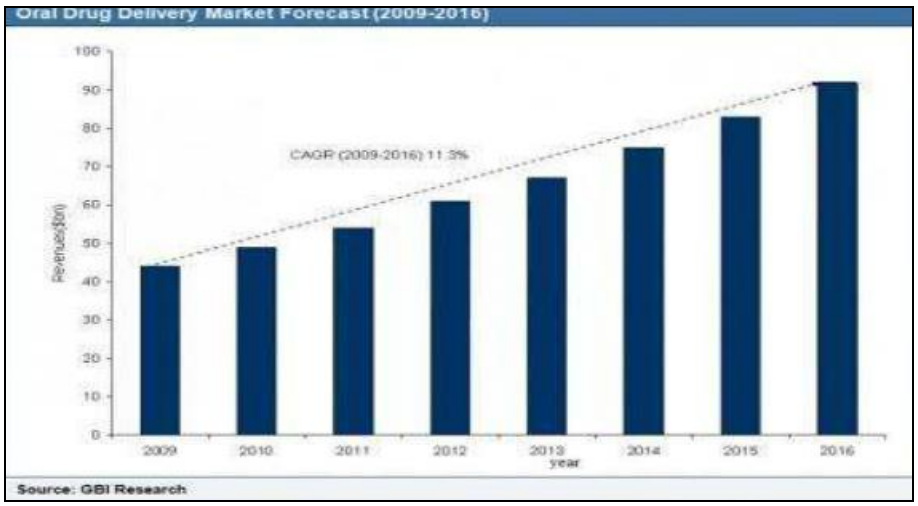

Fig 1: Oral drug delivery system market forecast (2009-2016)

Conclusion

The MDTs have potential advantages over conventional dosage forms, with their improved patient compliance, convenience, bioavailability and rapid onset of action had drawn the attention of many manufactures over a decade. MDTs formulations obtained by some of these technologies have sufficient mechanical strength, quick disintegration/ dissolution in the mouth without water. The pediatric and

geriatric populations are the primary, targets, as both the groups found it difficult to swallow conventional tablets. The basic approach followed by all the currently available technologies engaged in the formulation of Fast dissolving tablets is to maximize the porous structure of the tablet matrix and incorporate super disintegrating agents in optimum concentration so as to achieve rapid disintegration and instantaneous dissolution of the tablet along with good taste masking properties and excellent mechanical strength The availability of the various technologies and manifold advantages of Fast dissolving tablets will surely increase its popularity in the near future.

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