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A Review on Orodispersible Tablets – As a Novel Formulation for Oral Drug Delivery Systems

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ABSTRACT:

Oral route is presently the gold standard in the pharmaceutical industry where it is regarded as the safest, most economical and most convenient method of drug delivery resulting in highest patient compliance. Recent advances in novel drug delivery (NDDS) aims to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for ease of administration and to achieve better patient compliance. One such approach is orodispersible tablets (ODTs). ODTs are a solid unit dosage form, which disintegrates or dissolves rapidly in the mouth without the general requirement for swallowing, the chewing and water. Yet, dysphasia is the most common disadvantage of conventional tablets. To overcome such problems, certain innovative drug delivery systems, like 'Orodispersible Tablets' (ODT) have been developed. The aim of this article is to review the ideal properties, significance, characteristics, choice of drug candidates, challenges in formulation, various technologies for preparation of ODTs, Patented technologies on ODTs, and Suitable drug candidates for ODTs, Evaluation tests of ODTs and Marketed product of ODTs.

KEY WORDS: Orodispersible tablets, patented technologies, OTS, Novel drug delivery

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INTRODUCTION:

Oral route of drug administration is perhaps most useful and important route for drug delivery. Tablets are the most favored oral solid dosage form mainly because of several advantages like,

- Ease of administration
- Good chemical and microbiological stability
- Easy to swallowing
- Lowest cost among all other solid dosage form
- Dose precision and least content variability
- Ease of packing
- Self –medication
- Patient compliance

In fact, it is more popular dosage form and almost 70% of medicines are dispensed in tablet form.[1]

Drug Delivery Systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. DDS make a significant contribution to global pharmaceutical sales through market segmentation, and are moving rapidly. Drug delivery systems are becoming increasingly sophisticated as pharmaceutical scientists acquire a better understanding of the physicochemical and biochemical parameters pertinent to

their performance.[2] The oral route of administration still continues to be the most preferred route due to its diverse advantages including ease of administration, precise dosage, self-medication, versatility and most importantly patient compliance. Therefore, oral solid dosage forms are more popular. ODT are a solid single-unit dosage form that are placed in mouth, allowed to disperse/dissolve in the saliva without the need of water and provides a quick onset of action. Some drugs are absorbed from mouth, pharynx and oesophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is significantly greater than those observed from conventional tablet dosage form.[3]

Orodispersible tablets are also called as orally disintegrating tablets, mouth-dissolving tablets, rapid dissolving tablets, fast-disintegrating tablets, fast-dissolving tablets. Recently, European Pharmacopoeia has used the term orodispersible tablets. This may be defined as uncoated tablets intended to be placed in the mouth where they disperse readily within 3 min before swallowing. The United States Pharmacopoeia has also approved these dosage forms as orodispersible tablets. Thus, orodispersible tablets are solid unit dosage forms like conventional tablets, but are composed of super disintegrants, which help them to dissolve the tablets within a minute in the mouth in the presence of saliva without any difficulty of swallowing.

When put in the mouth, these dosage forms disintegrate instantly to release the drug, which dissolves or disperses in the saliva. Thereafter, the drug may get absorbed from the pharynx and oesophagus or from other sections of GIT as the saliva travels down. In such cases, bioavailability is significantly greater than that observed from conventional tablet dosage form. The performance of ODTs depends on the technology used in their manufacture. The orally disintegrating property of these tablets is attributable to the quick ingress of water into the tablet matrix, which creates porous structure and results in rapid disintegration. Hence, the basic approaches to develop ODTs include maximizing the porous structure of the tablet matrix, incorporating the appropriate disintegrating agent and using highly water-soluble excipients in the formulation.[4]

Food and Drug Administration of United States defined ODT as: “A solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly usually within a second when placed upon the tongue”. The disintegration time for ODTs generally ranges from several seconds to about a minute.[5]

ORODISPERSIBLE TABLET (ODT)

ORODISPERSIBLE TABLET (ODT)

It is a tablet that disintegrates and dissolves rapidly in the saliva, within a few seconds without the need of drinking water or chewing. A mouth dissolving tablet usually dissolves in the oral cavity within 15 s to 3 min. Most of the MDTs include certain super disintegrants and taste masking agents. Orally disintegrating tablets are also called as

- Oro dispersible tablets
- Quick disintegrating tablets
- Mouth dissolving tablets
- Fast disintegrating tablets
- Fast dissolving tablets
- Rapid dissolving tablets
- Porous tablets
- Rapid melts

However, of all the above terms, United States pharmacopoeia (USP) approved these dosage forms as ODTs.[6,7]

IDEAL PROPERTIES OF ODTS

- The performance of ODTs depends on the technology used during their manufacture.
- The necessary property of such tablets is the ability to disintegrate rapidly and disperse or dissolve in saliva, thereby obviating the need for water.
- Various technologies have been developed that enable ODT to perform this unique function.

An ideal ODT should meet the following criteria:

- does not require water for oral administration yet disintegrates and dissolves in oral cavity within a few seconds
- has sufficient strength to withstand the rigors of the manufacturing process and post manufacturing handling allow high drug loading
- has a pleasant mouth feel
- is insensitive to environmental conditions such as humidity and temperature
- is adaptable and amenable to existing processing and packaging machineries
- cost effective[8,9,10,11]

ADVANTAGES OF ORODISPERSIBLE DRUG DELIVERY SYSTEM

• Improved compliance/added convenience

•Ease administration for patients who are mentally ill, disable and uncooperative

• No water needed

•Can be designed to leave minimal or no residue in mouth after a dministration and also to

provide a pleasant mouth feel

• Better taste obtained by taste masking

•Improved stability, low sensitivity to environmental condition

• Suitable for controlled/sustained release actives

• Allows high drug loading.

•Ability to provide advantages of liquid medication in the form of solid preparation.

•Adaptable and amenable to existing processing and pack aging high speed machinery.

•Costeffective**,** lower production, packaging and distribution c osts compared to current commercially available products.

•The technology is versatile and suitable for the development of enhanced products for veterinary medicines, OTC, Rx medicines & line extensions.

•The new proprietary method allows the incorporation of microencapsulated drugs for enhanced bioavailability, flexib ility of dosing & immediate and/or controlled release.

• For superior therapeutic benefit**.**[12-15]

DISADVANTAGE

- Fast dissolving tablet is hygroscopic in nature so must be keep in dry place.
- ODT requires special packaging for properly stabilization & safety of stable product.

THE NEED FOR DEVELOPMENT OF ODTS

The need for non-invasive delivery systems persists due to patients' poor acceptance of, and compliance with, existing delivery regimes, limited market size for drug companies and drug uses, coupled with high cost of disease management.

PATIENT FACTORS

Orally 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:

- Pediatric and geriatric patients who have difficulty in swallowing or chewing solid dosage forms
- Patients who are unwilling to take solid preparation due to fear of choking
- Very elderly patients who may not be able to swallow a daily dose of antidepressant.
- An eight-year old with allergies who desires a more convenient dosage form than antihistamine syrup
- A middle-aged woman undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2-blocker
- A schizophrenic patient in an institutional setting who may try to hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic
- A patient with persistent nausea, who may be journey, or has little or no access to water

EFFECTIVENESS FACTORS

- 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. Buccal, 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.
- Furthermore, safety profiles may be improved for drugs that produce significant amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism, and for drugs that have a substantial fraction of absorption in the oral cavity and pregastric segments of GIT**.**

MANUFACTURING AND MARKETING FACTORS

- Developing new drug delivery technologies and utilizing them in product development is critical for pharmaceutical industries to survive, regardless of their size.
- 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 under-treated patient populations
- As examples, Eisai Inc. launched Aricept ODT, a line extension of donepezil for Alzheimer's disease, in Japan in 2004 and in the U.S. in 2005 in response to a generic

challenge filed in the U.S. by Ranbaxy. Merck's Japanese subsidiary launched Lipola M (simvastatin ODT), a line extension of its blockbuster, Zocor®, a cholesterol-lowering drug, in response to seventeen generic registrations of simvastatin applied for in Japan in 2004

- Marketers build a better brand and company image when they offer a unique easier-to-take form that satisfies the need of an underserved patient population.[9-12,16]

CHALLENGES IN FORMULATION OF ODTs[17]

1. DISINTEGRATION TIME AND MECHANICAL STENGTH

ODTs are formulated to obtain disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge. Many ODTs are fragile and there are chances that such fragile tablet will break during packing, transport or handling by the patients. Tablets based on technologies like Zydis need special type of packaging. It is very natural that increasing the mechanical strength will delay the disintegration time. So a good compromise between these two parameters is always essential.

2. TASTE MASKING:

Many drugs are bitter in taste. A tablet of bitter drug dissolving/ disintegration in mouth will seriously affect patient compliance and acceptance for the dosage form. 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. Number of techniques are developed for masking the bitter taste of most of the drugs, that includes formation of pellets by extrusion, spheronization or mass extrusion, coating of drug using a taste masking polymer , spray drying the drug dispersed in a polymeric solution, complexation of drug by inclusion in cyclodextrin, drug-resinate complex formation, microencapsulation of drug by polymer enhanced solubility of carvidiol by ß- cyclodextrin as a complexing agent. Solubility studies were Chandira R.M et al.performed to investigate the drug carrier interaction. I.R. and D.S.C studies carried out to investigate any interaction and stability of formulation. Tablets were prepared by direct compression technique. Prepared tablets were evaluated for thickness, uniformity of weight, hardness, friability, wetting time, in-vitro disintegration time, drug content and in vitro drug release. It can be concluded that Carvedilol can be successfully complexed with Beta-cyclodextrin to preparefast dissolving tablets in the ratio of 1: 4 .

2. SENSITIVITY TO ENVIRONMENTAL CONDITIONS:

ODTs generally should exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in ODTs are meant to dissolve in minimum quantity of water.

4. MOUTH FEEL:

ODTs should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the ODTs should be as small as possible. ODTs should leave minimal or no residue in mouth after oral administration. Moreover addition of flavours and cooling agents like menthol improve the mouth feel.

5. COST:

The technology used for ODTs should be acceptable in terms of cost of the final product. Methods like Zydis and Orasolv that require special technologies and specific packaging increase the cost to a remarkable extent.

TECHNOLOGIES USED TO MANUFACTURE ORODISPERSIBLE TABLETS CAN BE CLASSIFIED AS

TECHNOLOGIES	
CONVENTIONAL TECHNOLOGIES	**PATENTED TECHNOLOGIES**
i. Freeze Drying.	i. Zydis Technology.
ii. Tablet Molding.	ii. Durasolv Technology.
iii. Sublimation	iii. Orasolv Technology.
iv. Spray Drying.	iv. Flashdose Technology.
v. Mass extrusion.	v. Wowtab Technology.
vi. Direct Compression	vi. Flashtab Technology.
	vii. Sheaform Technology

LYOPHILIZATION OR FREEZE-DRYING

Formation of porous product in freeze-drying process is exploited in formulating ODT. Lyophilization is a process, which includes the removal of solvent from a frozen suspension or solution of drug with structure-forming additives. Freeze-drying of drug along with additives imparts glossy amorphous structure resulting in highly porous and lightweight product. The resulting tablet has rapid disintegration and dissolution when placed on the tongue and the freezedried unit dissolves instantly to release the drug. However, the ODTs formed by lyophilization have low mechanical strength, poor stability at higher temperature, and humidity.

MOLDING

Molding process includes moistening, dissolving, or dispersing the drug with a solvent then molding the moist mixture into

tablets (compression molding with lower pressure than conventional tablet compression), evaporating the solvent from drug solution, or suspension at ambient pressure (no vacuum lyophilization), respectively . The molded tablets formed by compression molding are air-dried. As the compression force employed is lower than conventional tablets, the molded tablet results in highly porous structure, which increases the disintegration and dissolution rate of the product. Molding process is employed usually with soluble ingredients (saccharides) which offer improved mouth feel and disintegration of tablets.However, molded tablets have low mechanical strength, which results in erosion and breakage during handling.

COTTON CANDY PROCESS

This process is so named as it utilizes a unique spinning mechanism to produce floss-like crystalline structure, which mimic cotton candy. Cotton candy process involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is partially recrystallized to have improved flow properties and compressibility This candy floss matrix is then milled and blended with active ingredients and excipients and subsequently compressed to ODT. This process can accommodate high doses of drug and offers improved mechanical strength. However, high-process temperature limits the use of this process.

SPRAY DRYING

Highly porous, fine powders are obtained by this method. Allen et al. utilized this process for preparing ODT. The ODT formulations consisted of hydrolyzed/unhydrolyzed gelatin as supporting agent for matrix, mannitol as bulking agent, and sodium starch glycolate or cross carmellose sodium as disintegrating agent. Disintegration and dissolution were further improved by adding effervescent components, i.e. citric acid (an acid) and sodium bicarbonate (an alkali). The formulation was spray dried to yield a porous powder.The ODT made from this method disintegrated in <20 s.[18-23]

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 tablets.

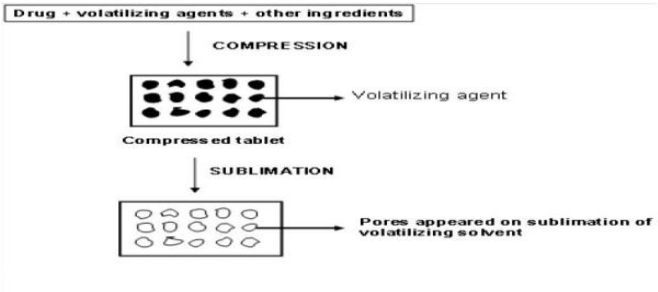
MELT GRANULATION

Abdelbary et al. prepared ODT by incorporating a hydrophilic waxy binder (super polystate) PEG- 6stearate. Superpolystate is a waxy material with an M.P of 33-37°C and a hydrophilic lipophilic balance of 9. It not only acts as a binder and increases the physical resistance of tablets, but also helps the disintegration of tablets as it melts in the mouth and solubilizes rapidly leaving no residue.[24,25]

PHASE TRANSITION PROCESS

Investigated the disintegration of ODT by phase transition of sugar alcohols using erythritol (m.p. 122°C),xylitol (m.p. 93-95°C), trehalose (97°C), and mannitol (166°C). Tablets were produced by compressing a powder containing two sugar alcohols with high- and lowmelting points and subsequent heating at a temperature between their melting points. Before heating process, the tablets do not have sufficient hardness because of low compatibility. The tablet hardnes was increased after heating process, due to the increase of inter particle bonds or the bonding surface area in tablets induced by phase transition of lower melting point sugar alcohol. [26

SUBLIMATION



The presence of a highly porous structure in the tablet matrix is the key factor for rapid disintegration of ODT. Even though the conventional tablets contain highly water-soluble ingredients, they often fail to disintegrate rapidly because of low porosity. To improve the porosity, volatile substances such as camphor can be used in tableting process, which sublimated from the formed tablet. Koizumi *et al.* developed ODT utilizing camphor; a subliming material that is removed from compressed tablets prepared using a mixture of mannitol and camphor. Camphor was sublimated in vacuum at 80°C for 30 min after preparation of tablets.[27]

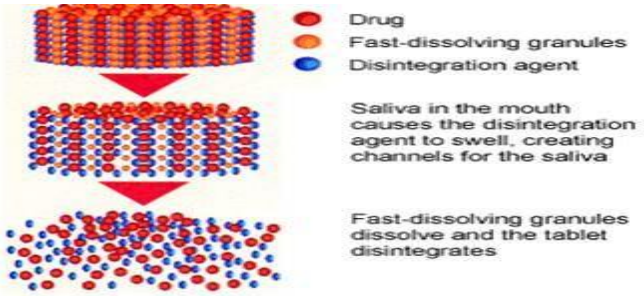
DIRECT COMPRESSION

Direct compression represents the simplest and most cost effective tablet manufacturing technique. This technique can now be applied to:

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. For the success of fast dissolving tablet, the tablet having quick dissolving property which is achieved by using the superdisintegrants.



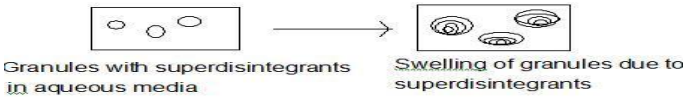
BASIC MECHANISM OF SUPER DISINTEGRANTS.

MECHANISMS OF SUPERDISINTEGRANTS

There are four major mechanisms for tablet disintegration as follows:

1) SWELLING

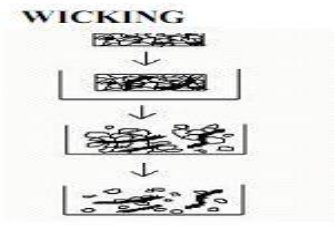
Although not all effective disintegrants swell in contact with water, swelling is believed to be a mechanism in which certain disintegrating agents (such as starch) impart the disintegrating effect. By swelling in contact with water, the adhesiveness of other ingredients in a tablet is overcome causing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



MECHANISM OF SUPERDISINTEGRANTS BY SWELLING

2) POROSITY AND CAPILLARY ACTION (WICKING):

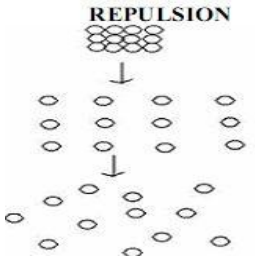
Tablet in the aq. Media leads to penetration of the medium into tablet and thus replacement of air adsorbed resulting in weakening of intermolecular bond and breaking of tablet into fine particles.



MECHANISM OF SUPERDISINTEGRANTS BY POROSITY AND CAPILLARY ACTION (WICKING)

3) DUE TO PARTICLE-PARTICLE REPULSIVE FORCES:

The electric repulsive forces b/w particles responsible for disintegration. It is secondary to wicking.



4) DUE TO DEFORMATION:

During tab. compression, disintegrated particles gets deformed and in contact with aq. media returns to normal structure(inc. in size).Eg: starch.

b) SUGAR BASED EXCIPIENTS:

This is another approach to manufacture ODT by direct compression. The use of sugar based excipients especially bulking agents like dextrose, fructose, isomalt, lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol, which display high aqueous solubility and sweetness, and hence impart taste masking property and a pleasing mouthfeel.

Advantages-: It is cost effective due to low manufacturing cost, conventional equipments and limited number of processing steps.

Disadvantages-: Differences in particle size and bulk density b/w the drug and diluents may lead to stratification within the granulation. Large dose may present problem if it is not easily compressible by itself. [29,30,31,32]

EVALUATION PARAMETER OF ORODISPERSIBLE TABLETS

WEIGHT VARIATION TEST

To study weight variation, 20 tablets of each formulation were weighed using an electronic balance and test was performed according to Indian Pharmacopoeia.

CRUSHING STRENGTH

It is the force required to break a tablet by compression in the radial direction. In the present study the crushing strength of the tablet was measured on the day of compression, using Monsanto hardness tester. An average of three observations is reported.[44]

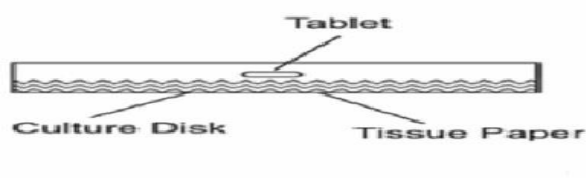
FRIABILITY TESTING

The crushing strength test may not be the best measure of potential behavior during handling and packaging. The resistance to surface abrasion may be a more relevant parameter. The measurement is based on tablet weight loss, expressed as a percentage, after certain numbers of revolutions in the Roche Friabilator. A low friability value represents better tablet strength. Friability of each batch was measured in the Roche Friabilator. Ten pre-weighed tablets were rotated at 25 rpm for 4 min. The tablets were then re-weighed and the percentage of weight loss was calculated.

F= Finalweight – Initialweight/ Initialweight×100

SIMULATED WETTING TIME

Wetting time of dosage form is related with the contact angle. Wetting time of the MDT is an important parameter, which needs to be assessed to give an insight into the disintegration properties of the tablet. Lower wetting time implies a quicker disintegration of the tablet. A piece of tissue paper folded twice was placed in a Petri dish with 10 cm diameter. Ten ml of water (containing water soluble dye Eosin) was added to the Petri dish. A tablet was placed on the surface of the tissue paper. The time required for complete wetting wasmeasured as the wetting time.[33]



SIMULATED WETTING TIME MEASUREMENT

***IN-VITRO* DISINTEGRATION TIME**

The assessment of the in vitro disintegration profile of ODT is very important in the evaluation and the development of such formulations. So far neither the US Pharmacopoeia nor the European Pharmacopoeia has defined a specific disintegration test for ODT. Currently, it is only possible to refer to the tests on dispersible or effervescent tablets for the evaluation of ODTs disintegration capacity. The disintegration test for ODT should

mimic disintegration in mouth with in salivary contents. One tablet was placed in a beaker/ Petridis (10 cm diameter) containing 10 ml of pH 6.8 phosphate buffer at 37 ± 0.5 °C. The time required for complete dispersion of the tablet was measured. This method embraces physiological conditions of the oral cavity, as a screening tool for developing ODT products.

IN-VITRO DRUG RELEASE

The development of dissolution methods for ODTs is comparable to the approach taken for conventional tablets, and is practically identical. Dissolution conditions for drugs listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent ODT. Other media such as 0.1N HCl and buffers (pH - 4.5 and 6.8) should be evaluated for ODT much in the same way as their ordinary tablet counter parts. The USP 2 Paddle apparatus is used for this purpose which is the most suitable and common choice for orally

disintegrating tablets, with a paddle speed of 50 rpm commonly used. Typically the dissolution of ODT is very fast when using USP monograph conditions; hence slower paddle speeds may be utilized to obtain a profile. The USP 1 Basket apparatus may have certain applications but sometimes tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle where little or no effective stirring occurs, yielding irreproducible dissolution profiles.

STABILITY STUDY (TEMPERATURE DEPENDENT)

The fast dissolving tablets stored under the following conditions for a period as prescribed by ICH guidelines for accelerated studies.

i.40 ± 1°C
ii.50 ± 1°C
iii.37 ±1°C and RH 75% ± 5%

The tablets were withdrawn after a period of 15 days and analyzed for physical characterization such as visual defects, Hardness, Friability, Disintegrations, and Dissolution etc. The data obtained is fitted into first order equations to determine the kinetics of degradation. Accelerated stability data are plotting according Arrhenius equation to determine the shelf life at 25°C.[34]

A PROMISING FUTURE

The tablet is the most widely utilised oral dose format. A nove l tablet concept which offers ease of oral administration and b enefits of increased patient compliance is the ODT. A number of ODT are commercially available for human use using techno logies developed by pharmaceutical companies such as Car dinal Healthcare, Jannsen Pharmaceutical, Bioavail, and Eur and, Yamanouchi. However, these technologies use either expensive processing technology producing fragile tablets that require costly specialised packaging or use conventional

tableting procedures which give longer than desired disinte gration & still require specialised packaging. Dr Zeibun Ra mtoola and her team at the Royal College of Surgeons in Ireland have addressed the above shortcomings by develop ing a novel, cost effective one step ODT manufacturing pr ocess using conventional tableting technology for the produc tion of robust tablets suitable for conventional packaging.

ODT technologies entered the market in the 1980s, they have grown steadily in demand and importance, and their product p ipeline is rapidly expanding. In 2004, ODT products generated revenues of well over $2 billion, an increase of 20% over 2003, according to a 2005 report by Technology Catalysts I nternational.[35,36]

CONCLUSION

The techniques and technologies described in this article represent how recent advances in formulation development and processing technologies make the efforts to achieve orodispersible tablets. ODTs have better patient acceptance and compliance and may offer improved biopharmaceutical properties, improved efficacy, and to provide the patients with the most conventional mode of administration, there was a need to develop rapidly disintegrating dosage form, particularly one that disintegrates and dissolve/disperse in saliva and can be administered without need of water. The basic approach followed by all the available ODTs technologies is to maximize the porous structure of tablet matrix to achieve rapid tablet disintegration in the oral cavity along with good taste-masking properties and excellent mechanical strength.

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