A REVIEW ARTICLE ON ORODISPERSIBLE TABLETS

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ABSTRACT

The common and preferred route of drug administration is through the oral route. Orodispersible tablets are gaining importance among novel oral drug-delivery systems as they have improved patient compliance and advantages compared to other oral formulation. They are also solid unit dosage forms which disintegrate in the mouth within a minute in the presence of saliva due to super disintegrates in the formulation. Thus this type of drug delivery helps a proper per oral administration in pediatric and geriatric population where swallowing is the problem. Various researchers have prepared orodispersible tablets by following various methods. However, the most common method of preparation is the compression method. Other methods are molding, melt granulation, phase-transition process, sublimation, freeze-drying, spray-drying, and effervescent method. Since these tablets dissolve directly in the mouth, so, their taste is also an important factor. Various approaches have been considered in order to mask the bitter taste of the drug. A number of scientists have explored several drugs in this field. Like all other solid dosage forms, they are also evaluated for the hardness, friability, wetting time, moisture uptake, disintegration test, and dissolution test.

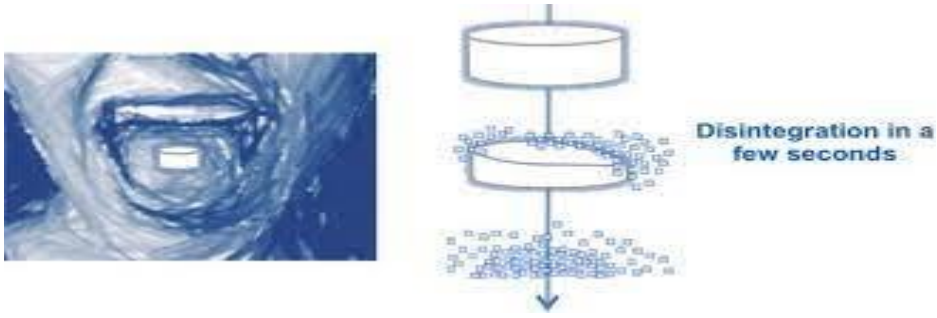
KEYWORDS

0ral disintegrating tablets, Fast dissolving tablets, MOA of superdisintergrants, Patent technology, Evalutions.

INTRODUCTION

Direct ingestion is intended in most pharmaceutical dosage forms which are formulated for oral administration. The oral route is the best or convenient way of drug administration for patients and this way is used by most of the therapeutic agents for producing effects of the oral route. A term used by the "European Pharmacopoeia" orodispersible tablet, this table disperses in the mouth within 3 seconds before swallowing it. The orodispersible tablets also called "ODTs" and it is quickly disintegrating tablet or it dissolves in the mouth quickly because it is a mouth dissolving tablet and also a fast responding tablet with porous and rapid melting nature. Freezing & drying, tablet molding, spray drying, mass extrusion, sublimation, and direct compression are the conventional methods that are used for the preparation of orally disintegrating tablets. ODTs response time is very fast & its disintegration time is few seconds to a minute and according to the United States, Food and Drug Administration (FDA) ODTs is a Solid form substance having active ingredient & medicinal substance which dissolve in a mouth fastly when placed on a tongue in a few seconds. Because, when bioavailability in comparison to conventional dosage form due to this tablet getting dispersed or disintegrated. The hydrophilic nature excipients are used in ODT technology and it ODTs come in contact with saliva it releases active drugs that provide maximum drug is selected on the basis of drug physicochemical property mainly hydrophilicity or hydrophobicity. In saliva, the active agent dissolves rapidly and no matter whatever membrane encounter, unless it is protected by pre-gastric absorption and the current review is aimed to study present development of ODT technology and sustainability of drug candidates and their characterization of ODT.

Figure:1 Disintegration in a few seconds



Ideal Properties of Orodispersible tablets

Orodispersible tablets,

1. Does not require water or substitute liquid to swallow.
2. Rapidly dissolves and disintegrates in saliva within a matter of seconds.
3. Have a pleasant taste and mouth feel.
4. Easily transportable and mobile.
5. Leave no/negligible residue in the mouth after administration.

6. Be able to manufacture in a simple conventional way with low cost.
7. Withstand environmental conditions like humidity.

OBJECTIVE

1. To improve patient compliance
2. To increase bioavailability
3. To enhance stability
4. To test masking
5. To hormone adjusting blood glucose level.

Limitations of Orodispersible Tablets (Odts)

- Many times the soluble diluents used for formulating the ODTs might give hygroscopic
- dosage which may lead to stability issues
- The tablets are unpleasant to taste and/or roughness in the mouth if not formulated
- properly
- Specialized packing might be required for hygroscopic and light-sensitive drugs.
- Precautions to be taken while administering immediately after removing from the pack.
- Light sensitive drugs, ODTs may not be suitable as no option for film coating

Advantages of Formulating Orodispersible Tablets

The benefits of Orodispersible tablets include the ease with which it may be given to individuals who have trouble swallowing, such as the elderly, stroke patients, and children. ODTs provide most of the characteristics of solid dosage forms, including good stability, consistent dosing, ease of manufacture, small container size, and ease of handling by patients. ODTs benefit from liquid formulations, like the ease of administration and minimal danger of asphyxia due to a dosage form's physical blockage. Since people travelling have limited access to water, this promotes compliance among chronic patients Drugs with a pleasant mouth taste may help reinforce psychological beliefs about medicine. The administration is simple for both young and elderly individuals. Drug absorption from the pre-gastric regions of the GIT is faster and more efficient, enhancing bioavailability and effectiveness. Since only a few components are required, the cost is kept to a minimum; dispense dissolved or dispersed medication in the solid dosage form.

Disadvantages of Orodispersible Tablets

The mechanical strength of the tablets is generally insufficient. As a result, it needs special packaging and handling process. Another drawback is that ODT may leave an unpleasant taste and grittiness on the tongue if not correctly prepared. Difficulties generating massive dosages (usually greater than 500 mg) and substantial taste masking of bitter-tasting.

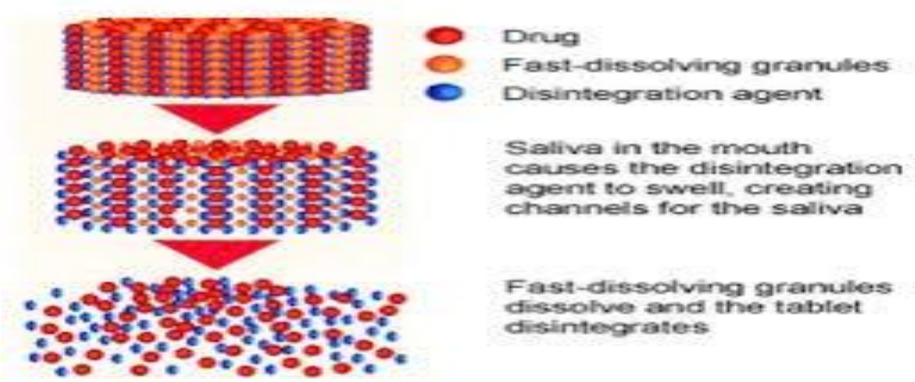
Historical Development of Oro-dispersible Tablets

Absorption and many have similar absorption and bioavailability to standard oral dosage forms with the primary route remaining GI absorption. However, a fast disintegration time and a small tablet weight can enhance absorption in the buccal area. The first ODTs disintegrated through effervescence rather than dissolution, and were designed to make taking vitamins more pleasant for children .This method was adapted to pharmaceutical use with the invention of microparticles containing a drug, which would be released upon Tablets designed to dissolve on the buccal (cheek) mucous membrane were a precursor to the ODT .This dosage form was intended for drugs that yield low bioavailability through the digestive tract but are inconvenient to administer parenterally, such as steroids and some narcotic analgesics Absorption through the cheek allows the drug to bypass the digestive tract for rapid systemic distribution. Not all ODTs have buccal effervescence of the tablet and swallowed by the patient Dissolution became more effective than effervescence through improved manufacturing processes and ingredients (such as the addition of mannitol to increase binding and decrease dissolution time. Catalan Pharma Solutions (formerly Scherer DDS) in the U.K., Cima Labs in the U.S. and Takeda Pharmaceutical Company in Japan led the development of ODTs. The first ODT form of a drug to get approval from the U.S. Food and Drug Administration(FDA) was a Zydis ODT formation of Claritin (loratadine) in December 1996. It was followed by a Zydis ODT formulation of Klonopin (clonazepam) in December 1997, and a Zydis ODT formulation of Maxalt (rizatriptan) in June 1998. FDA guidance issued in Dec 2008 is that ODT drugs should disintegrate in less than 30 seconds. This practice is under review by the FDA as the fast disintegration time of ODTs makes the Disintegration test too rigorousfor some of the ODT formulations that are commercially in the market.

Superdisintergrants:

Disintegrating agents overpower the cohesive strength provided during compression, thereby helping to dissolve the tablet and increasing the surface area for dissolution.Several newer agents have been synthesized that are more efficient at lower concentrations with greater mechanical strength and disintegrating efficiency. These agents are called 'Superdisintegrants'. Superdisintegrants play a major role in achieving the desired rapid melt / oral disintegration of tablets.

Figure 2 superdisintergrants granules



Superdisintegrants are classified into two categories,

Natural Superdisintegrants:

Examples: Plantago ovata seed mucilage, Lepidium sativum mucilage, Gum Karaya, Guar gum, Gellan gum, Xanthan gum, Cassia fistula gum, Fenugreek seed mucilage, Mango peel pectin, Agar and treated agar etc.

Synthetic Superdisintegrants:

Examples: croscarmellose sodium (Ac-Di-Sol) sodium starch glycolate (Primogel and Explotab) and crospovidone (Polyplasdone XL) etc.

Ideal properties of Superdisintegrants

1. Poor solubility.
2. Poor gel formation.
3. Good flow properties and mould capabilities.
4. No propensity for the drugs to form complexes.
5. Possess a good mouth feel.
6. Compatible with other excipients and have desirable properties in tableting.

Mechanism of Superdisintegrants.

Superdisintegrants acts in four major ways they are as follows,

Figure 3 Mechanism of superdisintegrants

Swelling:

While not all effective disintegrating agents swell in interaction with water, swelling is known to be a process in which some disintegrating agents (such as starch) trigger disintegrating results. By swelling in contact with water, the adhesion to other materials in a tablet is resolved, allowing the tablet to break apart.

Porosity and capillary action (wicking):

The tablet in the aqueous media contributes to the penetration of the medium into the tablet and hence to the replacement of the adsorbed air resulting in the degradation of the intermolecular bond and the rupture of the tablet into fine particles.

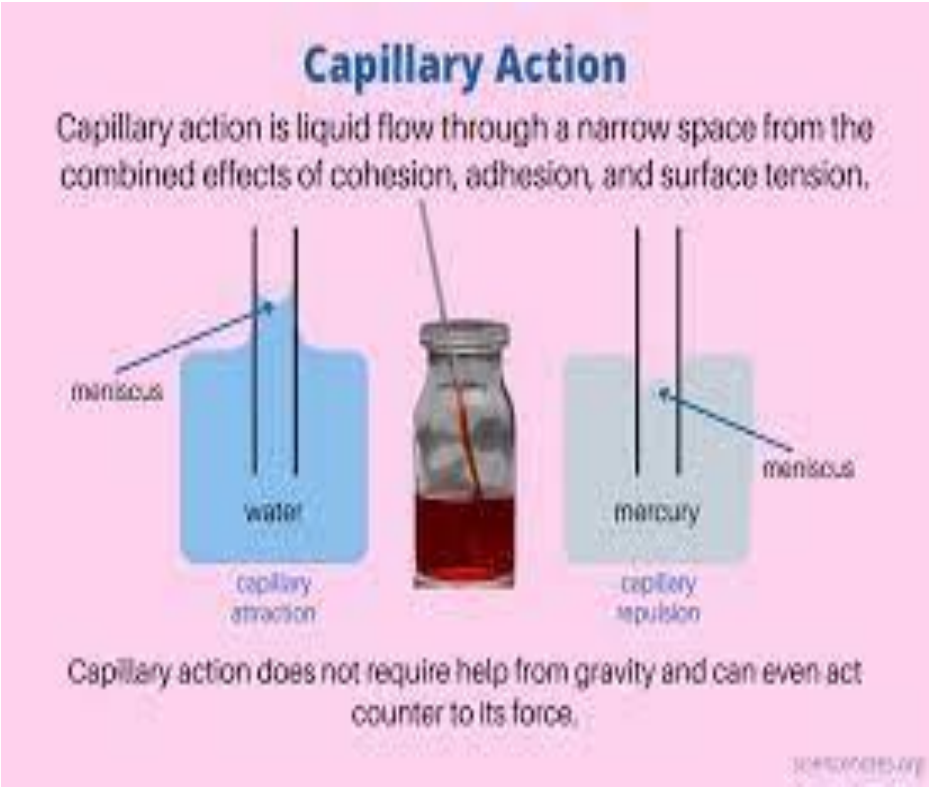


Figure 4 Capillary action

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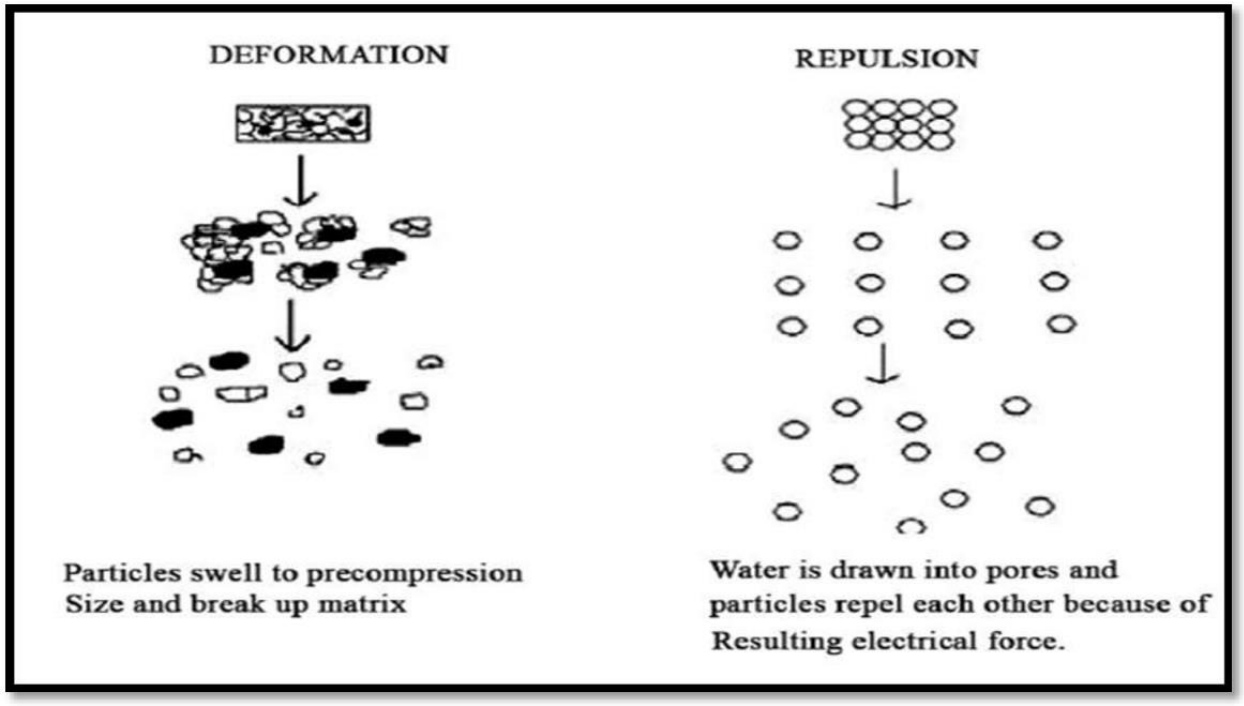
Due to particle-particle repulsive forces:
Electrical repulsive forces between particles responsible for disintegrating
Deformation:
On the tab. Compression, disintegrated particles are deformed when in contact with aq. Media is back to regular structure (Inc. in size)

Figure 5 Deformation and Repulsion



By enzymatic reaction:

Enzymes found in the body function as disintegrants. These enzymes disrupt the binding action of the binder and help to disintegrate. In fact, due to swelling, pressure applied in the outer direction or radial direction, it allows the tablet toburst or rapid absorption of water contributing to an immense increase in the volume of granules to facilitate disintegration.

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Excipients used for the formulation of ODT's.

The role of excipients plays a major role in the design and formulation of Orodispersible tablets. Excipients balance the properties of the activities in oral disintegrating tablets. A thorough understanding of the chemistry and mechanism of these excipients is needed to prevent interaction and inhibition between their activities. The aspect of cost has to be addressed by the formulator. When the excipients are added in the formulation they impart desired organoleptic properties and improved efficiency of the product. Excipients can be used for a broad range of activities.

Bulking agents:

Bulking agents are crucial in the formulation of ODT's since they contribute functions of diluent, filler and reduce cost. Bulking agents enhance the characteristics of texture and enhance the disintegration in mouth. The suggested bulking agents for the delivery should be more sugar-based such as mannitol, polydextrose, lacitol, DCL (directly compressible lactose) and starch hydrolysate for aqueous solubility. Mannitol specifically has high aqueous solubility and good sensory perception. Bulking agents are added in the final composition range of 10 to 90% by weight.

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Emulsifying agents:

Emulsifying agents are major excipients in the formulation of oral disintegrating tablets as they aid in the swift disintegration and release of drug without chewing, swallowing or water. Furthermore, incorporation of emulsifying agents proves to be useful in stabilizing immiscible blends and enhancing the bioavailability. Alkyl sulfates,propylene glycol esters, lecithin, sucrose esters etc. are some of the widely used emulsifiers. They are used in the range of 0.05% to 15% by weight of the final composition.

Lubricants:

Lubricants though not an essential component, help in the manufacturing process. Lubricants prevents the adherence of powder blend to the die cavity during the process of punching. Lubricants overcome the grittiness and helps in the transport of drug from mouth along the oesophagus till it reaches the stomach. Different hydrophilic and hydrophobic lubricants are used based on the nature and property of the drug used in the formulation.

Sweeteners and flavours:

Flavours and sweeteners make products more palatable and appealing to patients. The use of these ingredients tends to overcome the bitterness and undesirable taste of certain active ingredients. Both natural and synthetic flavours can be used to enhance the organoleptic properties of fast-melting tablets. Formulators can choose from a widevariety of sweeteners like sugar, dextrose and fructose as well as synthetic/ non-nutritive sweeteners like aspartame, sodium saccharin, sugar alcohols and sucralose. The inclusion of sweeteners adds both good flavour and the bulk to the formulation.

Surface acting agents:

Sodium lauryl sulphate, polyoxyethylene sorbitan fatty acids esters (tweens), sodium doecyl sulphate, sorbitan fatty .

Colours:

FDA approved colours are permitted in the formulation. Examples are sunset yellow, amaranth etc.

Various Techniques Used In Preparation of Orodispersible Tablets

Various technologies used in the manufacture of orodispersible tablets consist of:

- Direct compression
- Sublimation
- Freeze-drying or lyophilization
- Tablet Molding
- Spray drying
- Cotton candy process
- Mass extrusion
- Phase transition
- Nanonization
- Fast dissolving films

Direct compression

Direct compression characterizes the simplest and most cost-effective tablet manufacturing technique. This method can now be practical to the research of ODT because of the accessibility of enhanced excipients mostly super disintegrants and sugar-based excipients.The mixture to be compressed must have suitable flow of the properties and cohere under pressure thus assembly pretreatment as the wet granulation is excessive .Limited drugs can be directly compressed into tablets of standard quality. The disintegrant addition technology is cost-effective and easy to implement at the industrial level compression method.

Sublimation method

The slow dissolution of the compressed tablet containing even highly water-soluble ingredients is due to the low porosity of the tablets.This volatile material is then removed by sublimation separation to the behind as a highly porous matrix. Tablets manufactured by this method have generally disintegrated in 10-20 sec. Even solvents like cyclohexane, benzene can be used as pore-forming agents.

Freeze-drying or lyophilization

A process in which water is sublimated as of the product after freezing is so-called freeze-drying. Freeze-dried methods offer more quick dissolution than other available hard products.Freeze-dried forms offer more rapid dissolution than other available solid products. The lyophilization method imparts a smooth amorphous structure to the bulking agent and sometimes to the drug, thereby improving the dissolution physical characteristics of the formulation.

Tablet Moulding

Tablets produced by molding are solid dispersions. The physical form of the drug in the tablets can be determined by whether and to what extent it dissolves in the molten carrier. The drug can exist as discrete particles or microparticles dispersed in the matrix.The molded tablets shaped by compression molding are air-dried. As the molding process is employed

usually with soluble ingredients (saccharides) which offer better mouthfeel and breakdown of the tablets. But, molded tablets have low mechanical strength, which results in erosion and flouting during handling.

Spray drying

The preparation limited hydrolyzed and unhydrolyzed gelatin as a supporting agent for the medium, mannitol as a bulking agent and sodium starch glycolate/croscarmellose as a disintegrant. For getting immediate dissolution (<20 sec) this method is used, but this approach involves both high cost and time of production and produces tablets of very poor mechanical strength.This then mixed with the active ingredient and compressed into tablets.

Cottoncandy process

This process contains the formation of a matrix of polysaccharides by simultaneously action of flash melting and spinning.The matrix is then cured or partially recrystallized to provide a compound with good flow properties and compressibility. The candyfloss can then be milled and blended with active ingredients and other excipients and subsequently compressed into ODT. However, the high processing temperature limits the use of this technology to thermostable compounds only.

Massextrusion

This technology contains softening the dynamic blend using the solvent mixture of water-soluble polyethylene glycol and methanol and ensuing removal of making softer mass through the extruder or syringe to get a cylinder of the product into even segments using a heated blade to form tablets.

Phase transition

In this method mixture of the low and high melting point sugar alcohols, as well as a phase transition in the manufacturing method, is main for the creating ODTs without any difference in the apparatus. Tablet is prepared in two phases. FDT was prepared by decreasing powder comprising xylitol (melting point: 93 95 °C) and erythritol (melting point: 122 °C) and then heating at about 93 °C for 15 min. After heating, the medium pore size of the tablets was increased and tablet hardness was also improved. The increase of the tablet hardness with heating and the storage did not depend on the crystal state of the lower melting point of the sugar alcohol.

Nanonization

The ionization process contains a reduction in the particle size of the drug to nano-size by milling technique. The drugs are stabilized against agglomeration surface absorption on selected stabilizers. This process is suitable for poorly water-soluble drugs.

Fast dissolving films

It contains a nonaqueous solution having water-soluble film-forming polymers (pullulan, carboxymethyl cellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose,hydroxypropyl cellulose polyvinyl pyrrolidone, polyvinyl alcohol or

sodium alginate.), a drug and another taste-masking agent which are used to develop a film as the solvent evaporates. In the case of bitter-tasting drugs resin adsorbate or coated microparticles of a drug can be used in a film.Characteristics: These are thin films of 2×2 inches dimensions; dissolve fast within 5 seconds,with heating and the storage did not depend on the crystal state of the lower melting point of the sugar alcohol.

Sintering:

When thermal energy is applied to a compact powder, the compact is densified and the average grain size increases. The basic phenomena that occur during this process called sintering are densification and grain growth.

Moulding:

The moulding process involves moistening, dissolving or dispersing the drug with a solvent and then moulding the moist mixture into tablets (lower pressure compression moulding than standard tablet compression), evaporating the drug solvent from drug solution or suspension (no vacuum lyophilization) at ambient pressure, respectively The tablets formed by this technique are air dried. Moulded tablets results in a highly porous structure, which increases the product's disintegration and dissolution rate, since the compression force used is lower than traditional tablets. To further improve the dissolution, the powdered mixture should be sieved through a very fine screen or mesh 22.Tablets produced by the moulding technique are easier to scale up for industrial production in contrast to the lyophilisation technique .

Patented Technologies

Zydis Technology

Zydis formulation is a unique freeze drying method which produces tablet in which drug is physically entrapped or dissolved within the tablet matrix. The matrix consist the fast dissolving carrier material. When Zydis OTDs are taken orally, this freeze-dried structure disintegrates instantly and does not require water to aid swallowing. Composition of Zydis matrix is being done with special material to achieve a number of objectives, e.g, imparting strength and resilience during handling by using polymers such as gelatin, dextran or alginates. Due to the use of these polymers, tablet gets a glossy amorphous structure, which imparts strength By use of saccharides such as mannitol or sorbitol high crystalline structure, elegance and hardness are being achieved. For getting porous structure water is used in the manufacturing process. This is to achieve rapid disintegration.

Flashtab Technology

Flashtab technology is used by Prographarm laboratory and they patented this method. In this technology, rapidly disintegrating tablets are prepared in the form of microcrystals with active ingredient by using the many conventional techniques like coacervation, extrusion-spheronization, simple pan coating methods and microencapsulation

by which drug microgranules may be prepared. These microcrystals of microgranules of the active ingredient are then added to the granulated mixture of excipients which is prepared by wet or dry granulation, and compressed into tablets. Whole processing operates through conventional tableting technology. Prepared tablets are found to have good mechanical strength and disintegration time less than one minute by experts.

Nanocrystal Technology

For rapid disintegration of tablet matrix good pharmacokinetic quality is required. Orally administered nanoparticles (<2 microns) are taken in the form of a rapidly disintegrating tablet matrix. The basis of product differentiation is combination of proprietary and patent-protected technology elements. Manufacturing process which is cost-effective must utilize conventional, scalable unit operations. Durability of drug must be exceptional that enable use of conventional packaging, equipment and formats (i.e., bottles and/or blisters). Wide range of doses (up to 200mg of API per unit) is available. Inactive components that are used must be of conventional compendia. Nanocrystal colloidal dispersions of drug substance are combined with water-soluble GRAS (Generally Regarded as Safe) ingredient which are filled into blisters, and lyophilized. Wafers made by this procedure are extraordinarily tough, still gets dissolve in very small quantities of water in seconds. For handling potent or hazardous materials, this method is very effective as it does not involve rigorous manufacturing operations like granulation, blending, and tableting. All these steps generate large quantities of aerosolized powder and present much higher risk of exposure. When drug quantity available is very less, by freeze-drying approach that also can be converted into ODT dosage forms because losses due to manufacturing are minor.

Wowtab Technolgy

Japanese market has been massive user of the Wowtab fast-dissolving/disintegrating tablet formulation technique for long time. This technique is patented by Yamanouchi Pharmaceutical Co. The WOW in Wowtab signifies the tablet is to be given “With out Water”. It has just recently been introduced into the U.S. In this technology, sugar and sugar-like (e.g., mannitol) excipients are needed. In this method a combination of low mouldable saccharides (property of rapid dissolution) and high mouldable saccharides (property of good binding property) is used. By combination of two different types of saccharides adequate hardness and fast dissolution rate in the formulation can be achieved. Thus, Wowtab formulation is a bit more stable to the environment than the Zydis or OraSolv because of its significant hardness. Formulation made by this method can be easily packed into conventional bottle and blister packaging. Good taste masking agent is used and also produce best mouth feel due to use of patented SMOOTHMELT action. Dissolution time is very less upto 15 seconds.

Durasolve Technology

Cima's second-generation fast-dissolving/disintegrating tablet formulation is DuraSolv. During tableting higher compaction pressure is used in Durasolv Technology, due to this high mechanical strength formulations are produced than Orasolve.These tablets are made by conventional tableting equipment and have good rigidity (friability less than 2%). Thus, products are produced with a faster rate and in more cost-effective manner. Traditional blister packaging, pouches or vials are used for packing DuraSolv tablets.

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

Orodis Technology

Orodis is compressed technology. It produce tablets with a fast disintegration time in the mouth (15 to 30 seconds). It has many advantages against other technologies.

1. It produces hard tablets, not fragile so formulations are easy to handle.
2. Tablets produced don’t require specific packing. They can be packaged in push -through blisters.
3. Tablets give smooth mouth feel.
4. Due to use of taste masking agents and flavors, tablets are of pleasant taste.
5. All the materials used in this method meet USP and EP standards.
6. Conventional manufacturing equipment – not difficult to transfer to final production site.
7. Cost effective

Manufacturing process of ODTS

- Drug was geometrically mixed with microcrystalline cellulose, lactose, and sifted through sieve no.40.
- This blend was further mixed with starch and ferric oxide yellow in a rapid mixer granulator.
- Binder solution was prepared by dissolving hydroxypropyl methylcellulose under stirring in purified water.
- This binder solution was added to the mixture in the rapid mixer granulator.
- The granular mass was air-dried for 5 to10minutes and further dried at 450C-550C For 5 to 10 min.and passed through sieve no.10.
- Dry granules were sifted through sieve no.30using vibratory sifted.
- In a clean dry blender, the dried granules were mixed with hydroxypropyl methylcellulose and magnesium stearate.

- These lubricated granules were compressed to form tablets in a tableting machine.
- The tablet was coating with a coating pan.

Packaging

Packaging special care is required during manufacturing and storage to protect the dosage of other quick-dissolving route of administration. Fast-dispersing and/or dissolving oral route, the method can be packaged using various potential, such as single pouch, blister card with multiple units, multiple unit dispenser, and continuous roll dispenser, depending on the application and marketing targets.

Evaluation parameters of ODT's.

Evaluation parameters which are mentioned in the pharmacopoeias regarding tablets along with some special tests are supposed to be conducted,
Pre-compression parameters**.**

The powder blend was evaluated for flow properties such as angle of repose, bulk and tapped density, Carr's index and Hausner's ratio.

Angle of Repose:

Fixed funnel method was used to determine the angle of repose for the powder blend. The accurately measured quantity of powder mixture was taken in a funnel. The height of the funnel was maintained in such a manner that the top of the funnel had just touched the apex of the powder heap. The powder was allowed to flow through the funnel without any resistance to the surface. Measurement of the diameter and height of the powder cone and the angle of repose was determined using the equation:

$$\tan \Theta = h/r$$

h= height ,
r= radius of the powder cone, respectively.

Bulk density and tapped density:

Powder weighing 5g from each formula was introduced into a 25-ml measuring cylinder. It was initially gently shook to split any agglomerate that may have formed. The original volume was noted and the cylinder was allowed to fall under its own weight to a hard surface from 2.5cmin
height at 2-second intervals. The tapping was continued until a constant volume was obtained.

LBD (loose bulk density) and TBD (tapped bulk density)
were calculated using the formulas:
LBD = weight of the powder/ volume of packing.
TBD = weight of the powder/ tapped volume of the packing.

Compressibility index and Hausner's ratio:

The following formula was used to calculate the granule compressibility index and Hausner's ratio.

Carr's index = [(TBD – LBD) x 100] / TBD.

Hausner's ratio = Tapped density / Bulk density.

Post-compression parameters.

The formulated tablets were evaluated for the following parameters,

Tablet hardness:

Hardness is a critical and vital parameter that avoids tablet breakage during shipping, handling and storage. The crushing intensity limit for ODT is typically held in a lower range to facilitate early disintegration in the mouth. The hardness of the tablet was measured with the Monsanto hardness tester and expressed in terms of kg/cm
An average of three observations is reported.

Tablet thickness:

From the formulated tablets a few were chosen at random and placed between the two arms of the Vernier calliper and thickness was determined. An average of five measurements were taken.

Weight variation:

Twenty tablets were arbitrarily selected at random from each formulation and weighed individually using a digital balance. The individual weights were noted down and compared with the average weight of the tablets to determine the weight variation.

Friabilty:

The formulated tablets should be well within the bound limits (0.1 – 0.9%) and it is a challenge to the formulator since all the factors involved in manufacturing of ODT's are responsible for rise in friability value. Twenty tablets were taken at random, weighed and then placed in a plastic chamber friabilator USP type Roche friabilator attached to a motor revolving at a speed of 25rpm for 4mins. The tablets re-weighed, and the %loss was calculated using,

Friability =[(initial weight – Final weight) /(initial weight)] x 100

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In-vitro disintegration time:

The time to disintegrate ODTs is usually <1 min and the actual time to disintegrate the patient's experiences varies from 5 to 30 secs. The disintegration time of all the formulations was determined using the tablet disintegration apparatus. Six tablets were placed individually in each of the tubes of disintegration test apparatus. The medium was maintained at a temperature of 37± 2º c and the time was noted for the disintegration of the entire tablet. The ODT disintegration test should imitate disintegration in the mouth with salivary contents.

Wetting time and absorption ratio(R):

The ODT wetting time is another significant parameter that needs to be measured in order to gain insight into the tablet's disintegration properties. A petridish (internal diameter of 5cm) containing 6ml water was taken and a tissue paper was taken and folded twice & p laced in it. The ODT tablet was cautiously placed on top of it. The time taken for the water to reach the upper surface of the tablet and to completely wet it was noted as wetting time. Water absorption ratio was then determined with the equation,

$$R = 100 \times (Wa - Wb)/Wb.$$

Where, Wa and Wb are weights of the tablet before and after water absorption.

Dissolution test:

The development of dissolution methods for ODTs is similar to the methodology adopted for traditional tablets and is essentially equivalent. Dissolution apparatus USP 1 & 2 are used.USP 2 apparatus is used because although USP 1 have various applications, but often tablet pieces and disintegrated fragments gets stuck on the interior of the basket at the spindle resulting in no efficient stirring andunreproducible dissolution profiles.USP 2 is the most suitable and common choice for ODT's with a paddle and speed of 50rpm. Typically, the dissolution of ODT is very fast when using USP monograph conditions; thus, slower speeds of ODT can be used to obtain the profiles.

Friability

Because all preparing orodispersible tablets tend to raise the percentage of friability, maintaining the ratio of friability within the limit might be challenging. The Roche Friabilator, which is used to measure tablet friability and is reported as a percentage, is used to estimate hardness also. The range is 0.1–0.9% in all aspects. Initially, ten pills were weighed, placed in a friabilator, and spun at 25 rpm for 4 minutes before being reweighed. The acceptability value was computed using the pharmacopoeia employed to measure friability, the loss in tablet weight due to abrasion.

Disintegration Test

The disintegration test device was used to determine the in-vitro disintegration time. The disintegration duration of ODTs is the essential feature since they must break down in a minimal amount of saliva in a brief period, typically 1 minute. The real disintegration time

that patients might experience ranges from 5 to 30 seconds. One tablet is placed into each of the apparatus's six tubes. The conventional technique for performing disintegration tests has numerous drawbacks for these dosage formulations. Researchers began to look for alternative tests because there was no ODT-specific disintegration test. According to assumptions, the disintegration test for orodispersible tablets is intended to imitate the Disintegration in the mouth within salivary contents.

Moisture-uptake Studies

In this investigation, the tablets' stability is evaluated. Ten tablets were kept in desiccators over calcium chloride at 37°C for 24 hours. For two weeks, weighted tablets were subjected to 75% relative humidity at room temperature. Desiccators were filled with a saturated sodium chloride solution for three days to produce the required moisture. One tablet was retained as a control (without super disintegrant) to measure the moisture absorption due to the formulation's other excipients. The % increase in weight of the tablets is observed.

Water Absorption Ratio

A piece of tissue paper folded twice was kept in a Petri dish(internal diameter 5.5cm) containing 6mlof purified water. The tablet was placed on the tissue paper and allowed to we completely. The wetted tablet was ratio, R was determined according to the following equation (Bandari et al., 2008).

$$= wa-wb/\ wawb \times 100$$

Where,

Wb and Wa are the weight before and after water absorption, respectively.

Conclusion

A large portion of the world's population consists of paediatric and geriatric patients, the introduction of fast dissolving tablets has helped overcome the problems encountered during administration of drugs. This technology is mostly used for drugs to treat mental disorders, anti-allergic and analgesics. Dysphagia is also one of the major problems which was dealt with the invention of this novel drug delivery system. ODT's are the novel delivery system that have various advantages over conventional drug delivery in aspects of improved patient compliance, bioavailability and rapid onset of action. ODT's dissolve/disperse in saliva and can be administered without the need of water. The basic approach in the ODT technology is the maximize the porous structure of the tablet matrix to achieve rapid disintegration in the oral cavity & also provide excellent mouth feel, good taste masking properties of bitter drugs and good mechanical strength. Intensive investigation is much needed in this promising area which can result in better result of newer cost-effective technologies and improved excellent products.

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