IJCRT.ORG

ISSN: 2320-2882



INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

ORODISPERSIBLE TABLETS: A NOVEL APPROACH TO PHARMACEUTICAL ADMINISTRATION

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ABSTRACT:

Recently the orally dispersible tablets have become the most desirable dosage forms especially for a special category of patient's i.e. pediatric, geriatric, bedridden, mentally ill, and uncooperative patients. An orally dispersible tablets are solid unit dose forms similar to normal tablet but they contain super disintegrant that allow the tablet to dissolve in the mouth in the presence of saliva within a minute without difficulty in swallowing. Basically, swallowing problems also are happened in young individuals because of their under developed muscular and nervous systems. In some cases, such as motion sickness, coughing, and unavailability of water, swallowing of conventional tablets may become difficult or improper. The term "orodispersible tablet" was established by the European Pharmacopeia to describe a tablet that disperses or dissolves in the mouth before being swallowed in less than three minutes. The current article focuses on ideal qualities, benefits and drawbacks, various technologies created for ODT, evaluation techniques, new research, and prospects in the future.

Keywords: Orodispersible tablet, Direct compression, Freeze drying or lyophilization, Molding method

INTRODUCTION:

The oral route of drug administration is one of the most acceptable routes for drug delivery. The oral route of drug administration is that the most vital and suitable method for administering drugs for systemic effects. Difficulty in swallowing (Dysphagia) is a common problem in all age groups, especially the elderly and pediatrics, because of physiological changes associated with these age groups. Other categories that having experience the problems using conventional oral dosage forms that include the mentally ill, uncooperative and nauseated patients, those with conditions of motion sickness, sudden allergic attack and coughing. Sometimes, it may be difficult to swallow conventional products due to unavailability of water. These problems lead to the development of a novel type of solid oral dosage form called mouth-dissolving tablets. They are also known as fast dissolving tablets, melt-in-mouth tablets, rapid melts, orodispersible, quick dissolving or rapidly disintegrating tablets.

To overcome these problems orodispersible tablet is a novel drug delivery approach that disintegrates rapidly in saliva without the need for drinking water. It also includes the Superdisintegrants substances that are added to tablet formulations to promote the breakdown of the tablet into smaller fragments in an aqueous environment. It is done to increasing the available surface area and promoting a more rapid release of the drug substance at lower concentrations with greater disintegrating efficiency and mechanical strength.

Oral routes of drug administration have wide acceptance up to 50-60 % of total dosage forms. Solid dosage forms are popular because of ease of administration, acute dosage, self-medication, pain avoidance and most important is the patient acceptance.

TABLET:

According to the Indian Pharmacopoeia, Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drugs or a mixture of drugs, with or without diluents. Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients. They vary in shape and differ greatly in size and weight, depending on amount of medicinal substances and the intended mode of administration

Advantages:

- 1. Low in cost
- 2. Light in weight
- 3. They are Easy to handle and use
- 4. Suitable for large scale production
- 5. Easy to handle

Disadvantages:

- Difficult to swallow in case of children and unconscious patients.
- Irritant effects on the GI mucosa by some solids
- Possibility of bioavailability problems resulting from slow disintegration and dissolution
- Problem with compression to crystalline drug.
- 5. Hygroscopic drugs are not suitable for compressed tablets. Drugs with low or poor water solubility, slow dissolution, may be difficult to formulate.
- 6. Cost of production may be increase because of coating and encapsulation to
- 7. Remove bitter and unpleasant taste.
- 8. Swallowing is difficult especially for children and ill (unconscious) patients.

Types of Tablets:

(A) Tablets ingested orally:

- 1. Compressed tablet, e.g Paracetamol tablet
- 2. Multiple compressed tablet
- 3.Delayed release tablet, e.g. Enteric coated Bisacodyl tablet
- 4.Sugar coated tablet, e.g. Multivitamin tablet
- 5. Film coated tablet, e.g.. Metronidazole tablet
- 6. Chewable tablet, e.g. Antacid tablet

(B)Tablets used in oral cavity:

- 1. Buccal tablet, e.g. Vitamin-c tablet
- 2. Sublingual tablet, e.g. Vicks Menthol tablet
- Troches or lozenges
- 4. Dental cone
 - (C) Tablets administered by other route:
 - 1. Implantation tablet
 - 2. Vaginal tablet, e.g.Clotrimazole tablet
 - (D) Tablets used to prepare solution:
- 1. Effervescent tablet, e.g.Disprin tablet (Aspirin)
- Dispensing tablet, e.g.Enzyme tablet (Digiplex)
- 3. Hypodermic tablet

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4. Tablet triturates e.g.Enzyme tablet (Digiplex)

ORAL DISPERSIBLE TABLETS:

Oral dispersible tablet is also known as Oral disintegration tablets, Mouth dissolving tablets, Oro dispersible tablets, fast dissolving tablets, melt-in-mouth tablets, rapid melts, , quick dissolving or rapidly disintegrating tablets.

An orally disintegrating tablet or orally dissolving tablet (ODT) is a drug dosage form available for a limited range of over-the-counter (OTC) and prescription medications. ODTs differ from traditional tablets in that they are designed to be dissolved on the tongue rather than swallowed whole.

Ideal characteristics of ODTs:

- Water is essential to their administration.
- They have high drug loading capability.
- Better after taste than other dosage forms.
- They provide lot of stability.
- It involves simple manufacturing process hence it is low cost.

Limitations of ODTS:

- Their mechanical strength is quite low so proper handling is must.
- As their mechanical strength is very limited, proper handling is required.
- High drug loading is not possible for dispersible tablets.
- Taste masking is quite a big challenge in the formulation of dispersible tablets.

Problems with the current oral dose form:

- The patient can have tremors, making it challenging for them to take powdered or liquid medications.

 Gastrointestinal ulcers may result from physical obstructions and adhesion to the esophagus in dysphasia.
- Ingestion of solid dosage forms like tablets and capsules can give rise to difficulties for young adults by causing hindrance in the development of muscular and nervous system.
- Because liquid medications such as suspensions and emulsions are packed in multi-dosage containers, content homogeneity in each dose may be reduced.
- Buccal and sublingual formulations may irritate the oral mucosa.

Advantages of ODTS:

- Suitable for patients who are not comfortable with conventional tablet.
- It immediately releases the medication after administration.
- Dispersible tablets reduce the risk of dose dumping.
- The dose adjustment is quite convenient.
- The onset of action of drug is quite fast.

Disadvantages of ODTS:

- Due to their hygroscopic nature, they must be stored in a dry environment.
- They have a low mechanical integrity.
- Because of its unstable nature, special packaging is required.
- Maintaining dose consistency in these pills is very difficult.

ODT Drug release technology or mechanism of releasing drugs:

Overall Mechanism of drug release of ODT:

According to official publication European Pharmacopoeia the ODT should be disperses or disintegrates in less than three minutes. The fundamental approach used in development of ODT is the use of superdisintegrants like sodium starch glycol ate (Primo gel,carboxymelhylcellulose (Croscarmeliose), Polyvinylpyrrolidone (Polyploidies) etc. which provides rapid disintegration of tablet after putting in mouth, and release the drug in saliva. Bioavailability of certain drugs may be increased due to absorption of drugs in oral cavity and may be due to pregastric absorption of saliva which contains dispersed drugs which pass down into the stomach. The amount of drug which is subject to undergo first pass metabolism is reduced.

MECHANISM OF ODT DISINTEGRATION Major mechanism of ODT are: DRUG Fast dissolving granules Disintegrating Agent Saliva in mouth causes disintegrating agent to swell creating channels for saliva PARTICLE REPULSIVE FORCE Fast dissolving granules dissolves and tablet disintegrate

Fig.1 MAJOR MECHANISM OF ODT

SELECTION OF DRUGS FOR THE ODT:

ODTs are typically created as bio-equivalent upgrades to already-existing oral dose forms. In these conditions, it is presumable that drug absorption from ODTs takes place in the post gastric gastrointestinal tract segments, much like it does with traditional oral dose forms. But this situation might not always be true. The pharmacokinetic profiles of medications will change as a result of an ODT's variable levels of pregastric drug absorption5. The ODTs will not be bioequivalent to the traditional dose forms as a result. For instance, the pharmacokinetic profile of ODT formulations of selegiline, apomorphine, and buspirone differs dramatically from the name dose given in a traditional dosage form. Pregastric absorption may prevent first-pass hepatic metabolism in the presence of noticeably increased plasma levels. It may be necessary to consider and evaluate these implications for medication distribution and efficacy in a marketing application for an ODT5. A medication should have the following properties to dissolve in vivo from an ODT:

- i. No bitter flavor,
- ii. Small to medium molecular weight, in II.
- iii. Excellent stability in saliva and water.
- iv. The pH of the oral cavity is a little non-ionized.
- v. Capacity to diffuse and partition into the upper GIT epithelium (log P greater than 1, or ideally greater than 2).
- vi. The capacity to enter oral mucosal tissue.
- vii. A minimal dose should be used.

GENERAL CONSIDERATIONS IN DOSAGE FORM DESIGN

Before deciding on a novel dosage form, certain physicochemical parameters should be covered. The primary issues to be considered during the formulation of a dosage form are as follows: the formulation qualifying the target parameters is considered the master formulation, and any batch formulated must adhere to the master formula specifications. For oral use tablets and capsules are prepared f systemic effect as they can be easily handled by most of the patients, and if intended in emergency condition injectable form is applied for quick results. Other dosage forms include the patches and suppositories can be applied according to the patient condition.

Why ODT?

- 1. Clinical
- Improved bioavailability
- Enhanced oral absorption
- Minimized first pass effect
- Faster onset of action
 - 2.Medical
- **Improved Compliance**
- No tablet or capsule to swallow or chew
- Better taste, no water needed
 - 3.Technical
- Accurate dosing compared to liquid products
- Use common process and conventional equipment
 - 4.Business
- Unique product differentiation
- Value-added product line extension
- Provide exclusive marketing
- Extend patent protection



Techniques For Preparing Orodispersible Tablets

Direct compression:

The most easiest and cost effective way to prepare tablets, By using a small number of processing stages, conventional compression machines with common materials are used. Rapidly disintegrating pills are made by microcrystalline cellulose (MCC) and low substituted hydroxypropyl cellulose (HPC). Major drawback of effervescent form, is hygroscopicity i.e., the ability to absorb atmospheric moisture. To achieve good oral dispersibility with a pleasant feeling, super disintegrants are sometimes added in optimal concentration. Common examples of superdisinterants include sodium starch glycolate, crospovidone, alginic acid, calcium silicate and crosscarmellose. They give quick breakdown due to swelling caused by water absorption. Direct compression has cost-effective characteristics that are similar to conventional dosage forms, with the exception of containing a significant number of disintegrants in some situations, which can result in reduced tablet hardness.

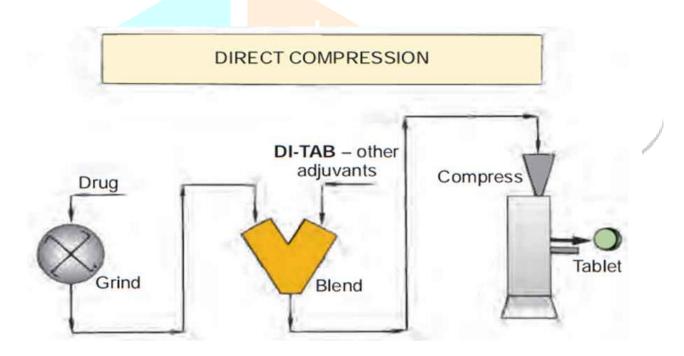


Fig.2: Direct Compression

Freeze drying or lyophilization:

It is a pharmaceutical procedure that allows for the drying of heat sensitive pharmaceuticals and biologicals at low temperatures using a vacuum to remove water through sublimation. Drugs are dissolved or dispersed in an aqueous solution of a carrier, transferred to manufactured blister packs, frozen out, and then placed in a refrigerator to complete the process. Characteristics of lyophilization techniques are, they possess high porosity and specific surface area, and gets dissolve rapidly in bioavailability. mouth presenting high The drug main Drug solution or disadvantage of this method is its high cost, timeconsuming procedure, fragility, which makes and traditional. packing inappropriate for this dose form and stability concerns under stress conditions causes eze-drying Fig.3: Freeze drying

Molding method:

In order to achieve maximal drug disintegration, hydrophilic substances are used in the formulation of tablets. A hydroalcoholic solvent is used to moisten the powder material before compression into a dosage form. After then, the solvent system stays to evaporate. Spray congealing the molten combination of hydrogenated cottonseed oil, sodium carbonate, lecithin, and polyethylene glycol with an active component into lactose-based tablet triturate develops a particular flavour of the medication particles. Very porous bulk, which encourages rapid breakdown, is one of the moulding method's characteristics because solvents are eliminated by drying and left behind.



Fig.4:Molding method

Sublimation

By integrating inert solid substances that volatilize fast, such as urea, camphor ammonium carbonate, ammonium bicarbonate, and hexamethylene-tetramine, into porous mass, one can achieve rapid disintegration and dissolution. They were compressed after being combined with additional components. By reducing pressure and raising the temperature just a bit, the volatile material is released, leaving the mass in a porous state. They are porous in nature and may be employed with solvents like cyclohexane and benzene, which are sublimation method characteristics.

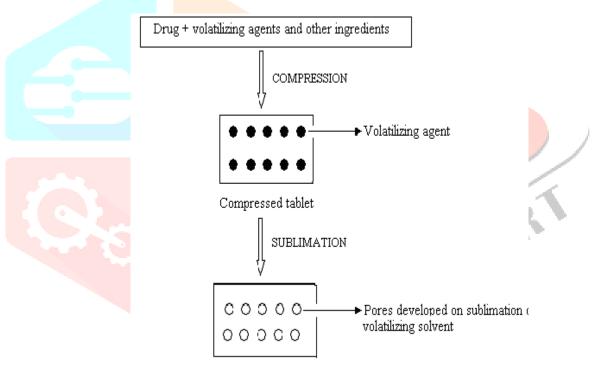
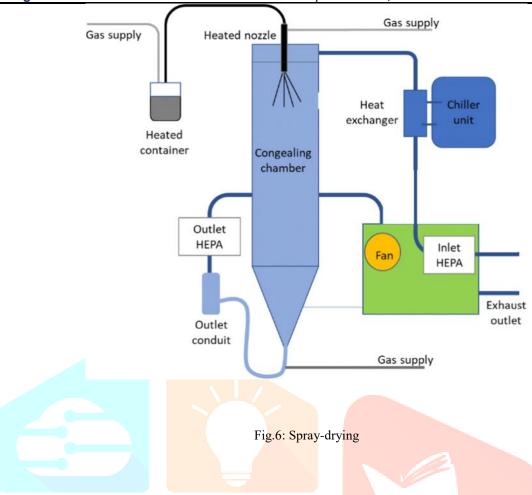


Fig.5: Sublimation

Spray-drying

By using sodium starch glycolate or crosscarmellose sodium as the disintegrating agent, hydrolyzed and nonhydrolyzed gelatins as binding agents, mannitol as a bulking agent, citric acid or sodium bicarbonate to promote dissolution, and sodium starch glycolate or sodium starch glycolate as the disintegrating agent, the ingredients are combined. When a dosage form comes into contact with an aqueous medium using the spraydrying method, the dosage form dissolves quickly.



Mass-extrusion

By applying methanol as a solvent and polyethylene glycol, which is water soluble, the combined materials are softened in this process before being extruded into thin cylinders. Characteristics of this method is these products can be used to mask bitter tasting drugs making small granules thus enhancing oral bioavailability

Cotton candy process

By using this technique, fast melting and spinning are done at the same time to prepare polysaccharide matrix. The active ingredient, excipients, and recrystallized candy floss matrix are then combined to create a fast-dissolving tablet. Characteristics of this method is high quantity of doses can be used in this dosage form with high mechanical strength.

Nanonization

The wet grinding method is used to reduce particle size to nano size. The generated nano crystals are then physically attached to the surface of an inert substance to prevent agglomeration. Characteristics of this technique is suitable for water insoluble drugs with low bioavailability.

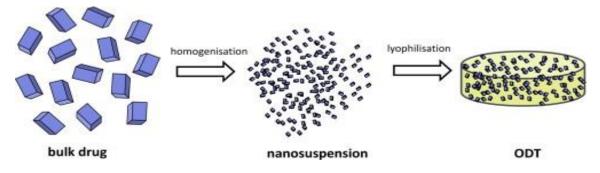


Fig.7: Nanonization

Compaction

It is formulated through Melt granulation with the addition of a hydrophilic waxy binder (super polystate) PEG-6-stearate. This binder has a dual function; it increases physical strength while also enhancing disintegration. Drugs like griseofulvin can be easily administered in this form. The compaction method has the advantage of rapidly melting in the mouth, leaving small residue.

Fast dissolving films

It contains a non aqueous solution containing water soluble film forming polymers (pullulan, carboxymethyl cellulose, hydroxypropyl methylcellulose, hydroxyethyl cellulose, hydroxypropy cellulose polyvinyl pyrrolidone, polyvinyl alcohol, or sodium alginate), a drug, and other flavor masking agents

that are used to form a film as the solvent evaporates. Characteristics of These are thin films of 2×2 inches dimensions; dissolve fast within 5 seconds, leaving a good after taste

EVALUATION OF ORODISPERSIBLE TABLETS

Hardness/crushing strength

The hardness of the tablet is determined using standard hardness tests such as the Monsanto hardness tester the restriction is set lower help in early breakdown in the mouth.

Friability

It is difficult to keep the percentage of friability within the limit because all techniques of preparing orodispersible tablets tend to increase the percentage of friability. In general, the range is between 0.1% and 0.9%. The traditional Roche friabilitor is used to assess the friability of tablets.

Disintegration test

For the purpose of this test, disintegration does not imply complete solution of the dosage unit or even of its active constituent.

Disintegration is defined as that state in which no residue of the unit under test remains on the screen of the apparatus or, if a residue remains, it consists of fragments of disintegrated parts of capsule component parts such as insoluble coating of the of capsule shells, or of any melted fatty substance from the pessaries or suppository or is a soft mass with no palpable core. If dises have been used with capsules, any residue remaining on the lower surfaces of the discs consists only of fragments of shells.

28-32 cycle (strokes) per minute IP

29-32 cycle (strokes) per minute BP/USP

Dissolution test

This is an important test because it can provide the drug-release profile. The USP dissolution test apparatuses can both be used. Dissolution of orodispersible tablets is very fast. Therefore, USP 2 Paddle-type apparatus at 50-100 r/min is used for dissolution testing. As a result, dissolution testing is performed using a USP 2 Paddle-type device at 50-100 r/min. Swammyetal. investigated the in vitro dissolution of pheniramine maleate orodispersible tablets in a type II apparatus with r/min 550 and 900 ml of pH 6.8 phosphate buffer at 37 0.5°C as a dissolution medium.

CHALLENGES IN THE PRODUCT DESIGN, FORMULATION AND MANUFACTURE OF ODTs:

Palatability: As most of the drugs are unpalatable, orally disintegrating drug delivery systems usually contain the medicament in a taste masked form. Delivery systems disintegrate or dissolve in patient's oral cavity, thus releasing the active ingredients which come in contact with the taste buds; hence taste masking of drugs become critical to patient compliance

Amount of drug: Application of technologies used for ODTs is limited by the amount of drug that can be Incorporated into each unit dose. In case of Lyophilized Dosage forms, drug dose must be less than 400mg –

Insoluble drugs less than 60mg – soluble drugs. This Parameter is particularly challenging when formulating A fast-dissolving oral films

Size of tablet: The degree of ease when taking a tablet depends on its size. It has been reported that the easiest size of tablet to swallow is 7-8 mm. While the easiest size to handle was one larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve

Aqueous solubility: Water soluble drugs pose various Formulation challenges because they form eutectic Mixtures, which result in freezing point depression and The formation of a glassy solid that may collapse upon Drying because loss of supporting structure during the Sublimation process. This collapse can be prevented by Using various matrix-forming excipients like Mannitol Which induces crystallinity and hence impart rigidity to The amorphous composite



Fig.8: Market Potential For ODT

CONCLUSION:

In the period of solid dosage forms, the new developed dosage-form is the oro-dispersible tablet. It is the ideal carrier for the active pharmaceutical ingredient because of its improved patient acceptability, quick breakdown, and optimal bioavailability. Additionally, as new procedures are developed daily by researchers, orodispersible pills are becoming the preferred dose form not only for adults but also for children, the elderly, and patients who are hospitalized. We tried to summarize the fundamental ideas and fundamental methods used in the development of oro-dispersible tablets in this review. Since it is a novel addition in solid dosage form, more

study and technological advancements are necessary so that the formulation's remaining drawbacks can also be turned into advantages.

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