ejpmr, 2022,9(5), 208-214

SJIF Impact Factor 6.222

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Review Article

ISSN 2394-3211

EJPMR

REVIEW ON NOVEL APPROACHES IN ORODISPERSIBLE TABLETS FORMULATION.

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Article Received on 17/03/2022 **Article Revised on 05/04/2022** **Article Accepted on 26/04/2022**

ABSTRACT

Over the past 3 decades, Orodispersible tablets (ODTs) have gained substantial attention as a most popular different to standard tablets and capsules thanks to higher patient compliance, improved solubility and stability. Mouth dissolving tablets (MDTs) has extended a lot of attention as a most popular different to standard oral dose type. ODTs square measure solid dose forms containing medicative substances that disintegrate quickly, sometimes during a matter of seconds, once placed on the tongue. New ODT technologies address several pharmaceutical and patient desires, starting from increased life-cycle management to convenient dosing for medicine, geriatric, and psychiatrical patients with disorder. Orodispersible drug delivery systems square measure extensively accustomed improve bioavailability and patient compliance. This has inspired each world and trade to get new orally disintegrating formulations and technological approaches during this field. The aim of this text is to review the event of ODTs, challenges in formulation, new ODT technologies, analysis methodologies, suitableness of drug candidates, and future prospects.

INTRODUCTION

For most therapeutic agents accustomed turn out general effects, the oral route still represents the well-liked method of administration due to its many blessings and high patient compliance compared to several alternative routes.[1] Tablets and capsules square measure the foremost standard solid dose forms. However, many folks face problem in swallowing tablets and laborious gelatin capsules. This problem in swallowing is named dysphasia. Orodispersible tablets don't seem to be solely indicated for folks that have swallowing difficulties, however are also ideal for active individuals. Oro-dispersible tablets are called mouth dissolving tablets, melt-in-mouth tablets, quick dissolving tablets, rapimelts, porous tablets and fast dissolving tablets. Thanks to the presence of super disintegrants, it gets dissolved quickly, leading to fast absorption of drug that successively provides fast onset of action. Some samples of superdisintegrants square measure croscarmellose, crospovidone, Na starch glycolate, and Mg atomic number 13 salt.[2] Since the absorption is happening directly from the mouth, so, bioavailability of the drug will increase. Medication gift in orodispersible tablets are not littered with 1st pass metabolism. This sort of drug delivery is changing into standard day by day thanks to its varied blessings. In conjunction with the fast market growth of ODT product, the technologies, too, have advanced significantly over the years. the latest generation of ODTs will turn out additional sturdy, versatile tablets that overcome a number of the constraints of earlier ODTs in conjunction with the fast market growth of ODT product, the technologies, too, have advanced significantly over the years. The latest generation of ODTs will turn out additional sturdy, versatile tablets that overcome a number of the constraints of earlier ODTs. Since the route of administration remains a similar, ODTs that square measure developed as bioequivalent line extensions or generic versions of associate existing oral dose kind have nominal clinical needs to realize approval.[3]

Advantages of ODT

Improved compliance/added convenience

- Ease administration for patients World Health Organization area unit insane, disabled and unco-operative.
- No water required.
- Is designed to depart minimal or no residue in mouth when administration and conjointly to supply a pleasing mouth feel.
- No change of state required.
- Higher style obtained by style masking.
- Improved stability, low sensitivity to condition.
- Appropriate for controlled/sustained unleash actives.
- permits high drug loading.
- Ability to supply blessings of liquid medication within the kind of solid preparation.
- Labile and amenable to existing process and packaging high speed machinery.

- Cost- effective, lower production, packaging and distribution prices compared to current commercially out there product.
- The technology is flexible and appropriate for the event of increased product for veterinary medicines, OTC, Rx medicines & line extensions.
- The new proprietary methodology permits the incorporation of microencapsulated medication for increased bioavailability, flexibility of dosing & immediate and/or controlled unleash.
- For superior therapeutic profit.[4]

Disadvantages of ODT's

- It needs correct packaging for safety and stabilization of stable medicine.
- It's absorbent in nature, thus should unbroken in dry place.
- It shows the delicate, effervescence granules property.
- If not developed properly, it's going to leave unpleasant style in mouth.[5]

Anatomy and physiology

Oral dispersible tablets (ODTs) square measure the novel dose kind that quickly disintegrates within the mouth (1-3 min) while not change of state upon oral administration and while not the necessity of water, totally different alternative typical oral solid dose kind.[6] The most effective time for Associate in Nursing orodispersible pill to urge separate is measured to be fewer than a second. Principally the degeneration times vary from five to thirty seconds and square measure ready to recount; direct compression, solid dispersion, freezing or molding techniques. ODTs square measure recognized by the addition of super disintegrants alike cross-linked polyose imitative; cellulose, atomic number 11 starch glycolate, polyvinylpyr-rolidone, that provides rush breakdown once gets in exchange with water or secretion secretions. Bioavailability of medication might rise because of oral and pregastric absorption, reducing the first-pass metabolism within the digestive tract. Figure no one. Shown in Mechanism of action of orodispersible pill.[7]

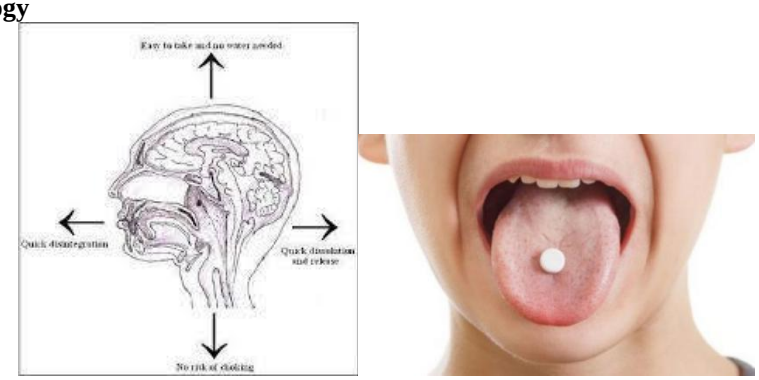

Figure 1: ***Mechanism of action of orodispersible tablet.***

Recent Trend of Manufacturing ODTs

The technologies used for preparation of orodispersible tablets embody freezing, moulding, direct compression, spun sugar method, spray drying, sublimation and nanonization. These ways ar made on the principles of accelerating permeableness and/ addition of the superdisintegrants and therefore the soluble excipients within the tablets. List of some expressed and marketed medication ar unconcealed in table one.[8]

Table 1: Some examples of recently prepared orodispersible tablets

Drug	Method	Reference
Ofloxacin	Taste disguised microspheres of the ofloxacin were ready as a victimization Eudragit and orodispersible tablets of the developed microspheres were victimization the character of the superdisintegrant.	
Nimesulide	Orodispersible tablets were then completed victimization bean gum as a natural of the superdisintegrant.	
Cetirizine dihydrochloride	Tablets were organized victimization cetirizine along side natural resin and Osmitrol in numerous amount Effervescent methodology	
Pheniramine maleate	Effervescent method	
Diazepam	ODTs were organized victimization differing kinds of superdisintegrants at modified concentration victimization wet granulation and direct compression strategies.	
Valsartan	Tablets were organized by freezing methodology	
Ondansetron HCl	Direct compression technique	
Roxithromycin	ODTs were organized victimization changed polysaccharides as quick disintegrating excipients.	
Indomethacin	The tablets were complete by the non-aqueous wet granulation methodology with	

	superdisintegrant enclosed each of the intragranularly and extragranularly.	

Methods of Orodispersible tablets[9]

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

- Direct compression.
- Sublimation.
- Lyophilization or Freeze-drying.
- Tablet molding.
- Spray drying.
- Cotton-candy process.

Direct compression

Direct compression characterizes the best and most efficient pill producing technique. This methodology will currently be sensible to the analysis of ODT owing to the accessibility of increased excipients principally super disintegrants and sugar-based excipients.[10] The mixture to be compressed should have appropriate flow of the properties and cohere harassed therefore assembly pretreatment because the wet granulation is excessive. restricted medicine may be directly compressed into tablets of ordinary quality. The disintegrant addition technology is efficient and simple to implement at the economic level. Figure 1.shown as Direct compression methodology.

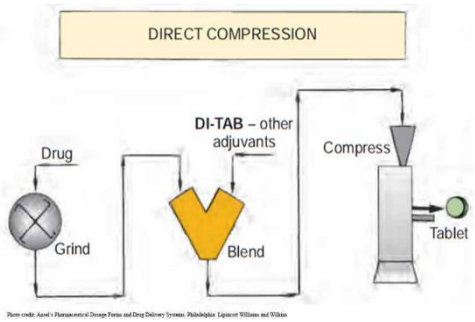

Figure 2: Direct compression method.

Sublimation method[11]

The slow dissolution of the compressed pill containing even extremely soluble ingredients is thanks to the low consistence of the tablets. This volatile material is then removed by sublimation separation to the behind as an extremely porous matrix. Tablets factory-made by this technique have usually disintegrated in 10-20 sec. Even solvents like cyclohexane, benzine may be used as pore-forming agents.

Freeze-drying or lyophilisation[11]

A method during which water is change as of the merchandise when state change is alleged drying up. Freeze-dried strategies provide additional fast dissolution than alternative obtainable exhausting merchandise. Freeze-dried forms provide additional fast dissolution than alternative obtainable solid merchandise. The drying up methodology imparts a sleek amorphous structure to the bulking agent and typically to the drug, thereby up the dissolution physical characteristics of the formulation. Figure 2. Shown as freeze drying methodology.

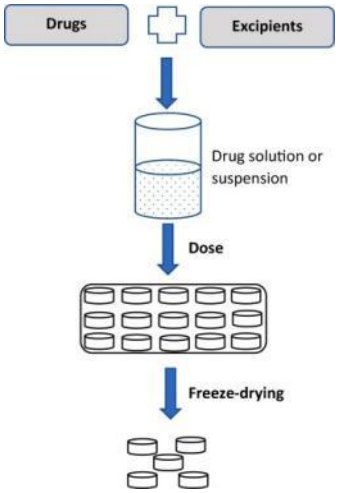

Figure 3: Shown as freeze drying method.

Tablet Moulding[11]

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. Figure 3. Shown as spray drying process.

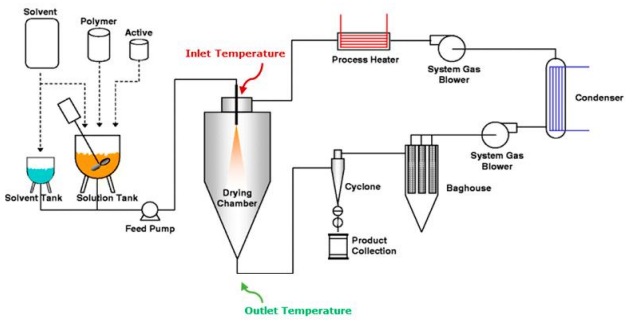

Figure 4: Shown as spray drying process.

Cotton candy 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.[12] However, the high processing temperature limits the use of this technology to thermostable compounds only.

Some novel methods used for orodispersible tablet

- *Mass extrusion*
- *Phase transition*
- *Nanonization*
- *Fast dissolving films*
- *Taste masking*

Mass extrusion

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.[13] 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.[14]

Nanonization

The ionization process contains a reduction in the particle size of the drug to nano-size by milling technique.[15] 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.[16] 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.

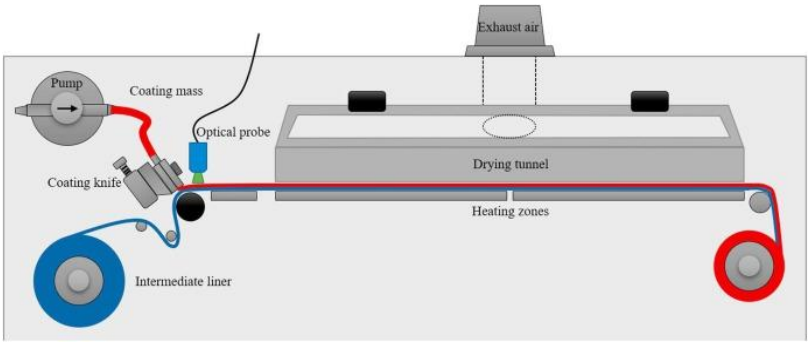

Figure 5: Fast dissolving film maker.

Taste Masking

Taste masking is an essential requirement for fast dissolving tablets for commercial success. Taste masking ingredients can be achieved by various techniques; Drugs with unacceptable bitter taste can be microencapsulated into pH sensitive acrylic polymers. Cefuroxime axetile is microencapsulated in various types of acrylic polymers (e.g eudragit E eudragit L-55 and eudragit RL) by solvent evaporation and solvent extraction techniques.

Future Prospects

These dosage forms may be suitable for the oral delivery of drugs such as protein and peptidebased therapeutics that have limited bioavailability when administered by conventional tablets.[17] These products usually degrade rapidly in the stomach. The next generation drugs Should be peptide based or predominantly protein, tablet may no longer be the dominant format for dosing such moieties.Injections generally are not preferred for use by patients unusually facilitated by twist autoinjectors. Inhalation is one of the correct approach systems to deliver these drugs, but the enhanced research into biopharmaceuticals so far has generated predominantly chemical units with low molecular weights. The developments of enhanced oral protein delivery technology by ODTs which may release these drugs in the oral cavity are very encouraging for the delivery of high molecular weight protein and peptide.[18]

Need of Innovative Drug Delivery System[19]

The orally administered drug delivery is still considered as a standard system in pharmaceutics field and still

considered safest, convenient and economical method of administration providing best route for patient compliance, however in case of tablet and capsule having a common drawback of difficulty in swallowing leading to poor compliance specially in geriatrics.

To improve compliance and making the administration convenient, design of new dosage forms gained significant importance.[20] Conventional oral drug delivery present a drug with quick and full release that may go as such without producing the desired effect may be due to the presence of food, pH of the stomach, enzymatic degradation, change in GIT motility as so forth, giving not enough time to get absorbed. Recently much light is being put on the area of designing drug delivery systems bearing organoleptic elegancy and maximum patient acceptability in pediatrics and geriatric groups.[21] A lot of innovative work is being done on drug delivery in which oral route is preferred because of ease of administration, cost effective therapy, self medication and non invasive method leading to patient compliance to a higher level.[22] Tablet coating is one of the parameter in drug delivery designing applied to minimize the bad tasting and side effects while enhancing elegancy and drug bioavailability.

Novel approaches

Now a days need of orodispersible tablet is very high because everyone requires quick action and very fast relief so we can approach more now a days. ODTs increases the bioavailability of the drug and also we can increase the surface area. It is mainly suitable for Hypertension, Angina, Antacid, etc. And for the better release of drug in mouth we can add effervescent mixture as the excepients because it release co2 that breaks down the tablet very fast so it is easy to swallow without water. It gives fast action as compare to capsule and film coated tablet.[23]

The fast-dissolving property of the tablet is attributable to a quickingress of water into the tablet matrix resulting in its rapid disintegration. Hence, the basic approaches to developing fast dissolving tablets include maximizing the porous structure of the tablet matrix, incorporating the appropriate disintegrating agent, and using highly water-soluble excipients in the formulation.[24]

Evaluation of Orodispersible Tablets

Hardness/crushing strength

The hardness of the tablet is measured by using conventional hardness testers like Monsanto hardness tester. The limit is toward the lower range in order to help early disintegration in mouth.[25]

Friability

It is a difficult job to maintain the percentage of friability within the limit, since all the methods of preparation of orodispersible tablets have a tendency to increase the percentage of friability.[26] In all aspect, the range is within limit of 0.1%-0.9%. Roche friabilator is used in conventional form in order to measure friability of the tablets.

Wetting time

Wetting time is the indication of the inner structure of the tablets and to the hydrophilicity of the excipients. Thus, wetting time of a dosage form is related with the contact angle. The lower the wetting time the quicker is the disintegration of the tablets.[27] The wetting time can be measured by using five circular tissue papers of 10 cm in diameter, which are placed in a petridish of 10 cm diameter.Ten millilitres of water-soluble dye like eosin solution is added to the petridish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as the wetting time. For measuring water-absorption ratio, the weight of the tablet before keeping in the petridish is noted (*W*b).The wetted tablet from the petridish is taken and reweighted (*W*a). The water-absorption ratio, R can be determined according to the following equation.

$R = 100 (Wa – Wb)/Wb$.[28]

Moisture-uptake studies

It is an important study in the case of orodispersible tablets. This study is carried out in order to assess the stability of the tablets. Ten tablets were kept in the desiccators over calcium chloride at 37°C for 24 h. The tablets were then weighted and exposed to 75% relative humidity, at room temperature for 2 weeks. Required humidity was achieved by keeping saturated sodium chloride solution at the bottom of the desiccators for 3 days.[29] One tablet as control (without super disintegrant) was kept to assess the moisture uptake due to other excipients. Tablets are weighed and the percentage increase in weight is recorded.

Disintegration test

The *in-vitro* disintegration time was determined by disintegration test apparatus. The time for disintegration of orodispersible tablets is generally <1 min and actual disintegration time that patient can experience ranges from 5 to 30 s. A tablet is placed in each of the six tubes of the apparatus, and one disc is added to each tube. The standard procedure of performing disintegration test for these dosage forms has several limitations.[30] It is expected that disintegration test for orodispersible tablets should mimic disintegration in mouth within salivary contents. Sunada *et al*. performed disintegration test by using modified United States.

Pharmacopoeia Apparatus II by taking 900 ml of medium maintaining 37°C with r/min 100. It was carried out by taking a 1 l cylindrical vessel. Orodispersible tablets were placed in basket sinker in the middle of the vessel with a distance of 6-8.5 cm. Even Narazaki *et al*. carried out the disintegration test with rotary-shaft method.[31] The apparatus consisted of stainless steel wire gauze on which orodispersible tablets were placed and

slightly immersed in medium. Here, the rotary shaft is used to provide rotation and mechanical stress.[32]

DISSOLUTION TEST

It is an important test as the drug-release profile can be obtained by performing this test. Both the USP dissolution test apparatus can be used. Dissolution of orodispersible tablets is very fast.[33] Therefore, USP 2 Paddle-type apparatus at 50-100 r/min is used for dissolution testing. Swammy *et al*. carried out *in vitro* dissolution study of pheniramine maleate orodispersible tablets in type II apparatus with r/min 550 using 900 ml phosphate buffer of pH 6.8 at 37 ± 0.5°C as a dissolution medium. USP type I basket apparatus have certain application in the case of orodispersible tablets, but tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle.[34] An erroneous-dissolution profile is obtained, where little or no effective stirring occurs. Thus, type II is more preferred due to reproducible-dissolution profile.[35]

CONCLUSION

Orally disintegrating tablets have better patient acceptance, compliance and may offer improved biopharmaceutical properties, improved efficacy, and better safety compared with conventional oral dosage forms. Prescription ODT products initially were developed to overcome the difficulty in swallowing conventional tablets among pediatric, geriatric, and psychiatric patients with dysphagia. Today, ODTs are more widely available as OTC products for the treatment of allergies, cold, and flu symptoms. The potential for such dosage forms is promising because of the availability of new technologies combined with strong market acceptance and patient demand. By paying close attention to advances in technologies, pharmaceutical companies can take advantage of ODTs for product line extensions or for first to-market products. With continued development of new pharmaceutical excipients, one can expect the emergence of more novel technologies for ODTs in the days to come.

ACKNOWLEDGEMENT

The authors are thankful to the faculties of H. K. collge of Pharmacy for guiding the preparation of this manuscript.

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