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Research Article

AN OVERVIEW ON ORO DISPERSIBLE TABLETS

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A B S T R A C T

In the design of delivery method, convenience in administration as well as improved patient compliance find predominance. Oral dispersible tablets (ODTs) are solid dosage forms which disintegrate in the oral cavity in below 60seconds and have been taken without water. Swift disintegration followed by fast dissolution and rapid commencement of action are advantages of ODTs. Other advantages include improved stability and bioavailability. ODTs are suitable dosage forms in pediatrics, geriatrics, the mentally sick, nausea patients, and patients having trouble in consuming tablets and capsules. When ODTs in the tongue, they disintegrate immediately, delivering the drug, that breaks down in the saliva. Few medications are absorbed from the mouth, oesophagus, and pharynx, as the saliva passes through the stomach. In such instances, the bioavailability of a drug is remarkably greater than those noticed from conventional tablet dosage forms. Various methods in ODT manufacturing include – direct compression, spray drying, sublimation, melt extrusion, cotton candy process, etc.

INTRODUCTION

Despite enormous innovations in delivery of drug, the oral route continues to be the preferred route for administering therapeutic agents because of precise dosage, inexpensive therapy, non-invasive method, self-medication, ease of management, giving rise to patient compliance[(1)]. Paediatric patients can have ingestion problems due to poor muscular and nervous control. Besides, patients travelling with less or no access to water restrict the use of orally administered conventional dosage forms [(2,3)]. Traditional oral dosage forms such as tablets and capsules have a swallowing problem for geriatrics and paediatrics [(4)]. Approximately 35% of the overall population suffers from dysphasia. Oral disintegrating tablets (ODTs) are tablets which are placed in the mouth and then they get dispersed in mucus without the water[(5)]. ODTs are investigated for their potential to improve the bioavailability of less water-soluble drugs by altering the drug's dissolving profile and increasing patient compliance[(6)]. The excipients used in ODT mechanism are generally hydrophilic and can be chosen based on the drug's physicochemical nature, like hydrophilicity or hydrophobicity[(7)]. In case the drug is hydrophobic, the dosage form is known as disintegrating tablet, and if it is hydrophilic, it is a fast-dissolving tablet[(8,9)].

Advantages of Oro dispersible tablets

- These are given to geriatric, paediatric, and psychologically disabled patients.
- Water is not required to swallow the tablet[(10)].
- After oral administration, no residue should be left in the oral cavity.
- Compatible with taste concealing and have a pleasant mouth feel[(11)].
- High drug loading.
- A precise dose is possible as compared to liquids.
- Fast dissolution and drug absorption, contributing a rapid onset of action.
- No risk of suffocation due to physical barrier when swallowed, thus offering enhanced safety[(12)].

Need to formulate mouth-dissolving tablets

The non-invasive drug delivery systems proceed on the basis of poor patient compliance with current delivery regimes and restricted market area for drug companies. FDTs are those dosage forms which are valuable for:

- Geriatric patients mostly suffer from conditions such as hand quakes and dysphasia.
- Pediatric patients cannot swallow easily as their internal muscles and central nervous system are not fully developed.
- Lack of access to water, to patients suffering from diarrhoea and motion sickness while travelling.
- Patients with continuous nausea for an extended period face difficulty in swallowing. Especially cancer patients, post chemotherapy, causes nausea after swallowing the H2 blockers prescribed to bypass gastric ulceration[(13)].

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Limitations of Oro dispersible tablets

- The tablets might leave a disgusting taste and grittiness in the oral cavity if not formulated appropriately[14].
- Drugs having large doses, leads to problems in formulating ODTs.
- Rapid disintegrating tablets are hygroscopic, so they should be maintained in a controlled environment, i.e., temperature and humidity[15].
- Absorption rate from the saliva and overall bioavailability affected.
- Stability of drug and dosage form [16].

Challenges in the formulation of ODTs

- **Taste masking**: Systematic taste masking of drugs which have bitter taste must be done [17].
- **Mouthfeel:** The particles generated after the ODTs disintegration must be microscopic. Adding flavours and cooling agents such as menthol enhances the mouth feel[18].
- **Cost:** The adopted technology for an ODT should be accepted in terms of price of the final product.
- **Mechanical strength and disintegration time:**The disintegration time will increase if the mechanical strength is high; good cooperation within these parameters is positive[19].
- **Size of the tablet:** It was stated that the maximum superficial tablet size to intake is 7-8mm, although the most available size to handle is higher than 8mm. Appropriately, manufacturing a pill size which is easy to take, but hard to maintain [20,21].
- **Hygroscopicity:** Hygroscopic ODTs destroy physical integrity at humidity conditions and temperature settings. Thus, they protected from humidity by a particular product container[22].

Drug Criteria in a selection of ODTs

- The drug must be dispersed, penetrated, and ionised in mucosa withoutresidue in the oral cavity[23].
- The active ingredient must be less than 50mg intended forcontinual use.
- Pleasant taste, smell, and short half-life.
- Resistance to harsh eco-friendly conditions.
- Production cost is low and well-coordinated with current processing and packing procedures make them constant appealing to industry and patients.
- Good stability in water and saliva[24].

Table 1 Drugs that are used in Oro dispersible tablets

Categories	Drugs
Anti-inflammatory agents andAnalgesics	Piroxicam, Ketoprofen and Ibuprofen
Anti-epileptics	Carbamazepine, Methsuximide, Phenytoin
Anti-fungal agents	Clotrimazole, Amphotericin, Griseofulvin
Anti-bacterial	Erythromycin, Ciprofloxacin, Clarithromycin
Diuretics	Amiloride, Chlorthalidone, Acetazolamide
Anti-parkinsonism agents	Lysuride maleate, Bromocriptine mesylate

Names and percentage weight of various major excipients

Name of excipients

Super disintegrants	-	1 to 15%
Anti-static agents	-	0 to 10%
Diluents	-	0 to 8%
Binders	-	5 to 10%

Preparation methods for orodispersible tablets

Water needs to get into the tablet structure rapidly to produce fast fragmentation and instant tablet dissolution. This is attained by including a satisfactory disintegration agent or extremely hydrophilic super disintegrants in tablet preparation.

There are two perspectives for preparing Oro dispersible tablets:

1.Conventional methods and
2.Patented methods[25].

Conventional methods

Direct compression

The easiest and economical way to prepare dosage form. Microcrystalline cellulose (MCC) and less substituted hydroxypropyl cellulose (HPC) yield rapidly disintegrating tablets. Fast disintegration can be attained by adding effervescent substances in a tablet to produce carbon dioxide, that helps in the taste masking of a preparation. The major limitation of the effervescent material is hygroscopicity, i.e., the capacity to absorb atmospheric humidity. Examples of super-disintegrants include sodium starch glycolate, cros povidone, and cross carmellose. They provide fast disintegration by swelling owing to absorption of water[23]. Properties of direct compression are economical, much closer toconventional dosage form, except, a high amount of disintegrants can cause low tablet hardness[26].

Lyophilization/freeze-drying

Formation of porous products in the freeze-drying procedure is explode in formulating ODTs. Lyophilization is a procedure that includes the solvent removal from a freeze suspension or drug solution with structure-creating additives. Freeze-drying of the drug and supplements/additives imparts a glossy amorphous form resulting in a high porous and less weight product. When placed on the tongue, the resulting tablet has fast disintegration and dissolution, and the freeze-dried component breaks down instantly for drug release. However, the MDTs formed by freeze drying has less mechanical strength and poor stability at high temperature and moisture. The major disadvantage of this process is its time-consuming procedure, high cost and fragility, making traditional packing unsuitable and stability issues under stress conditions [27].

Molding technique

Molded tablets are formulated using water-soluble excipients so that the dosage form dissolve entirely and quickly. The powder blend was humidified with a hydro alcoholic diluent and molded into drugs below reduced pressure compared to conventional tablet compression. Solvent was evaporated by airdrying. These contain a porous structure which increases dissolution. Tablets are formulated using water soluble constituents to get maximum dissolution. The powder mass is moistened with hydroalcoholic solvent followed by

compression into tablet. The solvent system is allowed to evaporate[29].

Cotton candy process

The present procedure is so named, as it utilizes a special spinning mechanism to formulate a floss-like crystalline form mimicking cotton candy. The cotton candy procedure involves the development of a matrix of polysaccharides by concurrent action of spinning and flash melting, which is then blended with active or inactive ingredients and manufactured into ODTs. The matrix which is formed is partly re-crystallized to have enhanced flow characteristics and compressibility. Here candy floss matrix is next milled and mixed with active pharmaceutical ingredients along with excipients and later produced to ODTs[30].

Spray drying

This technique is built on a particulate matrix developed by spray drying by an aqueous composition carrying matrix support and other constituents to form a highly porous powder. This is then blended with active ingredients and compressed to a tablet. Allen and Wang worked on a spray drying technique towards Oro dispersible tablets. In this technique, ingredients are combined by hydrolysed and non-hydrolyzed gelatin as supporting agents, sodium starch glycolate or cros carmellose sodium as disintegrating agents, mannitol as a bulking agent, alkali material (e.g., sodium bicarbonate), acidic material (e.g., citric acid), to enhance disintegration along with dissolution. A characteristic of the spray-drying technique is that this method gives quick dissolution (in 20 seconds) when the tablet encounters solvent[31].

Mass-extrusion

The powder ingredients are softened using water-soluble ingredients, i.e., polyethylene glycol, with methanol as solvent, flowing through an extruder producing thin cylinders. Whichfurther get chopped with a heated blade to formulate small tablets. Properties of this method are that these products can cover bittertaste of drugs making small particles, thus improve oral bioavailability[32].

Sublimation

A highly porous form of tablet matrix is a crucial factor for the fast disintegration of ODTs. Though conventional tablets possesshigh water-soluble ingredients, whichfrequently fail to disintegrate quickly because of low absorbency. To enhance the porosity, volatile constituentslike camphor is utilized in the tableting process, sublimating from the tablet formed. The volatile material is developed by reduced pressure then followed by applying low temperature leaving the formulation in porous forms [33]. The features of this method are that they are porous by nature, and solvents like benzene and cyclohexane are also used.

This technique removes camphor (a sublimating agent) from the compressed medicines by sublimation. Highly porous forms were produced due to removal of camphor from the crushed tablets[34]. The resulting tablets, distinguished by highly porous structures, could attainrapid disintegration in saliva. Further volatile materials include camphor, menthol,thymol,ammonium carbonateadipic acid, ammonium bicarbonate, palmitic acid, arachidic acid, myristic capric acidand urea. The temperature ranging from 40 to 60 °C[35].

Melt granulation

Melt granulation was formulated by adding hydrophilic waxy binder (super poly state) PEG-6- stearate. This binder has dual action; improved physical strength andalso enhances disintegration. Drugs like griseofulvin can be administered easily in such a dosage form. The characteristic of the compaction technique is that it melts rapidly in the mouth, leaving no residue[36].

Effervescent Method

Effervescent Oro dispersible tablets combine sodium bicarbonate along with tartaric disintegrants likecross povidone, crosscarmellose, andsodium starch glycolate. To eliminate residual/absorbed moisture,tartaric acid and sodium bicarbonate were heated at 80°C and combined in motor. The mixtures are lastlymade into tablet[37].

Nanonization

Nano melt is a recent innovation, nano-based system that reduces particle size of drug to be in particulate-scale range by means of a proprietary wet-grinding method. APIs, usually in nanocrystals ornanoparticles, are stabilized beside agglomeration by surface adsorption on a preselected stabilizing agents introduced into ODT systems. This method is suitable for ailinghydrophilic drugs, and the formed tablets exhibit fast disintegration and dissolution [38].

Patented technologies

Zydis Technology

Zydis is one kind oflyophilized tablet, that are physically trapped or liquified inside a matrix fast dissolving carrier material. While patientstakethese pills in oral cavity, the freeze-dried assemblyquickly disintegrates, so they do not require water to consume. The zydis matrix contains a mix of mechanisms collaborating to achieve different objectives. Polymers such as gelatin, alginates or dextranoffer strength and elasticity. These combine to yield a glossy amorphous form that confers stability. Zydis pharmaceuticals are packed in blister packs to store the formula from external dampness[39].

Orosolv Technology

Conventional blenders and tablet machineries are used, but a low compression strength speeds up the tablet breakdown. As Orosolv tablets are more fragile than conventional dosage forms, CIMA, the firm that manufactures them, devised a particular handling and packaging method to compensate[40].

Flash Tab Technology

The technique of tablet manufacturing has an active ingredient in microcrystalline form. Conventional methods such as coagulation, extrusion spheronization and microencapsulation can produce drugs in micro granules. Tablets are prepared using a matrix that consists of fibrous polysaccharides which are compressed to generate thin sugar fibers that breakdown rapidly when exposed to mucus. The tablets produced by this process remain soft, sensitive, brittle to humidity, and have a more surface area for liquefying, allowing them to disperse in few seconds[41].

Wowtab Technology

Yamanochi Pharmaceutical Firm has patented this method, and WOW abbreviatedas "Without water." Two different types of saccharides were used in the manufacturing of WOW tab, such as

saccharides which possess high moldability and rigidity (maltose,sorbitol and mannitol) are mixed with partial moldability saccharides (mannitol, xylitol,lactose, glucose) and compressed to prepare a tablet formulation with suitable hardness and rapid dissolving rate. WOWtab configuration is quite stable due to considerable hardness. A very good flavourcovering ingredient is used in this technique to generate a pleasantmouth feel by means oftrademarked smooth melt action. The Wow tab invention melts under 15 seconds[42].

Post-compression tests of odts

Weight variation

The weight of 20 random tablets is determined,next the mean weight was calculated[43].

Table 2 Limits of weight variation test according to IP/BP and USP

IP/BP	Limits	USP
<80mg	±10%	<130mg
80mg to 250mg	±7.5%	130mg to 324mg
>250mg	±5%	>324mg

Content Uniformity

From each formulation, randomly chosen three tables are powdered, and then UV absorbance of the mixture, equivalent to 1 mg was measured. If API remains less than 25mg, the content uniformity assessment is considered. Otherwise, a weight variation test stands applicable[44].

Hardness

Crushing strength of 6 randomly selected tablets were measured by means of a Monsanto hardness tester andis expressed in Newton. It shows the strength of tablets. The limits are ±5kgs[45].

Friability

The initial weight of 6 tablets was noted and put in Roche friabilator at 25rpm for 4min.Then, reduced weight is measured.Friability value was determined [44].

$$\%friability = \frac{initial\ weight}{final\ weight} \times 100$$

Disintegration time

The disintegration apparatus is used to determine in-vitro disintegration period. The disintegration time of ODTs is an essential feature, as they should break down in minimal number of oral fluids in a short period, typicallywithin a minute. The actual disintegration time,which patients experience, ranges from 5 to 30 seconds[46].

Porosity

Porosity is determined by a mercury porosimeter. Thisreasonably shows how much water penetratedin formulation [47].

Thickness and Diameter

The diameter and thickness of 10 randomly chosen tabletswas measured by placing them inVernier Caliper and recorded the thickness and average diameter[48].

Wetting time or Water absorption ratio

The initial weight of the individual tablet was measured. 10ml of eosin solution was poured into a petri dish, and the tablet is placed in it. Time taken for the eosin solution to reach the uppermost layer oftablet is measured. Short water absorption ratioleads towards fast disintegration[48].

Moisture uptake

Initial weight of 10 tablets is measured and next placed in a desiccator (37°C,1d) and tablets were exposed to 75% of relative humidity (25°C,15d), and an increase in weight was recorded. This test is used to assess the stability of formulation[49].

In-vitro drug release

Tablet dissolution apparatus (USP type II) is used. The initial weight of the tablet was noted and then placed in 900ml buffer in a dissolution flask at 37±0.5°C at 50rpm speed for specific time intervals, and sink conditions were maintained. The sample was examined under a UV-visible spectrophotometer[50].

Applications of ODTs[50]

- The number of drugs marketed applying various techniquesin formulating ODTs. Oro dispersible tablets have many benefits compared to other oral dosage forms, like betterimproved efficacy, patient compliance andbioavailability.
- Nonetheless, formulation challenges like limited manufacturing technology, disintegration time,tablet weight, friability, and packaging must be considered.
- Oro dispersible tablets can be assessed as anoptimal option for paediatrics and geriatricsin situations where parenteral cannot be utilized, especially for the gastrointestinal system disorders, central nervous system, and pain.

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