HOUSE OF WISDOM: JOURNAL ON LIBRARY AND INFORMATION SCIENCES

ISSN 3089-6002. Published by Universitas Muhammadiyah Sidoarjo

A Review on Manufacturing and Characterization Oro-Dispersible Tablet

Hiba Muhammed Suza Ali [1], Eman Bekir Al-Khedairy[2]
[1,2]Program Department of Pharmaceutics, College of Pharmacy, Uruk University, Baghdad, Iraq.
Email : hibam3449@gmail.com[1] , emanbekir@copharm.uobaghdad.edu.iq[2]

General Background: Oro-dispersible tablets have emerged as an important advancement in oral solid dosage forms due to their ability to rapidly disintegrate in the oral cavity without water. Specific Background: Their development is driven by patient demand for convenient medication, especially for pediatric, geriatric, and dysphagic populations who experience difficulty swallowing conventional tablets. Knowledge Gap: Despite wide application, comprehensive evaluation of fabrication methods, excipient functions, and characterization parameters across traditional and modern manufacturing technologies remains limited. Aims: This review analyzes the terminology, advantages, limitations, commonly used excipients, manufacturing techniques, and critical quality assessments of ODTs. Results: The study highlights diverse preparation approaches including lyophilization, sublimation, wet granulation, direct compression, mass extrusion, and emerging three-dimensional printing, each offering unique benefits related to disintegration behavior, mechanical strength, and processing efficiency. Novelty: The article synthesizes conventional pharmaceutics knowledge with recent technological innovations such as selective laser sintering and fused deposition modeling, demonstrating how modern techniques enhance precision and personalization of dosage forms. Implications: Findings underscore that optimized excipient selection and manufacturing strategies are fundamental to ensuring rapid disintegration, mechanical stability, acceptable taste, and enhanced bioavailability, reinforcing ODTs as a growing platform for patient-centered drug delivery.

Highlights:

1. Oro-dispersible tablets dissolve rapidly on the tongue, improving convenience for patients with swallowing difficulties.
2. Formulation uses specific excipients—especially superdisintegrants—to achieve fast disintegration and effective performance.
3. Can be produced using various traditional and modern manufacturing methods such as direct compression, sublimation, and 3D printing.

Keywords: Disintegration, Oral solid dosage form, Oro-dispersible tablet, Patients' compliance, Manufacturing techniques

Introduction

The way of oral taken medicine has published usage about from 50 to 60 % of all dosage forms. Solid dosage forms are the most common as a pharmaceutical dosage form are manufactured in the pharmaceutical factory and most present in the pharmacy because of easily administered and self-taken by the patient, accurate dose, painless and enhanced patient's compliance [1]. The food and drug administration center for drug evaluation and study of U S; defines Oro-

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dispersible tablet (ODT) as "a solid dosage form containing medicinal substances, which disintegrates rapidly usually within a matter of seconds, when placed upon the tongue" as shown in Fig. 1 [2,3]. That's fasted dispersed due to the super dispersible material that's found in the ODT which depend on the type and concentration of it; to obtain the desired dispersible time like crospovidone which get faster disintegrating with increased concentration; also, oro-dispersible tablet contain other excipient as which found in the ordinary tablets such as: flavored, sweetening agent, lubricant, filler, anti- adherent agents in addition to the active ingredient. So, this dosage form is preferred from persons at any life stage, especially patients suffering from problem in swallowing because its easily taken by patient without need water and can take it at any place like in travelling. Furthermore, named as "mouth dissolving tablets", "quick disintegrating tablets", "fast dissolving tablets", "fast disintegrating tablets", "rapid dissolving tablets" and "porous tablets" [3].

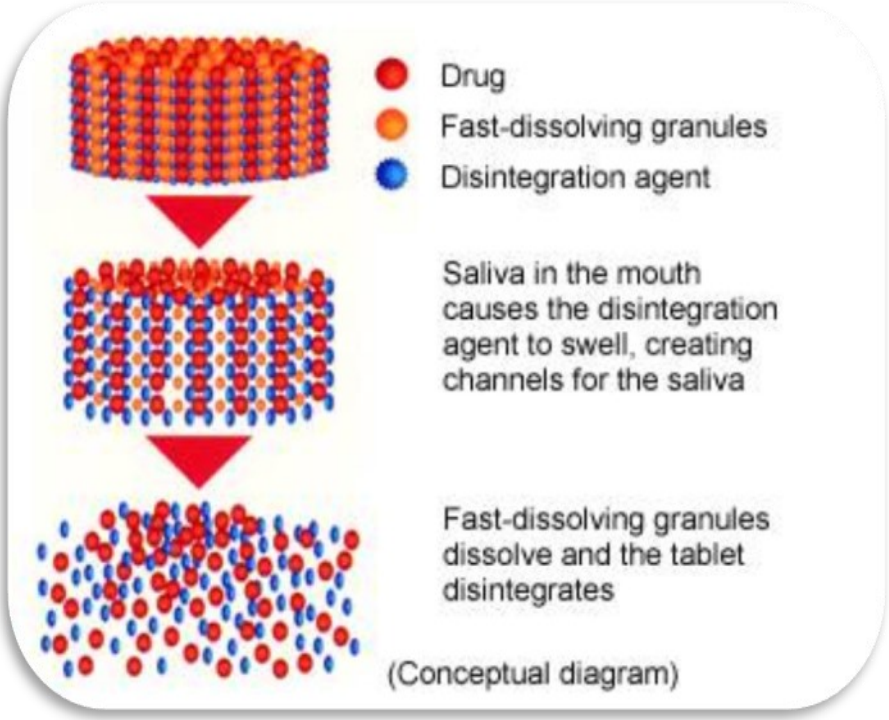

Fig. 1: The mechanism of disintegrant of oro- dispersible tablet [3]

Advantage of Oro- dispersible tablet

There are many advantages of oro- dispersible tablets which made it preferred than other oral dosage form, and can listed some of them below, like [4, 5]:

1. This dosage form can be simply administered to children and elderly patients.
2. More accurate in the dose than liquids dosage forms, furthermore it's easy for administration and transportation.
3. Fast in the dissolution and absorption of the active ingredient, in addition to rapid onset of action can be obtained.
4. Bioavailability of the active ingredient is improved as certain of these materials are absorbed from pre gastric parts like mouth, pharynx and esophagus.

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5. Suitable for sustained/ controlled release of drug.

Disadvantages of Oro- dispersible tablet

Similar to others dosage forms, oro- dispersible tablet had many disadvantages or limitation like [6, 7]:

1. difficult formulated a medicine with high doses as ODT, like antibiotic
2. low in mechanical strength of ODT because of it is form of porous or soft molded matrix which is important to disintegration in mouth, which also make it a friable pills and problem in handling.
3. Palatability of ODT, since it is planned to be dissolved in mouth. Greatest of the drugs have unpleasant taste and this bad taste can be covered with sufficient sweetener and flavors alone or in combination with other methods of taste masking like: adsorption, coating with polymers, ionic gelation and other methods.
4. Drug candidate should be stable in water and saliva.
5. ODT needs a specific packaging for keeping the stability of the product and provide the protection for it.
6. It is a task to reach rapid disintegration of a tablet.
7. The size of tablet is important. The easiest size to accept is 7 to 8 mm, whereas the suitable handling size is more than 8 mm.

Common techniques used for manufactured of Oro- dispersible tablet

Different techniques are used for formulation of the oro- dispersible tablets, and can listed most common old and modern techniques of these below:

Freeze drying (lyophilization)

Freeze drying is a procedure in which solvent is sublimated from the formation after freezing. This technique is used for thermal sensitive drugs and gets rapid dissolution times than further existing solid products because the porous structure that leads to rapid dissolution or disintegration. The usage of freeze-drying is limited because the time and handling requisite for processing and furthermore the high price of the apparatus and processing [8]. Dhahir R and Al-Kotaji M they succeeded in manufacturing of cinnarizine oral lyophilizates as ODT with rapid disintegration time within 56±12.73 second [9].

Sublimation

To get rapid disintegration and dissolution the formulation should makes with porous mass by mixing with volatile solid materials that volatilize rapidly such as urea, camphor and ammonium bicarbonate; and compressed. Then, by lowered pressure and temperature, the volatile material will volatilize leaving the mass in porous form [5,10]. SC Darade *et al* formulated piroxicam as ODT by sublimation method by using camphor as subliming agent which formed porous structure in the tablet, aids to easy penetration of fluid resulting in reducing disintegrating time to 30 second [11].

Three-dimensional printing (3DP)

A 3D printer is an apparatus which fabricates three dimensions models or products using processer helped strategy software programs. Thats apparatus can form a single copy of a

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product that is very hard to form by using old-style industrial approaches. Also, it has aptitude to form a product with multifaceted inner building geometries with low price and time. This method can used in prepared ODT by numerous techniques with powder bed inkjet printing, fused deposition modeling (FDM), semi-solid extrusion (SSE), selective laser sintering (SLS), and stereo lithography (SLA) [12]. Allahham N et al fabricated ondasteron as ODT by using SLS 3DP and got disintegration within 15 sec and released > 90% of the drug in 5 min [13].

Mass extrusion

In this technique the drug is mixed with solvent combination of hydrophilic polymer (polyethylene glycol) and methanol, then this unstiffened build is placed into an extruder, to obtain a cylinder-shaped formation which is cut it into small parts to from tablets [14]. Prabhat Sh et al masked bitter taste of Mirtazapine by Eudragit EPO as soluble polymer by mass extrusion technique, and formulated as ODT [15].

Direct compression

This is the greatest communal method for the formulation of ODT because of some advantages like: can used high doses, weight of the tablet can more that of further approaches, easy method, available tools and excipients are used, little numbers of processing steps are involved and with low cost [16]. In this technique, the drug is mixing with excipients then compressed into tablet directly without any primary treatment. The blend must have suitable flow properties to be compressed under pressure. Sugar grounded excipients are used as bulking agents like lactose, maltilol, mannitol and sorbitol which show great water solubility plus sugariness, and therefore inform taste covering property and a palatable taste [6]. Rai K et al formulated lornoxicam as ODT by using direct compression technique consuming mannitol as diluent [17].

Wet granulation

It is a process for enlarged the particle which known as "*agglomeration*". It consists of six steps: dry mixing, wet mixing, sieving of the wetted mass, drying, and sieving of the dried mass and finally blending with lubricant and compressed. This method had long processing time and not favorable for heat sensitive drugs [18]. Ahmed D K et al formulated prochloperazine maleate as ODT by wet granulation and used 10% (w/w) PVP in ethanol as granulated fluid and got disintegration time between 14.4- 22 seconds [19].

Zydis Technology

This method is one of patent technology of prepared of ODT, the drug dissolved within a carrier like alginate, gelatin which form a glossy amorphous structure, and can add some sugars like mannitol to produce some hardness and used water to permit some porosity to enhance the disintegration of tablet [20].

WOW tablet

At this method combine two types of saccharides to produce more harder tablet and more stable than zydis method in addition more taste mask of unpleasant tablets obtained at this technique [21].

Excipients commonly used for ODTs preparation

Many excipients are added to ODT in addition to the active ingredient (Figure-2), acts as [14,

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22]:

a) ***Super disintegrant*** is the main constituent in the ODT which responsible for disintegration rapidly of the tablet at different mechanism as shows at Table (1), also the rapid of the disintegration depends on the concentration in addition to the type of the super disintegrant agent like crospovidone and sodium starch glycolate they ranged from 1-10 % w/w concentration

Table (1): The mechanism of the super disintegrants agents [22, 23]

The mechanism	*Comments*
Swelling	Super disintegrant Swell when contact with saliva then breakdown the tablet like *gellan gum*
Porosity and capillary (wicking)	wetted the surface of the tablet with the saliva that's forms a pour which permit to penetrate of water inside it which lead to faster disintegration like *Crospovidone* and Croscarmellose sodium in addition to their swelling abilities
Particle- particle repulsive force	This mechanism depends on the electrical repulsive force that's cause a particle reject the other which lead to disintegration in the presence of the saliva or water like with swelling capable
Deformation	This mechanism is referring to higher elastic super disintegrant which capable to deform and form channels to penetrate the water and disintegrate like a *starch*
Hydration	This mechanism is referring to a hydrophilic super disintegrant which absorb water rapidly then swelling and rapturing the tablet (disintegrant) like: Cross-linked alginic acid
Gas formation	When contact the super disintegrant with saliva that's form a gas inside the tablet which create internal pressure that's leads to disintegrate of tablets like: sodium bi-carbonate

Abd Al Hamide Sh N. prepared sodium fluoride as ODT and used 3- D printer with different super disintegrant, then compared between them, she is found that; crospovidone was better than sodium starch glycolate and croscarmelose in disintegration time and wettability [24].

b) ***Binders*** which make a cohesiveness of blending powders, that's affords them adequate compressibility and durability. It is used within concentration of 0.5- 5%, furthermore they are used to upturn the mechanical strength of the tablet like PVP.
c) *Fillers* are used to formulate tablets with wanted size and mass such as lactose, starch and mannitol.
d) *Flavors* like peppermint, strow berry and vanilla.
e) *Sweetening agent* like mannitol, sucrose and saccharin
f) *Anti-adherents* and *lubricants* are added to the tablet formulation to improve its flowability, decrease friction and advance the possessions of powders through the tablet's compression.

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Furthermore, it avoids sticking of tablets to dies and punches of the tablet machine; like talc and magnesium stearate with amount about 0.5-1 %.

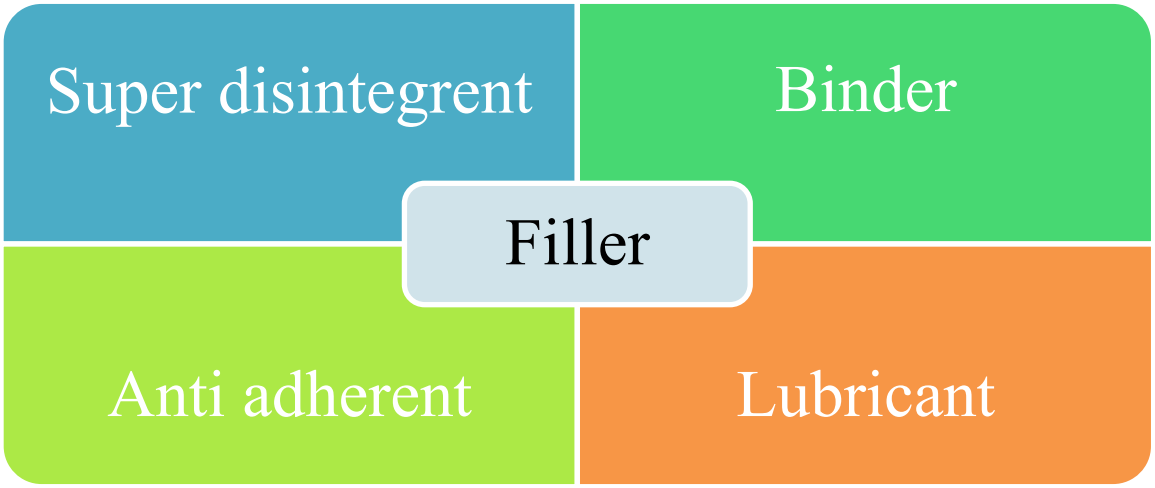

Figure -2: The commonly excipients used for ODTs preparation

The specific characterization of oro- dispersible tablet

Wetting time and water absorption

The method to detect the moistening period of ODTs, the filter paper was folded twice and placed in a Petri- dish with known diameter, that's contain (10 ml) of purified water; after that recorded the time that's required for wetting of ODT.

The water absorption% was calculated after known of the wetting time, and that's determined by handover the moistened tablets cautiously and get rid of the excess water by using a new filter paper; then weighed directly. The water absorption % was calculated by the equation below [25]:

$$Water\ absorbtion\% = \frac{Wa - Wb}{Wa} * 100$$

Where $\mathbf{W_a}$ is the weight of ODT after absorption water; $\mathbf{W_b}$ is the weight of ODT before absorption water.

Disintegration time

Disintegration time was determined by using "modified disintegration method" by using a Petri-dish which fuller with (10 ml) of phosphate buffer (pH 6.8) at temp. (37± 0.5 ºC); Then put the ODT in the center of the Petri- dish and record the time for the completely disintegration of the ODT into fine subdivisions [26].

In- vitro taste evaluation

One tablet was placed in 10 ml phosphate buffer (pH 6.8) at 37 ºC and shacked for one minute. Then the drug released was determined by many methods, like using UV- spectrophotometer and scanned at its specific λ max [27].

Conclusion

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Oro- dispersible tablet is one of the important and unique oral solid dosage form because of its many advantages in the pharmaceutics manufacturing and advantages for consumer by improve patient compliance. Many different techniques, old and modern are used in the prepare of this dosage form with different characterization for each method, such as freez drying, sublimation, mass extrusion, direct compression, 3- dimension printing, wet granulation and other techniques. And the specific evaluation or characterization of this dosage form like the evaluation of the ordinary tablets like flowability, weight variation, thickness, hardness, friability, drug content, stability study and drug release in addition to other the specific evaluation of oro-dispersible tablets like dispersed time, wetting time, water absorption and *in- vitro* or *in- vivo* taste evaluation.

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