



REVIEW ON ORAL DISPERSIBLE TABLET

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ABSTRACT

One of the most preferable methods for drug delivery is thought to be the oral route. Orally dispersible pills have recently emerged as the preferred dosage form, particularly for a certain group of patients, including pediatric, geriatric, those who are bedridden or mentally ill, and those who are uncooperative. Orally dispersible tablets shine above other conventional dosage forms due to their quick disintegration, higher patient compliance, and increased bioavailability. According to the European Pharmacopeia, orodispersible tablets are those that dissolve or disperse in the mouth before being swallowed in less than three minutes. The current article focuses on ideal characteristics, benefits and drawbacks, various methods for formulating orodispersible tablets and its evaluation, new research, and prospects in the future.

KEYWORDS

Oral dispersible tablets, bioavailability, formulation, new research

INTRODUCTION

Solid dosage forms are popular due to low cost, ease of administration, accurate self-medication, pain avoidance, and patient compliance.[1 2] Conventional tablets are widely administered, but some patients, such as pediatric, geriatric, bedridden, mentally ill, and uncooperative, find it difficult to swallow them, leading to high rates of non-compliance and unproductive treatment [3]. Pharmaceutical scientists have designed a novel oral dose form known as ODTs to meet these medical needs. ODTs dissolve quickly in saliva, typically in a matter of seconds, without the need for water intake. When compared to conventional dose forms, medication solubility and absorption, as well as the onset of clinical action and drug bioavailability, may be much higher [4 5].

Orodispersible tablets are defined by the European Pharmacopoeia as those that quickly dissolve in the mouth within three minutes before being swallowed.[6]

United States Food and Drug Administration defined ODT as “A solid dosage form containing a medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue.” The disintegration time for ODTs generally ranges from several seconds to about a minute [7].

These ODTs have many benefits, including no swallowing issues, improved patient compliance, quick action, enhanced bioavailability, and good stability.

The superdisintegrants cross carmellose sodium, cross povidone, sodium starch glycolate, poly vinyl pyrrolidone (PVP), and others are most frequently used in the development of ODTs.[8]

Super disintegrant is the main component that is required for the production of an ODT. A super disintegrant’s primary job is to dissolve the tablet when it comes into contact with water.[9]

Oral dispersible tablets can be made using a number of techniques, including direct compression, mass extrusion, sublimation, freeze drying, and spray drying. This review's major objective is to look into current developments in ODT technology, active pharmaceutical component requirements, and ODT evaluation methods.

IDEAL PROPERTIES OF ORODISPERSIBLE TABLETS [10]

- High drug incorporation.
- Without needing water to swallow, and dissolving or disintegrating in the mouth in a few seconds.
- It can be stable in environmental conditions such as humidity and temperature.
- compatible with various excipients and taste masking agent.
- After oral administration, leave no residue left in the mouth.

ADVANTAGES OF ORODISPERSIBLE TABLETS[11]

- It is a preferred dosage form, particularly for a certain group of patients, including pediatric, geriatric, those who are bedridden or mentally ill, and those who are uncooperative.
- Compared to liquid formulations, the ease of administration and accurate dosing
- Faster drug absorption through the mouth, pharynx, and oesophagus, which may result in a quick onset of effect.
- Pre-gastric absorption can lead to increased bioavailability, a smaller dose, and enhanced therapeutic performance by limiting side effects.
- As a result of using conventional drug manufacturing techniques, the production cost is fairly low.

DISADVANTAGE OF ORODISPERSIBLE TABLETS[12 13]

- Because they are hygroscopic, orodispersibles must be stored in a dry environment.
- ODT needs specialised packaging to ensure the safety and stability of stable products.
- Technically, dose uniformity is difficult.

Mechanism Of Drug Release

The drug release mechanism of ODT depends on the super disintegrant used in formulation. firstly When the tablet is being formed, the disintegrant particles are deformed during the compression stage, but when it is being administered and the disintegrants come into contact with water, they swell back to their precompression size and the tablet breaks[14]

The tablets are first dissolved in a little volume of liquid before administration so that the water can easily permeate the tablet and break it into tiny particles by capillary action [wicking] and Porosity [15 16].

Certain disintegrants exhibit their action by swelling; for example, when they come into contact with water, they eventually swell and leads tablet to disintegrate [17].

CHALLENGES IN FORMULATION OF ORODISPERSIBLE TABLETS

TASTES MASKING

Patient compliance and acceptance of the dosage form will be significantly impacted if a bitter drug tablet dissolves or disintegrates in the mouth. Hence, the bitter medications require effective taste masking to prevent oral cavity smell and taste [18].

MECHANICAL STRENGTH AND DISINTEGRATION TIME

ODTs are designed to achieve disintegration times that are typically under a minute. Maintaining sufficient mechanical strength while doing so is a major difficulty. There is a strong probability that a fragile ODT will break when being packed, transported, or handled by a patient. It makes perfect sense that increased mechanical strength will delay the disintegration mechanism. So, it is always important to find a good balance between these two characteristics [18].

AQUEOUS SOLUBILITY

Water-soluble drugs create a variety of formulation difficulties due to the formation of eutectic mixtures, which lower the freezing point and cause the formation of a glassy solid, which is susceptible to collapsing upon drying due to the loss of supporting structure during the sublimation process. Such collapse can occasionally be avoided by employing a variety of matrix-forming excipients, such as mannitol, which can induce crystallinity and thereby provide the amorphous composite stiffness [19].

SIZES OF TABLETS

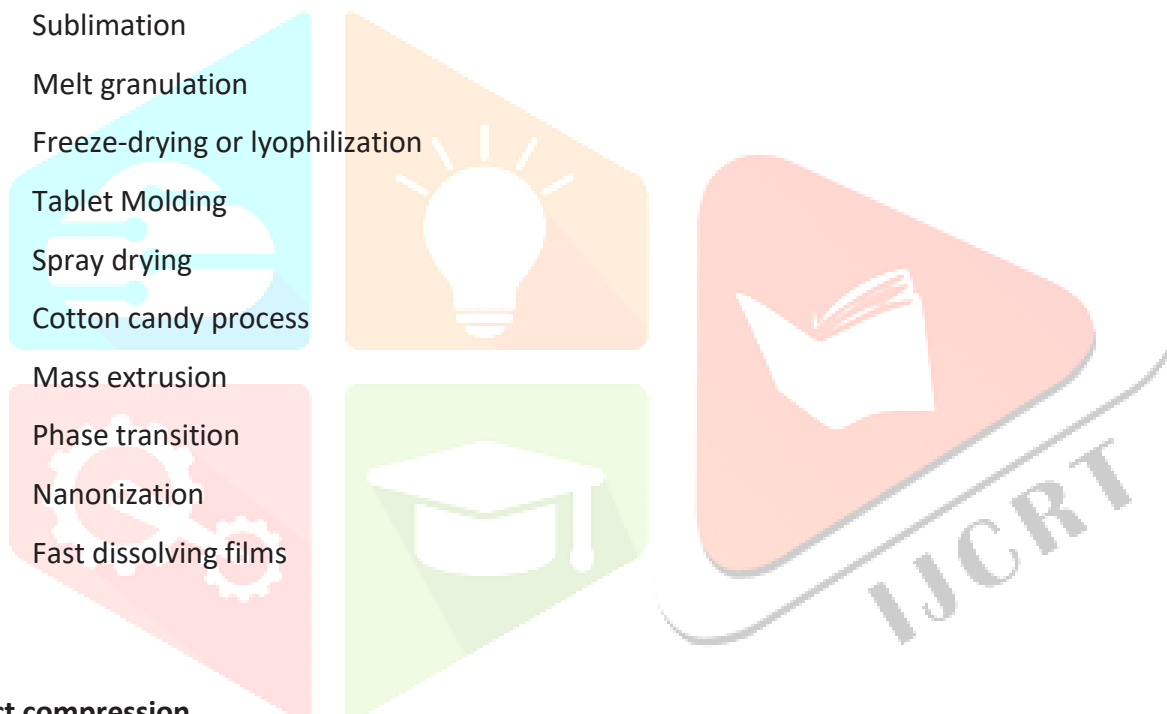
The size of the tablet affects how simple it is to swallow. 7-8 mm tablets are reportedly the simplest to swallow, while tablets larger than 8 mm were reported to be the easiest to handle. Thus, it is challenging to manufacture tablets that are both convenient to use and simple to handle [19].

HYGROSCOPICITY

Many hygroscopic orally disintegrating dosage formulations are incapable of maintaining physical integrity in the presence of normal temperature and humidity levels. As a result, they require humidity protection, which demands the use of specialized product packaging [10].

FORMULATION METHOD FOR ORODISPERSIBLE TABLETS

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



Direct compression

Considering the availability of tableting excipients with improved flow, compressibility, and disintegration properties, particularly tablet disintegrants, effervescent agents, and sugar-based excipients, direct compression represents the easiest and most economical tablet production method for ODTs [20].

Sublimation

The low porosity of the tablets causes slow dissolution. The additional materials for the tablet were combined with inert, solid components that easily volatilize (such as urea, ammonium carbonate, ammonium bicarbonate, hexamethylenetetramine, camphor, etc.), and the resulting mixture was compressed into tablets. After that, the volatile substances were eliminated by sublimation, which produces porous structures. Moreover, a number of solvents, including benzene and cyclohexane, can be employed as pore-forming agents [12].

Melt granulation

Pharmaceutical powders are effectively agglomerated by the melt granulation technique, which uses a meltable binder. As no water or organic solvents are required, this method has an advantage over traditional granulation. High shear mixers are used for this procedure, where the product temperature is elevated over the melting point of the binder by a heating jacket or by heat produced by friction between the impeller blades [21].

Freeze-drying or lyophilization

In the process of freeze drying, also known as lyophilization, the solvent is removed from a frozen drug solution that contains excipients that help the drug establish its structure. This method is employed to produce tablets that are typically very light and porous, allowing for fast dissolving. Enhanced dissolution of tablet is the result of the excipients' glassy amorphous porous nature and the freeze-dried drug component [22].

Tablet Molding

Water-soluble ingredients are often the main elements in molded tablets. A solvent (often ethanol or water) is used to wet the powder mixture before molding it into tablets at lower pressures than those used in conventional tablet compression. (This method is called compression molding.) After that, air drying can be used to remove the solvent. A greater porous structure is produced to help in the dissolution since molded tablets are typically compressed at a lower pressure than conventional compressed tablets. Usually, a very fine screen must be used to pass the powder mixture through in order to increase the dissolution rate [23].

Spray drying

Extremely porous, fine powders can be produced through the technique of spray drying. In the pharmaceutical sector, spray dryers are always used to produce very porous powders. According to Allen et al., this method was used to formulate fast-dissolving tablets [23].

Cotton candy process

The simultaneous action of flash melting and spinning is used in the cotton candy method to produce a matrix of polysaccharides or saccharides. For better flow and compressibility, the matrix generated is partially recrystallized. It is then compressed to ODT after being milled, and combined with the active ingredients, and excipients. High medication doses can be used with this method, which also provides better mechanical strength. Unfortunately, this technique's usage is limited by its high process temperature [24].

Mass extrusion

The active blend is softened using a solvent mixture of methanol and water-soluble polyethylene glycol, and the softened mass is then released through an extruder or syringe to get a cylinder of the product into even segments so that it may be formed into tablets [19].

Phase transition

A modern technique that uses the sugar alcohol phase transition to produce ODTs that are sufficiently hard. This method involves compressing and then heating tablets that contain two sugar alcohols, one with a high melting point and the other with a low melting point, to produce ODTs. The heating method improves the bonding between particles, giving tablets the necessary hardness that was previously absent due to low or minimal compatibility [24].

Nanonization

A recently developed method called Nanomelt which includes wet-milling a drug to reduce the drug's particle size to nanometers. Through surface adsorption of certain stabilizers, the drug's nanocrystals are prevented from agglomeration and incorporated into ODTs. This method is especially useful for drugs that are poorly soluble in water [11].

Fast dissolving films

In this method, a non-aqueous solution containing a drug, other taste-masking agents, and a water-soluble film-forming polymer (pullulan, carboxymethylcellulose, hydroxypropyl methylcellulose, etc.) is prepared and allowed to form a film after the solvent has evaporated. If the drug is bitter, resin adsorbate or coated microparticles of the drug may be added to the film. When the film is placed in the mouth, this film instantly dissolves, releasing the drug in the form of solution or suspension [20].

EVALUATION OF ORODISPERSIBLE TABLETS

- Tablet hardness
- Tablet thickness
- Weight variation test
- Tablet friability test
- Wetting time
- In-Vitro disintegration test
- In-Vitro Dissolution study

Tablet hardness

A tablet's hardness is essential for avoiding damage from improper handling and transportation. However, excessive hardness in dispersible tablets may result in low patient compliance. Thus, a dispersible tablet's hardness should be lower than a conventional tablets. The force necessary to break a tablet by compression in the radial direction is inversely proportional to the hardness of the tablet. To determine a tablet's hardness, testers made by Monsanto and Pfizer are probably used today [25].

Tablet thickness

Another crucial evaluating criteria is a tablet's thickness. Vernier Calipers are equipment that makes it simple to evaluate. Five tablets are randomly selected from the batch being tested, and they are each put into the testing apparatus one at a time. The results are then evaluated [26].

Weight variation test

This test is performed in order to ensure that each tablet in a batch contains the same amount of drug as stated on the labeling. We had to weigh 20 tablets that were chosen at random for this. The average weight is determined after weighing each tablet individually. If the results fall within the acceptable range, the batch is accepted. If the weights of the tablets do not fall within the acceptable range, the batch is rejected [27].

Tablet friability test

The friability of the tablets is often tested using the friability test apparatus. The purpose of this test is to determine whether the tablets can withstand handling and shipping mistakes. The specified number of tablets are taken and placed in the test instrument in accordance with Pharmacopoeia. Results are recorded after a given number of rotations and times [27].

Wetting time

A tablet must have excellent wetting characteristics in order to disintegrate properly. The tablet's ability to wet must therefore be evaluated. Furthermore, conclusions about the effects of various excipients other than the rate at which a tablet dissolves can be obtained. For this, a tablet is stored on a piece of tissue paper that has been folded twice and kept in a little Petri dish (ID=6.5 cm) with 6 ml of water, and the amount of time it takes for the tablet to completely wet is measured [28].

In-Vitro disintegration test

The disintegration test equipment is typically used to measure the disintegration time of the tested tablets. Six tablets are taken from the batch being evaluated and put into the apparatus's six tubes. These tubes contain an appropriate dissolving media that complies with pharmacopoeia specifications, and its

temperature must remain constant at 37° 2°C. The device is switched on after all the criteria are satisfied. The test is finished, and the result is determined [29].

In-Vitro Dissolution study

The same method used for conventional tablets can be used to test for dissolution in the case of oro-dispersible tablets. Other media such as 0.1 M HCl and buffer (pH 4.5 and 6.8) can be evaluated for ODT, With a paddle speed of 50 rpm, the USP 2 paddle apparatus most likely can be used for orally dissolving tablets [30].

Conclusion

In the time of solid dosage forms, the new emergent dosage-form is the oro-dispersible tablet. It is the ideal carrier for the active pharmaceutical ingredient because of its improved patient acceptability, fast disintegration, and excellent bioavailability. Additionally, as new procedures are developed daily by researchers, oro-dispersible tablets are becoming the preferred dose form not only for adults but also for the pediatrics, geriatrics, and patients who are bedridden. We tried to illustrate the fundamental ideas and methods used in the development of oro-dispersible tablets in this review.

Conflicts of interest

There are no conflicts of interest

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