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Review on Orally Dispersible Tablet

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Abstract: *: Nowadays, orodispersible drug delivery systems are extensively used to improve bioavailability and patient compliance. Recently, orally dispersible tablets have become the most desirable. dosage forms, especially for a special category of patients, i.e., pediatric, geriatric, bedridden, mentally ill, and uncooperative. Oral dispersible tablets are well-recognized dosage forms presented in the market. Since the 1980s, ODTs have become one of the fastest-growing segments of the oral drug delivery industry, and their product pipeline is rapidly expanding. An orally disintegrating tablet, or orodispersible tablet (ODT), is a drug dosage form available for a limited amount of over-the-counter (OTC) and prescription Rmedications. Basically, swallowing problems also happen in young individuals because of their underdeveloped muscular and nervous systems. The aim of this article is to review the formulation of ODTs, analyzing their advantages and limitations, challenges in formulation, use of new technologies, evaluation methodology, suitability of drugs.*

Keywords: oral dosage forms, oral disintegrating tablets, hepatic metabolism, novel techniques

I. INTRODUCTION

Orally disintegrating tablet (ODT) is a dosage form that contains active ingredients and disintegrates without extra water when placed into the oral cavity. A rapidly dispersible tablet is also known as an orally disintegrated tablet. They are uncoated. also solid dosage form.

HISTORY:

The first orally dispersible tablet form of a drug to get approval fro the U.S. food and drug administration. Was a Zaydis orally dispersible tablet formation of Claritin in December 1996. Cima Labs in the U.S. and TAKEDA Pharmaceutical Company in Japan led the development of orally dispersible tablets.

ADVANTAGES:

- Orally dispersible tablets have the advantages of liquid formulation, such as ease of administration and no risk of suffocation.
- The drug is released quickly from this dosage form and gets dissolved in the GIT tract without getting into the stomach.
- No water is needed.
- Better taste.
- Small to moderate molecular weight.
- Ease of administration to patients having difficulty swallowing.
- Convenience where water is not available.

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DISADVANTAGES

- Cost-intensive production process.
- Lack of physical resistance in standard blister packs.
- Limited ability to incorporate higher concentrations of active drug.
- Lack of mechanical strength.

WHY DO WE USE DISPERSIBLE TABLET?

Orally dispersible tablet benefits like enhanced bioavailability, rapid action, Not require water and should dissolve or disintegrate in the mouth within a few seconds. It is the estimated that a significant number of people have difficulty swallowing tablets or capsules, commonly referred to as dysphagia. The exact number of people affected by dysphagia is difficult to determine, but it is thought to be particularly prevalent in older adults, children, and individuals with certain medical condition such as Parkinson's disease, stroke and esophageal disorders

CRITERIA FOR EXCIPIENT USED IN FORMULATION OF ODTs

It must be able to disintegrate quickly. Their individual properties should not affect the ODTs. It should not have any interaction with drugs and other excipients. It should not interfere in the efficacy and organoleptic properties of the product. When selecting binder (a single or combination of binders), care must be taken in the final integrity and stability of the product. The melting point of the excipients used should be in the range of 30-35 ºC. The binder may be liquid, semi-solid, solid, or polymeric. In nature

EXCIPIENTS USED IN ODT'S PREPARATION

1. Super-disintegrants: a category of excipients that facilitate the swift disintegration of tablets within the oral cavity. As days pass, demand for faster disintegrating formulations increases. So, the pharmacist needs to formulate disintegrants, i.e., super disintegrants. e.g., sodium starch glycolate.

2. Sweeteners: Sweeteners are used in orally dispersible tablets to improve the taste and palatability of oral medicine. Sweeteners the taste and palatability of oral medicine. Sweeteners serve as excipients incorporated into orally dispersible tablets (ODTs) to enhance their flavor and overall acceptability. Notable examples of these sweeteners are aspartame, saccharin, and sucralose.

3. Flavors: Flavors serve as excipients incorporated into orally dispersible tablets (ODTs) to enhance palatability and conceal any undesirable tastes linked to the active pharmaceutical ingredient. Common flavoring agents include peppermint, cherry, and orange.

4**. Lubricants:** Lubricants serve as excipients incorporated into orally dispersible tablets (ODTs) to enhance their flow characteristics throughout

the manufacturing process and to mitigate the risk of adhesion. Common examples of such lubricants include magnesium stearate, stearic acid, and talc. Various lubricants frequently employed include magnesium stearate, stearic acid, sodium stearyl fumarate, micronized polyoxymethylene glycol (Macrogol 6000), leucine, and sodium benzoate.

5 **Binders**: Binders serve as excipients in orally dispersible tablets (ODTs) to enhance their mechanical integrity and minimize the risk of fracture. Notable examples of such binders include microcrystalline cellulose, sodium carboxymethylcellulose, and polyvinyl alcohol. Binders play a crucial role in ensuring the cohesion of tablet formulations with the active pharmaceutical ingredient during the compression process.

Example of some orally dispersible tablets:

Name of drug	Therapeutic use	Brand name	Manufacturing
Acyclovir	Antiviral agent	Acivir DT	Cipla
Cefixime	Antibacterial agent	Cefinar DT	Zydus Alidac

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Mirtazapine	Antidepressant	Remeron sol tab	Organon
Piroxicam	NSAIDs	Feldene fast melt	Pfizer, NY,

TECHNIQUES FOR PREPARING ORODISPERSIBLE TABLETS:-

Freeze Drying/ Lyophilization:

process in which water is sublimated from the product after freezing is called freeze drying.Freeze dried forms offer more rapid dissolution than other available solid products.

Moulding:

This method is one of the most suitable methods for the orally dispersible tablets. Only the watersoluble ingredients are selected so that the product dissolves quickly.

Spray drying :

This method is generally employed when there is a need of extremely porous and fine powders. In this method the gelatin is used as a supportive agent and Mannitol is used as bulk forming agent. It involves spray drying of blend containing drug, effervescent agent, bulking agent
and disintegrating agents which results in production of porous powder. Finaly this porous powder is compressed in to tablet 13

Sublimation :-

Sometimes the dissolution.rate of compressed tablets is delayed due to the low porosity of tablets. In Sublimation technique, the Active pharmaceutical ingredient,the voltilizing agent and the other adjuvant are combined toform a tablet. After compression the volatilematerial is evaporated by sublimation Tablet sprepared by this technique.The volatilizing agents such as ammonium bicarbonate, camphor, urea, ammonium carbonate 13

Effervescent Method:-

Orally dispersible tablets are also prepared by effervescent method by mixing sodium bicarbonate and tartaric contact angle.The lower the wetting time the quicker is the disintegration of the tablets. The wetting time can be measured by using five circular tissue papers of 10 cm in diameter, which are placed in a petri dish of 10 cm diameter.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.

Fig Effervescent tablet

Mass extrusion:-

This technology involves the process of softening a dynamic blend by utilizing a solvent mixture composed of water-soluble polyethylene glycol and methanol. Following this, the softened mass is removed via an extruder or syringe, allowing for the formation of cylindrical product segments. These segments are subsequently cut into uniform tablets using a heated blade.

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Nanonization:-

The ionization process involves the reduction of drug particle size to the nanoscale through a milling technique. Selected stabilizers are employed to prevent agglomeration and enhance surface absorption of the drugs. This method is particularly effective for drugs that exhibit poor solubility in water.

Evaluation parameters of orally dispersible tablets:

1. General Appearance: The powdered mixture was assessed for various parameters, including bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose. Additionally, the tablets underwent evaluation for thickness, hardness, friability, weight variation, drug content, and in vitro release rate studies. .

2. Size and Shape: 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 8mm.Dimensions and configuration of the tablet can be accurately characterized, observed, and regulated.

3. Tablet thickness: The thickness of a tablet is also an important parameter of evaluation. It can be assessed through a straightforward method. A sample of five tablets is selected, and their thickness is determined utilizing a Vernier Caliper.

4. Weight variation assessment: A random selection of 20 tablets from the batch was conducted, and each tablet was weighed individually to evaluate weight variation. The weight variation criteria were established in accordance with the specifications outlined in the Indian Pharmacopoeia (I.P.

5. Hardness: The fracture strength, defined as the force necessary to break a tablet through radial compression, is assessed using a tablet hardness tester, specifically the Monsanto hardness tester. This measurement is expressed in kg/cm^2.

6. Friability Assessment: The friability of a sample consisting of six tablets is evaluated utilizing a Roche Friabilator. This apparatus exposes the tablets to a combination of abrasion and impact within a plastic chamber that rotates at a speed of 25 revolutions per minute (rpm), allowing the tablets to drop from a height of 6 inches with each rotation. Initially, six tablets are weighed, and they are subjected to rotation at 25 rpm for a duration of 4 minutes. Following this process, the tablets are reweighed after the removal of fine particles using 60 mesh screens, and the percentage of weight loss is subsequently calculated.

$$\% \text{ Friability} = (\text{Loss in weight} / \text{Initial weight}) \times 100$$

7. Wetting time: Wetting time is an important characteristic of dosage forms, as it is closely associated with the contact angle. Evaluating this parameter provides valuable information regarding the disintegration properties of tablets; specifically, a reduced wetting time indicates a faster disintegration process. To assess this, a tablet is positioned on a piece of tissue paper that has been folded twice and placed within a small Petri dish (diameter = 6.5 cm) filled with 6 ml of water, after which the duration required for complete wetting is recorded.

8. Disintegration Time: The experiment involved six tablets and was conducted utilizing the apparatus outlined in I.P.-1996. Distilled water maintained at a temperature of 37ºC ± 2ºC served as the disintegration medium. The duration, measured in seconds, required for the tablets to fully disintegrate without leaving any residue in the apparatus was recorded as 28 seconds.

9. In-Vitro Dispersion Time Test: In vitro dispersion time assessment was conducted using a 10 ml measuring cylinder. Initially, 6 ml of distilled water was introduced into the cylinder, followed by the addition of the tablet. The duration necessary for the tablet to achieve complete dispersion was recorded.

10. In vivo clinical investigations: in vivo research demonstrates the real-time effects of Orally dispersible tablets (ODT) within the oral and esophageal regions, as well as their pharmacokinetic properties, therapeutic effectiveness, and patient acceptability. Studies utilizing gamma scintigraphy revealed that the dissolution and buccal clearance of these rapidly dispersible dosage forms occur swiftly. Furthermore, the transit time through the esophagus and the gastric emptying time are similar to those observed with conventional dosage forms, such as tablets, capsules, or liquid preparations.

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II. CONCLUSION

As a conclusion, when we compare the ODT's with conventional oral dosage forms, we can say that they have important advantages like higher bioavailability and patient compliance. Nowadays, these tablets are gaining more importance in industry targeting pediatrics, geriatrics, and all age groups. Their characteristic advantages, such as administration without water, anywhere, anytime, lead to their increased patient compliance in today's scenario of hectic life. As they have significant advantages of both solid and liquid dosage forms, as they remain solid during storage, which aids in the stability of dosage forms and transform into liquid form within a few seconds after their administration. Currently, ODTs are extensively utilized for managing conditions such as motion sickness, travel-related diarrhoea, common colds, allergies, and symptoms.

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