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ORODISPERSIBLE TABLETS AS MODERN ORAL SOLID DOSAGE FORMS

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ABSTRACT

High blood pressure is a leading cause of heart problems and death worldwide. To control it, people usually need to take blood pressure medicine every day for a long time. However, some patient groups—especially young, elderly, and mentally ill patients—may have trouble swallowing traditional tablet formulations. Furthermore, quickly dissolving oral dosage forms are crucial in situations like motion sickness or the unavailability of water. ODTs offer a promising solution to these problems by enabling the medication to dissolve quickly in the mouth without the need for water, which speeds up the onset of action. Patients are generally treated either with ARBs or ACE inhibitors such as valsartan, telmisartan, enalapril, captopril, ramipril, etc.

Losartan potassium is a medication that blocks angiotensin II receptors and is commonly prescribed for managing high blood pressure. But, it has low oral bioavailability (about 32%) because it is broken down quickly in the first-pass metabolism. Developing an orodispersible tablet (ODT) can enhance the effectiveness of the medication by enabling quicker absorption via the oral mucosa, which allows the drug to avoid both the digestive system and first-pass metabolism in the liver.

Keywords: Hypertension management, Losartan potassium, Orodispersible tablets, Superdisintegrants - Natural and synthetic

1. Introduction

1.1 Hypertension

Hypertension, more commonly known as high blood pressure, is a condition where the pressure in your arteries stays elevated over time. This condition is a major reason behind many serious cardiovascular issues like heart attacks and strokes, It is also known as "the silent killer" because it often shows no symptoms in its early stages[1].

Blood pressure is measured in millimeters of mercury (mmHg) as two numbers: the systolic value (when the heart contracts) over the diastolic value (when the heart relaxes). According to the American Heart Association (2023),you may be diagnosed with hypertension if your systolic pressure is consistently 130 mmHg or higher or your diastolic pressure is 80 mmHg or above[2].

High blood pressure can be caused by a number of circumstances. A high sodium diet, obesity, a lack of physical activity, excessive alcohol use, and other lifestyle choices are typical causes of hypertension. The development of hypertension can also be influenced by a variety of medical conditions, including heredity, kidney or hormone abnormalities, and others[3]. Vital organs such as the brain, kidneys, and heart can be gradually harmed by persistently elevated blood pressure. About 80% of instances of essential hypertension in males and 65% in women are caused by obesity, making it a significant factor in this situation[4]. Other disorders could also be to blame, such as renal artery stenosis, which is a constriction of the arteries supplying the kidneys Padmanabhan et al.

As a first line of treatment, people with hypertension are often advised to make lifestyle changes. These may include eating foods high in potassium and limiting or eliminating salt intake, as well as losing weight, maintaining a balanced diet, reducing alcohol consumption, quitting smoking, exercising, and effectively managing stress[5].

When it comes to drugs, angiotensin receptor blockers (ARBs), such as losartan, are frequently chosen. By blocking the receptors that cause blood arteries to narrow, these medications help lower blood pressure while also protecting vital organs like the kidneys and heart[6]. The first medication of its sort, losartan, is still often recommended today due to its ability to successfully control hypertension and provide extra heart-health and kidney health, Julius *et al.*[7].

Compared to other blood pressure drugs, losartan offers a number of benefits. It usually doesn't result in the dry cough that ACE inhibitors frequently induce, and it works especially well to stop left ventricular hypertrophy, or the thickening of the heart muscle[8], One issue with losartan, though, is that some patients—particularly youngsters and older adults—have difficulty swallowing the regular tablets, which may make it harder for them to take the drug regularly[9].

1.2 Oral drug delivery system

Oral drug delivery is the most preferred and convenient option as the oral route provides maximum active surface area among all drug delivery system for administration of various drugs[10,11]. Due to its ease of use, affordability, and high patient compliance, the oral route is most frequently used for drug administration. Here, the medication enters the body through the mouth and is then absorbed gradually in the digestive system. This approach offers a number of advantages, including being easy to use, requiring no invasive procedures, and being broadly applicable to various medication formulations. But also, there are significant problems, such as inadequate absorption, poor solubility, and the possibility that some medications would degrade in the

body too quickly. To ensure that the medication is efficient and enters the body in the proper quantity, these issues must be addressed.

Oral drugs must be designed to dissolve correctly, stay stable, and release the active ingredients in a controlled way in order to be considered effective. However, despite their ease of use, creating these formulations can be difficult, primarily because many medications are poorly soluble in water and have difficulty crossing the body's membranes.Alqahtani et al. In addition, factors such as meals, variations in stomach acid, and variations in intestinal motility can all impact the drug's absorption[12]

Poor bioavailability, patients who don't follow their treatment regimens, and medication instability are some of the problems that need to be addressed in order to overcome the difficulties in oral drug delivery. Innovative methods, such employing nanotechnology (such as liposomes or nanoparticles), can enhance the way medications dissolve and are absorbed by the body. Modified-release formulations help with adherence by ensuring that the medicine remains in the system at a constant level, requiring fewer doses. Some breakdown issues can also be avoided by using prodrugs, which don't start working until after metabolism. Providing patients with shorter dosage instructions or combination therapies can make it easier for them to take their medications as prescribed. Furthermore, investigating alternative drug delivery methods including sublingual or cheek delivery can increase efficacy, especially for drugs that are impacted by the liver's first-pass metabolism[13]

2. Orodispersible tablets

Solid dose forms known as ODTs dissolve quickly in the mouth and don't require chewing or water. Bandari et al. Patients' lives are being made easier by this new ODT technology, which offers a quick and easy way to take medication, particularly for young patients, the elderly, and people who have trouble swallowing. It successfully satisfies patient comfort and medical criteria[14]

When a tablet comes into contact with fluids, disintegrating agents are frequently employed in tablet formulations to help the tablet break up into tiny pieces more quickly. This facilitates the body's absorption and dissolution of the active substances[15]

In addition to being robust enough to withstand standard packaging and shipping without the need for further protection, the ideal ODT should melt rapidly in the mouth, particularly when applied to the cheek[16]

2.1 Disintegrants

Widely used disintegrants like starch, microcrystalline cellulose, croscarmellose sodium, and sodium starch glycolate are important to ensure that tablets break down rapidly after ingestion. Their primary mechanism is to swell when they come into contact with moisture and attracts water into the tablet matrix through wicking, which accelerates disintegration and enhances the release of the drug[17,18]

2.2 Superdisintegrants

A superdisintegrant is an excipient that is added to a tablet to help break up the compacted mass in a fluid environment by promoting rapid disintegration by a combination of swelling and water absorption[19,20]. In the case of losartan ODTs, choosing the right superdisintegrant is important for optimal drug release and patient compliance, as these are used to improve the effectiveness of solid dosage forms, which is achieved by reducing the disintegration time and resulting in drug-enhanced dissolution rate[21,22].

2.2.1 Natural Superdisintegrants

These are the superdisintegrants that occur naturally[23] and are usually preferred over synthetic superdisintegrants as they are also nontoxic, non-irritating, cheaper and widely available in nature[24,25].

2.2.2 Synthetic Superdisintegrants

These are the polymers that are chemically modified to improve disintegration through increased swelling and water absorption. Crospovidone, for example, is used because of its fast capillary action and minimal capacity to create gels[26]. Sodium starch glycolate disintegrates tablets by rapid water uptake and swelling, though concentrations above 8% may lead to gel formation that slows disintegration. Various examples of natural and synthetic superdisintregrants have given in Table 1.

3. Mechanism of superdisintegrants

3.1 Swelling

Swelling is believed to be one way certain disintegrants, such as starch, help break apart tablets. When these substances absorb water, they expand and push against the other ingredients in the tablet, causing it to fall apart. However, it's important to note that not all disintegrants work by swelling—some are effective through different mechanisms[27]. Swelling mechanism has been depicted in Fig. 1

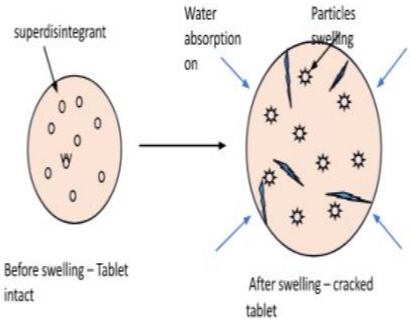

Fig. 1 Mechanism of superdisintegrant- Swelling

3.2 Porosity and capillary action (Wicking)

Some disintegrants that don't swell help tablets break apart through porosity and capillary action. The tiny pores in a tablet allow liquid to flow in, thanks to the structure created by the disintegrant particles, which don't stick together tightly. As water is drawn into these pathways by capillary action, it disrupts the bonds holding the tablet together, causing it to disintegrate. Crosscarmellose and

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crospovidone are examples of disintegrants that work in this way[28].

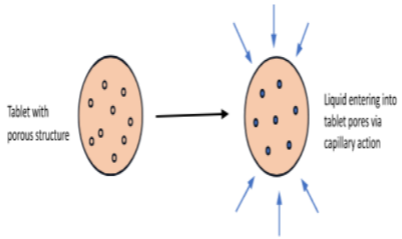

Fig. 2 Mechanism of action of ODTs (superdisintegrants)- Wicking

Due to release of gases

When the tablet gets wet, the carbonate and bicarbonate inside react with citric and tartaric acids, creating carbon dioxide gas. This gas builds up pressure within the tablet, helping it break apart and dissolve faster. This fizzy reaction is often used by experts to make tablets that dissolve or disintegrate quickly. Strict environmental control is necessary during tablet manufacturing because these disintegrants are extremely sensitive to even minute variations in temperature and humidity[29].

3.4 Repulsive forces

Another way tablets can break apart involves a different process, especially when using "nonswellable" disintegrants. Research by Guyot-Hermann showed that even particles that don't swell can help tablets disintegrate. He introduced the particle repulsion theory, which suggests that these particles push away from each other, leading the tablet to break apart. Wicking is more significant than repelling, according to research[30].

3.5 Deformation

The tablet disintegrates because the distorted particles have gotten bigger, the deformation recovery theory suggests that when tablets are made, the disintegrant particles get squished and change shape during compression. Once the tablet gets wet, these particles bounce back to their original shape, helping the tablet break apart.This effect may have a major impact on the way disintegrants with little to no swelling, such as starch and Crospovidone, work[31].

3.6 Enzymatic Reaction

The body's natural enzymes, such as protease, which breaks down gelatin, amylase and starch, may also cause the tablet dissolution. These enzymes become ineffective when binders come into contact with them, which accelerates the dissolution of the tablet[32].

4. Ideal properties of ODTs

- It is convenient and simple to administer because it doesn't require water to be swallowed orally; instead, it should dissolve or disintegrate in the mouth in a few seconds.
- Give the mouth a pleasing sensation. Sharma et al.
- Be in harmony with other excipients and taste concealing.
- After oral delivery, virtually no residue remains in the mouth.
- withstand the handling that occurs after manufacture.
- insensitive to temperature and humidity levels in the surroundings.
- flexible and inexpensively compatible with standard processing and packaging equipment.

Table 1 Examples of natural and synthetic superdisintregrants

S.No.	Type	Examples
(A)	**Natural Superdisintegrants**	
1.	Starch	Corn starch, Potato starch
2.	Isapghula Husk	Psyllium
3.	Aloe Vera Powder	Aloe vera gel extract
4.	Guar Gum	Guar plant seeds
5.	Fenugreek Mucilage	Fenugreek seeds
6.	Pectin	Citrus peels, Apples
7.	Lecithin	Soybeans, Egg yolk
(B)	**Synthetic Superdisintegrants**	
1.	Croscarmellose Sodium (CCS)	Cross-linked Carboxymethyl Cellulose
2.	Sodium Starch Glycolate (SSG)	Cross-linked starch derivatives
3.	Crospovidone	Cross-linked polyvinylpyrrolidone
4.	Kollidon CL	Polyvinylpyrrolidone (PVP)
5.	Explotab	Cross-linked starch

5. Drug selection criteria for ODTs

"A medication meant for an orodispersible tablet should ideally follow that.."

- Diffusion across the buccal mucosa is easy
- Sufficient solubility and stability in saliva
- Have a low to moderate molecular weight
- Remain uncharged at buccal pH[33]

6. Advantages of ODTs

Several advantages of orodispersible tablets have been illustrated in Fig. 3.

Fig. 3 Advantages of orodispersible tablets

- Patient compliance
- Quick dissolving and disintegration
- No water needed
- Removal of swallowing issues
- Quick drug distribution from dosage forms
- Cost effectiveness[34]

7. Method of preparation of ODTs

Several methods have been used in the development of ODTs, which are listed below:

7.1 Direct compression

This is most commonly used process. In this process, after mixing the active ingredient (API) with excipients like lubricants, flavoring agents, superdisintegrants, and diluents, the mixture is directly compressed into tablets

Advantages: Cost-effective, easy scalability, and requires fewer processing steps[35]

7.2 Freeze drying

In this API and excipients are combined in a liquid formulation that is frozen and then sublimated under vacuum to create a highly porous tablet that dissolves quickly in the mouth.
Advantages: Produces highly porous tablets with very fast disintegration time[36]

7.3 Spray drying

A hot drying chamber is sprayed with the drug and excipients solution, which produces a dry powder that is later compressed into ODTs.
Advantages: Produces highly porous powders with improved dissolution[37]

7.4 Molding

In this process, the drug is moistened with a solvent like ethanol or hydroalcoholic solution to form the desired shape of the tablet by molding it, which is then dried. It forms tablets with a highly porous structure, improving disintegration and dissolution.
This method is classified into two types:
Compression Molding
Heat Molding
Advantages:
Dissolution is improved due to high porosity.
No high-pressure compression is needed, reducing the chances of drug degradation.
Disadvantages:
Lower mechanical strength than direct compression tablets.
Solvent use and drying lead to higher manufacturing costs[38,39]

7.5 Sublimation

In this process, the tablet matrix contains volatile substances like camphor, menthol, thymol, etc., which are then removed via sublimation, which enhances the disintegration by creating a porous structure behind.
Advantages: Improved tablet porosity and faster disintegration[40,41]

7.6 Cotton candy process

This method involves flash melting saccharides (sugars like sucrose or mannitol) into a fibrous, floss-like matrix, which is then milled and blended with the active drug before compression into tablets. The process is similar to making cotton candy, hence the name.
Advantages:
Extremely fast disintegration (within seconds) due to high porosity.
Provides a smooth mouthfeel, making it ideal for pediatric and geriatric patients.
Disadvantages:
Expensive and complex manufacturing process.
Requires special equipment for flash melting and fiber formation[42] these development methods are in Fig. 4.

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Fig. 4 Method of preparation of orodispersible tablets

Conclusion

Orodispersible tablets have emerged as a valuable solution in oral drug delivery, especially for patients who find swallowing difficult such as children and the elderly. Their ability to dissolve quickly in the mouth without the need for water improves patient comfort and adherence while allowing for a faster therapeutic effect. Additionally, these tablets can enhance the absorption and bioavailability of certain drugs. Although formulation poses unique challenges, advancements in technology and excipients continue to improve their performance and widen their clinical applications. Overall, orodispersible tablets offer a convenient, effective, and patient-friendly alternative among oral dosage forms.

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