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A Novel Approach on Fast Dissolving Tablet- A Review

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Abstract
Fast-dissolving tablets have lately started to gain popularity and acceptability as cutting-edge drug administration methods. Fast-dissolving tablets are easy to use and increase patient compliance. Common preparation methods include spray drying, freeze drying, direct compression, moulding, and sublimation, while new technologies have been developed to generate oro-dispersible tablets. The fast dissolving tablet (FDT) is one such new and distinctive medication delivery mechanism that is swiftly gaining favour in the present rapid-dissolving technological environment. The fastest and safest mode of medicine delivery is oral administration since a wide range of pharmaceuticals may be delivered through this route. Fast-dissolving tablets (FDT), developed by researchers, swiftly dissolve or disintegrate in oral saliva without the need for water.

Keywords: *Fast Dissolving Tablet, Solubility, Superdisintegrants*

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I.INTRODUCTION:

It may be difficult to use a novel drugs in health management without compromising its safety and effectiveness. Despite the unique drug's invention's enormous success, there are still unmet medical needs that need for high-quality medical attention.1 Due to business potential and company competitiveness, large dosages of drugs with subpar biological qualities are being approved. For pharmaceutical chemists, drugs with low water solubility "less than 1 mg/mL" are a critical downside. Candidate medicines with poor water solubility and consequently low bioavailability present significant challenges during the industrial development of a novel pharmacological ingredient or product.2 One-fourth of the novel chemical entities have low solubility. A drug's ineffectiveness un vivo is hampered by poor water solubility, which causes limited bioavailability, an atypical pharmacokinetic profile, and inter-subject / inter-species variance, leading to expensive and time-consuming research. According to studies, the discovery and development of novel drugs is insufficient to attain therapeutic excellence and reap economic benefits3. Any type of solvent will dissolve a liquid, solid, or gaseous solute to create a homogeneous mixture. Solubility is the term used to describe this property of a solute. The solubility of a material depends on the solvent's temperature and pressure. The saturated concentration is determined by the maximum solubility of a solute in a particular solvent 4. A crucial step in the creation of pharmaceuticals is the evaluation of solubility. Solubility has a big impact on drug bioavailability and absorption. It is the most significant factor determining pharmacokinetic parameters and the solubility of drugs. The drug's solubility is a crucial parameter5 in cases when dissolution is a rate-limiting phase.

Phase joining and dissolving happen simultaneously as a result of solubility, which takes place in a condition of dynamic equilibrium.

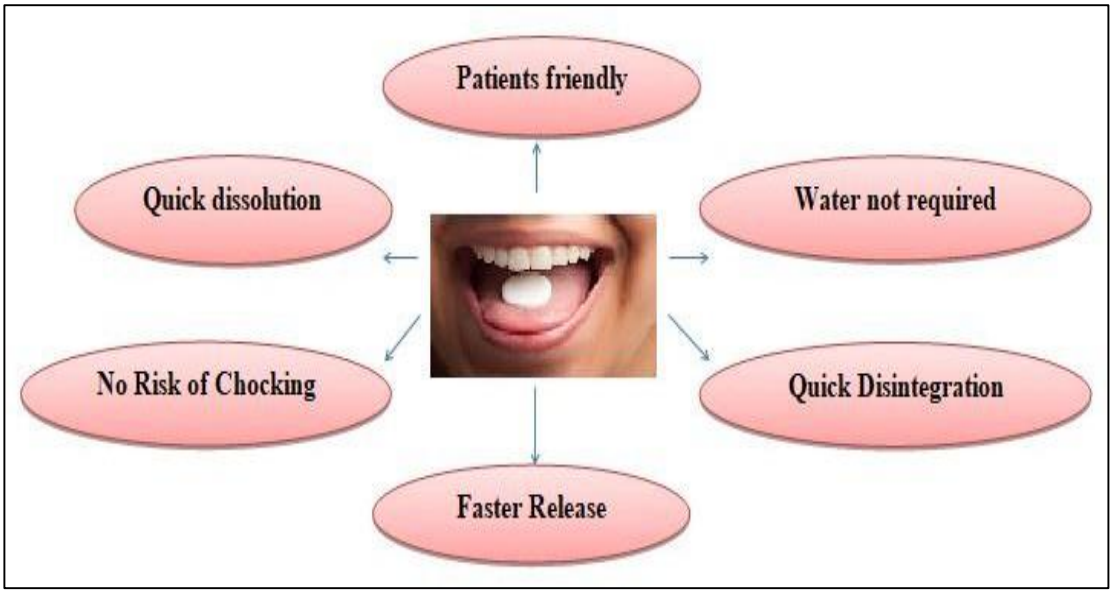
The greatest dosage strength that is soluble in 250 mL or less of medium with a pH range of 1 to 7 is used to assess how soluble a substance is.5. The estimated volume of 250 mL obtained from bioequivalence research data that describes giving a drug product to human volunteers who are fasting a glass of water.[6.]

The oral route medication delivery method offers several advantages, including easy administration, increased patient compliance, low cost, and the least amount of sterility restriction. Therefore, taking drugs orally is very common and advised. As a result, the majority of pharmaceutical companies select bioequivalent drugs.[7,8]. However, one of the most difficult aspects of development is inadequate bioavailability. The oral bioavailability of a medication is influenced by a number of factors, including its water solubility, permeability, first-pass metabolism, rate of dissolution, and sensitivity to efflux mechanisms. Low permeability and poor solubility of the medicine are the main causes of low oral bioavailability. The drug's solubility is the key factor limiting the pace at which an appropriate concentration may be reached in the systemic circulation. Solubility of the substance has an impact on the pharmacological reaction. Insufficient solubility might be a major challenge for formulation scientists[9] .

Fast Dissolving Tablets

Dosage forms are created in a way that makes them easy to administer, safe, and effective for a variety of patient populations. FDTs are currently the most popular dose forms due to their improved rapid action, less side effects, and medical preference for patients of all ages, particularly those who are young, old, or psychotic.10 As illustrated in figure 1, these tablets offer benefits over traditional tablets and have shown to be a better dose form than both conventional tablets and liquid dosage forms.

Figure 1: FDTs benefits over conventional tablet



FDTs have been prioritised in order to provide patients with comfort and convenience so that they won't hesitate to take the medication. These FDTs are appropriate for individuals who have trouble swallowing, especially elderly and paediatricpatients.When hearing about FDTs, the main idea or characteristic that comes to mind is that as soon as the FDT comes into contact with saliva, it should quickly dissolve and have a nice tongue feel.[11] These dosage forms quickly breakdown when they come into touch with saliva, and the medicine is then released within a few seconds of that. These pills are easier to swallow than traditional tablets and capsules. Anyone may readily administer even when travelling if they do not have access to water.[12]It makes administration easier since they just disappear after being placed on the tongue in the mouth. The FDT idea was introduced in 1970, and research to enhance preparation and technique is still ongoing. FDTs have a quicker dissolving rate and disintegration time (DT). FDTs aid in improving the solubility of medications that aren't very soluble. FDTs are a cost-effective, practical, and secure dosage form, and there are a variety of ways to enhance the disintegration.13 Figure 2 below outlines the benefits and drawbacks of FDTs.

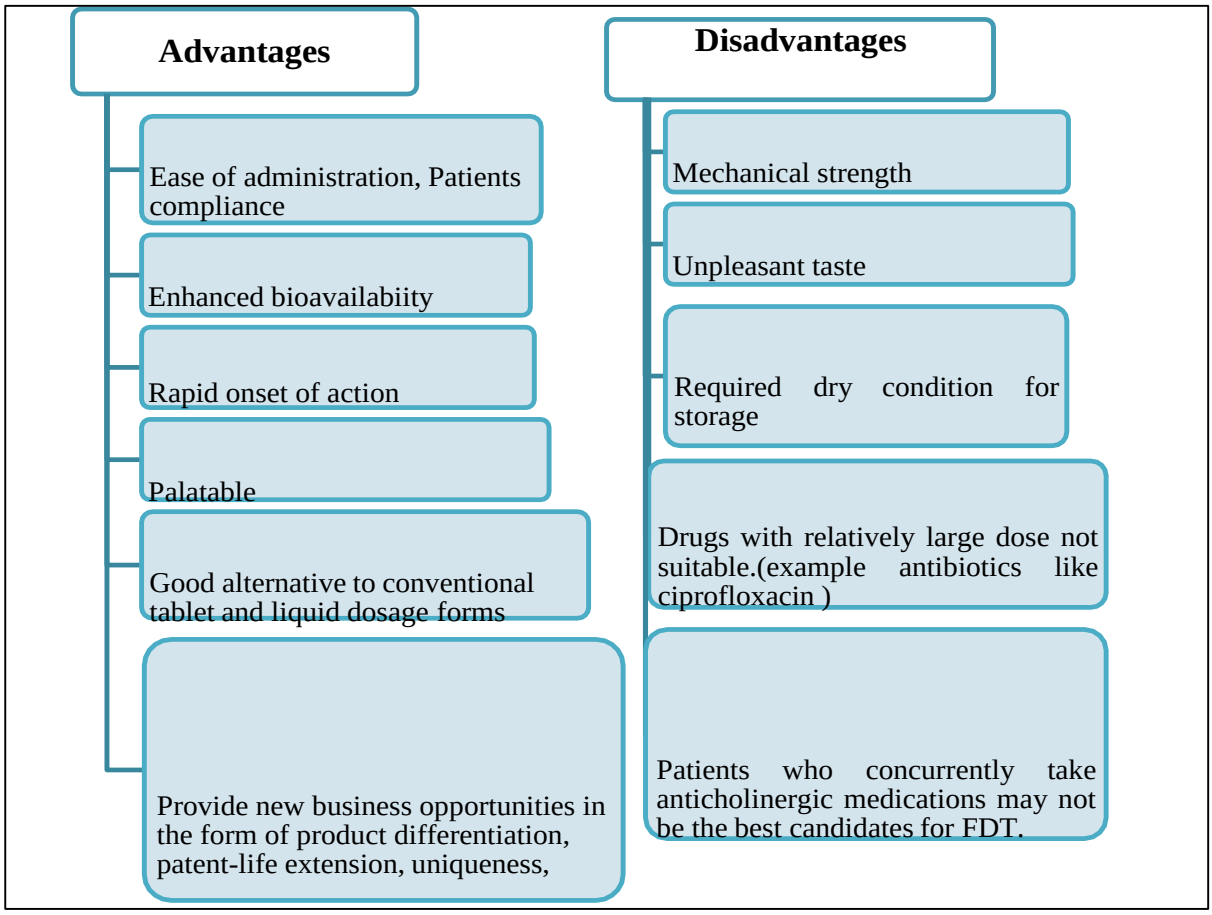
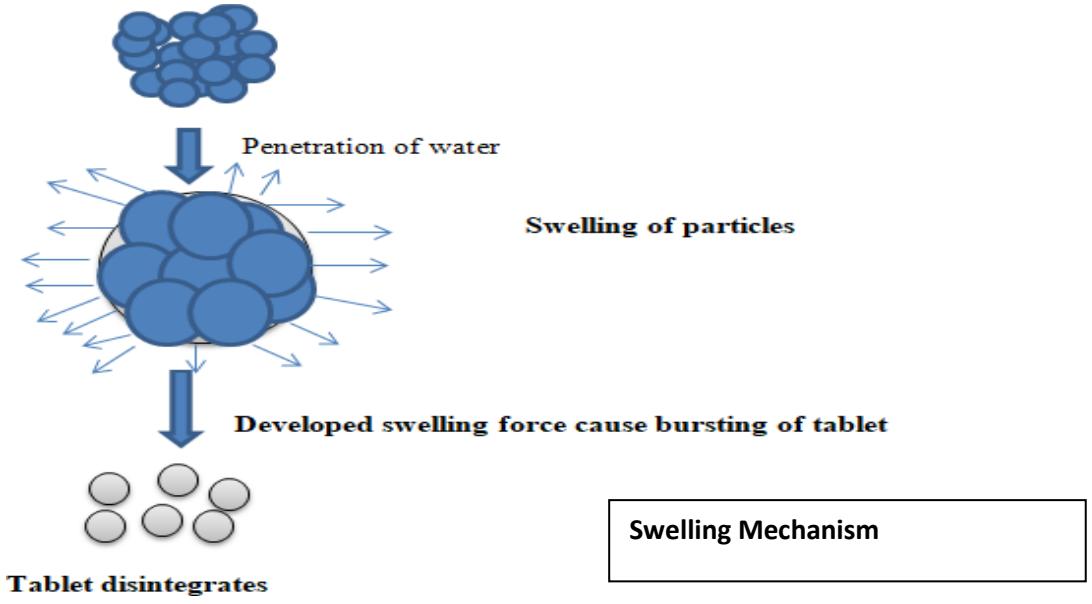


Figure 2: Merits- Demerits of FDTs.

SUPERDISINTEGRANTS

Tablets are broken down by superdisintegrants in a variety of ways, including swelling, wicking, chemical reactions, repulsive forces between particles, heat owing to wetness, enzymatic processes, and recovery after deformation.14 However, a mechanism known as swelling and wicking, which is shown below in diagrammatic form in figure 3, is responsible for 90% of the superdisintegrants.



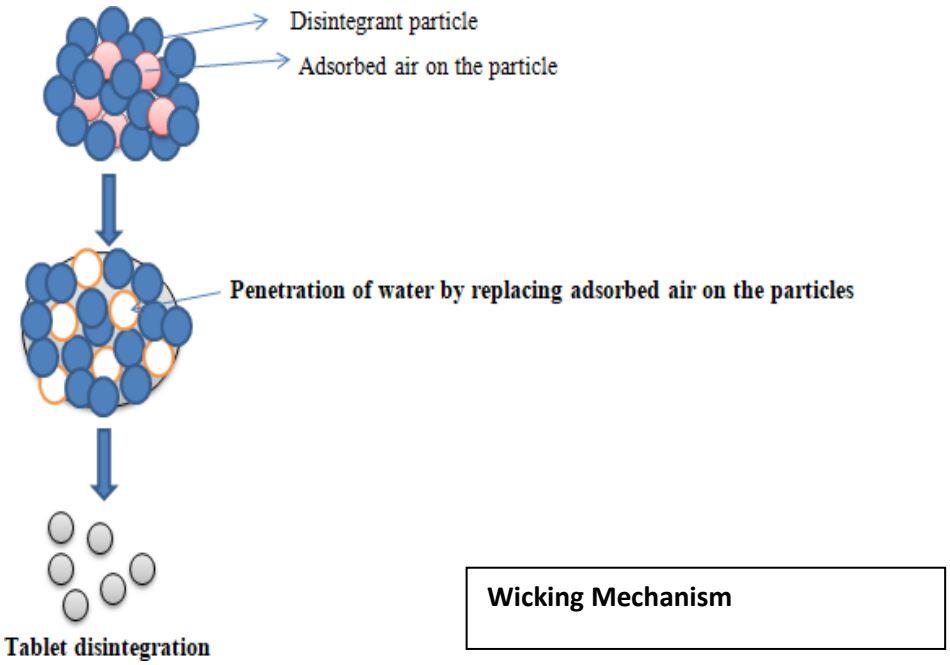


Figure 3: Swelling and Wicking Mechanism

Heatof wetting

With disintegrants that have exothermic characteristics, this approach can be applied. The capillary air expansion that happens as a result of these disintegrants coming into touch with the proper medium and being moist leads to localised stress, which leads to the tablet disintegrating[15].

Chemicalreaction(Acid-basereaction)/Duetoreleaseofgases

Tablets break down mostly as a result of internal pressure created by the release of carbon dioxide from water caused by tartaric acid or citric acid's reaction with alkali carbonates or bicarbonates (acid reacts with bases). The release of carbon dioxide gas improves both active component dissolution and flavour masking. Since these disintegrants are extremely sensitive to even tiny changes in temperature and humidity, environmental conditions should be properly maintained. Effervescent mixes are introduced either before compression or in this situation.[16]

Particlerepulsiveforce

This approach, which is based on Guyot-Hermann's particle repulsive theory, produces tablet breakdown via non-swellable disintegrant particles. Water is necessary for tablet breakdown because of the electrostatic attraction between the particles. Researchers discovered that wicking comes second to repulsion. According to Guyot-Hermann repulsion theory, "Tablet in contact with suitable medium, water penetrates into the tablet through hydrophilic pores leading to the formation of continuous starch-like network which helps in transfer of water from one particle to another and creates hydrostatic pressure."This causes the hydrogen bonds and other forces holding the tablet particles together to break.[17]

Deformationrecovery

Deformation recovery is essentially based on the idea that some disintegrant particles' structures change or are altered during compression, and that when these particles come into contact with aqueous solutions after compression, they revert to their pre-compression structures, which causes the tablet to disintegrate. For instance, once the granules are squeezed, starch has demonstrated greater swelling capability.18 Because of the strong compaction force and energy-rich potential during compression, starches with high elastic properties, such as maize and potato starch, distorted into plasticity. Tablet disintegration happens when a particle that has been deformed comes into touch with water because this activates the distorted starch's energy-rich potential.[19]

Enzymaticreaction

Some enzymes in our bodies that function as disintegrants by reducing the binding power of the binder cause tablets to disintegrate. Tablets can burst due to swelling that increases pressure in the outer direction, or

they can disintegrate faster due to increased water absorption. Our bodies produce Amylase, Protease, Cellulase, and Invertase, which aid in the breakdown of tablets.[20]

Combinationaction

In this instance, the disintegrant breaks down the pill by combining the swelling and wicking mechanisms. For illustration, crospovidone works by both swelling and wicking.[21]

Classificationofsuperdisintegrants

Superdisintegrants may be divided into three categories based on where they came from: natural, synthetic, and co-processed.

Superdisintegrant natural

In the composition of tablets, natural superdisintegrants are frequently employed to speed up pill disintegration.

Advantages

• Locally available
• Biodegradable and eco-friendly
• Cheaper than synthetic and renewable sources

Superdisintegrant synthetic

In the composition of tablets, synthetic superdisintegrants are frequently employed to speed up pill disintegration.22

Synthetic superdisintegrants provide the following advantages over starch: • Effective at low concentrations.
• More effective intragranularly; little impact on compressibility and flow ability.

Limitations

• Hygroscopic by nature and may interfere with medications that react negatively to water.

TECHNOLOGIES

FDTspreparationcanbedonebydifferentmethods.Someoftheimportantwidelyused methodsaregiven below.

1. FreezeDryingorLyophilization: The formulation of the fast-dissolving tablets involves lyophilization.[23]

2. Moulding: Water-soluble components and active substances were combined, then the mixture was shaped into tablets that dissolve quickly. The high porosity and specific surface area of lyophilization procedures, together with their fast dissolution in the mouth and excellent drug bioavailability, are characteristics of the process. To create the medication particles, a molten combination of cottonseed oil, polyethylene glycol, lecithin, hydrogenated sodium carbonate, and another active ingredient is spray-congealed with the lactose-based tablet triturate. The drying process removes the solvents, leaving a porous aggregate that facilitates quick dissolution, giving the moulding method its very porous characteristics. The main drawbacks of this method are its high cost, lengthy process, and fragility, which renders traditional packaging inappropriate for this dosage form and causes stability problems under pressure.[24]

3. Direct compression: In order to create tablets that dissolve quickly, super disintegrants are directly added to the formulation. Granulation may be a part of this procedure before the final mix. The action of super disintegrants, water-soluble excipients, and effervescent agents, either separately or in combination, provides the basis for the direct compression tablet's disintegration and solubilization. Sodium starch glycolate, crospovidone, alginic acid, calcium silicate, and croscarmellose are typical examples of super disintegrants. They offer quick disintegration by expanding as a result of absorbing water.[25]

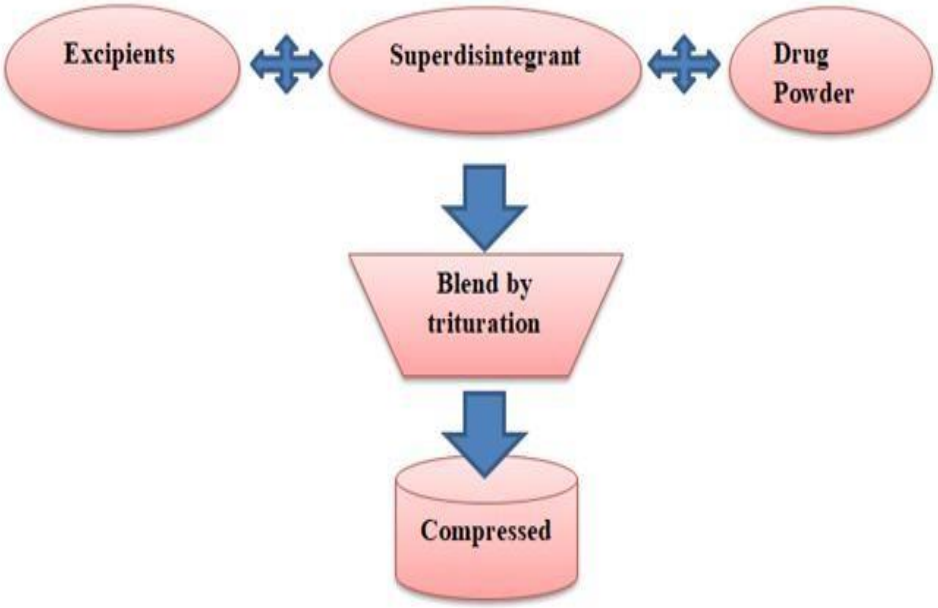


Figure 4 Direct compression process

4. Spray drying: This method involves combining bulking agents, API, and both hydrolyzed and non-hydrolyzed ingredients to create fast-dissolving tablets.[26] The ultimate particle size of spray drying, which is widely employed in the pharmaceutical and biochemical industries, is controlled by a variety of variables, including the size of the processing nozzle. The recipe produces a porous powder by spray-drying. This technique produced a fast-dissolving tablet that vanished within 20 seconds.[27]

5. Sublimation: In this, the API is combined with volatilized inert solid components, which are then compacted into FDTs by sublimating the volatilized substance.[28] The ultimate particle size of spray drying, which is widely employed in the pharmaceutical and biochemical industries, is controlled by a variety of variables, including the size of the processing nozzle. The recipe creates a porous powder by spray-drying.[29]

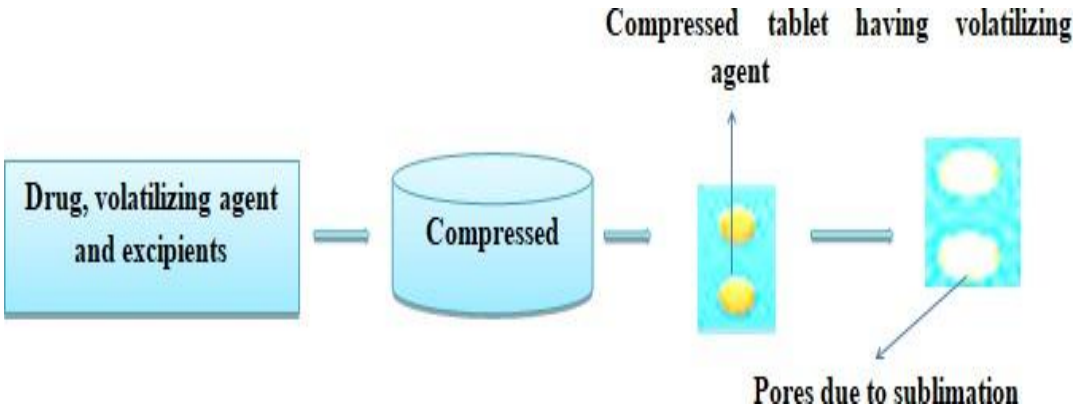


Figure 5: sublimation process

6. Compaction - The formulation is made ready for compaction by adding the hydrophilic waxy binder PEG-6- stearate. This adhesive has a dual effect that both strengthens the body and speeds up disintegration. Such a dose form makes it simple to deliver medications like griseofulvin. The compaction process is distinguished by its quick melting in the mouth and absence of residue.[30]

7. Mass-extrusion - Using methanol as a solvent, the mixture is softened by water-soluble components such polyethylene glycol before being extruded into thin cylinders and then cut into little tablets using a hot blade. Small granules made with this technology can be used to disguise the bitter taste of medications, increasing oral bioavailability.[31]

Some of the FDT products are in global markets mentioned in Table 1.[32]

Trade Name	Active drugs	Manufacturer
Domray MD	Domperidone	Ray Remedies
Romilast	Montelukast	Ranbaxy Labs Ltd.,
Insure-MD	Nimesulide	SuzenPharma
Zofran ODT	Ondansetron	GlaxoWellcome,
Allegra ODT	Fexofenadine	Sanofi Aventis

II. Conclusion

Modern dosage formulations are considered to include fast-dissolving tablets. The advantages of these dose formulations and their manner of administration include higher effectiveness, a speedier onset of action, greater bioavailability, and better patient compliance. FDTs must be created for patients who are actively travelling, are bedridden, old, young, or psychotic, as well as for individuals who might not have access to water. Tablets produced using the most recent manufacturing procedures act more rapidly, have a better bioavailability, have less side effects, and are safer.

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