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Brief Review on Oral Disintegrating Tablet.

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ABSTRCT:
The oral route of administration is considered the most used route of administration due to its ease of administration and preparation. Formulations such as orodispersible tablets (ODTs), minitablets, and orodispersible minitablets (ODMTs) are considered promising for use in children. ODTs can be suitable drug delivery systems, especially for pediatric patients, due to their rapid disintegration property, use without water and without swallowing problems. In addition, a new design method has recently been developed.When planning dosage forms, the convenience of drug administration and the consent of the patient are very important. Recent and new technologies can produce durable, versatile tablets with exceptional taste and controlled release. Orodispersible tablets (ODT) are solid dosage forms that disintegrate in the mouth in less than 60 seconds and are thus swallowed without water. The rapid disintegration of the tablet leads to rapid dissolution and thus a rapid onset of action. ODT drugs are a suitable dosage form for special groups such as children, geriatrics, psychotic, dysphagic, bedridden, unconscious patients, young patients with underdeveloped muscle and nervous system, patients with hands. patients with tremor problems and frequent travelers. It offers good stability, accurate dosage, easy preparation, reduced packaging; self-dosing is possible during the trip, because no water is needed.

I. INTRODUCTION: [1,6]

The oral route of administration is considered the most used route of administration due to its convenience of administration and preparation, and the cheapest solid dosage form is the tablet. Electrostatic drug coating and coating and computer 3D printing for tablet production have also recently become available. But the most common complaint is the size of the pill, followed by the taste. However, the problem of swallowing tablets is more evident in children under 5 years of age (Sastry et al. 2000). Researchers have developed liquid dosage forms for many commonly used pediatric medications. w However, liquid dosage forms are often unstable and have a short expiration date. Accurate measurement and dosing of the prescribed dose is also a problem. Alternatively, chewable tablets ab may be available for pediatric patients, but this must be delivered by external assistance (Singh et al. 2008). Therefore, ordispersible formulations offer solutions to the above limitations, as it can be administered without external assistance and, when placed in the mouth, quickly disintegrates and dissolves in saliva without additional water.Oral administration of drugs is advantageous due to its ease of swallowing, avoidance of anxiety, versatility and, above all, patient consent. Many patients have difficulty swallowing tablets and capsules and do not take their medication as directed. Around 50% of the population suffers from this problem, which ultimately increases the chance of non-adherence and ineffective treatment. For these reasons, gold dispersible tablets have attracted enormous attention [1]. Solid dosage forms such as oral tablets occupy the most important place among all pharmaceutical preparations [2]. Tastemasking is a critical step in the production of an acceptable fast dissolving/disintegrating tablet.An The desire tablets for better taste in oral products has led to the development of many formulations with better performance of many formulations with better performances and acceptability. God dispersible tablets are an emerging trend in new drug delivery systems and have seen a steady increases in demand over the past decades. The field has emerged as a rapidly growing area in the pharmaceutical industry and is gaining popularity due to ease of compliance of particularly in geriatric and single dose formulations that dissolve with or without chewing and water. this type is achieved by adding various excipients, adjuvants. several new ones in recent years.

The mouth dissolving solid dosage form turns into a soft paste or liquid form on administration. This kind of property in dosage

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form can be added by inclusion of property in dosage form can be added by inclusion of right disintegrants which play key role in formulation of mouth dissolving tablets leads to quick disintegration of tablets and hence improve dissolution.

disintegration plays an important role in tablets dissolution before the active drug substance is finally released from the tablets structure into the body therefore type, concentration, and efficacy of disintegrants to a large extent affects the disintegrant properties and the ratio of crushing strength -friability to disintegration time of formulated tablet. The solid dosage form which dissolves in the mouth, turns into a soft paste or liquid it is administered when. This feature ofthe dosageform can be improved by adding suitable disintegrant, which play a key role in the preparation of orodispersible tablets. The addition of disintegrants to rapidly dissolving tablets and thus improves solubility.

because disintegration plays an important role in tablet dissolution prior to the final release of the active ingredient from the tablet structure into the body, the type, concentration, and efficiency of disintegrants greatly affect the disintegration characteristics (eg, disintegration time [DT]. and the ratio of crushing force to friability to disintegration time of the formulated tablet.

Researchers are currently looking for new,safe and efficient crushers that can quickly break up tablets with a crushing force greater than 3.5 kg. Analyzing the behaviour of the disintegration time and wetting time with surface free energy in the oral cavity, we learned that for a faster wetting of the molecule, there must be a polar component with a high surface free energy, and substances that meetthisspecialrequirement are called over degradants. the energy availability of this agents and the simplicity of the direct compression process suggest that their use would be a more profitable alternative to the advanced and proprietary technologies in the manufacture of ODT. 0rodispersible tablets (ODTs), also known as orodispersible tablets, are type of dosage form designed to dissolve or disintegrate quickly in the mouth without the need for water. they have gained popularity due to their ese for use, especially for patients who have difficulty swallowing conventional tablets or capsules. ODTs are usually formulated to have a pleasant taste and are available in different flavours to improve patients complex especially in children and the elderly. they are often used in medicines such as antihistamines, pain relivers and antiemetics. the rapid disintegration of ODTs in the oral cavity allows the pharmaceutical active in ingredients to be absorbed in to the blood stream more quickly. which can lead to a faster on set of action.

Various techniques are used to prepare ODTs, including lyophilization, direct pressing, and sublimation. these tablets benefit to patients which special needs such as dysphagia, pediatric and elderly patients, and people on the go who may not have access to water. However, it is important to note that ODTs may have limitations in term of drug stability and the need for special manufacturing processes.

OVER VIEW OF MUCOSA:[17,18]

The intact stratified squamous epithelium, supported by the Lamina propria, forms a mechanical barrier to oral microorganisms. Continuous removal of epithelial pits from defoliation limits microbial colonization of the surface. Membrane coat granules released extracellularly in the granular layer, antibody transudation through the mucosa, and the barrier formed by the basement membrane contribute to mucosal protection. Intraepithelial dendritic cells Langerhans cells are peripheral antigen-presenting cells that can process antigen in their MHC class II-rich intracellular compartments. They migrate to regional lymph nodes to present antigenic peptides complexed with MHC-II molecules that form naive helper T cells. The oral epithelium is also part of the communication network of the immune system, where signals are regularly exchanged in dynamic interactions.

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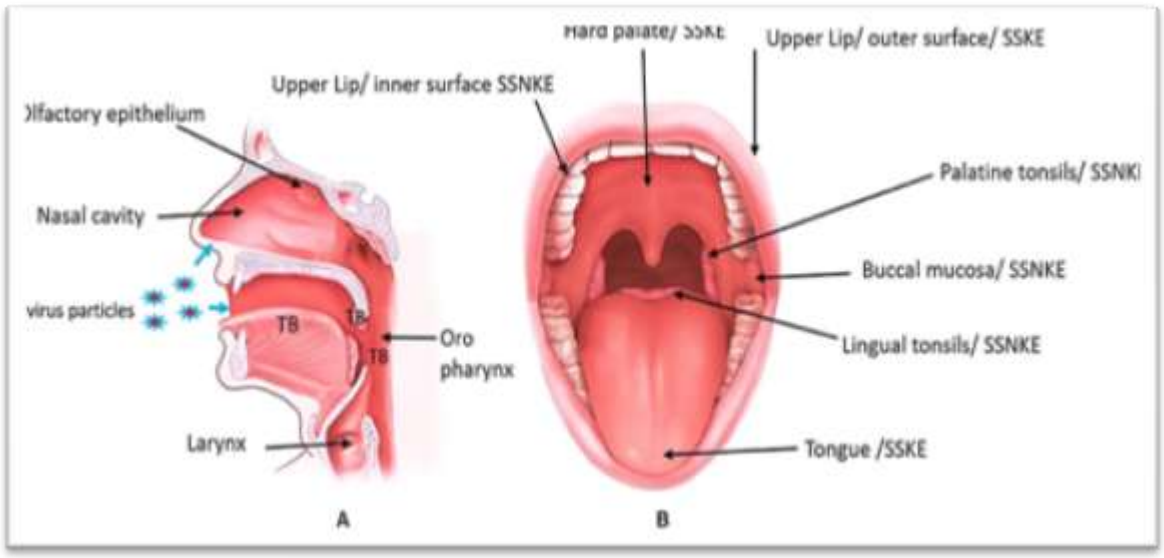

Figure 1: overview of oral mucosa

Ideal characteristics of suitable drug candidate[21,22]

Suitable drug candidates must possess several ideal characteristics, including:

Efficacy: The drug should effectively treat or control the target disease or condition.

Safety: It should have a favourable safety profile with minimal side effects Stability.

Selectivity: The drug must target specifically designed molecular pathways or receptors, minimizing side effects.

Pharmacokinetics: It must have adequate absorption, distribution, metabolism and elimination properties to ensure adequate bioavailability and appropriate dosage.

Stability: The drug must be chemically stable to maintain its integrity during storage and administration. Route of administration ideally, the drug should be appropriate for the intended route of administration (example oral, intravenous, topical) and patient population.

Silent features drug of ODTs:[19,20]

PreciseDosage: The fixed unit form offers the luxury of precise dosing, allows for high drug loading and is an ideal choice for pediatric and elderly Patients.

PatientConsent: No water is needed to swallow the dose. This is convenient for traveling patients and busy people who do not have immediate access to water.

Easytouse: easy to dose especially for the elderly, children, intellectually disabled and uncooperative patients with swallowing difficulties.

Unobstructed: there is no risk of suffocation when swallowing from physical obstruction of the airway, which improves safety and fulfillment.

Bettertaste: leaves little or no residue in the mouth, so it gives a good mouth feel and also uses a taste masking technique to avoid the bitter taste of the medicine.

Goodstability: Good stability because it is less sensitive to environmental conditions. Simple packaging: can be packed in a blister pack.Thereforeno special packaging is required.

BusinessOpportunities: Provide new business opportunities in the form of product differentiation, product promotion, product range, uniqueness and life cycle management.

Cost-Effective: Proves to be cost-effective as manufacturing, packaging and distribution costs are lower compared to other commercially available products.

VersatileTechnology: Due to its versatility, this technology is suitable for the development of advanced products for veterinary, OTC and Rx drugs.

Formulation Processes for Making Fast Dissolving Tablets:[23-24]

Various processes can be used to develop orally disintegrating tablets with different methodologies and the ODTs formed vary in various properties such as,

1. Mechanical strength of tables
2. Taste and mouth
3. Absorptive capacity
4. Dissolution of the drug in saliva

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5. Bioavailability
6. Stability

Several processes used to make ODTS include freeze drying, direct pressing, cotton wool process, molding, spray drying, sublimation, mass extrusion,nanoning, densification, and fast dissolving films. Direct compression is the simplest and most cost-effective tablet manufacturing technique. This technology can now be applied to ODT production due to the availability of advanced fillers, especially superdispersants and sugar-based fillers.

Super disintegrants:

Disintegrants often added to tablet formulations to help break down the concentrated pulp into primary particles, facilitating the dissolution or release of the active ingredients when placed in a liquid medium. They support moisture penetration and diffusion of the tablet matrix. The main task of disintegrators is to neutralize the effectiveness of the binder of the tablet and the physical forces that act during compression to form the tablet.

Recently, new materials called "superdispersants" have appeared. were developed to improve dissolution processes Superdispersants are another version of superabsorbent materials with tailored swelling properties. These materials are not designed to absorb significant amounts of water or aqueous solutions, but they are designed to expand very quickly. Superdisintegrants are used as structurally weaker of disintegrating solid dosage forms. They are physically dispersed in the matrix of the dosage form and swell when the dosage form comes into contact with a moist environment. These newer agents are more effective at lower concentrations, with greater disintegration efficiency and mechanical strength 19. Superdisintegrants are generally used at low levels in the solid dosage form, typically 1 to 10% by weight of the total dosage unit 20 weight. Their particles are usually small and porous, which allows the tablet to disintegrate quickly in the mouth without the unpleasant mouthfeel caused by large particles or gelation.

The particles are also compressible, which improves tablet hardness and friabilit Effective superdisintegrants improve compressibility, compatibility, and do not adversely affect the mechanical strength of high-dose drug formulations. In general, one gram of superdispersant absorbs 10-40 g of water or an aqueous medium. After absorption, the diffusion pressure and the isotropic expansion of the overdiffusion particles form stress-concentrated regions where a gradient of mechanical properties occurs, resulting in the breakdown of the entire structure.

Figure 2: oral disintegrating tablet.

Selection of Superdisintegrants:[25, 26]
superdisintegrant is used as an excipient in the composition of tablets, it must meet certain criteria in addition to swelling properties. The requirements for the tablet crusher must be clearly defined. An **Ideal decomposer should have** –

1. Poor solubility.
2. Poor gel formation.
3. Good wetting ability.
4. Good molding and flow properties. 5. There is no tendency to form complexes with drugs.
5. Good mouth feel.

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6. It should also be compatible with other excipients and have the desired tablet properties.
While some are better than others, the superdisintegrants currently on the market have an optimal combination of properties.

Advantages of ODTS[27,28]
The advantages of ODTS are:

No water is needed to swallow the tablet.Compatible with taste masking and pleasant mouthfeel. Can be easily given to children, for elderly and intellectually disabled patients.There is no residue in the oral cavity after administration Tablet production can be done with traditional processing andpackaging equipment at low cost. Allow a high drug load.Precise dosage can be given compared toliquids.Dissolution and absorption of the drug is fast, which ensures a quick onset of action.Inexpensive compared to liquid medicines, both in terms of administration and transport.Some drugsare absorbed from the mouth, pharynx and esophagus as saliva moves into the stomach, which reduces first-pass metabolism.

Disadvantages of oral disintegrating tablets:

Oral disintegrating tablets (ODTs) offer several advantages, such as ease of administration, rapid drug absorption, and improved patient compliance. However, they also have some disadvantages:
Taste and palatability: ODTs often contain sweeteners and flavoring agents to mask the bitter taste of some drugs. However, not all patients may find the taste acceptable.
Stability: ODTs can be sensitive to moisture and heat, which can reduce their shelf life and stability compared to traditional tablets.
Cost: Manufacturing ODTs can be more complex and costly than conventional tablets, which can lead to higher medication prices.
Limited drug loading: Some drugs may not be suitable for ODT formulation due to their physicochemical properties, which can limit the types of medications available in this dosage form.
Fragility: ODTs are more fragile and prone to breakage compared to conventional tablets, making them less suitable for patients who need to split or crush their medication.
Allergies and sensitivities: Some individuals may have allergies or sensitivities to the excipients used in ODT formulations, such as artificial sweeteners or binding agents.
Not suitable for all patients: ODTs may not be appropriate for patients with severe dysphagia or those who require a different dosage form for specific medical reasons.
Despite these disadvantages, ODTs remain a valuable option for patients who have difficulty sallowing traditional tablets or capsules.

Limitations of ODTs:

Tablets usually have insufficient mechanical strength. Therefore, conscientious usage is essential. Tablets can leave an unpleasant taste and roughness in the oral cavity if the composition is not correct. Medicines containing high doses can cause problems with their formulation as ODTs. • Patients taking concomitant anticholinergic drugs are not suitableODT candidates.

Mechanisms of action of oral disintegrating tablets:[31,32,33,34]

Orally disintegrating tablets are designed to rapidly disintegrante in the mouth, making them easy to swallow without the need for water. Several mechanisms are employed to achieve this:
Superdisintegrants: These are substances like crospovidone, croscarmellose sodium, a and sodium starch glycolate, which the need for water. Swell, and create mechanical forces that break the tablet apart.
Porous structure: ODTs are often formulated with a porous structure that enhances their ability to disintegrate. This can be achieved through freeze - drying, sublimation, or other techniques.
Sugar-based excipients: Some OTDs contain excipients like mannitol or sorbitol, which dissolve rapidly in saliva, aiding in tablet disintegration.
Effervescence: Effervescent OTDs contain acid and carbonate components that react with saliva, releasing carbon dioxide gas and promoting tablet disintegration.
The mode of action of oral disintegrating tablets (ODTs) involves several key steps when taken by a patient:

MODE OF ACTION:[32,34]
Placement in the mouth: when an ODTs is placed on the tongue or in the oral cavity, it comes into contact with saliva.
Saliva absorption: ODTs often contain superdisintegrants, such as crospovidone or croscarmellose sodium, that are hydrophilic and rapidly absorb saliva. This absorption of saliva leads to rapid wetting and sweeling of the tablet.
Sweeling and disintegration: as the superdisintegrants absorb saliva, they swell and

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create mechanical forces within the tablet. This swelling action, along with the porous structure of the tablet, leads to its disintegration or breaking apart into fine particles.

Dissolution of the drug: as the tablet disintegrants, the active pharmaceutical ingredient (API) within its exposed to saliva. The fine particles of the API rapidly dissolve in the saliva.

Mucosal Absorption: the dissolved API is then absorbed through the mucous membranes in the oral cavity, such as the buccal or sublingual mucosa. This allows for quick absorption of the drug into the bloodstream, bypassing the gastrointestinal tract and first-pass metabolism.

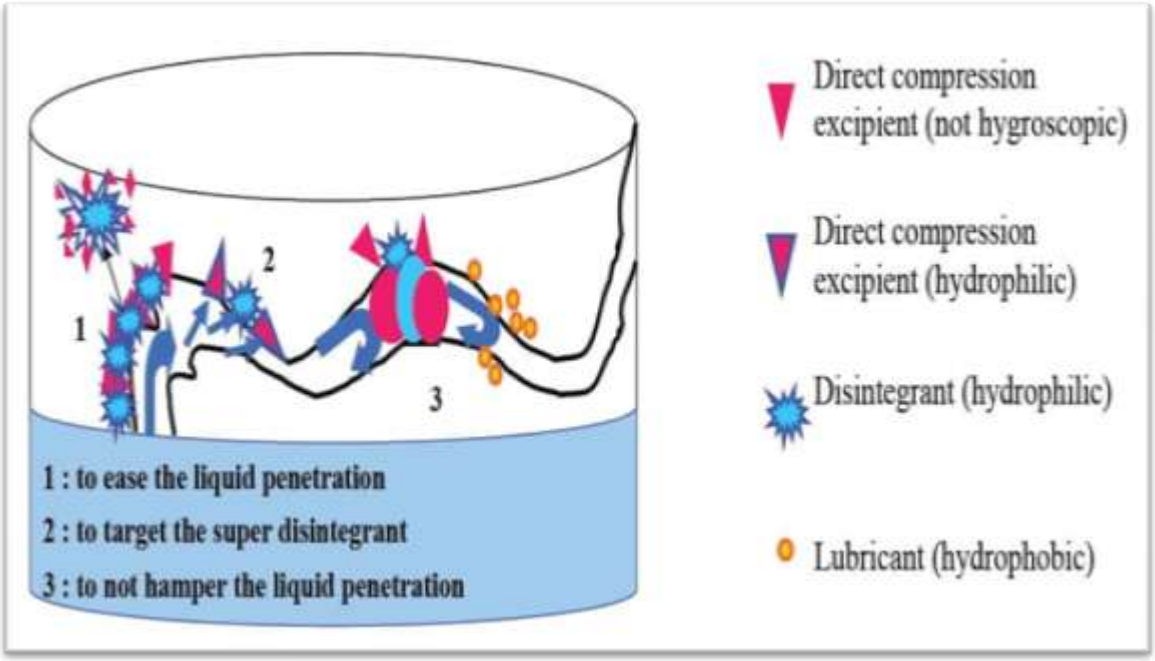

Figure 3 : Mechanisms Action Of Oral Disintegrating Tablet .

II. CONCLUSION: [35,36]

All available ODTS technologies work on the primary concept of maximizing the porous structure of the tablet matrix for rapid disintegration of the tablet in the oral cavity, as well as good taste-masking properties and satisfactory mechanical strength. Future challenges for many ODT producers include cost reduction with traditional equipment, different package sizes, better mechanical strength, and finding production methods with flavor masking potential. Thus, patient demand and the availability of various technologies have increased the acceptance of orodispersible tablets, which in turn increases the patent life of the drug. The technologies and techniques described in this article demonstrate how recent advances in formulation and processing technologies contribute to the creation of gold dispersible tablets. In the coming days, we may consider the emergence of new ODT technologies. Thus, ODT has a great impact as a delivery system for most drugs in the near future.

ODTs have potential advantages over conventional oral formulations in terms of improved patient compliance; comfort, rapid onset of action and bioavailability, which have attracted the attention of many manufacturers. Children and the elderly are the main ones whose problems are easily targeted by ODTS, as both groups had difficulty swallowing regular tablets. ODTS aims to maximize the pore structure of the tablet matrix and incorporate superdisintegrants at optimal concentrations to achieve rapid tablet disintegration and immediate dissolution, as well as good taste masking properties and excellent mechanical strength. Many drugs can be added to ODT, especially unpleasant drugs. The study is still ongoing. There must be more products commercialized to use this technology properly. Thu ODTs may be developed for most of the available drug in near the future. All collaborated and modified fillers play a key role in the development of simple, atmosphere-friendly dosage forms. The improved physical, chemical

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and mechanical properties of such excipients compared to existing excipients have helped to overcome formulation problems such as flowability, compressibility, hygroscopicity, taste, solubility, degradation, adhesion and dust generation. Due to the increasing demand for new drug delivery, rapidly degrading drug delivery system has become one of the milestones of current research. Although there are many superdegradants, the search for new degradants continues and researchers are experimenting with modified natural products such as formalin casein, chitin, chitosan, polymerized agar-acrylamide, xylan, smecta, key-yo clay, cross-linked carboxymethyl guar, mango peel pectin, cassia.

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