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"A COMPREHENSIVE REVIEW ON ORALLY DISPERSIBLE TABLETS: INNOVATIONS, FORMULATION STRATEGIES, AND FUTURE PROSPECTS"

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ABSTRACT:

The require for conveying drugs to patients effectively with least side impacts has incited pharmaceutical businesses to be locked in in advancement of modern medicate conveyance frameworks. To troubleshoot such issues a modern measurement frame known as orally crumbling tablet (ODT), has been created which quickly deteriorate & break up in spit and after that effectively gulped without need of water which could be a major advantage over customary measurement frame. In expansion, patients enduring from dysphasia, movement affliction, rehashed emesis and mental clutters lean toward such planning since they cannot swallow expansive amount of water. Agreeing to European Pharmacopoeia, the ODT ought to disperse/disintegrate in less than three minutes. ODT can be arranged by numerous advances like lyophilization, molding, splash drying, cottoncandy and compression etc. These methods render crumbling of tablet quickly and dissolving mouth without chewing or extra water admissions. But among these innovations coordinate compression is most helpful and cheap way to deliver tablets with adequate auxiliary keenness. The bioavailability of a few drugs may be expanded due to assimilation of drugs in verbal depth additionally due to progastrin retention of spit containing scattered drugs that pass down into the stomach. In addition, the sum of medicate that's subject to to begin with pass digestion system is decreased as compared to standard tablets. The current article is centered on perfect characteristics, focal points and drawbacks, different advances created for ODT, assessment strategies along side later investigate and future potential.

KEYWORDS: ODT, Conventional and Patented techniques, Disintegrating.

INTRODUCTION:

Tablets that contain a uncommon detailing, which rapidly crumbles in water to create a drinkable suspension. It gives the ease of gulping and the upgraded bioavailability of most sedate details are managed orally within the frame of capsules, tablets or liquids. Dispersible tablets are characterized as uncoated or film-coated tablets aiming to be scattered in water earlier to organization, which gives homogeneous scattering. As a rule, a dispersible tablet is scattered in water and the consequent scattering is given to the persistent. Dispersible tablets are a substitute to customary a definition with exact dosing. Pharmaceutical dynamic compounds which are not steady in watery arrangement may be steady as a dispersible tablet.The dispersible tablet offers a valuable dose frame, diminishing the require for different details of the same medication. The imaginative concept of a quickly dispersible sedate conveyance framework stems from the desire to supply the quiet with a customary implies oftaking the medicate. In later times, verbal organization of the detailing has gotten to be the foremost prevalent course of organization due to its consolation of utilization, painlessness, flexibility andabove all persistent compliance

AIM AND OBJECTIVES:

AIM : "A COMPREHENSIVE REVIEW ON ORALLY DISPERSIBLE TABLETS: INNOVATIONS, FORMULATION STRATEGIES, AND FUTURE PROSPECTS"

OBJECTIVES :

1. To explore the historical background and evolution of orally dispersible tablets as a novel drug delivery system.
2. To review various formulation techniques employed in the development of ODTs, including direct compression, lyophilization, sublimation, and other advanced methods.
3. To identify and evaluate the role of excipients and superdisintegrants in enhancing the performance and stability of ODTs.
4. To summarize the standard quality control parameters for ODTs, including disintegration time, mechanical strength, friability, drug release profile, and palatability.

5. To examine innovations and emerging technologies in ODT development, such as 3D printing, nanotechnology, and novel excipient systems.
6. To assess the advantages and limitations of ODTs in terms of patient compliance, bioavailability, and clinical effectiveness.
7. To highlight regulatory requirements and market trends associated with ODTs across global pharmaceutical industries.
8. To suggest future directions and research opportunities for improving ODT technology and expanding its therapeutic applications.

IDEAL PROPERTIES OF ORALLY DISPERSIBLE TABLETS:

It ought to be Cost-effective. Ideally dispersible tablet require a littler amount of water for verbal organization. The detailing must have adequate hardness It ought to be steady. The medicate stacking capacity of the dispersible tablets must be tall. The detailing ought to deteriorate or break down rapidly after verbal organization within the verbal depth for fast activity. Thefirst pass impact which increments the bioavailability of the quick dispersible tablets.

Over a decade, strong dose shapes have picked up notoriety due to its cheaper rate, ease of organization, exact dose, but generally due to quiet compliance. Tablets and capsules are the foremost common measurement shape. [1,2] Dysphagia, or trouble in gulping is one of the foremost common issues related with tablets and capsules among all age bunches. Common complaints around the trouble in gulping tablets are estimate, surface, and taste of tablets. Geriatric and pediatric patients and roaming patients, who may not have get to to water, are for the most part in require of simple gulping dose forms.[3] A novel verbal measurement frame known as ODTs was created which crumble quickly in spit, more often than not inside a matter of seconds, without the ought to take water. ODTs discharges the medicament within the mouth for assimilation through nearby verbal mucosal tissue and through pre-gastric (verbal depression, pharynx, and esophagus), gastric (stomach), and post-gastric (little and huge digestive system) fragments of the gastrointestinal tract (GIT).[4] ODTs are too called as verbal dispersible tablets, fast crumbling tablets, mouth dissolving tablets, quick crumbling tablets, quick dissolving tablets, rapid-dissolving tablets. Joined together States Pharmacopoeia (USP) endorsed these measurement shapes as ODTs. Joined together States Nourishment and Sedate Organization characterized ODT as "A strong dose shape containing a restorative substance or dynamic fixing which deteriorates quickly as a rule inside a matter of seconds when set upon the tongue." The deterioration time for ODTs for the most part ranges from a few

seconds to almost a minute.[5] Deteriorating property of this dose shape depends on its fabricating prepare. Its property to deteriorate is due to the fast entrance of water into the tablet network, which makes permeable structure and comes about in quick crumbling. Subsequently, the essential approaches incorporate expanding the permeable structure of the tablet network, joining the suitable crumbling specialist and using profoundly water-soluble excipients within the formulation.[6]

IDEAL CHARACTERISTICS OF ODTS [7]

The ideal characteristics of ODTs which distinguish it from conventional dosage form include

1. It should dissolve or disintegrate in the mouth usually within fraction of seconds and requires no water.
2. High drug loading.
3. Compatible with taste masking and other excipients.
4. It should be portable without the concern of brittleness.
5. Leave negligible or no residue in the mouth after oral administration.
6. Exhibit low sensitivity to altered environmental conditions such as humidity and temperature.
7. Have a pleasing mouth feel.
8. Adaptable and amenable to manufacturing, processing and packaging equipment at nominal expense.

ADVANTAGES OF ODTS:[6]

1. ODT are suitable to those patients who cannot ingest tablet/capsules, such as the elderly, stroke victims, bedridden patients, patients with esophageal problems, patients affected by renal failure & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients.
2. Improved compliance.
3. ODT is most suitable for disabled, bedridden patients, travelers, and who do not have access to water.
4. No specific packaging required and can be packaged in blisters.
5. Cost effective.
6. Good stability as conventional oral solid dosage form.
7. Allow high drug loading.
8. Provides rapid drug delivery from dosage forms.
9. Provide advantage of liquid medication in form of solid preparation.
10. No chewing needed.
11. 11. Versatile and amiable to existing handling and bundling apparatus. 12. apid onset of activity.

LIMITATIONS OF ODTS:

1. Due to its hygroscopic nature it must be kept in dry place.
2. Bad tastes drugs are difficult to formulate.

3. Low tablet compression and soft molded metrics makes tablet friable & brittle thus making it difficult to handle.
4. ODT requires special packaging for properly stabilization & safety of stable product
5. Challenges in the Formulation of ODT [8-13]
6. Mechanical strength and disintegration time
7. The disintegration time of ODT is usually less than a minute with a good mechanical strength. Numerous ODTs are delicate, and there are numerous chances that such delicate tablet will break amid pressing, transport or taking care of by the patients. It is exceptionally normal that expanding the mechanical quality will delay the deterioration time. Consequently, both the parameters are of prime concern. Tastefulness:
8. As most drugs are unpalatable, it becomes a major challenge while formulating oral disintegrating tablets that the drug should be in taste masked form. ODTs crumble or break down in patient's verbal depression, hence discharging the dynamic fixings, which come in contact with the taste buds; thus, taste concealing of the drugs gets to be basic to persistent compliance Mouth feel:
9. Sensation of a tablet that's delivered in mouth upon chewing or crumbling. A relieving or cooling sensation (e.g.-Pearlitol) with smooth surface is favored.
10. Grittiness:
11. Particle size exceeding 50µm may feel gritty. Dirty (e.g.-Calcium Carbonate) or Gummy surface is undesirable.
12. After-effect:
13. After-effects such as numbing sensation of a portion or the whole surface of the mouth and tongue for eg. sharp antihistaminic - Promethazine HCl. Another impact is after- taste for eg. Saccharine in tall sum which leads to severe after- taste.

Hygroscopicity:

14. Several orally disintegrating dosage forms are hygroscopic in nature hence cannot maintain physical integrity under normal conditions of temperature and humidity. So they require assurance from mugginess, which requests for specialized item bundling.

15. Cost: The method employed for manufacturing of an ODT should be acceptable in terms of cost of the final product. Strategies like Zydis and Orasolv that require extraordinary strategies for fabricating and bundling increments the taken a toll to a momentous degree.

Size of tablet:

The degree of ease when taking a tablet depends on its estimate. It has been detailed that the least demanding estimate of tablet to swallow is 7-8 mm whereas the most straightforward measure to handle was one bigger than 8 mm. So to achieve the measure of the tablet that's both simple to require and handle, is troublesome.

TECHNIQUES FOR PREPARATION OF ODTS: [14-19]

The techniques used to manufacture ODTs can be classified as: -

a. Conventionaltechniques
b.Patented techniques
a. ConventionalTechniques:

The various conventional technologies are developed for the preparation of Orally Disintegrating drug delivery system that are Freeze drying, Spray drying, Molding, Phase transition process, Melt granulation, Sublimation, Mass Extrusion, Cotton Candy Process, Direct compression.

b. Patented Techniques:

Rapid-dissolving characteristic of ODTs is generally attributed to fast penetration of water into tablet matrix resulting in its fast disintegration. Several technologies have been developed on the basis of formulation aspects and different processes and resulting dosage forms vary on several parameters like mechanical strength, porosity, dose, stability, taste, mouth feel, dissolution rate and overall bioavailability.

A. CONVENTIONAL TECHNIQUES: [17-22]

1. Freeze-Drying or Lyophilization:

Freeze-drying or lyophilization may be a handle in which dissolvable is evacuated from a solidified sedate arrangement or suspension containing structure-forming excipients. This innovation comprises of three stages:

i. The materials are freezed underneath its eutectic zone.

ii. Dampness is decreased to around 4 % w/w of dry item by essential drying or sublimation.

iii. Bound dampness is diminished by auxiliary drying or desorption to get the desired last esteem. This strategy is valuable for warm touchy drugs i.e. thermo labile substances. Through this method deterioration of tablet is accomplished in less than 5 seconds due to fast entrance of spit in pores when set within the verbal depression.

2. Tablet Molding:

Powdered mix (containing sedate and excipients like authoritative specialists e.g., Maize starch, gelatin, polyvinyl pyrrolidone etc.) are passed through an awfully fine screen (to ensure fast disintegration) and after that dampened with a hydro-alcoholic dissolvable and are molded into tablets by utilizing weight lower than that for ordinary tablets. The dissolvable is at that point discuss dried. Distinctive molding strategies can be utilized to get ready ODTs.

a. Heat molding:

In this prepare the medicate is broken up or scattered into liquid lattice which can be specifically molded into ODTs 39. In this handle, the suspension or arrangement of sedate, agar, and sugar is ready and after that poured into the blister packaging which is at that point cemented at room temperature to make a jam and dried at 30°C beneath the vacuum.

b. Compression molding:

In this handle the powder mix is dampened with a hydro alcoholic dissolvable went with by compressing into form plates to make a wetted mass, which is, assist discuss dried to evacuate the dissolvable.

3. Spray Drying:

This handle includes arrangement of particulate bolster lattice, arranged by splash drying the watery composition containing bolster lattice and other components to create a profoundly permeable and fine powder. This mix is at that point blended with dynamic fixings and compressed into tablets. The details are joined by hydrolyzed and non hydrolyzed gelatins as supporting operators, mannitol as bulking specialist, sodium starch glycolate or crospovidone as deteriorating specialist and an acidic fabric (e.g. citric corrosive) and/or soluble base fabric (e.g. sodium bicarbonate) to improve deterioration and disintegration. Tablet compressed through this procedure is more often than not deteriorated inside 20 seconds when inundated in an fluid medium.

4. Mass-Extrusion:

This technology utilizes the softening of the active blend with a solvent mixture of water-soluble polyethylene glycol and methanol, followed by expelling the softened mass through an extruder or syringe to produce a cylinder of the product into uniform segments, using a heated blade to shape it into a tablet. The dehydrated cylinder can coat the granules of unpleasant tasting medications, thus concealing their bitter flavor

5. Phase Transition:

In this method, the combination of sugar alcohols with low and high melting points, along with a phase change during production, is crucial for creating ODTs without the need for specialized equipment. Tablet is made in two stages. Initially, a powder comprising two sugar alcohols with differing melting points is compressed, and subsequently, it is heated to a temperature that falls between these two melting points. Orally disintegrating tablets were made by compressing a powder mixture of erythritol (melting point: 122°C) and xylitol (melting point: 93-95°C), followed by heating at approximately 93 °C for 15 minutes. Heating generally raises the average pore size of the tablets and enhances their hardness. The increase in tablet hardness due to heating and storage does not depend on the crystal state of the sugar alcohol with the lower melting point

6. Melt granulation:

In this procedure, pharmaceutical powders are effectively agglomerated by employing a binder, which can be a molten liquid, a solid, or a solid that melts during the operation. This method employs high shear mixers, where the product temperature increases above the binder's melting point through the heating jacket or the frictional heat produced by the impeller blades. Abdelnaby et al. formulated an orally disintegrating tablet by adding a hydrophilic waxy binder PEG 6-stearate (Superpolystate®) into the mixture. It has a melting point ranging from 33 to 37°C and an HLB value of nine. It serves as a binder and enhances the physical strength of tablets. It aids in the quick

breakdown of a tablet when put in the mouth and does not leave any residue in the oral cavity. The granules were created with polyethylene glycol (PE G-4000) serving as a melting binder and lactose monohydrate acting as a hydrophilic filler, without utilizing solvents or water

7. Sublimation:

During this process, volatile components (such as camphor, ammonium bicarbonate, naphthalene, urea, urethane, etc.) are combined with additional tablet excipients, and the resulting blend is subsequently compressed into tablets. The entrapped volatile material is eliminated through sublimation, resulting in a porous structure. Tablets with significant porosity (around 30%) quickly dissolve in saliva within 15 seconds. A combination of active ingredient and carbohydrates (such as glucose, mannitol, xylitol, etc.) is utilized, which is then hydrated with water (1-3% w/w) and pressed into tablet form. Elimination of water produces a tablet with high porosity.

8. Cotton candy technology:

This procedure is called so because it employs a unique spinning mechanism to create a floss-like crystalline formation that resembles cotton candy. This method is also referred to as the cotton candy process. It entails the creation of a matrix of saccharides or polysaccharides through the concurrent processes of flash melting and spinning. The matrix created is partially recrystallized to enhance flow characteristics and compressibility. The candy floss matrix is milled and mixed with active ingredients and excipients, then compressed into ODT. This method can handle bigger medication doses and provide enhanced mechanical durability. Nonetheless, this procedure is limited because of the elevated process temperature.

9. Nanonization:

In this procedure, the drug's size is diminished to the nano scale through the wet-milling technique. The drug's nanocrystals are stabilized against aggregation through surface adsorption on specific stabilizers, which are subsequently included in ODTs. This is utilized for drugs that have low water solubility. It results in increased bioavailability and decreased dosage, along with a cost-effective manufacturing method.

10. Direct compression method:

This method is the easiest and least expensive way to create tablets with adequate structural strength. Direct compression (DC) is favored due to its simplicity, speed, cost-effectiveness, and reliability. Thus, for any active pharmaceutical ingredient (API), the formulator ultimately aims to create it in DC tablet form. Previously, it was believed that only crystalline materials were suitable for DC; however, the situation is evolving, and this method is now being utilized for various non-crystalline materials as well. The primary reason for moving from the traditional wet granulation technique to DC, despite the benefits of the former such as consistent content, enhanced segregation resistance, and a more hydrophilic compact, is the drawbacks of wet granulation including stability issues from moisture exposure, excessive processing steps, lengthy processing times, and ultimately increased tablet production costs. Currently, several excipients are commercially available that convert non-compressible APIs into materials that can be directly compressed. The commonly utilized options include microcrystalline cellulose, ethyl cellulose, and metal phosphates and carbonates.

ADVANTAGES WITH DIRECT COMPRESSION:

1. Since no agglomeration stage is involved disintegration is directly due to the primary particles.
2. Fewer unit operations, short processing time and low energy consumption are employed in comparison to wet granulation.
3. There is no requirement of granulator and dryer since critical steps such as granulation and drying are not used.
4. Hard tablets, not fragile and easy to handle.
5. Can be easily packaged in push through blisters hence no specific packaging is required.
6. Smooth mouth feel and pleasant taste.
7. Cost effective.

B. PATENTED TECHNOLOGIES: [20, 21]

1. Zydis Technology:

Zydis, the most recognizable of the rapid-dissolving tablet formulations, was the initial new technology tablet introduced to the market. The tablet dissolves in the mouth within seconds after being placed on the tongue. A Zydis tablet is made through lyophilization or freeze-drying the medication in a matrix typically made of gelatin. The item is quite delicate and light, and should be packaged in a specific blister pack. Patients should peel the film away to free the tablet. The Zydis product is designed to melt on the tongue within 2 to 3 seconds. The Zydis formulation prevents microbial growth because the final water content in the freeze-dried product is excessively low

2. Durasolv Technology:

Durasolv is the proprietary technology of CIMA Labs that necessitates a drug, fillers, and a lubricant, all processed using standard tableting machinery and exhibiting strong rigidity. They can be effortlessly packed into standard packaging systems such as blisters. Durasolv is an ideal technology for

products that need minimal active ingredients.

3. Orasolv Technology:

Orasolv Technology was created by CIMA labs. In this formulation, the active drug is taste-masked and includes an effervescent disintegrating agent. To reduce oral dissolution time, tablets are manufactured using the direct compression method with minimal compression force. Standard blenders and tablet machines are utilized to create the tablets. The tablets manufactured are soft and crumbly and are packaged in a uniquely designed pick and place system.

4. Flash Dose Technology:

Fuisz has patented the flash dose technology. Nurofen meltlet, a novel type of ibuprofen in the form of melt-in-mouth tablets, created using flash dose technology, is the initial commercial offering released by Biovail Corporation. Flash dose tablets are made up of a self-binding shear form matrix known as "floss." Shear form matrices are created through rapid heat treatment.

5. Wowtab Technology:

Wowtab Technology is patented by Yamanouchi Pharmaceutical Co. WOW stands for "Without Water." This method involves mixing saccharides with low mouldability and those with high mouldability to create a strong tablet that melts quickly. The active component is blended with a low mouldability sugar, granulated with a high mouldability sugar, and then compressed into tablets.

6. Flashtab Technology:

Flashtab technology has been patented by Prographarm laboratories. Tablets formed by this system contain an active component as micro crystals. Micro granules can be produced utilizing traditional methods such as coacervation, microencapsulation, and extrusion spheronization.

BASIC COMPONENTS OF ORALLY DISPERSIBLE TABLET FORMULATION: [33-36]

a. Drug:

High dosage, highly water soluble, poorly compressible and hygroscopic drugs represent the greatest difficulty in a dispersible compressible formulation.

b. Disintegrates:

A Disintegrant accelerate the rate at which a tablet breaks up in water. E.g. Sodium Starch Glycolate,Crospovidone,Croscarmellose.
c. Binder:
The binder and solvent in wet granulation have a reflective effect on the disintegration properties of the tablet.
E.g. Hydroxy ethyl cellulose, Hydroxy propyl methyl cellulose.
d. Diluents:
A diluent or filler facilitates the compression of a formulation and confers resistance and acceptable appearance to the tablet
E.g. Calcium carbonate, Calcium phosphates, microcrystalline cellulose, Starch, Mannitol, Lactose etc.
e. Lubricants:
Stearic acid salts, like Magnesium stearate, are potentially unsuitable in dispersible tablet formulations because they are hydrophobic.
E.g. Magnesium Stearate, Polyethylene Glycol.

MECHANISM OF SUPERDISINTEGRANTS:[22]

There are four major mechanisms for tablets disintegration as follows:
1. Porosity and capillary action (Wicking):
Capillary action causes breakdown. When the tablet is immersed in an appropriate aqueous solution, the solution infiltrates the tablet and displaces the air that was adsorbed on the particles, thus

reducing the intermolecular connection and fragmenting the tablet into small particles. The drug/excipients' hydrophilicity and the tableting conditions influence the water absorption by the tablet. For these disintegrants, it is essential to maintain a porous structure and low interfacial tension with aqueous fluid, facilitating disintegration by forming a hydrophilic network around the drug particles.

2. Swelling:

Swelling-induced disintegration is the most commonly recognized general mechanism of action. Insufficient swelling force results in inadequate disintegration, attributing to elevated tablet porosity. Conversely, ample swelling force is applied in the tablet with minimal porosity. However, when the packing fraction is extremely high, the fluid cannot infiltrate the tablet, leading to a further slowdown in disintegration.

WICKING SWELLING:

WICKING. The material will absorb water, creating a capillary network that allows liquid to infiltrate the tablet. Water will subsequently cause swelling of disintegrants and the dissolution of soluble particles. SWELLING. Material expands with water upon contact, creating pressure inside the tablet that surpasses the tablet's cohesiveness.

The physical connection between particles in matrix form is disrupted when water is drawn in by swelling disintegrant particles.

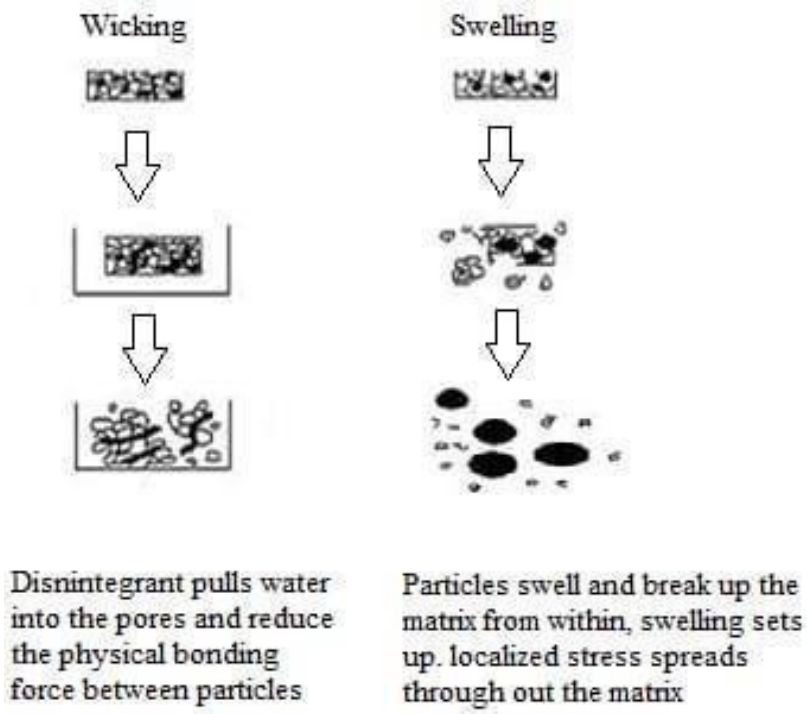

Fig.1: Wicking Swelling.

3. Disintegrating particle/particle repulsive forces:

Drawing from the observation that non-swelling particles lead to tablet disintegration, Guyot-Hermann proposed a theory of particle repulsion. The forces of electric repulsion among particles serve as the mechanism for disintegration, and water is necessary for this process. Researchers discovered that repulsion has only recently become secondary to wicking.

4. Due to deformation:

Tablet compression causes disintegrated particles to deform, which revert to their original structure when they come into contact with water or aqueous media. At times, the swelling ability of starch is enhanced when granules undergo significant deformation during compression. This enlargement of the altered particles leads to a disintegration of the tablet. This might be a mechanism of starch and has started to be researched.

DEFORMATION REPULSION:

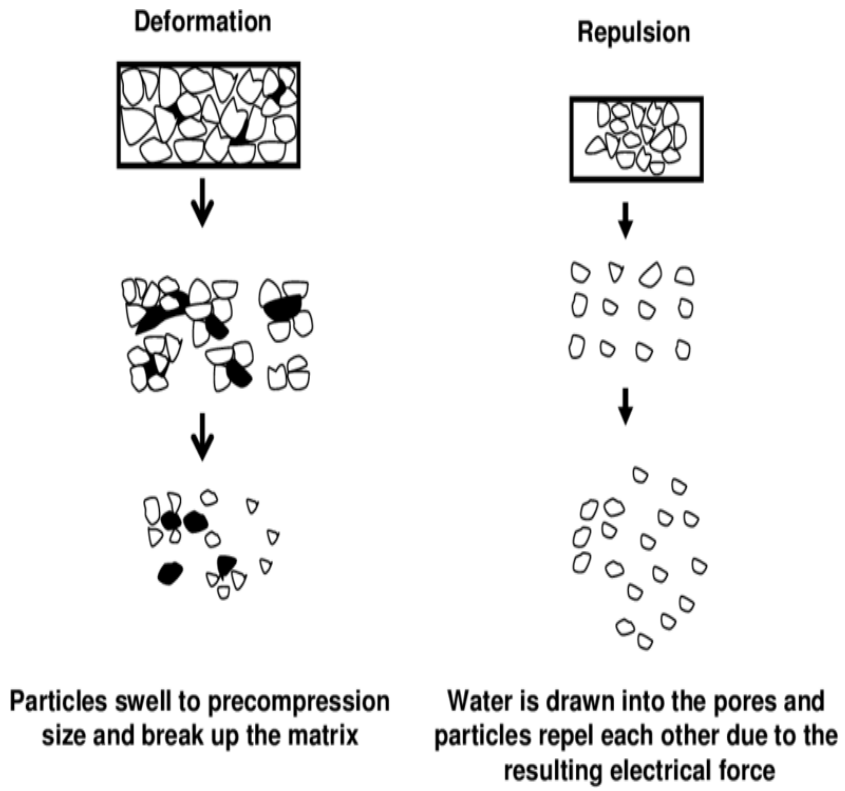

Fig.2: Deformation Repulsion

5. By Enzymatic Reaction:

Here, enzyme present in the body act as disintegrants. These enzymes destroy the binding action of binder and helps in disintegration. EVALUATION OF ODT: [23-32]

1. Hardness/crushing strength:

The crushing strength limit for an ODT is typically maintained at a lower level to promote quick disintegration in the mouth. The tablet's crushing strength can be assessed with a standard hardness tester. It is indicated in Kg/cm2.

2. Friability:

The friability test is conducted to evaluate the impact of friction and shocks that can frequently lead to tablets chipping, capping, or breaking. The Roche friabilator exposes several tablets to both abrasion and shock by employing a plastic chamber that rotates at 25 rpm, dropping the tablets from a height of 6 inches with every turn. A preweighed sample of tablets was put into the friabilator, which was then run for 100 revolutions. Tablets were cleaned of dust and weighed again. Compressed tablets must not decrease in weight by more than 1%.

Friability = [(Initial weight – Final weight) / Initial weight] * 100

Fig.3: Friability test Apparatus

3. Weight Variation Test

The weight variation test involves weighing 20 tablets separately, calculating the average tablet weight, and then comparing each tablet's weight to the average weight.

Average weight of Tablet	**% Deviation**
80 mg or less	**10.0**
More than 80 mg but less than 250 mg	**7.5**
250 mg or more	**5.0**

1. Content Uniformity: The uniformity of content test relies on analyzing the individual content of drug substance(s) in several dosage units to verify if the individual content falls within the specified limits. The amount of active ingredient is measured in each of the 10 randomly selected dosage units by employing the method outlined in the assay. The preparation meets the requirements of the test if every single component is between 85-115% of the average content.

2.Dispersion Time:

Dispersion time refers to the duration needed for the tablet to completely dissolve in water. A glass beaker was filled with 20 ml of water, and then a tablet was gently positioned in the beaker. The duration needed for the tablet to dissolve in water is referred to as the dispersion time.

3. Uniformity of Dispersion:

The consistency of dispersion was evaluated by adding two tablets to 100 ml of water (at 25°C in a beaker). The tablets were permitted to break down, and the mixture was stirred with a glass rod until a uniform dispersion was achieved. The dispersion was filtered through a 710µm sieve (British standard sieve series mesh No. 22 and ASTM No. 25), and the sieve was examined for any retained material.

4. Measurement of Tablet Porosity:

The mercury porosimeter can be utilized to assess the porosity of tablets. The tablet porosity (ε) can be determined using the equation below:

$\varepsilon = 1 - m / (\rho t V)$

Where ρt represents the actual density, m and V denote the mass and volume of the tablet, respectively.

5. Wetting Time and Water Absorption Ratio:

The contact angle is linked to the wetting time of the dosage form. Reduced wetting time signifies a faster breakdown of the tablet. The disintegration duration for ODT must be adjusted as

Disintegration must occur without water; therefore, the test should replicate disintegration in saliva.

A petridish (10 cm diameter) was filled with 10 ml of water for this purpose. The tablet was gently positioned in the middle of the petri dish, and the duration taken for the tablet to fully break down into fine particles was recorded. The water absorption ratio, R, can be determined using the equation below:

$R = 100 (Wa - Wb) \div Wb$

Wb: - The mass of the tablet before placing it in the petridish, Wa: - The soaked tablet taken from the petridish is then weighed again.

6. Disintegration test:

The disintegration time for ODTs is typically less than 1 minute, while the actual disintegration time a patient may experience varies from 5 to 30 seconds. The conventional method for conducting disintegration tests on these dosage forms has multiple limitations and is inadequate for measuring extremely short disintegration times. The disintegration test for ODT must simulate disintegration in the mouth with salivary components. The time it took for the tablet to disintegrate was assessed in water (37°C) using the USP disintegration test device.

7. Disintegration in oral cavity:

The time required for complete disintegration of tablets in mouth was obtained from six healthy volunteers, who were given tablets from the optimum formulation.

8. Dissolution test:

The advancement of dissolution techniques for ODTs parallels the method used for traditional tablets and is nearly the same. Media like 0.1 N HCl and buffers (pH - 4.5 and 6.8) ought to be utilized for assessing ODT similarly to traditional tablets. Apparatus 1 and 2 for USP dissolution may be utilized. USP 1 Basket apparatus can have specific uses; however, tablet fragments or broken tablet masses may occasionally become lodged at the top inside the basket near the spindle, where stirring is minimal or absent, resulting in inconsistent dissolution profiles. Kancke suggested the USP 2 Paddle apparatus, recognized as the most appropriate and frequently used option for ODTs, typically operating at a paddle speed of 50 rpm. Generally, the dissolution of ODT occurs rapidly under USP monograph conditions; therefore, reduced paddle speeds can be employed to achieve a profile. Dissolution aliquots were analyzed using a UV spectrophotometer.

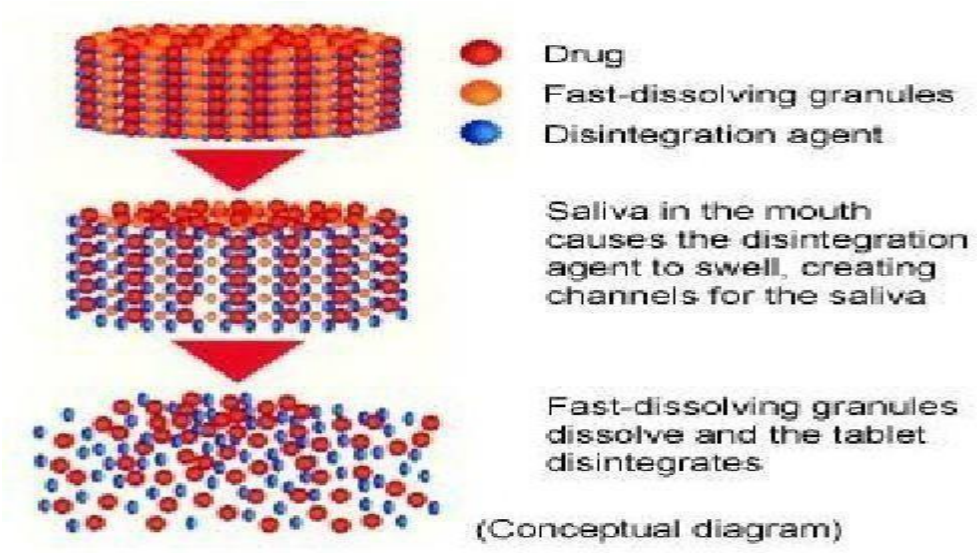

Fig.4: Mechanism of Oro-dispersible Tablet.

I NNOVATION IN MANUFACTURING OF ODT: In recent times, dispersible tablets have transformed from traditional formulations into advanced drug delivery systems aimed at fulfilling the increasing needs for patient-focused, effective, and individualized treatments. Essential advancements propelling this transformation encompass:

1. Advanced Superdisintegrant TechnologiesSuperdisintegrants play a crucial role in dispersible tablets, and continuous advancements have resulted in the development of synthetic and natural types with enhanced swelling and wicking characteristics. Contemporary superdisintegrants like crospovidone, croscarmellose sodium, and sodium starch glycolate have been refined for reduced application levels, quicker disintegration, and improved mechanical strength. Research on innovative natural disintegrants such as Plantago ovata husk, mucilage from fenugreek seeds, and starch derived from jackfruit seeds has shown encouraging disintegration efficiency along with biocompatibility and affordability.

2. Nanotechnology-Enhanced Dispersible Systems The integration of nanotechnology into dispersible tablet designs has tackled a major constraint — the inadequate water solubility of specific APIs. Nanocrystals, solid lipid nanoparticles, and nanostructured lipid carriers incorporated into dispersible tablets have demonstrated increased dissolution rates, greater bioavailability, and quicker therapeutic action. Dispersible tablets containing nanocrystalline celecoxib showed a 2–3 times increase in bioavailability in comparison to traditional formulations.

3. Sophisticated Taste Masking Techniques As dispersible tablets typically break down in the mouth, effective taste masking is essential for patient compliance. Innovations consist of: Ion-exchange resins for binding bitter medications. Microencapsulation methods employing polymers such as Eudragit®. Inclusion complexes employing cyclodextrins to encapsulate undesirable substances. Lipid-based taste masking systems that envelop drug

particles while ensuring quick disintegration. These technologies have enabled the development of bitter APIs like ciprofloxacin and ornidazole into acceptable dispersible tablets, greatly enhancing patient adherence.

3D Printing Technology The use of three-dimensional (3D) printing, especially fused deposition modeling and selective laser sintering, has facilitated the creation of dispersible tablets featuring intricate shapes and regulated porosity, which directly affects disintegration duration and drug release characteristics. This technology has created opportunities for tailored medication.

FUTURE PROSPECTS:

1. Artificial intelligence (AI) and machine learning (ML) models are being investigated for optimizing predictive formulations. Through the examination of extensive datasets related to formulation variables, excipient interactions, and pharmacokinetics, AI can assist in creating dispersible tablets with enhanced disintegration, dissolution, and stability characteristics, reducing the need for experimental repetitions
2. Biodegradable Dispersible Tablets from Natural Polymers Due to the demand for eco-friendly pharmaceutical items, there is an increasing focus on creating dispersible tablets using natural, biodegradable polymers such as chitosan, pectin, and alginate
3. Intelligent Dispersible Tablet Systems The creation of intelligent dispersible tablets that can modify disintegration and release characteristics in reaction to distinct stimuli like pH, temperature, or enzymatic activity represents a promising future opportunity. These systems would provide customized drug delivery profiles, improving therapeutic accuracy, particularly in conditions such as pediatric epilepsy, geriatric hypertension, and acute infectious diseases
4. Integration with Digital Health Technologies Future dispersible tablets may be integrated with ingestible sensors or digital adherence monitoring systems, providing real-time data on medication intake, disintegration behavior, and patient compliance supporting personalized and connected healthcare models.

RESULT AND DISCUSSION:

This review gathers and synthesizes theoretical data from established scientific literature regarding the formulation, development, and evaluation of Orally Dispersible Tablets (ODTs). The results reflect patterns and conclusions drawn across multiple studies, as outlined below:

1. Formulation Approaches Literature consistently indicates that the most commonly employed methods for ODT formulation include:

- Direct Compression: Preferred for its simplicity, cost-effectiveness, and industrial scalability.
- Lyophilization (Freeze-Drying): Results in highly porous structures that disintegrate rapidly but are mechanically weak.
- Sublimation and Molding: Used to enhance porosity and disintegration but involve more complex processes.

2. Use of Super disintegrants Super disintegrants are key to achieving rapid tablet disintegration. Theoretical reports confirm:

- Crospovidone, Croscarmellose Sodium, and Sodium Starch Glycolate are the most effective, frequently used either alone or in combination.
- Their efficiency is attributed to swelling, wicking, and capillary action mechanisms.

3. Disintegration and Dissolution

- Ideal ODTs demonstrate a disintegration time of less than 30 seconds, as per pharmacopeial guidelines (USP, Ph. Eur.).
- In vitro dissolution typically exceeds 80% drug release within 15 minutes, depending on the active pharmaceutical ingredient (API) and formulation design.

4. Taste Masking and Palatability

- Studies report that palatability is crucial for patient compliance, especially in pediatric and geriatric populations.
- Theoretical techniques include:

o Use of sweeteners (e.g., aspartame, mannitol)
o Flavoring agents (e.g., peppermint, fruit flavors) o Inclusion complexes (e.g., cyclodextrins)
o Ion-exchange resins for bitter drug masking

5. Mechanical Properties

• Theoretical values for acceptable ODTs include:
o Hardness: Typically 2–4 kg/cm2
o Friability: Less than 1%

o These values ensure sufficient tablet strength for handling without compromising rapid disintegration.

6. Packaging and Stability

- ODTs are moisture-sensitive, requiring protective packaging.
- Theoretical guidelines suggest alu-alu blisters or desiccant-containing containers to

  maintain stability under ICH-recommended storage conditions.

DISCUSSION:

The findings emphasize the ongoing development and enhancement of ODT technology. Direct compression became the most frequently utilized technique because of its affordability and simplicity in scaling up. Nonetheless, methods such as lyophilization, despite being expensive, provide excellent disintegration times and are appropriate for heat-sensitive medications.

The dominance of super disintegrants such as crospovidone and croscarmellose sodium highlights their efficiency in swiftly decreasing disintegration time while maintaining tablet hardness and friability. Additionally, the application of co-processed excipients has been noted to enhance both mechanical and sensory characteristics, indicating a movement towards multifunctional excipients.

Patient-focused aspects, particularly in pediatric and geriatric groups, highlight the necessity for efficient taste-masking methods. The findings indicate that incorporating flavors, sweeteners, and complexing agents has become a common approach in the majority of commercial and experimental ODT formulations.

Ultimately, although ODTs excel in typical storage situations, their vulnerability to humidity requires suitable packaging options, like desiccant-lined or alu-alu blister packs.

The review indicates a favorable trend in ODT development, emphasizing enhanced patient adherence, swift drug effectiveness, and conformity with regulations.

CONCLUSION:

The aim of Oral Dispersible tablets is to address certain issues found in traditional solid dosage forms (tablets and capsules), such as the challenge of swallowing. The pediatric and geriatric populations are the main groups whose issues are readily addressed by ODTs, since both demographics struggle with swallowing traditional tablets. It also enhances efficacy, bioavailability, rapid onset of action, and improved patient compliance owing to its swift absorption from the mouth to the gastrointestinal tract as saliva flows. Their distinct benefits, like operating without water and offering flexibility in location and timing, enhance patient adherence in today's fast-paced lifestyle. Currently, oral dispersible tablets are increasingly offered as over-the-counter items for managing allergies, as well as symptoms of colds and flu. The prospects for advancements in Rapid disintegrating and drug delivery are promising, yet the technology remains quite recent.

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