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Review Article

A Detailed Study on Disintegrating Agents and an Overview on Oral Disintegration Tablet

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Abstract: -

Nowadays, the administration of drugs through the oral route is becoming less common, accounting for only about 75% of all drug administrations compared to other routes. A new type of dosage form called oral disintegrating tablets has gained popularity in recent decades due to their rapid disintegration and dissolution. These tablets disintegrate in the mouth within seconds (25-40 seconds) without the need for water, as the oral mucosa alone is sufficient for the tablet to dissolve. The selection of a suitable disintegrating agent is crucial to achieve optimal bioavailability. A preparation may contain one or multiple disintegrating agents to ensure maximum disintegration and bioavailability. These tablets are also known as Oro disintegration tablets. Disintegrating agents are rarely used in solid unit dosage forms, typically comprising only 1-10% of the total dosage unit. The use of super disintegrates in these tablets enhances the drug's efficacy by promoting rapid dissolution. Various disintegrating agents, super disintegrates, and excipients are employed in the formulation of oral disintegrating tablets. This review article provides an overview of different types of disintegrates, including natural, polymer, and synthetic ones, as well as formulation methods, applications, and various parameters of oral disintegrating tablets. These tablets are particularly well-liked by pediatric patients and those who prefer generic medications. Oral disintegrating tablets are highly preferred in the treatment of dysphagia and oraldisorders among patients.

Keywords: - Oral disintegrating tablets, Oro disintegrating tablets, Disintegrates, Super disintegrates and Fast dissolution tablet.

Introduction

Compared to different methods of administration, oral root administration is widely accepted as it allows for the administration of various types of formulations. One such new formulation is oral disintegrating tablets, which effectively address the challenges faced by individuals with dysphagia (swallowing problem). These tablets are particularly suitable for geriatric, pediatric, and mentally challenged individuals. The lack of availability of water during travel can make it difficult to take medication in tablet form. However, oral disintegrating tablets (ODTs) provide a convenient solution for those facing this problem. The demand for ODTs has increased due to their ability to improve patient compliance. Despite facing challenges such as size, surface, and taste, ODTs have been widely accepted by people and have played a crucial role in the pharmaceutical industry for several decades. Most ODT drugs are available over-the-counter, allowing people to self-medicate and self-administer.

People tend to choose these tablets quickly because they dissolve rapidly and disintegrate easily, often swelling in the process. They can be taken without water and typically disintegrate in less than a minute due to the hydrophilic nature of the disintegrating agent among the excipients. This agent can be used in both internal and external granulated formulations, breaking the tablet into smaller granules. When a hydrophilic drug is used, it disintegrates quickly, while a hydrophobic drug dissolves more slowly. Disintegrating agents can be single or mixed in a formulation, and increasing moisture content can aid in breaking the tablets into smaller pieces in an aqueous environment. These tablets release the drug rapidly into the gastrointestinal tract and are known by various synonyms, including Oral disintegrating tablet, Oro disintegrating tablet, Fast dissolution tablet, Fast disintegrating tablet, and Rapid dissolution tablet. The choice of disintegrating agent and its performance are carefully calculated before use,and in recent years, there has been a focus on developing superintegrants for even faster disintegration in the mouth. To use these types of disintegrating agents, the ODT should possess certain ideal characteristics. [4-7]

Ideal Character of Different Disintegrating Agent:

-The substance should dissolve within seconds, independent of water assistance.

-The ODT should disintegrate in either saliva or water.

-The drug should have a noticeable taste.

-The active ingredient's weight should not exceed 50mg.

-No material or residue should remain in the mouth after disintegration.

-The low compression of the ODT during manufacturing should not pose any issues for its rapiddissolution in the mouth [7-8]

Advantage:

1.Facilitates administration for individuals who have difficulty swallowing tablets.2.Unlocks fresh prospects in the realm of business.

3. The manufacturing process poses no hazards.

4. Offers a pleasant sensation in the mouth with a range of flavors.
5. Rapid absorption in the buccal cavity results in increased bioavailability.
6. Convenient for busy individuals to administer.
7. Ensures precise dosing.
8. No need to chew and dissolves without water. [7-9]

Disadvantage:

1. The tablet's mechanical strength is significantly low.
2. It is not possible to include high doses in it.
3. To achieve rapid disintegration, the tablet size must be reduced.
4. Technical difficulties may arise in achieving uniform drug distribution.
5. There is no adequate packaging available.
6. Protection from moisture is necessary. [7-8]

Drug Selection Criteria:

1. Must undergo disintegration within the oral mucosa.
2. Exhibits partial ionization at the pH level of the oral cavity.
3. Medication requiring frequent dosing is not formulated as an ODT
4. Bitter-tasting drugs that cannot be masked are not formulated as ODT.
5. Medications with shorter shelf life and half-life are not formulated as ODT.

Method of preparation of FDT:

The following techniques are employed in the preparation of FDT's

1) Tablet moulding

This procedure involves two methods for preparing FDT's. In the solvent method, the mixture is moistened with an alcoholic solvent and the tablet is compressed with minimal pressure. These tablets are then subjected to the air-drying process. On the other hand, the heat moulding method involves preparing a suspension using the drug and solidifying substance. The mixture is then poured into blister packing apparatus, where it solidifies into a jelly-like substance with the aid of a solidifying agent. These tablets are then kept under vacuum at a temperature of 30 degrees centigrade. Tablets prepared using this method exhibit excellent mechanical strength.

2) Sublimation method

The sublimation process involves the formation of a porous structure to facilitate rapid disintegration, which is achieved by adding volatile substances and other excipients during preparation. Upon compression, the volatile substances undergo sublimation, resulting in the formation of a porous structure that enables the ODT to disintegrate in the mouth within 10-20 seconds. Examples of volatile agents include camphor, benzoic acid,

naphthalene, urea, ammonium carbonate, and urethane.

3) Lyophilization or freeze drying

The method described here is specifically designed for creating heat-sensitive drugs. By using a sublimation process, water is removed and porous structures are formed. The drug is then suspended or dissolved in an aqueous solution and poured into blister packaging. Liquid nitrogen is used to freeze the mixture and maintain stability. The apparatus is then moved to a refrigeration room for further freezing. The only drawback of this method is that the resulting product is less fragile.

4) Direct compression method

The process involves creating a mixture of all the excipients and the drug, which is then compressed directly, similar to tablet molding, resulting in a cost-effective method. Additionally, a suitable amount of super disintegrants is added to achieve rapid disintegration.

5) Spray drying method

The blend is sprayed and compressed into tablets, resulting in a rapid disintegration time of less than 20 seconds. The primary super disintegrants utilized in this process are sodium starch glycolate and croscarmellose sodium.

6) Mass extrusion

Mass extrusion is a technique that entails drying the active blend by employing solvents such as alcohol or ethylene glycol. The mixture is prepared and then passed through cylindrical tubes, such as a syringe, to form the desired shape. The extruded material is subsequently cut into pieces andundergoes a drying process.

7) Nanoinization

The wet milling procedure is utilized to decrease the size of particles in this newly developed method. Appropriate stabilizers are employed to prevent surface adsorption and subsequent agglomeration of the particles mentioned below.

8) Coated film method

This is an innovative and straightforward approach to extracting bitter-tasting medication. The water-soluble film is dissolved in a non-aqueous solution. The drug and other ingredients are combined with the film, which forms a solid film when the solvent evaporates. In the case of a bitter-tasting drug, the film allows for the rapid release of the coated drug particles by dissolving them.

Excipient used in formulation of ODT'S

ODTs must dissolve quickly in the oral cavity. Excipients play a vital role in the disintegration of the tablet. There are various types of excipients that have been used for many decades. In this particular formulation, excipients not only act as super disintegrants but also include modified sugars, modified sweeteners, and innovative excipients. The newly developed excipients exhibit improved flowability, compressibility, hygroscopicity, palatability, and stickability compared to traditional excipients. The ideal properties of a disintegrating agent should include rapid dissolution in the mouth, masking the taste of drugs, and withstanding different drug loadings as well as temperature and humidity conditions.

a) Coprocessid blends of excipients

If multiple excipients are added and prepared using various manufacturing techniques, thequality of the drug can be enhanced. Examples of such excipients include Ludiflash, F-Melt, and Pharm Burst, which are presented in a tabular column.

b) Modified mannitol's and sugars

Mannitol serves as sweeteners that are utilized to enhance the taste for patients. In recent times, these have been modified and formulated as pharmaceutical aids by expanding their range of applications. Similarly, sugars are employed to improve the taste for patients, and as they undergo modifications, they also prove beneficial in terms of factors such as humidity and flow ability. Examples of mannitol include Orocell, Pearlitol, and manogem, while sugars like advantose, Glucidex, and Galen are also commonly used.

1) Orocell

It possesses excellent disintegrating capabilities, providing a refreshing cooling sensation in the mouth and a pleasant tactile experience. It serves as a carrier for intermediate disintegrating tablets and exhibits properties of both binders and fillers in different formulations. Additionally, it showcases exceptional attributes such as excellent flowability and remarkable strength.

2) ManogemEZ

This substance offers advantages such as a remarkable ability to dissolve. Its open crystal linear structure grants it a high compressibility. This particular material possesses a pleasant and smooth texture, minimal moisture absorption, and is chemically inert. It is primarily designed for the direct compressible method. Moreover, it exhibits heightened taste perception and exceptional binding capabilities.

3) Pearlitol

Due to the porous crystalline particles, this substance dissolves rapidly. Pearlitol is included in the formulation through direct compression method, lyophilization method, and freeze drying method, acting as a highly effective binder. Additionally, this substance is odorless and slightly sweet, withhigh hygroscopicity.

4) Advantose 100

This spray-dried maltose powder consists of a combination of crystalline and fine particles, which contribute to its excellent flow properties such as free-flowing nature, rapid dispersion, and dissolution. These desirable characteristics are primarily attributed to the presence of fine crystalline particles. Additionally, it enhances the

disintegration of materials like mannitol, lactose, and cellulose. Moreover, it significantly improves the compressibility of low-density powder particles due to its spherical shape. Furthermore, it exhibits higher solubility compared tolactose. This product is widely recognized for its safety and exceptional mouthfeel qualities, particularly in lozenges.

5) Glucidex it

Mostly discovered in a finely granulated form developed by roteqque, it is commonly found in the malto dextrin family. One of its advantages is its ability to disperse quickly and dissolve rapidly in water. The range of Glucidex varies depending on the amount of dextrose obtained through starch hydrolysis. Glucidex is utilized in various applications, including being a diluent for tablets, capsules, and sachets, as well as a carrier for spray drying as a source of carbohydrates. It is predominantly used in direct compression formulations. The amount of dextrose obtained from starch hydrolysis can be found in Table No.2 and 3, with Table No.3 indicating a high concentration of dextrose. Glucidex is a trade name for dextrose.

6) Galen Iq

This is a recipe that does not contain sugar and has low hygroscopicity, making it highly chemically stable. It is commonly used in the direct compression method due to its excellent compatibility and unique morphology, which facilitates thorough mixing. Additionally, it serves functions such as filling and binding. Its organoleptic properties and non-carcinogenic naturemake it an ideal excipient.

Modified resins

This are type of disintegrants used in the formulation of ODTs

1) Prolacrliln potassium

The disintegration of the acidic cation exchange resin occurs as a result of its significant selling mechanism in an aqueous solution. When hydrated, the resin undergoes tablet swelling.

This is efficiently utilized in 1-2% of solid dosage forms. It possesses hydrophilic properties and has the ability to rapidly absorb water. Disintegrants containing cellulose, such as carboxy methyl cellulose sodium and Cross carmellose sodium, exhibit high adhesive characteristics. During the disintegration process, the bonds between molecules within the tablets need to be overcome in order to release the drug.

2) Superdisintgrants

As we know that super disintegrant are additives used in ODT's for quicker and faster dissolution. Rapid disintegration of tablet takes place with help of this super disintegrant. And dissolves tablet within 5-300 seconds range with 100% bioavailability. To commit upon this action of super disintegrant some methods of mechanisms are available those are discussed later. Super disintegrants also sometimes does not work and does not give complete dissolution in following reasons:

1. The amount of surfactant utilized.
2. Tablet firmness.
3. Characteristics of the medication.
4. Existence of both drug and excipient concentrations.

5. Existence of a combination of two excipients.
6. The proportion of surfactant employed.
7. Characteristics of other excipients employed in the formulation.
8. During the process of mixing and screening.

Mechanism of disintegration swelling:

Maybe this represents the process by which disintegrating agents, such as starch, facilitate the disintegration of the tablet and subsequently release the drug into the surrounding medium. The adhesive properties of other ingredients in the tablet are diminished and overcome to achieve thiseffect.

1) Porosity and capillary action

When a tablet is placed in an appropriate aqueous solution, such as water, this technique is employed. The water infiltrates the medium, causing the intermolecular bonds to weaken and the tablet's hardness to decrease. The disintegration of the tablet is determined by the drug's hydrophilicity rate.

2) Deformation

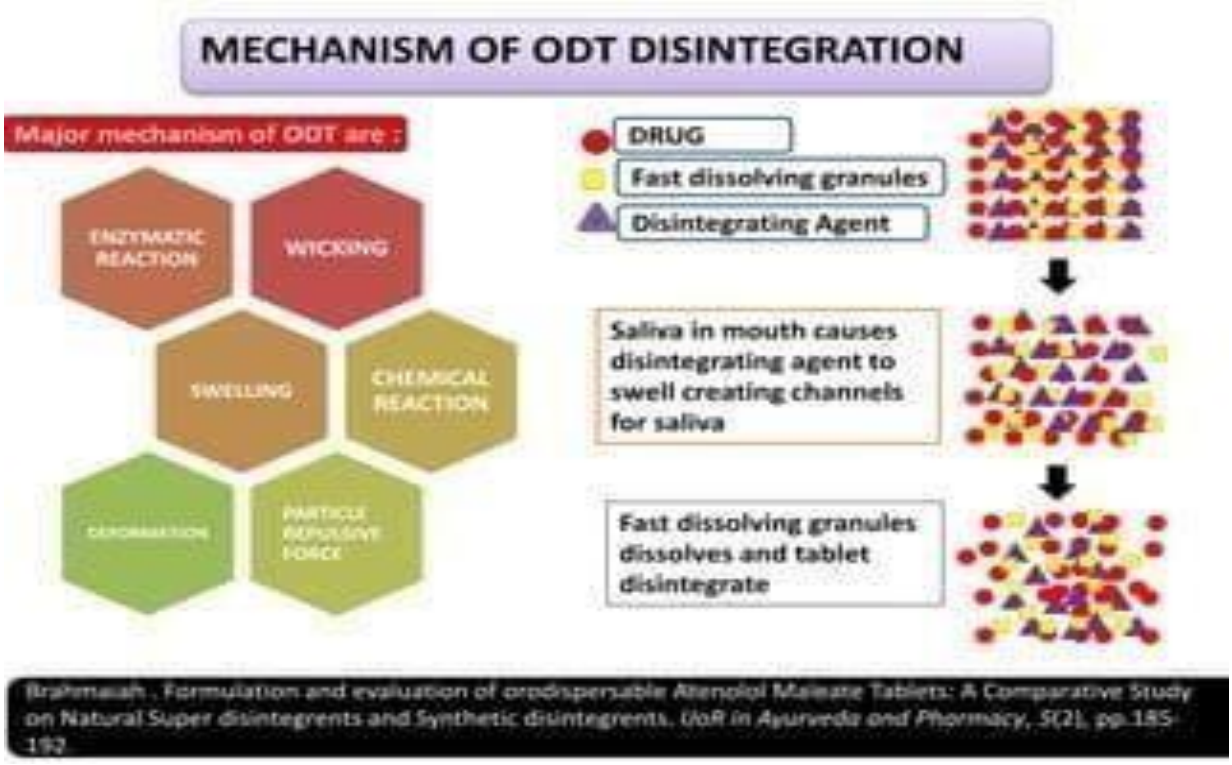
The super disintegrant undergoes deformation upon direct compression, as observed in these mechanisms. Subsequently, when it comes into contact with an aqueous medium, the medium permeates the tablet, causing the super disintegrant to revert to its original morphology. As a result, the super disintegrant swells, leading to the disintegration of the tablet.

3) Repulsive forces

The disintegration of a tablet occurs through the use of non-swelling disintegrating agents. In order for this type of disintegration to take place, water is necessary. This requirement is primarily attributed to the repulsion forces between the particles. This process is also referred to as the secondary wicking process. It is important to note that the mechanism of disintegrants does not rely on a single mechanism, but rather encompasses all major mechanisms.

4) Enzymatic reaction

The body contains a variety of enzymes, some of which aid in breaking down tablets by disrupting the binding forces within the body. These enzymes reduce the binding forces of the tablet, resulting in faster absorption of water and an increase in the size of the particles within thebody. This ultimately leads to the disintegration of the tablet. [22-25]



Method for Incorporating Disintegrants

The following methods are present to incorporate granulation.

1) Intragranular Method

In this the super disintegrates are tousle with all other excipients and sent for granulation process.In this super disintegrates are incorporated within the granules.

2) Extra granular Method

In this method super disintegrates mixed with granules and directly sent for pinch of the tablet.Here the super disintegrates mixed up with the granules.

3) Incorporation of both Intragranular and Extra granular

In this a part of super disintegrates are widow both within the granules and with the granules. This shows good and largest results than type-1 and type2.

Type of super disintegrants

Based upon their route of production the super disintegrates are categorized into following.

1. Synthetic
2. Natural
3. Co-processed

1) Synthetic Super disintegrants

a) Polyvinyl Pyrrolidone Crosslinked

Because of its micro-graded particles, this super disintegrant is scarce consistently; hence, the formulation using it had a concentration of 1-3 percent. By using hydrostatic pressures and volume expansion, it rapidly wicks saliva and disintegrates. When examined under an electron microscope, these appear to be granular and extremely porous. The mechanism of action of this crosslinked poly vinyl pyrrilodine involves both swelling and wicking. Because of its porous nature and more cross-linked structure, which aids with the swelling procedure, it has a highly wicking whoopee. Some super disintegrants, however, gel because they have fewer cross-links. Because of its distinct shape, this is much more compressible than other super disintegrates and walks out without forming a gel plane when utilized in higher usage.

b) Low Substitued Hydroxy Methyl Cellulose

It has high degree of swelling due to its large particle size and used to prevent capping. It is widely used now a day in wet granulation method and directly compressible method. Here the combination of micro crystalline cellulose and low hydroxyl propyl cellulose are used for rapidly disintegrating the tablet. As the ratio of these both of 8:2 and 9:1 to get rapid disintegration.

c) Sodium Starch Glycolate

As it is prepared from various types of starches the potato starch is highly useful to get well- constructed rapid disintegrating properties and mostly in formulations the concentrations used is nearly well-nigh 1.0-4.0% but is increased up to 6.0% which may lead to formation of gel as completion of without its mechanism of whoopee swelling. To disrupt the hydrogen bonding with in the molecule's large hydrophilic carboxy methyl cellulose groups are added in order to increase the penetration of water in to molecule to increase the water-soluble fraction of polymer. So, the navigate linking is wilt less and rapid uptake of water and quick dispersion is allowed.

d) Micro Crystalline Cellulose

This tablet breaks down by allowing water to penetrate its porous structure and dissolve into hydrogen. Good disintegration is achieved when the cellulose particle bonds are broken. This was produced from start cellulose and is partially depolymerized. The uncontrived pinch method is primarily employed with this. The MCC particles' dislocation and slip planes cause them to deform when crushed, giving rise to plasticity. Because to its

interlocking mechanism and compact size, Avicel 102 is utilized here as both a diluent and a disintegrant. Its advantages include improved tightness strength and quick disintegration.

e) Calcium Cillicate

It is light in weight disintegrate with mechanism of action of wicking. When used in the concentration of 5%.

f) Chittin and Chitosan

Moisture absorption with water uptake is main mechanism of action for super disintegration while swelling also plays a small role in dissolution of the tablet.

g) Starch Partially Pre-Gelatinised

This is made directly from starch grains using a compressed process that leaves the granules intact and partially hydrolyzed. It also contains pharmacological aids such as a disintegrant, filter, and binder. The concentration employed in this case is primarily between 5 and 10%, and the primarymechanism of whoopee is swelling.

2) Natural Super disintegrants

a) Isapghula husk

The plant ago seeds are stored in distilled water and stored for 48hrs then this is boiled for15mins and2% of the solution acts as good disintegrating agent. As gupta et al has investigates these seeds and shows upper disintegration at low concentration.

b) Fenugreek Seed Mucilage

Trigonella foenumgraceum known as fenugreek the fast mouth disintegrating wage-earner coming under Leguminosae family. As investigated with various ranges like 2-10% the concentration shown at 4% is rapid in disintegration and acts good pharmaceutical adjuvant andgood disintegrating agent

c) Lepidus Sativum

K. Mehta ripened fast disintegrating tablets using the extraction of Lepidus sativum with insulated moreover, other rapidly using disintegrating agents with nimsulide and studied various factors like pH., particle size, swelling ratio, weight loos on drying. So prepared tablets are taken for invitro dissolution and the Lepidus sativum shows less disintegration at 10%mucilage and 10% mannitol at 5.27 sec and other preparation of nimsulide at 17 sec. It moreover acts as herbalmedicine and pharmaceutical excipient.

d) Locust Stone Gum

It is with a mechanism of whoopee with swelling and capillary action. This is a vegetable gum extracted from seeds of carob tree found medittarian region and widely used as thickening and swelling agent. And moreover, have advantages like bio wrapper and solubility enhancement properties. Swelling is observed with less than 20sec and got appreciable capability of super disintegrant, compared with standards super disintegrants like

carsomellose sodium. Disintegration time of 13 sec is least that containing 105 of locust stone gum is used.

e) Hibiscus Rosa Sinesis Linm Mucilage

This belongs to malvaceae family and this mucilage is highly used as super disintegrant.It contain cyclo propanoids, methyl sterculate, methyl-2- hydroxy sterculate, 2- hydroxyl methyl sterculate malate and beta Rosa sterol. Shah et al prepared acelofenac oral disintegrating tablets by direct compression metos using hibiscus Rosa sinesis linm mucilage and shows the disintegration of tablet with in less than the time of 20 sec.

f) Xanthum Gum

This product is produced directly from the starch grains by a compressed process, leaving the granules unharmed and partially hydrolysed. It contains pharmacological additives such as a breakdowner, a filter, and a binder. In this case, the concentration used is mainly between 5% and 10%. The main mechanism of the whoopee reaction is swelling. starches improved the physical properties of the tablet in a few easy steps, leading to significantly lower prices and ramified formation of ales. The chemical formula of this product allows for rapid drug release (24–31).

g) Soy Poly Saccharide

This is a naturally occurring super disintegrate that does not come from any other source and does not have any starch or sugar in it. It can also be used as a nutritional product.

h) Gellan Gum

Linear tetra saccharide (LTS) is anionic polysaccharide with super-degradable properties comparable to that of modified starch and cellulose. It is a saccharide derived from the bacteriumPseudomonas elodea.

i) Ocimum Americanum Seed Mucilage

Patel etal prepared the propanolal hydrochlorise tablets using ocimum anericanum seed mucilageusing various concentrations like 2, 4, 6, 8, 10% the
optimum concentration of mucilate for rappid dissolution is shown at 10% and the sameconcentration with starch and propanaolal
hydrochloride is prepared and shows disintegration time of 269 seconds while ocimum shows thedisintegration in 154 seconds. The hardness friability drug content are within limit.

j) Co-processed super disintegrants

This is based on the novel concept that 2-3 excipients interact at particle level, the objective of which is used to provide a synergy of functionality development as well as masking the undesired properties of individuals. Co-processing excipients leads to the insemination of excipient granules with superior properties. Compared with physical mixtures of componentslike improved flow property and compressibility. Better dilution
potential full uniformity and reduced lubricant sensitivity Several co-
processed super disintegrates are available [29-31]

Table No.1: Result of various excipients in ODT's under different methods

Sr no	Excipients	Approach used	Result
1	Ludiflash	Direct compression	Disintegration in 27 sec.
2	Pharm burst	Spray drying method	Disintegration in 30 second
3	F-MELT	Direct compression using 10 % to 65% w/w	Disintegration below 30 sec.
4	Orocell 200 and 400	Direct compressible	Disintegration time of 5 sec.
5	Pearlitol SD	Wet granulation	Disintegration time of 85s. 100% release
6	GalenIQ	Direct compression	Even without super disintegrant, by containing isomalt degrades in 200 sec
7	Polacrilin potassium	Direct compression	Disintegration time of 45 s. 100% release

S.No	Grade	Dextrose equivalent
1	Glucidex 2	5 max
2	Glucidex 6	5-8
3	Glucidex 9	8-10
4	Glucidex 12	11-14
5	Glucidex 17	15-18
6	Glucidex 19	18-20

Table No.2: Dextrose obtained on starch hydrolysis

Conclusion

As this vendible conclude this oral disintegrating tablets are wonted form of the spoonful forms and modes of manufacturing methods present satisfy all types of drugs and super disintegrates. And coming to the rate of disintegration of ODT's the available super disintegrates satisfy all the properties of different types of drugs in order to unzip rapid disintegration. Coming to the factors nature and availability of bioavailability with disintegrating agents has no whoopee on the drug and if we see the rate of availability might be increased but not be decreased. And in present and coming days as we compared with previous the rate of use of ODT's are reduced. In coming generation the presented disadvantages of the ODT's should be covered and collection and applications of super disintegrants must moreover be increased. Today the most allergies, unprepossessed fevers ODT's are widely used and coming to the forfeit factor the forfeit of the oral dis integrating tablets are very less and meanly misogynist to a common person. The industry people should also increase and ventilate of ODT's should moreover be increased in order to educate the advantages and disadvantages of ODT's. Any there is unexceptionable scopein futurefor ODT's if all the people get well known about it

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