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A DETAILED STUDY ON DISINTEGRATING AGENTS AND AN OVERVIEW ON ORAL DISINTEGRATION TABLET

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ABSTRACT

Now-a-days administration from oral route is getting more passive of about 75%, when compared to the drugs that are administrated from various parts of body. And novel formulation using the disintegrates leads to a new type of dosage form i.e. Oral disintegrating tablets and these are peak in demand from few decades due to their rapid disintegration followed to dissolution. These are directly disintegrated in the mouth within seconds (25-40 seconds). Without the help of the water only oral mucosa is enough for the dissolution of the tablet. The selection of disintegrating agent is also required to get optimum bio-availability and Disintegrates might be single or many for a preparation to ensure maximum disintegration and bio availability. This is also known as orodisintegration tablet. Disintegrating agents are used very rarely in solid unit dosage forms nearly 1-10% of their total dosage unit. These super disintegrates improve the efficacy of drug by rapid dissolution and various disintegrates and super disintegrates, excipients are used in formulation of ODT. Here in this review article we are going to overview about of various disintegrates like natural, polymer, synthetic. And formulation methods, applications and various parameters of ODT's. These are completely likeable to the patients of pediatrics and generics. ODT's are highly preferred in the treatment of the dysphagia and the patients of oral disorders.

KEYWORDS

Oral disintegrating tablets, Orodisintegrating tablets, Disintegrates, Super disintegrates and Fast dissolution tablet.

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INTRODUCTION

Compared to various root of administrations oral root administration is widely acceptable where many type of formulations are administrated. Oral disintegrating tablets are new formulation that overcomes the following difficulties. People suffering from 'dysphagia" (swallowing problem) can be swallowed easily. These are most friendly with geriatric, pediatric and mentally challenged people. Even though persons without any problem

are using oral disintegrating tablet in travelling time due to lack of availability of water. So, ODT is good solution for the people facing all the above problem. This makes a demand for the development of the oral disintegrating tablets and increased to get solution for the patients compliance Oral disintegrating tablets are widely accepted by the people. And these are playing a crucial role in the pharmaceutical industry from past few decades and also gained various difficulties like size, surface. Taste and various factors. These are type of formulations that people can self-medicate and as well as self-administrated because most of the ODT drugs are OTC's formulated and present in the market¹⁻³.

These are quickly chosen by the people due to their rapid dissolution followed by the disintegration mechanism like swelling. These tablets can be administrated without water and disintegrates with in less than a minute. This disintegration is achieved by disintegrating agent out of all their excipients. Disintegrating agent must be hydrophilic in nature where the drug may be either hydrophobic or hydrophobic in nature. A disintegrate in granulated formulation if used both internally and externally and there by acting up the tablet into smaller granules When we use the hydrophilic drug then it gets disintegrates and hydrophobic for dissolution. Disintegrating agents may be single or mixtures in a formulation. To facilitate the breakup of the ODT's into small slugs in aqueous environment by increasing the moisture content. It releases drug rapidly into gastro intestinal tract. It has various synonyms like Oral disintegrating tablet, Orodintegrating tablet, Fast dissolution tablet, Fast disintegrating tablet, Rapiddissolution tablet. The choice of disintegrate and its performance has been completely calculated before using it. In recent years high attention is paid for rapid disintegrating tablet in the mouth not only for fast dissolving or fast disintegrating tablet. For this super integrants are developed. For using this type of disintegrating agents the ODT should possess some ideal characters⁴⁻⁷.

IDEAL CHARACTERS OF ORAL DSINTEGRATING TABLET^{7,8}

1. It should dissolve in matter of seconds without the help of water.
2. Either in saliva or water the ODT must disintegrate.
3. There must be appreciable taste of drug.
4. The weight of the active ingredient should be less than 50mg.
5. Any type of mater or residue should not leave in the mouth after disintegration.
6. In the process of manufacturing no problem should be faced because of its low compression for quick dissolving in mouth.

Advantages⁷⁻⁹

1. Ease for administrating of for people who cannot swallow the tablets.
2. Provides new opportunities in business fields.
3. No risks in manufacturing process.
4. Good feel in mouth by using various flavors.
5. Sharp absorption in the buccal cavity leads to higher bioavailability.
6. Convenient for administration of busy people.
7. It provide accurate dose.
8. No chewing is required and disintegrates without water.

Disadvantages^{7,8}

1. Mechanical strength of the tablet is very less.
2. High doses cannot be incorporated into it.
3. Tablet size should be less to get fast disintegration.
4. Technical challenges may take place for drug uniform distribution.
5. No good packing is present.
6. Protection from the moisture.

Drug Selection Criteria⁸⁻¹⁰

1. Should disintegrate in oral mucosa.
2. Partially Non-ionized in the oral cavity pH.
3. Drug that should be dosed frequently not formulated as ODT.
4. Drugs that having bitter taste and are not mask able are not formulated as ODT.
5. Lesser shelf life and half-life of drugs are not formulated as ODT.

METHOD OF PREPARATION OF FDT

These are the methods following in the preparation of FDT's.

Tablet Moulding

This method contains two procedures in preparation of FDT's. In the *solvent method* all mixture is moistened using any alcoholic solvent and the tablet is compressed with very less pressure and these prepared tablets are sent for the air drying process.

In *heat moulding method* the suspension is prepared by using the drug and solidifying substance. All the mixture is poured in the apparatus of blister packing. These will form solidified like a jelly substance with help of solidifying agent. And these are sent to keep in 30 degree centigrade under vacuum. Tablets prepared in this method have good mechanical strength.

Sublimation Method

In this sublimation process porous is formed for the fast disintegration so that volatile substances are added in the preparation along all with their other excipients. After this compression the volatile substances get sublimated. Porous are formed so this type of ODT can disintegrate in mouth within the time of (10-20sec). Examples of various volatile agents are: camphor, benzoic acid, naphthalene, urea, ammonium carbonate, and urethane.

Lyophilization or Freeze Drying

This type of method is completely used for formulating the heat unstable drugs. The water is removed by sublimation process by forming porous upon it. The suspension or the aqueous solution of the drug are prepared and poured into the holes of blister packing as primary freezing liquid nitrogen is passed through the preparation to keep the mixture stable. The complete apparatus is sent for the refrigeration room to continue the freezing. The main disadvantage with this method is these are less fragile.

Direct Compression Method

In this method a blend is prepared by using all the excipients including the drug. To this mixture will be directly compressed as like tablet moulding with is cost effective. And an optimum quantity of super disintegrants is also used to obtain rapid disintegration.

Spray Drying Method

Here all the blend prepared is sprayed and directly compressed into tablets. This shows a fast disintegration less than of 20 seconds. Sodium starch glycolate and croscarmellose sodium are main super integrants used in this method.

Mass Extrusion

Mass extrusion involves the process of drying the active blend using the solvent like alcohol or ethylene glycol. The prepared mixture is passed through the syringe or any other type of cylindrical shape tubes. The extruded material is cut into the pieces and sent for drying.

Nanoionization

This method is recently developed and for this the particles of particles should be reduced by using the wet milling procedure. Surface adsorption is given for the following particles not to cause agglomeration using suitable stabilizers.

Coated Film Method

This is completely newer developing and simple process to take the formulations of bitter tasted drug. The water soluble film is dissolved in non-aqueous solution. Drug and all other excipients are incorporated into that film and gives film when solvent is evaporated. If the drug is bitter in taste the coated particles of the drug get released by the film by incorporating into it by dissolving rapidly¹¹⁻¹⁵.

EXCIPIENTS USED IN FORMULATION OF ODT'S

ODT's must dissolve rapidly in the mouth. Excipients play a crucial role in disintegrating the tablet. There are many types of excipients used over a many decade. Here in this type of formulation excipients are not only super disintegrants it involves modified sugars, modified sweeteners and novel excipients. Compared to excipients than now developed are good in flow ability, compressibility, hygroscopicity, palatability and stickability. The ideal properties of a disintegrating agent must be should dissolve in mouth rapidly, mask tastes of drugs, should withstand the drug loadings and various temperature, humidity conditions.

Some categories of excipients are as follows:

COPROCESSED BLENDS OF EXCIPIENTS

These types of excipients improve the quality of the drug if two (or) more excipients are added and prepared by using different manufacturing techniques.

Ex: ludiflash, f-melt, pharm burst. Are given in tabular column.

MODIFIED MANNITOLS AND SUGARS

Mannitols are nothing but sweeteners used to give good feel for patients. Now-a-days these are modified and prepared as pharmaceutical aid by improving the category of uses. Sugars are also used to improve the feel of patients as they got modified they are also helpful in various factors like humidity and flow ability.

Ex: Orocell, Pearlitol and manogem etc. for mannitol.

Ex: advantose, Glucidex and Galen etc. for sugars.

Orocell

It maintains a good disintegrating performance with cooling sensation in mouth with good feel. It acts as carrier for intermediate disintegrating tablet. And with characteristics like binder and fillers in various formulations. And it also has various outstanding performances like flow ability and high strength.

Mannogem Ez

It has benefits like high dissolving capacity. It has high compressibility due to its open crystal linear structure. This manogem has fresh and good mouth feel, less hygroscopicity and chemically inert in nature. This is mainly for directly compressible method. It has its high activity on increased taste feel and high binding activity.

Pearlitol

This dissolves very rapidly because of porous crystalline particles. Direct compression method, lyophilization method freeze drying method makes a part in their formulation with Pearlitol. It acts as binder highly for the direct compression method. This is odourless little sweet. It has high hygroscopicity, great organoleptic, non-carcinogenic and containing sugar properties of

powder. This is also used in the preparation of capsules and sachets.

Advantose 100

This is a spray dry maltose powder containing both crystalline and fine particles with good flow properties like free flowing, quick dispersion and dissolution because of the fine crystalline particles. And improves the disintegration of materials mannitol, lactose, cellulose. And it impress the compressibility of lower density particles of powder. Good properties due to spherical in shape. And high solubility than lactose. It is well known for safety and mouth feel qualities found especially in lozenges.

Glucidex It

Mostly found in micro granulated form developed by roteqque. And found in family of malto dextrin. It has an advantage of quick dispersion and rapid dissolution in water. Various ranges of Glucidex are present depend on amount of dextrose present upon starch hydrolysis.

Applications up to Glucidex19 are Diluent for tablets, capsules, sachets, carrier for spray drying as a carbohydrate source. Mostly used for direct compression formulation. The amount of dextrose obtained from starch hydrolysis is listed in Table No.2 and 3. Table No.3 indicates high amount of dextrose obtained. Glucidex is one of trade name for dextrose.

Galen Iq

It is a sugar free recipient with less hygroscopic and excellent chemical stability. Used in direct compression method because of good in its excellent compatibility and its abnormal morphology gives good at mixing. And also carries functions like filling, binding Etc. the organoleptic and non-carcinogenic characters keep it as an ideal excipient.

MODIFIED RESINS

These are type of disintegrants used in the formulation of ODT's.

Prolacrilin Potassium

Acidic cat ion exchange resin it's disintegrate action due to its large swelling mechanism in aqueous solution. Upon hydration it tablet swelling of resin.

This is used effectively in 1-2% of solid dosage forms. This is hydrophilic in nature and absorbs water rapidly. Cellulose containing disintegrant used in formulations like carboxy methyl cellulose sodium, Cross carmellose sodium, are most adhesive nature. At time of disintegration, bonds between molecules in tablets must be overcome for release of drug¹⁵⁻¹⁹.

Superdisintegrants

As we know that superdisintegrant 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% bio availability. 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 concentration of surfactant used.
2. Hardness of the tablet
3. Drug nature
4. Presence of concentration of both drug and excipient.
5. Presence of combination of two excipients.
6. Percentage of surfactant used
7. Nature of other excipient used in the formulation.
8. While mixing and screening^{20,21}.

MECHANISAM OF DISINTEGRATION

SWELLING: Perhaps this is mechanism of action that all the disintegrating agents like starch that impart that communicates the disintegration in the tablet and then releases the drug into the medium. The adhesiveness of other ingredient in a tablet is falled through a part and overcome.

Porosity and Capillary Action (Wicking)

This method follows when place a tablet in a suitable aqueous medium like water then water penetrates into the medium and makes the inter molecular bond weaken, hardness of the tablet become and less. And disintegration takes places with the rate hydrophilicity of the drug.

If this mechanism should follow means the disintegrant used should have high porosity and hydrophilic.

Deformation

These mechanism follows that superdisintegrant was deformed when compressed directly. And when it get contacted with aqueous medium. The aqueous medium get penetrated into tablet the superdisintegrant get back to its morphology the superdisintegrant got swelled and the tablet get disintegrated.

Repulsive Forces

This mechanism involves disintegration of a tablet with non-swelling disintegrating agents. For this type of disintegration water is required this is mainly due to the repulsion forces between the particles. This is also known as the secondary wicking process. In the mechanism of disintegrants is not involved single mechanism. It is involved all major mechanisms.

Enzymatic Reaction

In body various enzymes are present some of that enzymes help in disintegration of the tablet by disturbing the binding forces of the body. Enzymes decrease the binding forces of tablet and causes for accelerated absorption of water so the size of the particles gets increased in the body. And leads to disintegration in the tablet²²⁻²⁵.

METHOD FOR INCORPORATING DISINTEGRANTS

The following methods are present to incorporate granulation.

Intragranular Method

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

Extra granular Method

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

Incorporation of both Intragranular and Extragranular

In this a part of super disintegrates are added both within the granules and with the granules. This shows good and better results than type-1 and type-2²²⁻²⁵.

TYPES OF SUPERDISINTEGRATES

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

1. Synthetic
2. Natural
3. Co-processed

SYNTHETIC SUPERDISINTEGRATES

Crosslinked Polyvinyl Pyrrolidone

Formulation with this superdisintegrant had a concentration of 1-3% as it is dispersed uniformly due to its micro graded particles. It quickly wicks saliva and performs rapid disintegration by hydrostatic pressures and volume expansion. These appear as granular and highly porous when observed under electron microscope. This cross-linked poly vinyl pyrrolidone takes place both wicking and swelling mechanism of action. So it's highly wicking action is due to porous in nature and more cross-linked structure helps in mechanism of swelling. While other super disintegrants have less cross-linkages so they form gel. As this is highly compressible due to its unique morphology compared to other super disintegrates and exhibit no formation of gel even if it is used in high used.

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.

Sodium Starch Glycolate

As it is prepared from various types of starches the potato starch is highly useful to get complete rapid disintegrating properties and mostly in formulations the concentrations used is nearly about 1.0-4.0% but is increased up to 6.0% which may leads to

formation of gel as completion of after its mechanism of action swelling. To disrupt the hydrogen bonding with in the molecules 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 cross linking is become less and rapid uptake of water and quick dispersion is allowed.

Micro Crystalline Cellulose

This tablet disintegrates by allowing the water into its porous structure as it enters the hydrogen bonding between the cellulose particles are ruptured and it achieves good disintegration. This is partially depolymerized synthesized from alpha cellulose. This is mainly used for direct compression method. When compressed the MCC particles are deformed plasticity due to their slip planes and dislocation. Here avicel 102 is used as diluent as well as disintegrant with its mechanism of interlocking as it is small size has advantages like rapid disintegration and increased binding strength.

Croscarmellose Sodium

This follows the mechanism of action of both swelling and wicking then disintegrates less than time of 10sec. carsomellose sodium is a cross linked polymer of carboxy methyl cellulose with high swelling capacity and fast disintegration when used at 5.0%. Here in this the type of synthesis plays a crucial role in arrangement of crosslinks.

Calcium Cillicate

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

Chitin 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.

Starch Partially Pre-Gelatinised

this is synthesized directly from starch grains in directly compressed method with intact and partially hydrolyzed property and a pharmaceutical aid like binder, filter and disintegrant here the concentration mainly used in nearly about 5-10% and swelling is main mechanism of action here. The

ppg starches improved the tablet physical properties with few steps leading to less complex formation and dramatically lower costs. It has its chemical formula with rapid drug release²⁵⁻³¹.

NATURAL SUPER DISINTEGRATES

Isapghula husk

The plant ago seeds are stored in distilled water and stored for 48hrs then this is boiled for 15mins and 2% of the solution acts as good disintegrating agent. As gupta et al has investigates these seeds and shows high disintegration at low concentration.

Fenugreek Seed Mucilage

Trigonella foenumgraceum known as fenugreek the fast mouth disintegrating agent coming under leguminosae family. As investigated by ravikumar *et al.*, with various ranges like 2-10% the concentration shown at 4% is rapid in disintegration and acts good pharmaceutical adjuvant and good disintegrating agent.

Lepidus Sativum

K. Mehta developed fast disintegrating tablets using the extraction of Lepidus sativum with nimsulide and also other rapidly using disintegrating agents with nimsulide and studied various factors like pH., particle size, swelling ratio, weight loss 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 also acts as herbal medicine and pharmaceutical excipient.

Locust Bean Gum

It is with a mechanism of action with swelling and capillary action. This is a vegetable gum extracted from seeds of carob tree found mediterranean region and widely used as thickening and swelling agent. And also have advantages like bio adhesive and solubility enhancement properties. Swelling is observed with less than 20sec and got appreciable capability of super disintegrant, compared with standards super disintegrants like carboxymethyl sodium. Disintegration time of 13 sec is least that containing 105 of locust bean gum is used.

Hibiscus Rosa Sinesis Linn Mucilage

This belongs to malvaceae family and this mucilage is highly used as super disintegrant and it contains

cyclo propanoids, methyl stercolate, methyl-2-hydroxy stercolate, 2- hydroxyl methyl stercolate malate and beta rosasterol. Shah et al prepared acefenac oral disintegrating tablets by direct compression method using hibiscus Rosa sinesis linn mucilage and shows the disintegration of tablet with in less than the time of 20 sec.

Xanthum Gum

This is derived from xanthomonas campestris with a character of high hydrophilicity and low gelling tendency but it has low solubility and high swelling properties for fast disintegration.

Soy Poly Saccheride

This is natural superdisintegrant does not derived from any other and does not contain any starch or sugar also can be used as nutritional products.

Gellan Gum

It is a linear tetra saccharide of anionic poly saccharide derived from pseudomonas elodea having super disintegrating qualities as equal to modified starch and celluloses.

Cucurbita Maximum Pulp Powder

Malviya *et al.*, carried out the evaluation of cucurbita with diclofenac sodium and prepared various concentrations of 2.5, 5, 7.5, 10% and these also sent for various tested like friability drug content, drug disintegration time, and this study also proves that this is a good pharmaceutical adjuvant and disintegrating agent.

Ocimum Americanum Seed Mucilage

Patel *et al* prepared the propanolal hydrochloride tablets using ocimum americanum seed mucilage using various concentrations like 2, 4, 6, 8, 10% the optimum concentration of mucilage for rapid dissolution is shown at 10% and the same concentration with starch and propanolal hydrochloride is prepared and shows disintegration time of 269 seconds while ocimum shows the disintegration in 154 seconds. The hardness friability drug content are within limit²⁵⁻³¹.

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 formation of excipient granules with superior properties. Compared with physical mixtures of components like improved flow property and compressibility. Better dilution potential full uniformity and reduced lubricant sensitivity.

Several co-processed super disintegrates are available²⁹⁻³¹.

Ludipress
 Starlac
 Starcap 1500
 Ran explo-c
 Ran explo-s
 Pan excea
 Ludiflash

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

S.No	Excipients	Approach used	Result
1	Ludiflash	Direct compression	Disintegration in 27 sec.
2	Pharm burst	Spray drying method	Disintegration in 30 seconds
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 superdisintegrant, by containing isomalt degrades in 200 sec
7	Polacrillin potassium	Direct compression	Disintegration time of 45 s. 100% release

Table No.2: Dextrose obtained on starch hydrolysis

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.3: Dextrose obtained on starch hydrolysis (These are high amounts of dextrose obtained)

Glucidex 21	20-33
Glucidex 33	31-34
Glucidex 47	43-47

CONCLUSION

As this article conclude this oral disintegrating tablets are accepted form of the dosage 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 achieve rapid disintegration. Coming to the factors nature and Available online: www.uptodatereseachpublication.com

availability of bioavailability with disintegrating agents has no action 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 dis advantages of the ODT's should be covered and collection and applications of super disintegrants must also be increased. Today the most allergies, May – June 124

cold fevers ODT's are widely used and coming to the cost factor the cost of the oral disintegrating tablets are very less and meanly available to a common person. The industry people should also increase and advertise of ODT's should also be increased in order to educate the advantages and disadvantages of ODT's. Any there is bright scope in future for ODT's if all the people get well known about it^{32, 33}.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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