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Research Article

An Update On Various Excipients Employed for Orodispersible Tablets with A Special Focus On Superdisintegrants

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ABSTRACT
This article summarizes the use of various excipients in the formulation of orodispersable tablets (ODTs). Though excipients are the inactive ingredients, but they provide life to the active pharmaceutical ingredients by converting them into dosage forms. Sometimes they can be a key determinant of dosage form performance. Reviews of the literature on adverse reactions attributed to excipients showed that the available data on excipients safety are limited in quantity and variable in quality. Their effects on pharmacodynamics and pharmacokinetics although usually negligible without empirical conformation but sometimes are important. Specific excipients are suitable for ODTs, the categories of various excipients used in ODTs are discussed in the current review with special reference to diverse categories of superdisintegrants like natural, synthetic, and co- processed. To meet the needs of advanced tablet manufacturing, novel and improved superdisintegrants continued to be developed. It requires the development of various added functionality of excipients which are used to achieve formulations with desired end effects. In basic research and clinical trials those are sometimes included in the control substances in order to minimize commingling, which shows impact that the absence of the active ingredient is not the only variable involved, but also excipient.

Key words: ODTs, Pharmaceutical excipients, Superdisintegrants, Dosage forms, Co-processed.

INTRODUCTION

Drug delivery through oral route is the most common and preferred route of drug administration both for solid and liquid dosage forms. However solid dosage forms are popular because of ease of administration, precise dosage, self medication, pain avoidance and most importantly the patient compliance[1-6]. The International Pharmaceutical Excipients Council (IPEC) defines an excipient as any substance other than the active drug or prodrug that is included in the manufacturing process or is contained in the finished pharmaceutical dosage form[7]. The reasons for their use are several. In the preparation of a tablet, from a drug into dosage form, pharmaceutical excipients are required. Fillers are added to increase the bulk of the formulation, and lubricants to reduce friction during the tableting process. Some pharmaceutical formulations require a binder for tableting, which provides cohesiveness necessary for bonding the ingredients together as granules before compression. The quantity used must be carefully regulated since the tablet needs to disintegrate after administration to liberate the drug[8]. Disintegrants are usually added for the purpose of causing the compressed tablet to break apart when placed in an aqueous medium. For a successful formulation, equilibrium between binder and disintegrant concentrations must be reached for the ingredient granules to be easily compressed, to form a tablet and finally disintegrate after reaching an aqueous medium [9].

Excipient Selection

The nature and properties of the active ingredient affect the choice of an excipient, the dosage form to be introduced and the process by which it is manufactured. It is also important to know the patient group and clinical condition. Moreover an increasing intricacy of the formulation because of the number of excipients employed rises the risk of error in manufacturing of the formulation can result in product failure. Caution should be taken when consulting generally regarded as safe list, as it refers to compounds that have been administered orally and distinctively to food additives. The safety of excipients administered by other routes may be quite different than those administered orally [6, 7].

Excipient residues may also compromise safety, efficacy or tolerance. Residues in excipients can also affect quality and performance by interacting with the drug or other key components. Reducing sugar impurities in mannitol were responsible for the oxidative degradation of cyclic heptapeptide [6-8].

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Various excipients (used for the formulation of orodispersible tablets) can be classified as follows [9]:

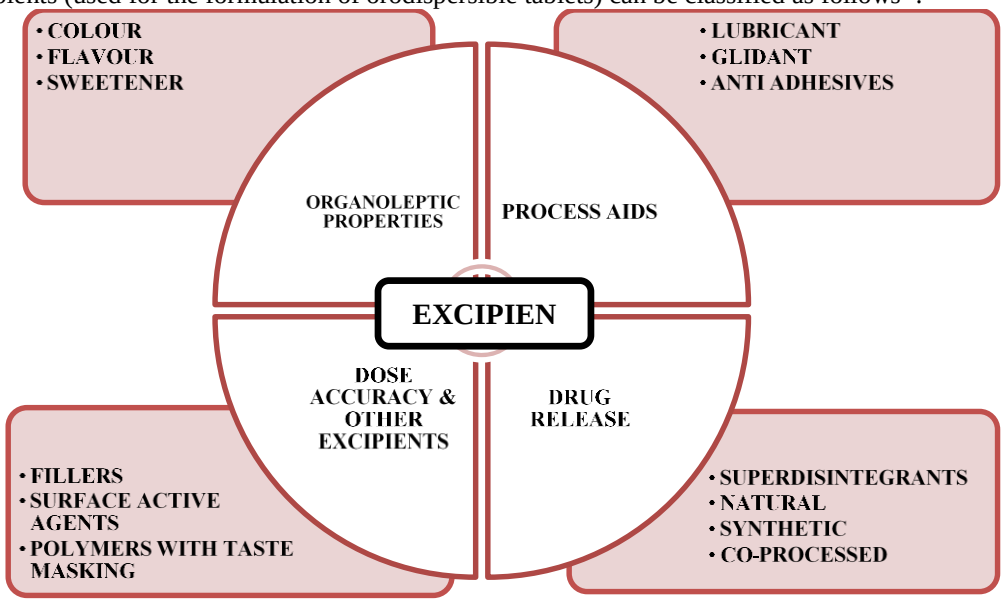

Figure 1: Classification of excipients used in orodispersible tablets

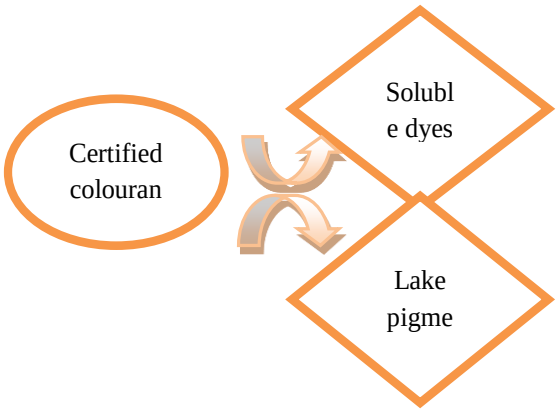

Figure 2: Classification of colourants

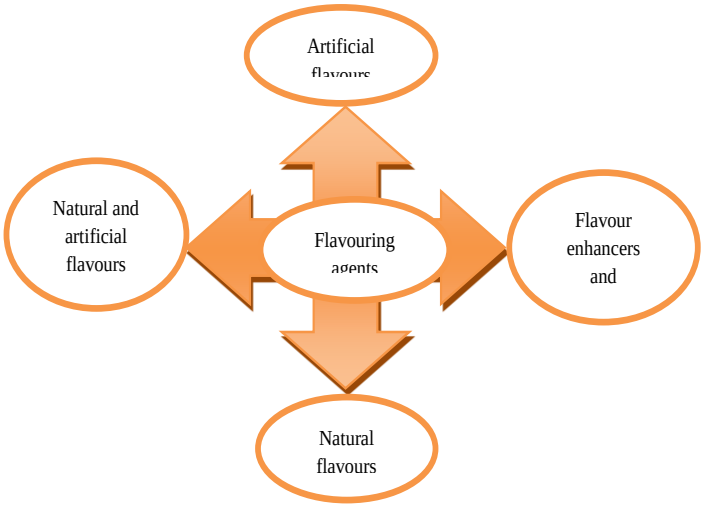

Figure 3: Classification of flavouring agents

Organoleptic Agents

These are essential for tablet formulations to improve palatability and appearance of the dosage forms.

Colours[7-10]: A colourant is an integral part of pharmaceutical preparation. The following are some of the colourants used in the tablet formulations.

Flavours[7-9]**:** Flavour or aroma is important in the pharmaceutical formulations being the first characteristic to be perceived.

Sweeteners[7]**:** Sweeteners are necessary to mask the unacceptable taste of the pharmaceutical preparation.

Excipients for Dose Accuracy:

Fillers[11-13]:

The solubility and compression characteristics of fillers, affect disintegration rate, mechanism and time of tablets. Soluble fillers increase the viscosity of the penetrating fluid which reduces the effectiveness of strongly swelling disintegrating agents and as they are water soluble, they are likely to dissolve rather than disintegrate. Insoluble diluents produce rapid disintegration with adequate amount of disintegrants.

e.g., Mannitol, sorbitol, xylitol, calcium carbonate, calcium phosphate.

Lubricants[13- 14]**:**

Lubricants are included in the tablet formulations to overcome certain problems of flow of granules from the hopper into the die cavity, sticking of material to the punches and die walls and release or free movement of the compressed tablets from the die cavity. e.g., Stearic acid, magnesium stearate, zinc, calcium, talc, polyethylene glycol, liquid paraffin, magnesium lauryl sulphate, colloidal silicon dioxide etc.Based on their ability to carry out these functions, lubricants have been differentiated into following two groups

Table 1: Classification of organoleptic agents

Organoleptic agents		
Colours	Flavours	Sweeteners
Colouring agents may be defined as substances employed in pharmacy for imparting colour which gives a pleasing appearance and as "sensory adjuvants" to the flavours which gives product distinctiveness [10].	Flavouring agents have been used to flavour foods and to make medicines palatable. Aroma can reach the olfactory region of the nose through multiple pathways including orthonasal perception (sniffing) and retronasal perception (swallowing) [10].	Sweeteners play a prominent role in the formulation of Orodispersible tablets especially those containing bitter or other unacceptable tastes[10].

Glidants: Glidants are those which facilitate flow of granules from hopper to the die cavity by reducing interparticulatefriction e.g., Corn starch and colloidal silica.

*Antiadhesives***:** Antiadhesives prevent adhesion of materials to the faces of punches and die walls. e.g., Talc and corn starch.

Surfactants[15]

Surfactants are recommended to decrease the hydrophobicity of the drugs because the more hydrophobic the tablet the greater the disintegration time. Surfactants are only effective within certain concentration ranges.

Superdisintegrants

Superdisintegrants primarily affect the rate of disintegration when used at high levels. They can also affect mouth feel, tablet hardness as well as friability in case of ODTs. Factors such as disintegration, compatibility, mouth feel and flow are considered for selecting a superdisintegrant. Depending on the level and characteristics of the active pharmaceutical ingredient (API) and the desired release profile, the levels of superdisintegrants used can be 10-20 % of the formulation weight and it can be higher or lower in some cases[16].

Water penetration rate and rate of disintegration force development are generally positively related to disintegrant efficiency in non soluble matrices. However such a positive correlation is not always observed between tablet disintegration time and drug dissolution rate[17-20].

Superdisintegrants provide quick disintegration due to combined effect of swelling and water absorption by the formulation. Due to swelling of the superdisintegrants, the wetted surface of the carrier increases, this promotes the wettability and dispersibility of the system, thus enhancing the disintegration and dissolution [21].

The ability to interact strongly with water is essential for disintegrant function. Combinations of swelling and or wicking and or deformation are the mechanisms of disintegrant action. The disintegrants have a major function to oppose the efficiency of the tablet binder and physical forces that act under compression to form the tablet [22].

There are three types of superdisintegrants used for ODTs [23, 24].

Natural superdisintegrants

Aegle marmelos gum (AMG) [25, 26]

It is obtained from the fruits of *Aegle marmelos* belonging to the family Rutaceae and is indigenous to India.

Kulkarni U *et al*. formulated Aceclofenac fast dissolving tablets using modified *Aegle marmelos* gum. Aceclofenac is a poorly soluble drug and has poor bioavailability after oral administration. Solubility of Aceclofenac was found to be enhanced with increase in concentration of AMG and modified AMG. They concluded that modified AMG could be used as potential determinant in the solubility and dissolution rate enhancement of poorly soluble drug. Increased dispersibility, surface area, wettability and solubilization effect of AMG and modified AMG enhances the solubility of water insoluble drugs.

Lallemantia reylenne seeds [27]

It is also known as Tukhmalanga in India and it belongs to Lamiaceae family. It is an annual herb cultivated in Northern India. The seeds are mucilagenous and have medicinal properties.

Malik K *et al.* formulated the orodispersable tablets of Nimesulide by using *Lallemantia reylenne* seed mucilage as a natural superdisintegrant. They observed profound increase in tablet porosity and decrease in disintegration time. The results obtained were better even than that of synthetic superdisintegrants like croscarmellose sodium.

Locust bean gum [28-30]

It is also known as Carobben gum. It is a galactomannan vegetable gum extracted from the seeds of carob tree (*Ceretonia siliqual*) found in Mediterranean region. Locust bean gum has been widely used in food industry as a thickening and gelling agent.

Malik K *et al*. formulated the Nimesulide orodispersable tablets by using Locust bean gum as natural superdisintegrant. The gum was evaluated for powder flow properties, swelling index and loss on drying. Excellent powder flow properties were observed, swelling index was found to be 20 secs which indicated appreciable capability of locust bean gum to be used as superdisintegrant. Disintegration time of the tablet containing 10 % locust bean gum was found to be 30 secs. The tablets disintegrated much faster and consistently when locust bean gum was used as superdisintegrant compared to croscarmellose sodium.

Mango peel pectin [31, 32]

Common name of *Mangifera indica* is mango and it belongs to Anacardiaceae family. It is non toxic and used as superdisintegrant, binder, suspending agent, emulsifying agent in different formulations.

Malviya R *et al.* formulated fast dispersible tablets using mango peel pectin as superdisintegrant. Tablets of mango peel were evaluated for weight variation, friability,

Table 2: Some of the provisionally listed colourants

Colour	Common Name	Colour Index Number
FD&C blue #1 lake	Brilliant blue FCF	42090
FD&C blue #2 lake	Indigotine	73015
D&C blue #4 lake	Alphazurine FG	42090
FD&C green #3 lake	Fast green FCF	42053
D&C green #5 lake	Alizarine cyanide green F	61575
D&C orange #4 lake	Orange II	15510:2
D&C orange #5 lake	Dibromoflourescein	45370:2
D&C orange #10 lake	Diiodoflourescein	45425:2
D&C orange #11 lake	Erythrosine	14700

Table 3: Some of the examples of natural flavours

Some of the examples of natural flavours		
Name	Source	Extraction Method
Anise	*Pimpinella anisum* (Umbelliferae)	Steam distillation
Cardamom	*Elettaria cardamom* (Zingiberaceae)	Steam distillation
Wild cherry	*Prunus serotina* (Rosaceae)	Fluid collection from bark small branches, twigs.
Lemon	*Citrus limonum* (Rutaceae)	Fluid extraction
Orange bitter	*Citrus aurantium* (Rutaceae)	Steam distillation
Orange sweet	*Citrus sinensis* (Rutaceae)	Expression
Peppermint	*Mentha piperita* (Labiatae)	Steam distillation

hardness, thickness, drug content, wetting time and de-aggregation time. The prepared tablets had comparatively lesser release of drug as compared with sodium starch glycolate for a specific period of time. Therefore, mango peel pectin cannot be used as promising superdisintegrant, but due to its good solubility in biological fluid and better swelling index it can be used to prepare fast dispersible tablets.

Lepidium sativum [33-35]

It is also called as Asaliyo and belongs to the family Cruciferae. Mucilage is extracted from the seeds of *Lepidium sativum* which is used as binder, disintegrant and gelling agent.

Mehta KK *et al.* formulated the fast dissolving tablets of Nimesulide using *Lepidium sativum* as natural disintegrating agent. The prepared fast disintegrating tablets were evaluated for uniformity of weight, hardness, tablet thickness, percentage friability, wetting time, *in vitro* disintegration time and *in vitro* dissolution. From this study it was concluded that higher tablet dissolution rate was obtained with increased concentration of *Lepidium sativum.*

Hibiscus rosasinensis mucilage [36, 37]

It is also called as shoe flower plant, China rose, Chinese hibiscus belonging to the family Malvaceae. Mucilages are used as thickeners, suspending agents, water retention agents, disintegrants etc.

Shah V *et al.* formulated dispersible tablets of Aceclofenac and compared with different concentrations i.e. 2, 4, 6 and 8% (w/w) of *Hibiscus rosa-sinensis* mucilage powder and Ac-Di-Sol®. Eight batches of dispersible tablets were prepared and evaluated for physical parameters like thickness, hardness, friability, weight variation, drug content, disintegration time and drug dissolution. The formulated tablets had good appearance and better release properties. The study revealed that the disintegrant in low concentration (4%) was effective. The mucilage was found to be a superior disintegrating agent than Ac-Di-Sol®.

Dehydrated banana powder (DBP) [38, 39]

Banana is also called as plantain. DBP is prepared from the variety of banana called Ethan and Nenthran (*Nenthra varsha*) belongs to the family Musaceae. It acts as binder, diluent and superdisintegrant.

Arun N *et al.* formulated orodispersable tablets of Ondansetron HCl, Propanalol, and Gabapectin using DBP as superdisntegrant. The tablets were evaluated for hardness, friability and wetting time. The results concluded that DBP increases the release of drug from the tablet.

Chitosan and gum Arabic [40-43]

Chitosan is cationic polysaccharide derived from the N-deacetylation of chitin. Gum arabic is a natural polysaccharide derived from the exudates of *Acacia senegal*.

Rishabha M *et al.* investigated the use of chitosan-gum Arabic coacervates as excipient in fast dissolving dosage form. The aim of this research work was to synthesize coacervates of two natural polymers i.e., chitosan and gum arabic. Further these coacervates were characterized and evaluated as an excipient in fast disintegrating dosage form for the treatment of chronic epileptic attack. The physicochemical evaluation results demonstrate that coacervates had good potential to be used as a pharmaceutical excipient. Thus, coacervates may have wide range of applications as polymer in different dosage forms.

Plantago ovata [44-46]

Mucilage of *Plantago ovata* is generally collected from the seeds by soaking these for 48 hrs in distilled water followed by boiling for few mins. Extracted mucilage at a

Table 4: List of commonly used sweetening agents

Sweetener		Brand Name	Sweetening Intensity	Comments
Caloric	Sucrose	---	1	Commonly used known as table sugar
	Fructose	---	~1.2	Rapid onset of apparent sweetness
	D-Glucose	---	~0.5-0.9	Commonly referred to as dextrose
	Acesulfame-k	Sunnet® Sweet One®	~200	Heat stable
Non- caloric	Aspartame	Nutra sweet® Equal®	~200	Unstable in solution
	Saccharine	Sweet'N Low	~500	Unpleasant after taste
	Sodium cyclamate	---	~30	Carcinogenic concern
	Sorbitol	---	~0.6	Pleasant taste
	Sucralose	Splenda®	~600	Heat stable and stable over a broad pH range

concentration of 2 % is found to be a good disintegrant and having additional advantage of being natural.

Khinchi M *et al.* prepared the orally disintegrating tablets of Fexefenadine HCl as model drug by direct compression method using microcrystalline cellulose and mannitol as directly compressible vehicle. The tablets were evaluated for quality control tests like organoleptic characteristics, weight variation, hardness, friability, *in vitro* disintegration time, *in vitro* swelling time, drug content and dissolution behavior. Among all the superdisintegrants, *Plantago ovata* mucilage showed the highest swelling index. Hence the present study revealed that *Plantago ovata* mucilage as a natural superdisintegrant.

Soy polysaccharide [47]

It is a natural superdisintegrant that does not contain any starch or sugar and thus can be used in nutritional products.

Taksande JB *et al*. prepared fast dissolving tablets of Lornoxicam using natural superdisintegrants like banana powder, soy polysaccharide and synthetic superdisintegrants like crosspovidone. Among all the formulations, the batches prepared with 8 % soy polysaccharide showed more than 90 % drug release in 15 mins.

Synthetic superdisintegrants

Croscarmellose sodium [48-50]

It is a modified cellulose and is a cross linked polymer of carboxy methyl cellulose. The disintegration rate of croscarmellose sodium is higher than that of sodium starch glycolate.

Rajeshree P *et al.* formulated fast dissolving tablets of Lisinopril using combination of synthetic superdisintegrants like croscarmellose sodium, crospovidone and sodium starch glycolate in a ratio of 5:10 and 10:5 respectively by direct compression method. The formulation of Lisinopril containing 10 % crospovidone and 5 % croscarmellose showed disintegration time of 145 ± 0.502 secs respectively with 99 % drug release within 30 mins.

Sodium starch glycolate [51, 52]

It is a cross linked polymer of carboxy methyl starch. The tablets formulated by using these superdisintegrants are disintegrated in less than 2mins.

Sasidhar RLC *et al*. formulated orodispersible tablets of Venlafaxine hydrochloride by sublimation method using camphor and menthol as subliming agents and sodium starch glycolate (SSG) as superdisintegrant.

Among all the formulations the tablets prepared by sublimating camphor with sodium starch glycolate as superdisintegrant showed faster disintegration and rapid drug release.

Crosslinked polypyrolidone (crospovidone, polyplasdone XL, XL10) [53, 54]: Crospovidones are synthetic insoluble crosslinked homopolymers of N-vinyl 2-pyrolidone.

Khalid K *et al*. Orodispersible tablets of diazepam were prepared using different types of superdisintegrants (Ac-Di-Sol, sodium starch glycolate, and crospovidone (CP)) and different types of subliming agents (camphor and ammonium bicarbonate) at different concentrations and two methods of tablets preparations (wet granulation and direct compression methods). The results revealed that the tablets containing CP as a superdisintegrant have good dissolution profile with shortest disintegration time.

Alginates [55-57]

These are hydrophilic colloidal substances extracted naturally from certain species of kelp or chemically modified from natural sources like alginic acid or salts of alginic acid. They are having higher affinity for water absorption and capable as excellent disintegrants.

Honey G et al. formulated fast dissolving tablets of ondansetron HCl using a novel superdisintegrant (chitosan-alginate (1:1) Interpolymeric complex and chitin). The results suggested that the used novel superdisintegrants not only improved the disintegration time but also made it possible to prepare fast disintegrating tablets with higher crushing strength as compared to tablets with known superdisintegrants.

Indion 414 [58-60]

It is an ion exchange resin and if used as superdisintegrants swells and hydrated without dissolution and devoid of adhesive tendency cause uniform tablet disintegration. Experiments were carried out to evaluate the disintegrating property of Indion 414 in fast disintegrating dosage form like mouth dissolving tablets.

Rasheed SH et al. developed fast dissolving tablets of salbutamol using croscarmellose sodium, sodium starch

Table 4: Effects of various surfactants on the disintegration of tablets

Surfactants	Remarks
Sodium lauryl sulfate	Good for various drugs
Polysorbate 20	Good
Polysorbate 40 & 60	Poor
Polysorbate 80	Good
Tweens	Poor
Poly ethylene glycol	Poor

(Note: Good – decrease in disintegration time, Poor – increase in disintegration time)

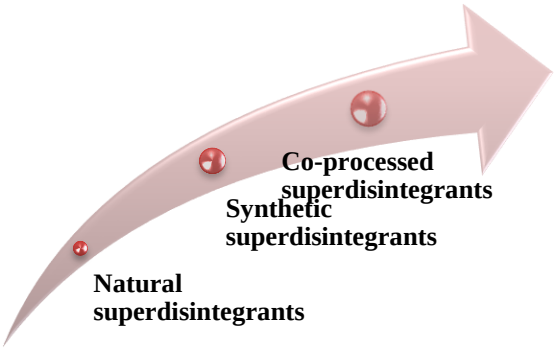

Figure 4: Types of superdisintegrants

glycolate and Indion 414 as superdisntegrating agents.

Formulations containing Indion 414 showed rapid *in vitro* disintegration time as compared to other formulations.

Co-processed superdisintegrants [61-64]

It involves the mixture blend of more than two excipients to satisfy the required quality using different techniques like spray drying and freeze drying etc. New and improved superdisintegrants continue to be developed to meet the needs of advanced tablet manufacturing. It requires the development of various added functionality of excipients which are used to achieve formulations with desired end effects.

Ludiflash [65-70]

Ludiflash is an innovative, unique co-processed blend of mannitol (95%), crospovidone (5%) and polyvinyl acetate (5%) manufactured in a validated patented process. It disintegrates rapidly within seconds with soft, creamy consistency. It gives extremely fast release rate.

Dhiraj AK *et al*. reviewed on diverse categories of synthetic, semi synthetic, co processed and multifunctional excipients. Co-processing is based on the novel concept of two or more excipients interacting at the sub particle level, the objective of which provides a synergy of functionality improvement as well as masking the undesirable properties of individual.

F-melt[71-75]

It is a spray dried excipient used in orally disintegrating tablets that contain saccharides, disintegrating agent and inorganic excipient. F-Melt exhibits excellent tableting properties and facilitate rapid water penetration for a fast disintegration time.

Shirshand SB *et al*. reviewed on novel co-processed superdisintegrants used in fast dissolving tablets. In recent years drug formulation scientists have recognized that single component excipients do not always provide the requisite performance to allow certain active pharmaceutical ingredients to be formulated or manufactured adequately. Hence, there is a need to have excipients with multiple characteristics built into them such as better flow, low moisture sensitivity, superior compressibility and rapid disintegration ability.

Pharmaburst[76-79]

Pharmaburst is a quick dissolving delivery system which includes an addition of active drug in a dry blend with Pharmaburst excipients before compressed by tablet machine.

Shihora H *et al*. reviewed on superdisintegrants, and their utility in dosage forms and their applications. The phenomenon of co-processed excipients is a field having vast scope for development of excipients with desirable property for direct compression as well as for specific method and formulation.

Modified chitosan with silicon dioxide[80]

Chitosan and silica are the new excipients based on co-precipitation. The physical interaction between chitosan and silica create an insoluble, hydrophilic, highly absorbent material resulting in superiority in water uptake and saturation for gelling formation.

Rashid I et al. reviewed on novel co-processed superdisintegrants. Processing of chitin with silica products offers significant advantages for the exploitation of multifunctional excipients in the pharmaceutical industry. Chitin-metal silicate co-precipitates have recently been reported to be useful excipients with appropriate binding and disintegration characteristics when compared to conventional superdisintegrants and fillers.

Modified mannitol pearlitol 200 SD [81, 82]

These are the granulated mannitol white, odorless, slightly sweet tasting crystalline powder. It has a unique blend of exceptional physical and chemical stability with great organoleptic, noncarcinogenic, sugar free properties. It can be used in different processes wet or dry granulation, direct compression etc. Pearlitol SD dissolves very rapidly because of its porous crystalline particles.

Jacob S et al. formulated fast dissolving tablets of glipizide using novel co-processed excipients of mannitol and microcrystalline cellulose by spray drying technique to be used as direct compression excipient in fast dissolving tablets. The co-processed formulation containing mannitol and microcrystalline cellulose in the ratio 1.25: 1 was found to be optimized with fast disintegrating property of < 15 secs.

Mannogen EZ [80, 81]

Mannogen EZ is spray dried mannitol specially designed for direct compression tablet. It has advantages of highly compatible, non hygroscopic, chemically inert, narrow particle size distribution and mainly rapid disintegration property that benefits quick dissolve application.

Avachat A *et al*. reviewed on characterization and evaluation of spray dried co-processed excipients and their

Figure 5: Fruits of *Aegle marmelos*

Figure 6: *Lallemantia reylenne* plant

Figure 7: *Locust bean* seeds

Figure 8: *Mangifera indica* tree

Figure 9: Seeds of *Lepidium sativum*

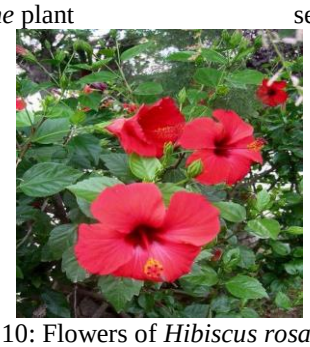

Figure 10: Flowers of *Hibiscus rosasinensis*

Figure 11: Seeds of *Plantago ovata*

application in solid dosage forms. Discovery of novel chemical entities day by day also increases the scope for further development and use of these excipients in future. Studies suggested that ease of availability of these co-processed excipients and its simplicity in the direct compression process developed more economical alternative in the preparation of oral drug delivery formulation than the patented techniques.

Modified resins [81]

Polacrilin potassium (KYRON T-314)

It is a crosslinked polymer of methacrylic acid and divinyl benzene supplied as a potassium salt. Polacrilin potassium is a weakly acidic cationic exchange resin. On coating, the resin swells by approximately 150 % thereby causing the tablet to disintegrate. Tablet disintegrating property is due to its extremely large swelling capacity in aqueous solutions.

Gandhi BR *et al*. formulated mouth dissolving tablets of Aceclofenac using KYRON T-314 (polacrilin potassium) as a novel superdisintegrant. Mouth dissolving tablets of Aceclofenac were prepared by wet granulation technique using KYRON T-314 as superdisintegrant and menthol as subliming agent. The study demonstrated potentials for rapid absorption, improved bioavailability, effective therapy and patient compliance.

Modified Agars [82]

Glucidex 17

Glucidex 17 is obtained by moderate hydrolysis of starch. Its microgranulated form enables almost instantaneous dispersal and dissolution in water. The improved physical, chemical and mechanical properties of such excipient as compared to existing excipients have helped in solving formulation problems such as flowability, compressibility, hygroscopicity, palatability, dissolution, disintegration, sticking and dust generation.

Block LH *et al*. reviewed on co-processed excipients and their applications in formulations of ODTs. co-processing excipients leads to the formulation of excipient granules with superior properties compared with physical mixtures of components or individual components like improved flow properties, absence of chemical changes, improved compressibility, better dilution potential, fill weight uniformity, and reduced lubricant sensitivity.

Polymers with taste masking ability [83, 84]

Copolymers of dimethyl aminoethyl, butyl methacrylate and methyl methacrylate have an ability to mask the taste of administered active substances, which is explained by the influence of complementary ionic groups. Taste masking is then an effect of the interaction between cationic drug and anionic polymer or vice versa.

Randale *et al.* had designed fast disintegrating tablets containing metoclopramide with the substances taste masked. They achieved this result through complexing the drug in different ratios by extrusion method and precipitation with amino alkyl methacrylate copolymer. In the conducted tests, the drug polymer complex with components ratio of 1:2 exhibited significant taste masking ability with a degree of bitterness at or below the threshold value (0.5) in 10 secs, whereas the substance itself metoclopramide orthosulphate was assessed in the same conditions as intensively bitter with a score of degree of bitterness 3 for 10 secs.

CONCLUSION

The availability of excipients and their ease in the direct compression process suggest that these would be more economic in the preparation of ODTs because of increase in demand of fast disintegrating drug delivery systems. The choice of formulation ingredients can have a significant effect on the rate and extent of drug dissolution. It is necessary to have excipients with excellent functional

properties to compensate poor mechanical properties and low aqueous solubility of the emerging active ingredients. Superdisintegrants increases the drug release rate from the tablets and decreases the disintegration time. Among various types of superdisintegrants used, natural superdisintegrants are nontoxic, economic, widely available and utilized in low concentrations. Around 80 % of the current drugs are not suitable for direct compression and so more advanced excipients need to be developed. Further, conventional grades of excipients are not suitable for advanced high speed rotary tablet presses which require powder with excellent flow, good compressibility, compactibility, particle size distribution and homogeneity of ingredients. So novel co-processed excipients need to be tailored continuously for enhancement of these functional properties.

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