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Review Article

Recent Trends in developments of Superdisintegrants: An Overview

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Abstract

Fast dissolving tablets are solid unit dosage forms that dissolve or disintegrate quickly in the mouth without using water. To provide this type of character in a dosage form, different excipients are required. Superdisintegrants are a class of novel agents that have emerged in recent years. Improving drug bioavailability in the pharmaceutical field is a challenge. The inclusion of superdisintegrants in the formulation enhances the formulation's efficacy. The main goal of this review article is to highlight current development in the superdisintegrants. Novel medication delivery techniques have recently advanced, resulting in a convenient dosage form for administration. New superdisintegrant formulations have recently investigated. These formulations are used to ensure patient compliance and safer, more effective drug delivery. This overview of superdisintegrants covers developed strategies, types (including synthetic and natural materials), dosage forms and techniques.

Keywords: Synthetic superdisintegrants, Conventional superdisintegrants, Fast disintegrating tablets, direct compression, dissolution, disintegration, Natural superdisintegrants, Co-processed excipients.

INTRODUCTION

Disintegrants are mixtures of substances added to a drug formulation to aid in the breaking up or disintegration of tablet content into smaller particles that dissolve more quickly. These smaller particles dissolved more quickly due to the presence of disintegrants.¹ Various attempts have been made to manufacture fast disintegrating tablets in order to overcome the difficulties associated with patient compliance. To achieve the rapid disintegration, superdisintegrants can be used in both tablets and capsules.² Native starches, which have been recently studied, assure rapid breakdown and dissolution. The natural starch in LYCATAB® ensures that tablets break quickly. The self-disintegrating property of Starlac® was demonstrated. Superdisintegrants such as sodium starch glycolate (SSG), croscarmellose sodium (Vivsol, AC-Di-Sol), and crospovidone (Polyplasdone) are routinely utilized.³ The novel synthesized superdisintegrant has an appropriate aptitude for application in the formulation of Fast disintegrating tablets. Because disintegration is so important process in the dissolving of a tablet before the active drug material is finally released from the tablet's structure into the body. Therefore, the type, concentration, and efficiency of added superdisintegrants influence the tablet's disintegration mechanism.^{4,5}

SELECTION OF SUPERDISINTEGRANTS^{6,7}

Superdisintegrant must meet specific criteria in addition to their swelling capabilities because they are used as an excipient in the tablet formulation. So, superdisintegrants must have the following properties:

1. Able to stay hydrated
2. Poor solubility
3. Solubility is poor.
4. Molding and flow qualities are excellent.
5. Good tableting consistency
6. Ineffective gel formation
7. Excellent mouth feel

METHOD OF ADDITION OF SUPERDISINTEGRANTS⁸

Superdisintegrants can be added in the formulations by the following methods:

1. External addition
2. Internal addition
3. Partially internal or external addition

These methods usually provide rapid disintegration of tablets. In table 1, different modes of addition of superdisintegrants are given;

Table 1: Method of addition of Superdisintegrants ⁹

S.NO	Methods	Inferences
1.	Extragranular/External addition (Prior to compression)	Before compression, superdisintegrants are added to already prepared granules.
2.	Intragranular/Internal addition (During granulation)	Superdisintegrants are added during granulation.
3.	Partially internal and external	A portion of the superdisintegrant is added during the granulation process (internally), and the rest is added thereafter.

CLASSIFICATION OF SUPERDISINTEGRANTS¹⁰

Superdisintegrants can be classified on the basis of their source of origin:

- Synthetic superdisintegrants
- Natural superdisintegrants
- co-processed superdisintegrants

Synthetic superdisintegrants

Synthetic superdisintegrants are primarily employed in tablet formulations to increase up the rate of drug disintegration. These superdisintegrants speed up the disintegration process; improve the dissolution, and solubility. Croscopovidone (crosslinked PVP), Crosslinked Cellulose (croscarmellose sodium), Soy Polysaccharides (Emcosoy), Chitin and Chitosan, and Sodium Starch Glycolate are some of the most commonly used synthetic superdisintegrants.¹¹

Natural superdisintegrants

Natural superdisintegrants are biologically originating and commonly used in tablet formulation which facilitates disintegration of tablet. These superdisintegrants are mostly used to certain demerits of synthetic superdisintegrants. Some commonly used Natural superdisintegrants are *Plantago ovata husk*, *Ocimum tenuiflorum*, *Aloe vera mucilage*, *Hibiscus Rosa Sinensis*, *Lipidium sativum*, *Mangifera indica pectin*, *guar gum*, etc.¹²

Co-processed superdisintegrants

New, improved superdisintegrants were being developed to satisfy the needs of modern tablet manufacturing, providing formulations with desired end effects. Some co-processed excipients blends were Ludipress, starlac, starcap 1500, Ran-explo-c, Ran-explo-s, ludiflast, etc.¹³

RECENT DEVELOPMENTS IN NOVEL SUPERDISINTEGRANTS¹⁴

Superdisintegrants are used in tablets and capsules to ensure the rapid breakdown into their primary particles, facilitating the dissolution or release of the active ingredients. Recently, several versatile ranges of disintegrating agents have been developed. These agents provide rapid disintegration of tablets and capsules.¹⁵ Various types of recently investigated superdisintegrants along with their method of preparation are shown in Table 2;

SOLUTAB®

Croscarmellose sodium is a superdisintegrant and acts as a dissolving aid with high efficacy. Due to the high affinity of water absorption, the mechanical action is radial expansion.

It provides complete and efficient disintegration of tablets or capsules. It is effective even at low dosages. It is insoluble in water. It may regenerate after being moistened. It is a white powder that is available in various forms, including SOLUTAB® A-IP, SOLUTAB®, and SOLUTAB® EDP.¹⁶ It can be used in tablets, capsules, or pellets formulations. The most common method used for the preparation is direct compression.¹⁷ The structure of Croscarmellose sodium is given in Figure 1;

GLYCOLYS® and EXPLOSOL®

These are the ranges of Sodium Starch Glycolate that come in various grades to fulfill specific formulation requirements. These two ensure the fast disintegration of tablets or capsules. Sodium Starch Glycolate is suitable for all types of dosage forms. GLYCOLYS® LV is designed for wet granulation and high-shear granulation. Low pH GLYCOLYS® is ideal for pH-sensitive medicines.¹⁸ The structure of Sodium Starch Glycolate is given in Figure 2;

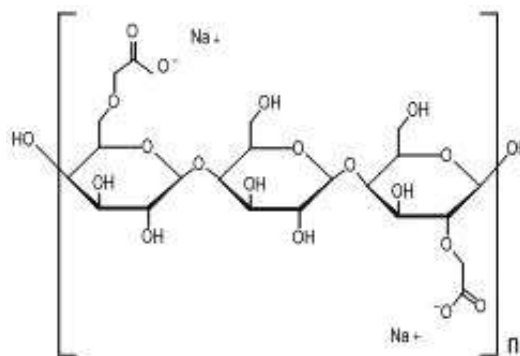


Figure 1: Structure of Croscarmellose sodium

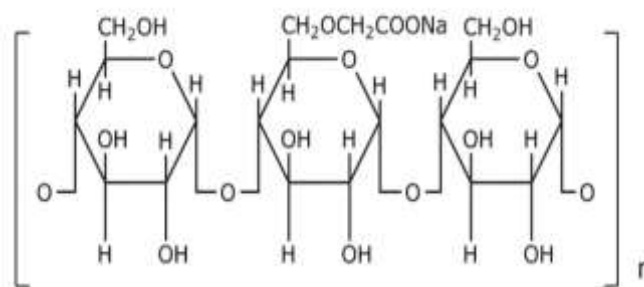


Figure 2: Structure of Sodium Starch Glycolate

PEARLITOL® FLASH

- Pearlitol® 100SD, mean diameter: 100 µm

- Pearlitol® 200SD, mean diameter: 180 µm

A novel Co-processed excipient for orodispersible tablets showed self-disintegrating properties. It is white-colored powder. PEARLITOL® FLASH melts rapidly within the mouth and showed quick action. It is directly compressed excipient. It is suitable for oro-dispersible tablets and provides fast disintegration of tablets.¹⁹

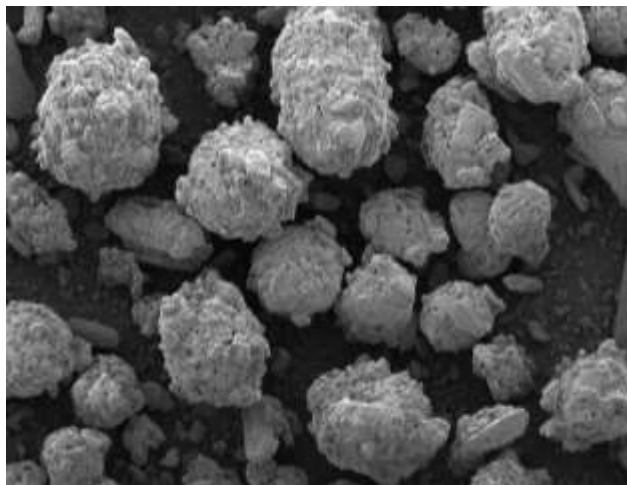


Figure 3: PEARLITOL® FLASH

INDION 414

It is an ion exchange resin in nature. It is used as a superdisintegrant and is readily available. It swells when hydrated without dissolving and has no sticky tendency, resulting in uniform tablet disintegration. If we compared it to traditional disintegrants, Indion 414 is a more effective superdisintegrant. It is used in concentrations ranging from 0.5 to 2 percent for effective disintegration of tablets.²⁰ Recently, research work was performed on the superdisintegrating property of Indion 414. Montelukast Sodium, an antiasthmatic agent, was used as a model drug. From the evaluation results, it was concluded that Indion 414 acts as a beneficial superdisintegrant in comparison to the conventional superdisintegrants.²¹

F-MELT®

F-MELT® is a spray-dried excipient used in oral disintegrating agents. F-MELT® showed excellent disintegration properties. It has rapid water penetration capability. It showed a disintegration time of 30 seconds, time-saving and cost-effective, less sticking or capping.

- It is suitable for those formulations which are manufactured by the direct compression methods.
- It is free-flowing due to the presence of spherically dense particles. Various research works have been performed on the disintegration property of the F-MELT®. From the results, it was concluded that F-MELT® showed good disintegration properties. As a result, dissolution occurs at a good rate.

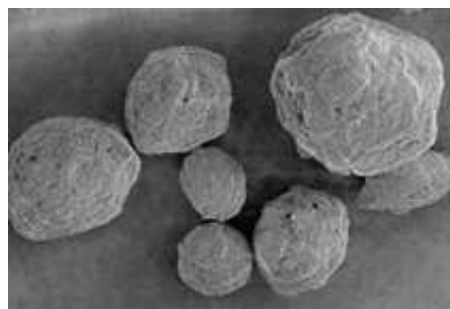


Figure 4: F-MELT® directly compressed excipient for oral disintegrating tablets

Pharmaburst

It is a quick-dissolving delivery technique. Pharmaburst is a co-processed excipient that enables the quick disintegration of tablets. The method of incorporation of Pharmaburst into tablet formulations was direct compression. It contains specific excipients which ensure rapid breakdown. For its performance and versatility, Pharmaburst 500 is the current gold standard. It's a popular choice among formulators because it solves development problems while also producing high-quality products.

Mannogem EZ

It showed excellent swelling properties. Low hygroscopicity for protection against moisture. It dissolved quickly. Higher production rates are possible with Mannogem Mannitol direct compression grades. It showed excellent Palatability through a creamy texture and mild sweetness.²²

Glucidex IT

It is made from starch that has been moderately hydrolyzed. Its microgranulated structure forms immediate dispersion in water. It also disintegrates rapidly into water. Different types of Glucidex IT products are available. It can be employed in the formulation of tablets, capsules. It functions as a binder in tablet formulation. The direct compression method is used in the preparation. It can be used in the formulation of vitamins and supplement tablets.²³

Polacrillin Potassium

Research studies had been performed on the effect of Polacrillin Potassium as Disintegrant on Bioavailability of Diclofenac Potassium Tablets (used as a model anionic drug). The effect of Polacrillin Potassium on the permeability of Diclofenac Potassium was studied using *in-vitro* and *in-vivo* methods. Results showed that Polacrillin Potassium acts as a good disintegrant and improved the solubility of tablets. It is a self disintegrant co-excipient.

Excipients that have been processed play an important role in the preparation of simple dosage forms that are robust to the environment. Flow ability, compressibility, hygroscopicity, palatability, dissolution, disintegration, sticking, capping and dust problems have all been solved due to the better physical, chemical, and mechanical properties of such excipients as compared to conventional excipients.²⁴

Table 2: Recent literature on fast dissolving tablets prepared by use of Novel superdisintegrants

Name of drug	Superdisintegrants	Method of Compression	Ref
Paracetamol, gabapentin	Chitin Silicon-dioxide	Direct compression	25
Aceclofenac	Starch Xanthate	Direct compression	26
Nimesulide	Starch Silicon-dioxide Coprecipitates	Direct compression method	27
Diclofenac sodium	Pea starch	Direct compression method	28
Olopatadine HCL	Crosscarmellose, Sodium starch glycolate, Crosspovidone (XL10)	Fluidized bed granulation method	29
Domperidone	Corn Starch-Neusilin UFL2 Conjugate	Direct compression	30
Pyrimidine maleate	<i>Salvia hispanica</i>	Direct compression	31
Nimesulide	<i>Lepidium sativum (Cruceferae)</i>	Direct compression	32
Diclofenac sodium	<i>Angle marmelos</i>	wet granulation	33
Irbesartan	Jackfruit	Direct compression	34
Diclofenac	<i>Abelmoschus esculentus</i>	Wet granulation	35
Diclofenac sodium	<i>Cucurbita maxima</i>	Direct compression	36
Piroxicam	Starch tartrate	Direct compression	37

FACTORS AFFECTING THE SWELLING BEHAVIOUR OF SUPERDISINTEGRANTS

Some factors influence the disintegration mechanism of superdisintegrants. These factors mainly affect the swelling behavior of superdisintegrants. As a result, dissolution and bioavailability generally get affected. These factors are as follows:

- **Ph values:** It mainly affects the ionizable groups of superdisintegrants.³⁸
- **Binders:** If we increase the concentration of binders in a tablet formulation, it results in enhancing the disintegration process.
- **Insoluble diluents:** The presence of insoluble diluents in a tablet formulation enhances the disintegration mechanism of tablets. For example, formulations made from spray-dried lactose (soluble filler) showed a slow disintegration mechanism. As a result, dissolution occurs slowly.
- **Mode of addition of superdisintegrants:** Superdisintegrants can be added by Intragranular, Extragranular, or use of both steps. Intragranular method results in the breaking of tablets into finer particles. The Intragranular method allows erosion of granules to fine particles.³⁹
- **Amount of superdisintegrant added:** For the development of adequate swelling to the outer membrane, a small amount of superdisintegrant is required.⁴⁰ One gram of superdisintegrants absorbs 10-40 g of water or aqueous solution. A small amount of concentration of superdisintegrants is sufficient to produce adequate swelling.⁴¹

APPLICATIONS OF SUPERDISINTEGRANTS

Different types of recently discovered excipients of superdisintegrants play a vital role in the disintegration mechanism. The advancements in the field of formulation of Fast disintegrating tablets are targeted at improving the dosage form's performance while also reducing the

disintegration time.⁴² Many superdisintegrants are available in the market, the search for newer disintegrating agents is going. Researchers are experimenting with several multifunctional superdisintegrants such as polyplasdone Superdry, kollidone CL-F, starch 1500, etc.⁴³

The use of superdisintegrants in a variety of formulations, as well as developments that have already been patented, are as follows:

1. **Fast disintegrating tablets** (US20050169986): Research work was carried on the fast disintegrating tablets containing Diclofenac sodium and various types of disintegrants such as croscarmellose cellulose, crospovidone, and sodium starch glycolate. However, research work was also carried on fast disintegrating tablets of diclofenac sodium by using natural superdisintegrants.⁴⁴
 2. **Disintegrating Loadable Tablets** (US20090186081): A disintegrant, or a mixture of disintegrants, must have a hardness of at least 20 Newton, a porosity of at least 40-45 percent v/v, and a loading capacity of at least 30 % of a liquid.
- Method of producing fast dissolving tablets** (US20100074948): This method is more efficient. This method does not require any granulation steps. The sugar alcohol that dissolves quickly is chosen such as mannitol, sorbitol, erythritol, xylitol, lactose. This method is mostly used because it is cost-effective. This method provides satisfactory results.
3. **Rapidly disintegrating tablet:** Research studies were performed on the Rapidly disintegrating tablets. Microcrystalline cellulose was also used. Amoxicillin and clavulanic acid (antibiotics) were used in this research work.⁴⁵

The use of superdisintegrants in tablets, capsules mouth-dissolving films is increasing day by day. The disintegration time of oral dispersible tablets (ODTs) and quick dispersible tablets, in particular, is optimized. Within a minute, ODTs must dissolve in the presence of saliva.⁴⁶ As a result, these formulations improve patient compliance in all age groups,

from pediatrics to geriatric. Table 3 shows the data for several superdisintegrants and the number of patents for each. It is a combination of data from the National Institute of Standards and Technology (NIC) and the United States Patent and Trademark Office (USPTO).⁴⁷

SELECTION OF AN OPTIMAL SUPERDISINTEGRANT

- Formulators no longer choose disintegrants based on the shortest disintegration time because the effect of the superdisintegrant on dissolution must also be considered. Drug dissolution is an important process for absorption by the body.⁴⁸
- Croscarmellose sodium and sodium starch glycolate can interact with cationic APIs and slow dissolution. Therefore, formulators must have considered the ionic, non-ionic nature of superdisintegrants, and also the impact of superdisintegrants on the characteristics of a dosage form. The requirement for the tablet disintegrant should be specified.⁴⁹
- In the case of immediate-release tablets, it becomes necessary to choose an effective disintegrant. In the past years, research was performed on the disintegration property of orange peel pectin as a superdisintegrant. The Diclofenac sodium (NSAIDs), used as a model drug. The outcome demonstrated that the orange peel pectin gave immediate disintegration of tablets.⁵⁰ In the case of poorly soluble APIs, it becomes important to choose an optimal superdisintegrant.
- The stronger the binder, the more effective must be the disintegrating agent.⁵¹

ADVANTAGES OF SUPERDISINTEGRANTS⁵²

- Compatible with commonly used therapeutic agents and excipients.
- Wetting has an unusual tendency to cause rapid disintegration.
- Patient compliance and provides onset action.
- There is no formation of lumps.
- Gives the tablet good mechanical strength.
- Eco-friendly, cheaper and some are easily available.

DISADVANTAGES OF SUPERDISINTEGRANTS⁵³

- Unstable for moisture-sensitive drugs.

- Hygroscopic in nature.
- Unsuitable for water-sensitive drugs.
- Some superdisintegrants cause irritation and toxicity.

NOVEL USE OF SUPERDISINTEGRANTS AS VISCOSITY ENHANCER⁵⁴

Research work was performed on the use of superdisintegrants as viscosity enhancer agents in biocompatible polymer films containing griseofulvin nanoparticles. Crospovidone, Sodium Starch Glycolate, Croscarmellose sodium were used as superdisintegrants along with Low MW HPMC, and high MW HPMC in the research studies. Griseofulvin, used as a model drug. From the evaluation parameters, the following results were concluded;

- In drug-loaded films, superdisintegrants were utilized as viscosity-enhancing agents (VEAs).
- Reduced aggregation.
- Increased the stability of drug nanoparticles in films.
- The performance of recently investigated superdisintegrants was superior to that of standard VEAs.
- High consistency of drug content and surface area retention.
- The use of superdisintegrants resulted in faster drug disintegration while also maintaining film strength.

Table 3: Superdisintegrant with their number of patents⁴⁷

Superdisintegrants	Patents
Co-processed starch	9
Chitin	3
Amylose	14 (highest patents)
Cellulose+methylacrylic acid	4
N-Vinyl pyrrolidone+sodium starch glycolate	15 (highest patents)
Compressed guar gum	3
Granulated starch + veegum	1(lowest patent)

Table 4: Examples of High-functionality excipients^{22,55}

Excipient	Manufacturer	Company
Mannogem® EZ	Spray-dried Mannitol	SPI Pharma
Mannogem®XL	Spray-dried Mannitol	SPI Pharma
Advantose® 100	Spray-dried Maltose	SPI Pharma
Advantose® FS95	Spray-dried Fructose	SPI Pharma
Tabulose®	Colloidal Microcrystalline Cellulose	Roquette Pharma
Pearlitol® Flash	Mannitol, starch	Roquette Pharma
Soluplus®	Polyethylene glycol polyvinyl acetate Polyvinylcaprolactame	BASF Pharma
HiCel™ HFE	Microcrystalline Cellulose, Mannitol	Sigachi Industries Pvt. Ltd
HiCellac™ 80 and 100	Microcrystalline Cellulose Lactose Monohydrate	Sigachi Industries Pvt. Ltd

Xylisorb®	Xylitol	Roquette Pharma
Prosolv® EASYtab Nutra CM	Microcrystalline Cellulose Silicon Dioxide Croscarmellose Sodium Magnesium Stearate	JRS Pharma
Sepitrap™ 80	Magnesium Aluminometasilicate Polysorbate 80 Sodium Magnesium Stearate	SEPPIC
Compressol® SM	Mannitol, Sorbitol	SPI Pharma
Lubripharm® SSF	Sodium Stearyl Fumarate	SPI Pharma
Prosolv® EASYtab Nutra CM	Microcrystalline Cellulose Silicon Dioxide Croscarmellose Sodium Magnesium Stearate	JRS Pharma

CONCLUSIONS

The use of recently investigated superdisintegrants in various pharmaceutical applications is increasing because they show faster disintegration. Superdisintegrants are essential in the formulation of oral dissolving tablets. These agents aid and facilitate tablet disintegration into smaller fragments. The selection criteria and methodology of various types of superdisintegrants have been researched and incorporated. The method of superdisintegrants addition by direct compression has gained popularity among researchers. FDTs typically have lower mechanical strength. FDTs with sufficient mechanical strength can be prepared using some new technologies and additives.

There is a huge opportunity for research on newer gums and mucilages derived from plants, which could be further exploited in the future as a novel natural polymer for the development of various drug delivery systems in the pharmaceutical industry. Superdisintegrants that swell showed slight retardation of disintegration due to the formation of a viscosity barrier. Future trends in drug delivery systems will continue to bring together different technological disciplines and formulation aspects to create novel superdisintegrants.

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