

# Utility of Synthetic Disintegrant in Design of Orally Disintegrating Tablet

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**Abstract**—Orally Disintegrating Tablets (ODTs) are solid dosage forms that rapidly disintegrate in the mouth without water, improving compliance in paediatric, geriatric, and dysphagia patients. Other fast-dissolving systems include oral films, fast caps, medicated gums, and freeze-dried wafers. Excipients are crucial for enhancing stability, palatability, compressibility, and bioavailability. Among them, super disintegrants play a key role in promoting rapid disintegration and dissolution. Synthetic types (croscopovidone, croscarmellose sodium, sodium starch glycolate, Low-Substituted Hydroxypropyl Cellulose, natural polymers (*Plantago ovata*, guar gum, chitosan), and co-processed blends are widely used. Their mechanisms include swelling, wicking, and strain recovery. The integration of such multifunctional excipients enables fast onset of action, improved absorption, and better therapeutic outcomes.

**Keywords**—Orally Disintegrating Tablets; Fast caps; Medicated Chewing gums; Freeze dried wafers; Synthetic disintegrants; *Plantago ovata*; Locust bean gum.

## I. INTRODUCTION

Orally Disintegrating Tablets (ODTs) are solid dosage forms that rapidly dissolve or disintegrate in the oral cavity upon contact with saliva, forming a suspension or solution. This property makes them particularly suitable for patients who experience difficulty swallowing conventional tablets or capsules, as administration becomes simpler and more convenient often without the need for water<sup>1</sup>. Swallowing difficulties are especially common among paediatric, geriatric, and psychiatric populations, which can lead to poor medication compliance and reduced therapeutic effectiveness. For example, geriatric patients frequently suffer from dysphagia (difficulty in swallowing), making traditional dosage forms challenging to use. ODTs overcome these limitations by disintegrating quickly in the mouth and releasing the active pharmaceutical ingredient (API) for immediate absorption, thereby facilitating rapid onset of therapeutic action<sup>2</sup>.

This technique provides several advantages, such as reduced processing time, lower manufacturing costs, and minimized exposure of moisture-sensitive drugs to water, thereby improving stability. In the formulation of oral Disintegrating Tablets (ODTs), the use of super disintegrants plays a vital role in achieving rapid tablet breakup upon contact with saliva. These agents disrupt the tablet matrix, facilitating quick disintegration, faster drug release, and enhanced dissolution of the active ingredient, ultimately leading to improved absorption and therapeutic effectiveness<sup>3</sup>.

## II. TYPES OF DOSAGE FORMS

### A. Orally Disintegrating Tablets (ODTs)

These are tablets designed to dissolve or disintegrate rapidly in the oral cavity without the need for water or chewing, offering convenience to patients with swallowing difficulties<sup>4</sup>.

### B. Fast-Dissolving Films (FDFs)

Despite the rapid disintegration of ODTs, some patients still experience a fear of swallowing solid dosage forms and a risk of choking. Fast-dissolving films are ultra-thin oral strips that release the active ingredient immediately upon contact with saliva. They combine the benefits of both tablets and liquid dosage forms, as the strip is placed on the tongue or mucosal surface, where it quickly hydrates, dissolves, and delivers the medication<sup>5</sup>.

### C. Fast Caps

This novel dosage form is based on gelatin capsules formulated with low-bloom strength gelatin and specific additives to enhance their mechanical strength and dissolution properties. Unlike conventional hard gelatin capsules, Fast Caps allow high drug loading, can accommodate both solid and liquid fillings, and do not require compression of coated taste-masked or extended-release particles. They also offer simple manufacturing, good stability, and mechanical robustness, though they may require special packaging<sup>6</sup>.

### D. Medicated Chewing Gums

These provide an innovative and convenient drug delivery option, functioning as a controlled-release system during chewing. They are particularly useful for pain relief, smoking cessation, motion sickness, and oral health applications such as breath freshening<sup>7</sup>.

### E. Freeze-Dried Wafers

These are thin, fragile matrices containing a medicinal agent that disintegrates almost instantly in the oral cavity without the need for water. Due to their delicate structure, they require unit-dose packaging for stability. Once disintegrated, the drug dissolves or disperses in saliva and is subsequently absorbed through the gastrointestinal tract<sup>8</sup>.

### III. EXCIPIENTS

Excipients are broadly defined as the non-active components of a formulation that support the delivery of the active ingredient. As drug compounds become increasingly complex to formulate, the demand for innovative excipients has grown. These advanced excipients are now essential in the development, manufacture, and performance of modern dosage forms<sup>9</sup>.

In recent years, traditional excipients have been replaced with more sophisticated, multifunctional compounds that not only improve the stability and bioavailability of the active ingredient but also enhance patient acceptability. Compared to conventional options, these improved excipients exhibit superior physical and mechanical properties, helping to address critical formulation challenges such as flowability, compressibility, hygroscopicity, palatability, dissolution, disintegration, sticking, and dust generation<sup>10,11</sup>.

An ideal bulk excipient for orally disintegrating dosage forms should possess the following properties

- Disperses and dissolves rapidly in the mouth within a few seconds, leaving no residue.
- Masks the unpleasant taste of the drug and provides a pleasant mouthfeel.
- Remains stable and unaffected by variations in humidity and temperature.
- Physiologically inert and safe for consumption.
- Chemically and physiologically stable throughout its shelf life.
- Free from microbial contamination.
- Does not interfere with the drug’s bioavailability.
- Commercially available in pharmaceutical-grade form and purity.
- Cost-effective and affordable.
- Complies with regulatory standards and requirements<sup>12,13</sup>.

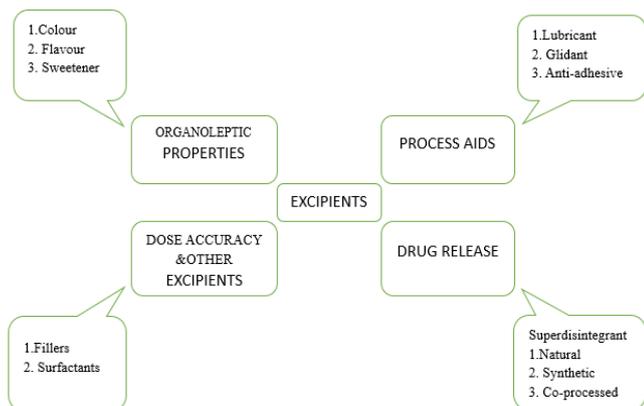


Figure 1: Various excipients used for formulation of orally disintegrating tablet

#### A. Diluents

Diluents, also known as fillers, are inert substances added to tablet formulations to increase the bulk when the drug dosage itself is insufficient to produce the desired tablet size. In dispersible and orally disintegrating tablets (ODTs), certain diluents also function as disintegrants, thereby improving the performance of the dosage form<sup>14,15</sup>.

TABLE 1: Commonly diluents used in ODTs

Diluents	Brand name	Properties
Mannitol	Pearlitol® SD200, Pearlitol® 25C	Pleasant cooling effect, sweet taste, good mouthfeel, high aqueous solubility, enhances patient acceptability.
Lactose (Spray-dried lactose)	FastFlo® Lactose	Good compressibility, slight sweetness, improves palatability, cost-effective.
Microcrystalline Cellulose (MCC)	Avicel® PH101, Avicel® PH102	Excellent binding property, enhances compressibility, promotes rapid disintegration, inert and stable.
Sorbitol	Neosorb®	Functions as diluent + sweetener, good mouthfeel, water-soluble, improves taste.
Dibasic Calcium Phosphate Dihydrate	Emcompress®	Good flow property, insoluble in water, stable, improves tablet hardness, used when high mechanical strength is needed.
Xylitol	Xylisorb®	Provides sweetness and cooling effect, non-cariogenic, improves taste masking, enhances patient compliance.

#### A. Binders

Binders are excipients added to tablet formulations to impart cohesive strength, ensuring that the powdered ingredients remain compressed and intact after tableting. They help convert loose powders into granules with sufficient hardness and mechanical stability. Binders can be incorporated in either dry or wet form during granulation, depending on the formulation requirements<sup>16,17</sup>.

TABLE 2: Commonly used binders in ODTs

Binder	Brand Name	Properties
Polyvinyl pyrrolidone (PVP / Povidone, K-30, K-90)	Kollidon® K30, Kollidon® K90	Excellent binding capacity, water-soluble, improves tablet hardness and stability, enhances dissolution of poorly soluble drugs.
Hydroxypropyl Cellulose (HPC)	Klucel®	Water-soluble, good film-forming property, enhances tablet integrity, promotes rapid disintegration at low concentration
Methylcellulose (MC)	Methocel®	Improves cohesiveness of powder blend, provides moderate viscosity, enhances disintegration.
Acacia (Gum Arabic)	Natural gum	Natural binder, good cohesiveness, biodegradable, but less commonly used due to variability.
Gelatin	Pharma-grade gelatin	Strong natural binder, forms elastic cohesive matrix, enhances tablet strength, dissolves rapidly in saliva.

#### B. Super disintegrants

Disintegrants are excipients incorporated into tablet formulations to facilitate the breakup or disintegration of the dosage form into smaller particles upon contact with fluids. This enhances the dissolution rate of the drug and promotes faster absorption. Super disintegrants are specially developed excipients that act more efficiently and at lower concentrations compared to conventional disintegrants. They are particularly important in the formulation of fast-disintegrating and orally disintegrating tablets (ODTs) to improve patient compliance, especially for paediatric, geriatric, and dysphagia patients<sup>18,19</sup>.

**Advantages of Super disintegrants**

- Rapid Disintegration
- Enhanced Bioavailability
- Low Concentration Required
- Patient Compliance
- Improved Drug Solubility
- Compatibility
- Effective at Various pH Levels
- Masking Unpleasant Taste
- Reduced Risk of Dose Dumping<sup>18</sup>

**Methods of Addition of Super disintegrants**

Super disintegrants can be incorporated into tablet formulations by different approaches

1. **External addition (Extragranular method)**  
The super disintegrant is added to the granules just before compression. This helps in rapid disintegration at the tablet surface.
2. **Internal addition (Intragranular method)**  
The super disintegrant is added during granulation. This promotes breakup of the tablet mass from within.
3. **Partially Internal and External Addition (Combination method)**  
A portion of the super disintegrant is added during granulation (internal), while the remaining part is added to the final blend before compression (external). This dual approach enhances both the rate and extent of disintegration<sup>22</sup>.

**Classification of Super disintegrants**

Super disintegrants are classified based on their source of origin

- **Synthetic super disintegrants:** e.g., Cross-linked polyvinyl pyrrolidone (Crospovidone), Croscarmellose sodium, Sodium starch glycolate.
- **Natural super disintegrant:** e.g., Plantago ovata (ispaghula husk), guar gum, fenugreek seed mucilage, gum karaya, locust bean gum, chitosan.
- **Co-processed superdisintegrants :** Mixtures of two or more excipients processed together to improve functionality, e.g., Crospovidone + MCC, Croscarmellose sodium + Lactose<sup>20,21</sup>.

**Mechanisms of Action**

Synthetic superdisintegrants act through one or more of the following mechanisms<sup>23,24,25</sup>

1. **Swelling:** They absorb water and expand, exerting pressure within the tablet matrix, leading to rupture and breakup.

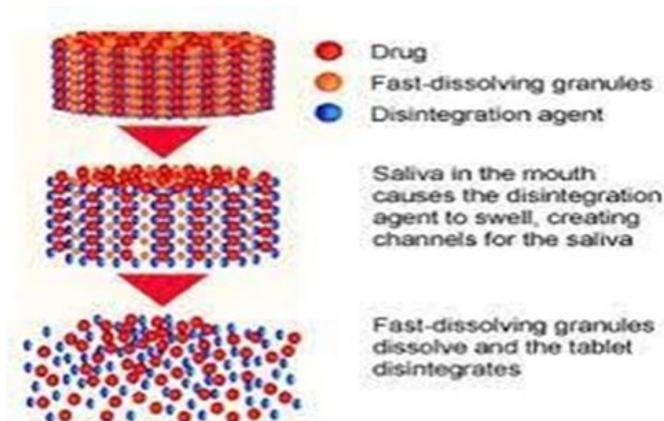


Figure 2: Swelling mechanism of ODT

2. **Wicking (Capillary Action):** They draw water into the porous structure of the tablet, which disrupts particle-particle bonds and promotes disintegration.

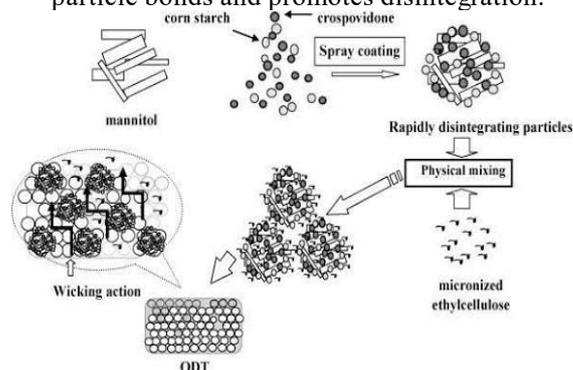


Figure 3: Wicking mechanism of ODT

3. **Strain Recovery (Elastic Recovery):** Particles that were deformed during compression expand upon exposure to fluids, aiding in the disintegration process.

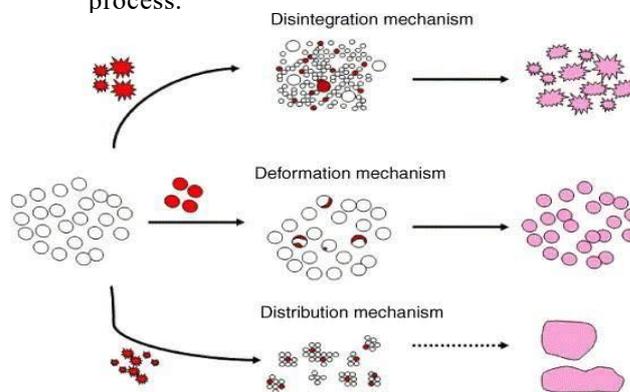


Figure 4: Deformation mechanism of ODT

**Synthetic Superdisintegrants**

Synthetic superdisintegrants are chemically engineered excipients specifically designed to enhance the rapid disintegration of tablets upon contact with moisture. They are often modified to optimize key properties such as swelling capacity, wicking ability, and hydration, which together facilitate the breakup of the tablet matrix. These excipients are

widely employed in tablet formulations to accelerate disintegration, improve dissolution, and enhance solubility, thereby increasing the bioavailability of drugs<sup>1,26,27</sup>.

TABLE 3: Commonly used super disintegrant in ODTs

Name	Brand name	Mechanism	Typical use (%)
Crospovidone	Kollidon® CL, Polyplasdone® XL	Wicking, strain recovery	2-5
Croscarmellose Sodium	Ac-Di-Sol®, Vivasol®, Solutab®	Swelling + wicking	0.5-5%
Sodium Starch Glycolate (SSG)	Explotab®, Primojel®	Swelling (gel formation)	2-8%
Low-Substituted Hydroxypropyl Cellulose (L-HPC)	Nisso HPC®	Swelling + disintegration	1-6%

formulations, especially in tablets and capsules, to promote rapid disintegration and drug release.

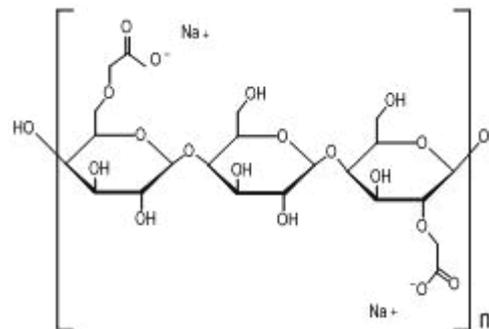


Figure 5: Structure of Croscarmellose sodium

### 1. Crospovidone

It is a cross-linked, insoluble homopolymer of N-vinyl-2-pyrrolidone. Unlike povidone (PVP), it is insoluble in water but has excellent swelling and wicking properties, making it an efficient disintegrant.

#### Advantages

- Fast and efficient disintegration, even at low concentration (2–5%).
- Does not form a viscous gel upon hydration (unlike sodium starch glycolate or croscarmellose sodium).
- Good flow properties and it helps in direct compression.
- Stable and compatible with most drugs.

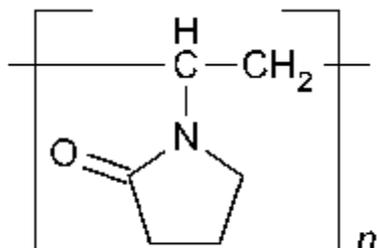


Figure 4: Structure of Crospovidone

### Advantage

- Extremely effective at low concentrations
- Provides very rapid disintegration and dissolution
- Particularly useful in immediate-release tablets
- Works well in direct compression and wet granulation
- Compatible with most drugs and excipients

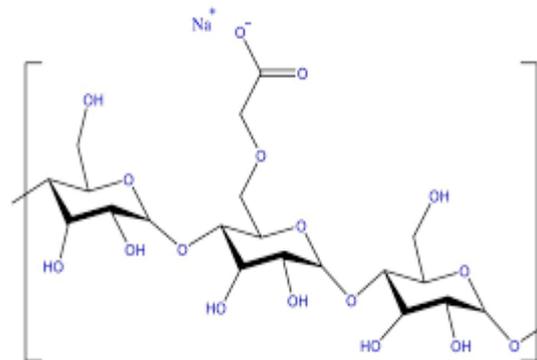


Figure 6: Structure of Sodium starch glycolate

### 2. Croscarmellose sodium

It is a cross-linked derivative of sodium carboxy methyl cellulose and is widely used in pharmaceutical formulations as a super disintegrant. It facilitates rapid tablet disintegration and promotes drug dissolution, thereby improving bioavailability.

#### Advantage

- Very effective at low concentration.
- Works well in both direct compression and wet granulation methods.
- Provides fast disintegration due to high water uptake and swelling.
- Stable, inert, and compatible with most drugs.

### 3. Sodium starch glycolate

Sodium starch glycolate is the sodium salt of a cross-linked carboxy methyl ether of starch. It is one of the most commonly used superdisintegrants in pharmaceutical

### 4. Low substituted hydroxyl propyl cellulose

It is a partially substituted, water-insoluble cellulose derivative widely used as a super disintegrant and binder in oral solid dosage formulations. Its unique balance of hydrophilicity and insolubility enables rapid water penetration and tablet disintegration without forming a viscous gel.

#### Advantage

- Combines binder + disintegrant functionality.
- Rapid disintegration due to swelling without gel formation.
- Useful in direct compression and wet granulation.
- Non-toxic, stable, and compatible with most APIs.
- Improves mechanical strength of tablets while ensuring fast disintegration.

#### Natural Superdisintegrants

These are excipients of biological origin that are incorporated into tablet formulations to facilitate rapid disintegration. They are often preferred over synthetic counterparts because they are biodegradable, biocompatible, cost-effective, and non-toxic, with a wide availability from natural sources. In addition, natural superdisintegrants are

generally safe for long-term use and acceptable to patients seeking plant- or naturally derived ingredients<sup>28,29</sup>.

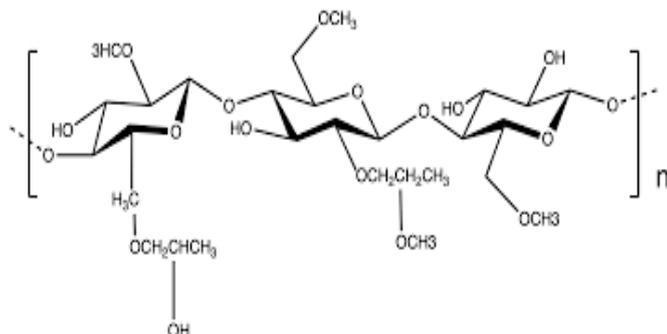


Figure 7: Structure of L-HPC

TABLE 4: Commonly used natural disintegrant in ODTs

Natural Polymer	Source	Mechanism	Typical Use (%)
Plantago ovata mucilage (Ispaghula husk)	Seeds of Plantago ovata	Swelling	2–8%
Guar gum	Seeds of Cyamopsis tetragonoloba	Swelling	1–5%
Locust bean gum	Seeds of Ceratonia siliqua	Swelling	2–6%
Lepidium sativum mucilage	Garden cress seeds	Swelling and wicking	2–6%
Mango peel pectin	Mangifera indica peel	Swelling	1–5%
Gellan gum	Fermentation by Sphingomonas elodea	Gelation, swelling	1–3%
Chitosan	Derived from crustacean shells	Swelling, electrostatic interaction	1–6%

### Co-processed Superdisintegrants

Co-processed superdisintegrants are multifunctional excipients developed by combining two or more ingredients at the sub-particle level using techniques such as spray drying, melt extrusion, or co-spray drying. The goal of co-processing is to overcome the limitations of individual disintegrants and enhance their performance by improving flowability, compressibility, and disintegration efficiency. These excipients are particularly valuable in the formulation of orally disintegrating tablets (ODTs) and other fast-disintegrating dosage forms, where rapid breakdown and patient compliance are critical<sup>30,31</sup>.

TABLE 5: Commonly used Co-processed disintegrant in ODTs

Name	Components	Key Functions
Ludi flash®	Mannitol + Crospovidone + Polyvinyl acetate	Filler + super disintegrant + binder
F-Melt® Type C/D	MCC + Crospovidone + Mannitol + Inorganic excipients	Filler + disintegrant
Pharma burst® 500/500 Plus	Mannitol + Sorbitol + Crospovidone + Lubricants	Filler + sweetener + disintegrant
Prosolv® ODT	MCC + Colloidal silica + Crospovidone + Mannitol	Filler + disintegrant + glidant
Disintequik™ ODT	Mannitol + Starch + Crospovidone	Filler + disintegrant

### C. Lubricants

Lubricants are excipients used in tablet manufacturing to reduce friction between the tablet and the die wall during compression. They prevent adhesion of the tablet mass to the dies and punches, thereby facilitating smooth ejection of tablets from the die cavity. Lubricants are broadly classified into two types

- Insoluble lubricants: Stearic acid, magnesium stearate, calcium stearate, talc, paraffin.
- Water-soluble lubricants: Sodium lauryl sulfate (SLS), sodium benzoate, polyethylene glycols (PEG 400, 600, 800, etc.)<sup>32,33</sup>.

TABLE 6: Commonly lubricant used in ODTs

Lubricant	Brand Name	Properties
Magnesium Stearate	Ligamed® MF-2-V, Ligamed® MF-3-V	Most widely used hydrophobic lubricant, prevents sticking to punches/dies,
Stearic Acid	– (pharma grade available)	Insoluble, provides good lubrication, prevents sticking, but can slow down drug release if used in excess.
Calcium Stearate	–	Acts as lubricant and flow aid, stable, used for moisture-sensitive formulations.
Talc	Pharmatalc®	Functions as both glidant and lubricant, prevents adhesion and enhances flow
Sodium Stearyl Fumarate	PRUV®	Hydrophilic lubricant, better suited for ODTs than magnesium stearate
PEGs (Polyethylene Glycols: PEG 4000, PEG 6000, PEG 8000)	Carbowax®	Water-soluble lubricants, improve mouthfeel, avoid hydrophobicity, suitable for fast-disintegrating formulations.

### D. Glidants

These are excipients added to tablet formulations to improve the flow properties of powders or granules. They facilitate the smooth movement of material from the hopper into the die cavity by reducing interparticle friction and cohesion. This ensures uniform filling of dies and consistent tablet weight<sup>34,35</sup>.

TABLE 7: Commonly used glidant in ODTs

Glidant	Brand Name	Key Properties
Colloidal Silicon Dioxide	Aerosil® 200, Cab-O-Sil®	Improves flowability of powders and granules, reduces interparticle friction, enhances uniform die filling, inert and chemically stable.
Talc	Pharmatalc®	Functions as both glidant and lubricant, improves flow and prevents sticking, inert and safe for oral use.
Corn starch	– (USP grade)	Natural glidant, improves powder flow, also acts as disintegrant in some formulations, biodegradable.
Magnesium Trisilicate	–	Reduces interparticle friction, improves flow, inert in formulation, sometimes used in combination with other glidants.
Hydrated Silica	Zeosil®	Improves flowability and powder dispersibility, compatible with most APIs, non-toxic.

### E. Anti-adhesive (or anti-adherents)

These are excipients incorporated into tablet formulations to prevent the sticking or adhesion of tablet material to the

surfaces of manufacturing equipment. Their role is essential for ensuring smooth tablet production, maintaining equipment efficiency and achieving uniform tablet quality<sup>36,37</sup>.

TABLE 8: Commonly anti adhesive used in ODTs

Excipient	Brand name	Properties
Talc	Pharmatalc®	Lubricant + anti-adhesive; hydrophobic
Colloidal Silicon Dioxide (Aerosil)	Aerosil® 200, Cab-O-Sil®	High surface area, improves flow, reduces adhesion
Magnesium Stearate	Ligamed® MF-2-V, Ligamed® MF-3-V	Primarily a lubricant, also provides anti-adherent effect
Calcium Stearate	--	Lubricant and anti-adherent in direct compression
Stearic Acid	--	Fatty acid-based, provides both lubrication and adhesion control

### F. Flavours

These are excipients incorporated into pharmaceutical dosage forms to mask unpleasant tastes such as bitterness, sourness or metallic aftertastes of active pharmaceutical ingredients (APIs). They enhance palatability, improve patient acceptability, and are especially important in paediatric and orally disintegrating formulations<sup>38</sup>.

TABLE 8: Common flavouring agents used in ODTs

Flavour	Application	Properties
Strawberry	Pediatric formulations	Sweet, fruity, widely accepted
Orange	All age groups	Fresh, slightly tangy
Mint / Peppermint	Adult and geriatric	Cooling effect, masks bitterness
Chocolate / Vanilla	Nutraceuticals, pediatric	Smooth, comforting taste

### G. Sweeteners

Sweeteners are excipients incorporated into pharmaceutical formulations to mask the unpleasant or bitter taste of active pharmaceutical ingredients (APIs), thereby improving palatability and enhancing patient compliance, particularly in paediatric and geriatric populations<sup>36,39</sup>.

#### Types of Sweeteners

- Natural sweeteners
- Artificial sweeteners

TABLE 9: Commonly Used Sweeteners in ODTs

Sweetener	Type	Brand name	Properties
Sucrose	Natural	Table Sugar, Saccharose	Sweet, water-soluble, adds bulk
Mannitol	Natural (polyol)	Pearlitol®SD200, Pearlitol® 25C	Cooling effect, non-cariogenic, good mouthfeel
Sorbitol	Natural (polyol)	Neosorb®	Humectant, low-calorie
Fructose	Natural	Fructopure®, krystar®	Sweeter than sucrose, hygroscopic
Stevia (Stevioside)	Natural	Rebaudioside A, Stevia Leaf Extract	Zero-calorie, plant-derived
Aspartame	Artificial	NutraSweet®, Equal®	Low calorie, good taste, not heat-stable
Sucralose	Artificial	Splenda®	Stable, high-intensity sweetener
Saccharin	Artificial	Sweet'N Low®, Sweet Twin®	Metallic aftertaste at high doses

### H. Surfactants

Surfactants, or surface-active agents, are compounds that reduce surface tension at the interface between two phases, such as solid–liquid, liquid–liquid, or liquid–air systems. In pharmaceutical formulations, they play a crucial role in enhancing solubility, wettability, disintegration, dissolution, and overall bioavailability of drugs. Surfactants are particularly valuable in orally disintegrating tablets (ODTs), where they promote rapid drug dispersion in saliva and facilitate faster absorption<sup>40</sup>.

TABLE 10: Common Surfactants in ODT Formulations

Surfactant	Type	Properties
Sodium Lauryl Sulfate (SLS)	Anionic	Improves wetting and dissolution
Polysorbate 80 (Tween 80)	Non-ionic	Solubilizer for lipophilic APIs
Span 20, 60, 80	Non-ionic	Used in solid dispersions
PEG 400 / PEG 6000	Non-ionic	Solubilizer, plasticizer
Lecithin	Zwitterionic	Used for emulsification and taste masking
Cremonophor RH40	Non-ionic	Used for poorly soluble drugs
Labrasol	Non-ionic (capryl caproyl macrogol-8 glyceride)	Enhances oral absorption

## IV. FUTURE OUTLOOKS OF EXCIPIENTS

The future outlook of pharmaceutical excipients is highly promising, focusing on enhancing drug performance through innovation and functionality. New generations of smart and multifunctional excipients are being developed to improve solubility, stability, and bioavailability of drugs. There is an increasing trend toward the use of natural, biocompatible, and eco-friendly materials, aligning with sustainable pharmaceutical practices.

Co-processed and novel excipients are expected to play a vital role in advanced drug delivery systems and rapidly disintegrating formulations. With the integration of digital tools, Quality by Design (QbD), and regulatory support, excipient development is becoming more efficient and science-driven, paving the way for personalized and 3D-printed medicines in the future<sup>41,42</sup>.

## V. CONCLUSION

Excipients play a pivotal role in the successful formulation of orally disintegrating tablets (ODTs), as they directly influence tablet stability, disintegration, taste, mouthfeel, and overall patient acceptability. Among them, diluents enhance bulk and palatability, binders provide mechanical strength, and superdisintegrants ensure rapid breakup of the tablet upon contact with saliva. Lubricants and glidants facilitate smooth manufacturing, while flavours and sweeteners improve taste-masking and compliance. Additionally, surfactants enhance solubility and drug dispersion, further improving bioavailability. The advancement of multifunctional and co-processed excipients has significantly improved the performance, stability, and cost-effectiveness of ODTs. Thus, careful excipient selection is essential to achieving rapid

disintegration, patient compliance, and therapeutic effectiveness in ODT formulations.

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