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Co-Processed Excipients: An Integrated Study of Preparation, Characterization, and Pharmaceutical Applications in Tablets

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ABSTRACT:

Co-processed excipients, which physically mix two or more excipients without changing their chemical makeup, have become a popular way to improve tablet performance. This review examines the flowability, compressibility, disintegration time, and mechanical characteristics of many co-processed excipients utilized in tablet formulation. Studies on co-processed excipients, such as mannitol–chitin combinations, lactose-based excipients (Cellactose® 80, CombiLac®, MicroceLac® 100, StarLac®), and xylitol–starch–croscopolvidone blends, show better tablet properties than physical mixes. The qualities of tablets are greatly influenced by several manufacturing processes, such as direct compression, freeze drying, and wet granulation. All things considered, co-processed excipients improve tablet production effectiveness and product performance, assisting in the future development of multipurpose tablet excipients. Orally disintegrating tablets (ODTs) have drawn a lot of interest since they are simple to administer and increase patient compliance, particularly for those who have swallowing issues. Making tablets with quick disintegration, strong mechanical properties, and palatable flavour is still difficult though.

INTRODUCTION:

Co-processed excipients are specifically designed mixtures of two or more pre-existing excipients that are meant to enhance their functional properties and change their physical makeup in ways that cannot be achieved by merely mixing the constituents [31]. Unlike chemical modifications, co-processing involves physical changes at the particle or sub-particle level without significant changes to the chemical structure. Sometimes this includes little in-situ chemical processes that enhance performance, such as the formation of salt. During the co-processing process, which is commonly achieved by techniques like co-drying, spray drying, granulation, or milling, one excipient is embedded into the particle structure of another. Because of their consistent

composition, pharmaceutical dosage forms particularly tablets have improved performance and manufacturability [29].

A number of significant benefits make co-processed excipients (CPEs) ideal for the manufacturing of pharmaceutical tablets [12]. These advantages include improved bulk density, higher sphericity, more porosity, and uniform distribution of particle size and shape, all of which enhance flowability and compressibility. Additionally, CPEs usually have a higher dilution potential, which means that less of them are needed to easily compress the active pharmaceutical ingredient (API) into a combination. They also have a decreased sensitivity to lubricants, which lessens the detrimental effect of glidants on compressibility [2]. Because the

**MANUSCRIPT ID: BTS0826011**

components of CPEs do not separate like they do in typical mixtures, blend homogeneity is improved. Tablets made with CPEs therefore have a tendency to dissolve more quickly and might possibly exhibit better active medication bioavailability. In the production of tablets, CPEs are frequently the preferred excipients because of these benefits. The physicochemical and compression properties of the CPE must be thoroughly understood in order to choose the best one [15]. Basic information is usually supplied by manufacturers, but it is frequently sparse, inconsistent, and not grounded in established procedures, which makes comparison challenging.

Additionally, it is difficult to directly assess any CPE's efficacy because most available research uses it in combination with other APIs or lubricants. This is addressed by the current study, which provides a thorough and comparative investigation of CPEs in their unadulterated, pure form. Generally speaking, CPEs fall into one of three major categories according to their chemical makeup and water solubility. The first and most prevalent category is organic and water-soluble, and it consists of sugar alcohols and polysaccharides like different kinds of lactose, as well as sorbitol, mannitol, and starches on occasion [24]. Microcrystalline cellulose (MCC) and its derivatives are the main organic, water-insoluble excipients in the second group. The third category, which is inorganic and water-insoluble, comprises substances like alkaline earth salts of mineral acids, such as calcium and magnesium phosphates and sulphates, and silicates, such as magnesium aluminometasilicate. (Prasanth et al., 2023)

These days, scientists have found that a single excipient frequently falls short of providing the performance needed for the production or formulation of specific active pharmaceutical ingredients (APIs) [11]. Since many excipients are made from food-grade ingredients, the excipients sector has historically developed as a continuation of the food industry. Their typically good safety profile has been aided by this genesis [34]. However, the need for increased control has been fueled by expanding regulatory expectations for increased standardization, safety, and purity (G & P, 2020). In order to solve these issues and promote the creation of superior pharmaceutical excipients, the International Pharmaceutical Excipients Council (IPEC) was founded as a global organization [20].

In order to increase patient compliance, oral disintegrating tablets (ODTs) were created in the 1970s. The best ODTs are those that dissolve quickly without the need for water, have a pleasing taste, are stable and robust, are inexpensive, easy to make (for example, by direct compression), and permit high drug loading [1]. Co-processed excipients, which combine several components, are used to improve qualities including flowability, compressibility, and homogeneity because no single excipient can satisfy all of these requirements. An ideal excipient must explicitly optimize these properties for ODT formulations, as many commercial co-processed excipients have limits for ODTs [38].

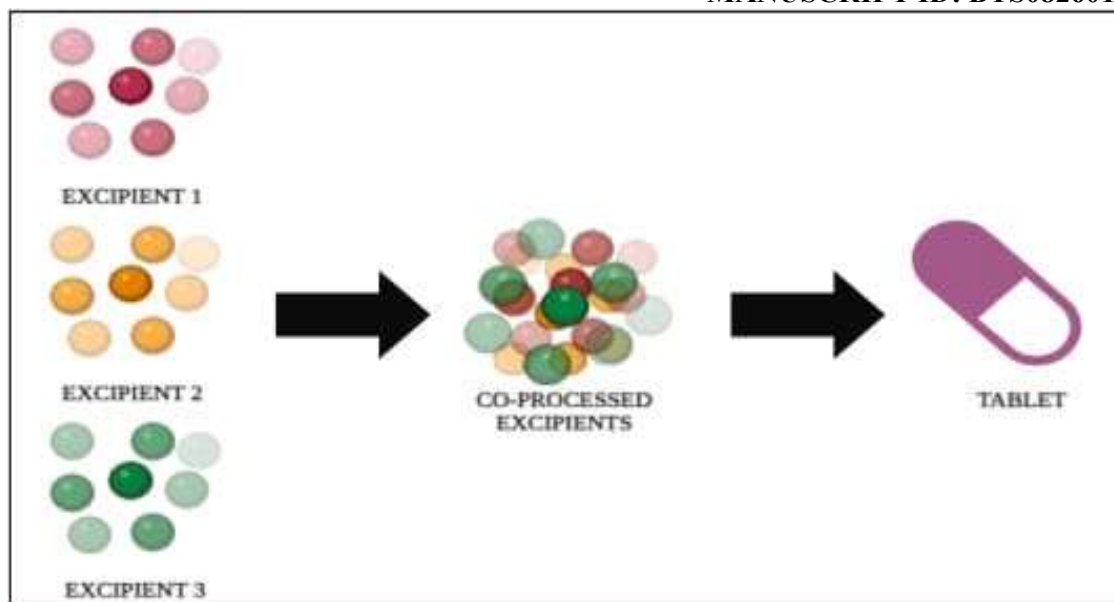


Figure no:1-The figure depicts the transformation of individual excipients into a co-processed excipient system through physical or physicochemical integration. Co-processing combines complementary properties of multiple excipients to improve flowability, compressibility, and functional performance. The resulting co-processed excipients facilitate the manufacture of robust tablets with enhanced quality and consistency.

PREPARATION OF CO-PROCESSED EXCIPIENTS:

Basic Steps in Developing Co-Processed Excipients:

1. Identification and Selection of Excipients: Determine the desired particle size and functional requirements. Analyze the material characteristics of individual excipients. Select appropriate excipients in specific proportions based on their compatibility and intended performance [26].

2. Selection of a Suitable Co-Processing Technique: Choose an appropriate manufacturing method such as melt granulation, roller compaction, spray drying, or solvent evaporation. The choice depends on the physical and chemical properties of the selected excipients and the desired end-product functionality.

3. Optimization and Final Product Development: Use optimization strategies and *Design of Experiments (DOE)* to refine process parameters [36]. The goal is to obtain a co-processed excipient with improved properties like enhanced flowability, compressibility, and functional performance suited to the intended dosage form.

The various techniques employed in the development of co-processed excipients are briefly outlined below.

Spray Drying: In this method, a solution or suspension of excipients is atomized into a hot drying chamber, where rapid solvent evaporation results in the formation of dry, spherical particles. Spray drying improves



flow properties, compressibility, and uniformity [7].

Melt Granulation: This technique involves melting a binder, mixing it with excipients, and allowing the mixture to solidify upon cooling [18]. It is solvent-free and particularly useful for moisture-sensitive materials. It results in strong, cohesive granules.

Roller Compaction (Dry Granulation): Excipients are compressed between two rollers to form dense ribbons, which are then milled into granules. This dry method is suitable for materials sensitive to moisture and heat, and it enhances flow and packing density [33].

Freeze Drying (Lyophilization): A frozen mixture of excipients is dried under vacuum, removing water by sublimation. This creates a highly porous structure ideal for fast-disintegrating formulations like ODTs.

Solvent Evaporation: Excipients are dissolved or suspended in a solvent, mixed thoroughly, and then the solvent is evaporated. This allows for uniform dispersion at a molecular level and is useful for polymer-based systems and solid dispersions [27].

MANUSCRIPT ID: BTS0826011

Co-Precipitation: Two or more excipients are precipitated together from a solution, resulting in a homogenous composite material [5]. This improves compatibility and functional synergy between components.

Crystallization-Co-Agglomeration: This technique involves simultaneous crystallization and agglomeration using a good solvent, a bridging liquid, and a poor solvent. It produces spherical agglomerates with improved compressibility and flowability.

Fluidized Bed Processing: In this method, excipient particles are fluidized in an air stream while being sprayed with a binder or coating solution. It allows for uniform coating or granulation and is useful for taste masking and modifying surface properties [3].

Milling: A variety of mills, including roller, ball, jet, hammer, bead, and millstone mills, can be used to co-process excipients by milling. Using this method, the excipients are premixed and then rapidly fed into the milling machine [8]. Particles come into close contact and create connections as a result of the applied forces. The co-processing of calcium silicate with cross-linked polyvinyl pyrrolidone is an illustration of this technique.

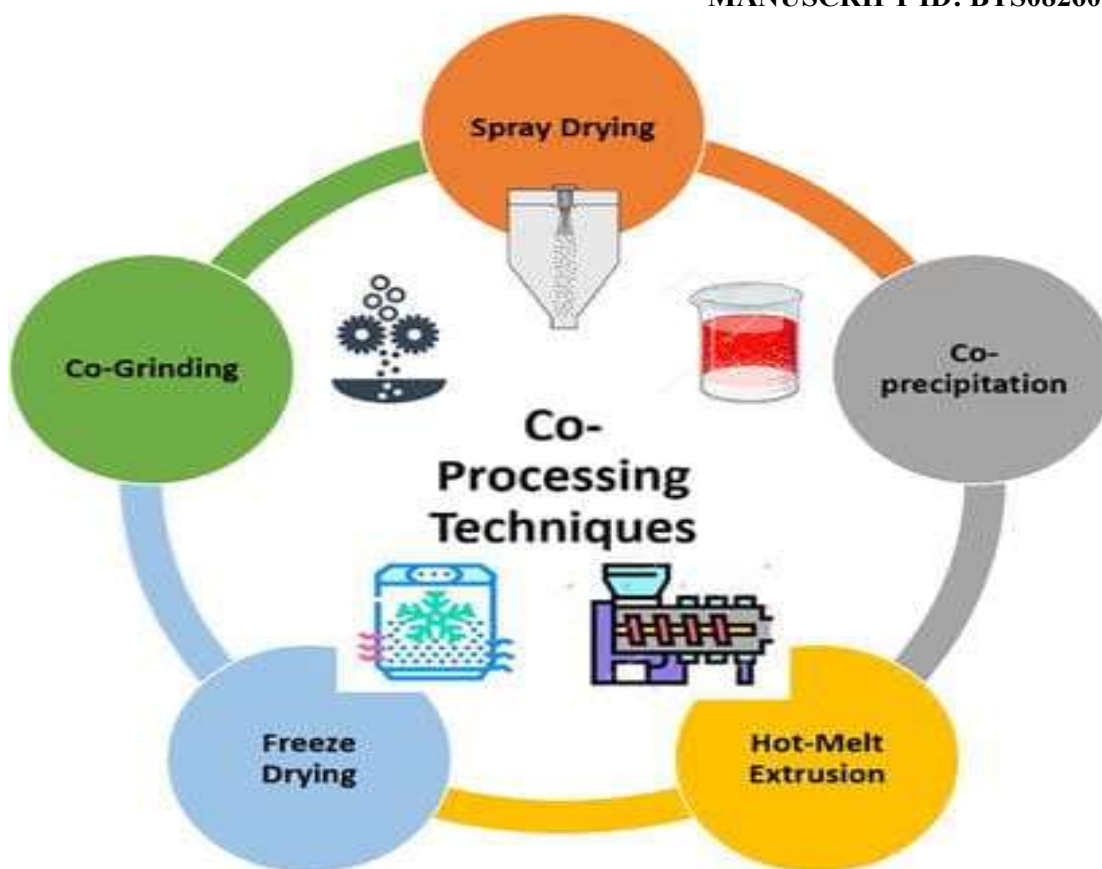


Figure no:2: This figure illustrates major co-processing techniques including spray drying, co-precipitation, hot-melt extrusion, freeze drying, and co-grinding used in pharmaceutical formulation. These approaches enable intimate drug–excipient integration, leading to improved solubility, dissolution, flowability, and stability. Co-processing supports the development of advanced solid dosage forms and multifunctional excipients for enhanced therapeutic performance.

MARKETED CO-PROCESSED EXCIPIENTS:

MCC and HPMC: Spray-drying an aqueous slurry comprising hydroxypropyl methylcellulose (HPMC) and microcrystalline cellulose (MCC) allowed Deorkars et al. (2011) to create a co-processed excipient. Comparing the final formulation to the constituent parts, it demonstrated better blend homogeneity, increased API loading capacity, improved

flowability, and improved compressibility [13].

Chitosan and Eudragit S-100: Pawar et al. (2014) developed a co-processed excipient composed of chitosan and Eudragit S-100 using the solvent evaporation method. This excipient was utilized in the formulation of sustained-release venlafaxine HCl tablets via direct compression [35].

Acacia and maize starch: Olowosulu et al. (2011) co-dried a well-dispersed aqueous mixture of acacia and maize starch to create



MANUSCRIPT ID: BTS0826011

a co-processed excipient. To examine the effects of partial and full gelatinization, drying was done in a water bath at 50°C and 80°C for 15 minutes while stirring constantly. While the partially gelatinized form yielded tablets with adequate friability and enhanced crushing strength, the fully gelatinized form showed poor crushing strength but good flowability [32] (Pabbiniddi & Kotra, 2024).

MCC and maltodextrin: Buliga et al. (2002) prepared a co-processed excipient by blending microcrystalline cellulose (MCC) with maltodextrin and spray-drying the dispersion. The resulting product was further combined with carboxymethyl cellulose to create a dry blend suitable for use as a stabilizer in food and cosmetic applications [10].

Sorbitol and mannitol: Norman et al. (2006) reported the development of a sorbitol-mannitol blend prepared by dissolving both powders in solution, followed by drying using an airstream. The resulting composition was designed to dissolve completely in the oral cavity within 60 seconds, making it suitable for use in orally disintegrating tablet (ODT) formulations [30].

Pharmatose DCL 40: It is a co-processed excipient made up of 5% anhydrous lactitol and 95% β -lactose. It has outstanding flowability because to its spherical form and ideal particle size. Because of its better binding qualities, it has a higher dilution

potential than other lactose-based products. Furthermore, even in situations with high humidity, it exhibits little moisture uptake [6].

Pregelatinized starch: (Insta Starch, Lycatab, Sepistab) is made by heating a starch slurry (up to 42% w/w) with gelatinisation aids and surfactants at 62–72°C, followed by spray, roll, or drum drying. It serves as a binder-diluent with enhanced flow and compression, ideal for direct compression tablets and capsules [25].

Lentinus tuber regium base co-processed excipient: Ugoeze and Nkoro (2015) developed a co-processed excipient based on *Lentinus tuber regium* by combining it with sodium bicarbonate, tartaric acid, and citric acid using the solvent evaporation method (Chowdary, 2018). The resulting product was a compactable, tasteless, off-white powder with no distinct odour, exhibiting improved flowability, compressibility, and dilution potential [9].

Starch and magnesium silicate: Adnan et al. (2011) combined starch and magnesium silicate to create a co-processed excipient. First, the starch was suspended in water, and then magnesium silicate was added. Filtration, washing, and drying were done on the resultant mixture. The finished dried product was then utilized in tablet formulations that showed minimal lubricant sensitivity, strong mechanical strength, and quick disintegration [17].

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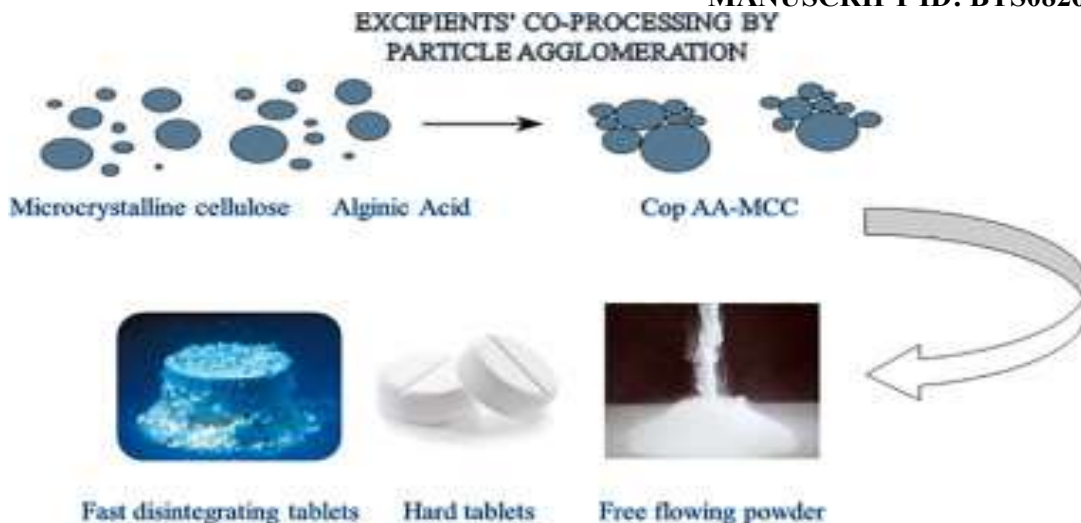


Figure no:3: Co-processing of excipients by particle agglomeration combines microcrystalline cellulose with alginic acid to form Cop AA-MCC. This process improves particle size distribution, flowability, and compressibility of the excipient blend. The resulting material supports the development of fast-disintegrating tablets, hard tablets, and free-flowing powders.

Table no:1 List of Pharmaceutical Excipients Available Commercially in Market

Trade name	Excipients	Manufacturer	Functionalities
Avicel ce-15	Microcrystalline cellulose and guar gum	FMC Corp.	Less grittiness and minimal chalkiness
Starlac	Lactose and maize starch	Meggle	Good flowability due to spray drying, the acceptable crushing force due to lactose content and rapid disintegration depending on starch
Ludiflash	Mannitol, cross povidone and polyvinyl acetate	BASF	Suitable for high-speed tableting, low friability, and good flowability



MANUSCRIPT ID: BTS0826011

Trade name	Excipients	Manufacturer	Functionalities
Pharmaburst	Carbohydrate system, made from compendia ingredients	SPI Pharma	High compatibility, high loading in, small tablets, smooth mouth, feel, rapid, disintegration
Tap-400	Processed tartaric acid pellet	Pharmatrans	As an acidic core for drug Delivery technologies
Cel-O-Cal	Microcrystalline cellulose and calcium sulphate	FMC Biopolymer	Directly compressible binder
Microcelac	Microcrystalline cellulose and lactose	Meggle	Capable of formulating high dose, small tablets with poorly flowable active ingredients
Ludipress	Lactose, kallidon 30, kallidon CL	BASF	Low degree of hygroscopicity, good flowability, tablet hardness independent of machine speed
Starch 1500	Amylose, amylopectin, and starch	Colorcon	It is a direct compressible, free-flowing, USP grade of partially hydrolyzed cornstarch.
Xylitab	Xylitol and sodium carboxymethylcellulose	Danisco	Directly compressible and good palatability

MANUSCRIPT ID: BTS0826011

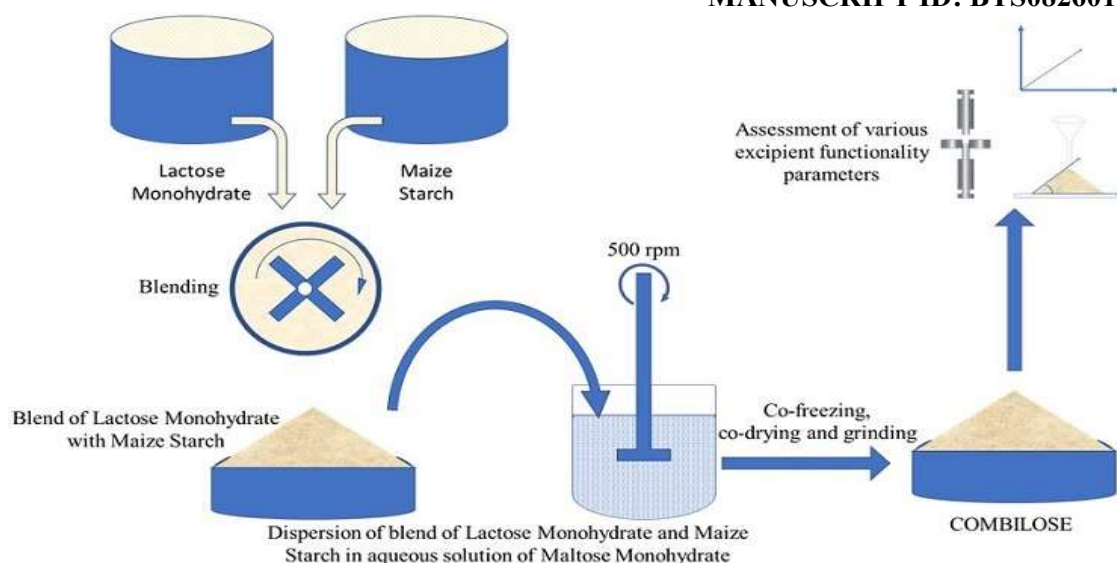


Figure no:4-The figure illustrates the preparation of a co-processed excipient (CombiLose) using lactose monohydrate and maize starch through blending, aqueous dispersion, co-freezing, co-drying, and grinding. This process enables intimate particle-level integration of excipients, resulting in improved flowability, compressibility, and functional performance.

CHARACTERIZATION OF CO-PROCESSED EXCIPIENTS:

Comparison of Four Lactose-Based Co-Processed Excipients' Flow and Compression Properties:

Martin Dominik and Barbora Vraníková (2021) conducted a comparative study on lactose-based co-processed excipients (CPEs) used in orally disintegrating tablets (ODTs) that were made through direct compression. They evaluated four CPEs: Cellactose®80, CombiLac®, MicroceLac®100, and StarLac® for flow, consolidation, and compression behavior using granulometry and rheological methods [19]. Even though these CPEs were similar in composition and preparation, they showed notable differences in performance. Cellactose®80 had strong consolidation and low ejection force, but it was very fragile [39]. CombiLac® had great flow, but its friability

was low under low pressure. StarLac® performed well in flow and dissolution, but it had weak compact strength and a high ejection force. All CPEs needed high ejection forces, which required lubricants during compression. Most of them, except MicroceLac®100, needed higher pressure or additional excipients for better tablet integrity [28]. Lactose-based CPEs broke down quickly within 180 seconds, making them ideal for ODTs because of lactose's solubility. They continue to be effective fillers for fast-disintegrating formulations (Lakshmi et al., 2019).

Evaluation of a New Co-processed Chitin and Crystalline Mannitol Excipient

To enhance tablet performance, Nidal Darghemeh, Jyadh Rashid, and colleagues (2010) created a co-processed excipient that blends crystalline mannitol with α -



chitin. Chitin by itself has weak compaction and poor flow. Mannitol is difficult to compress and can result in capping. However, the combination (Cop-MC) performed significantly better in flow, disintegration, and compaction when these two were co-processed, particularly employing wet granulation at a 2:8 mannitol-to-chitin ratio. Compared to dry granulation and direct mixing, which produced weaker tablets, wet and spray granulation techniques produced superior granules [37]. This held true whether different particle sizes or the lubricant magnesium stearate was used. In comparison to the studied 1:9 and 3:7 ratios, the 2:8 mixture was more robust and less friable. Cop-MC worked well with both highly compressible and poorly compressible APIs [16]. It was a potential multifunctional excipient with outstanding binding, flowability, and super-disintegrant qualities.

Multifunctional Roles of Co-processed Excipients in Oral Tablets:

Co-processed xylitol-starch excipient designed for application in orally disintegrating tablet (ODT) formulations.

A study by Kai Bin Liew et al. (2020) aimed to create a new co-processed excipient for use in oral disintegrating tablets (ODTs) that included xylitol, starch, and crospovidone XL-10. The effects of two formulation techniques--freeze drying and wet granulation--on the characteristics of the excipient were assessed. With smaller particle size, quicker disintegration, and superior compressibility, the freeze-dried excipient performed better than the wet granulated variant. F6, which had a 3:6:1 ratio of xylitol, starch, and crospovidone, had the best results out of all the formulations that were evaluated. Its in-

MANUSCRIPT ID: BTS0826011

vitro disintegration time was 135.33 ± 11.52 seconds, while its in-situ time was 88.67 ± 13.56 seconds. A synergistic process including the wicking effect of crospovidone, the swelling of starch, and the breakdown of xylitol caused the tablet to disintegrate [21]. Because of its capacity to expand, it was discovered that increasing the starch content further shortened the disintegration time. The consistency of the tablets and the flow of the powder were also enhanced by freeze drying. The tablets demonstrated strong mechanical strength and adequate friability, despite only having fair flowability. The investigation came to the conclusion that the co-processed excipient that was freeze-dried provides a realistic, economical, and effective alternative for ODT formulations that disintegrate quickly [23].

Effect of co-processed *Manihot esculenta* starch on the tablet properties of directly compressed diclofenac and paracetamol formulations:

In order to improve the tablet characteristics of formulations of diclofenac and paracetamol, Olubunmi's Olayemi et al. (2024) studied the development and evaluation of co-processed excipients made from *Manihot esculenta* (cassava) starch and povidone [14]. Using pre-gelatinized starch (EXP-A) and gelatinized starch (EXP-B), two kinds of co-processed excipients were made. Both were mixed with povidone, dried, and sieved. Important physical characteristics such as flowability, moisture content, swelling index, hydration capacity, and particle density were evaluated for the resultant excipients. EXP-B had better properties than the other one, including better flow, greater swelling and hydration capacities, and a lower moisture content [22]. These excipients were used to generate tablets that were uniform in



weight, had appropriate hardness (4.5–11 kp), and had friability ranging from 0.45% to 4.02%. EXP-A demonstrated superior resistance to friability. The co-processed excipient formulations showed improved mechanical strength and regulated drug release, while the unmodified starch formulations disintegrated more quickly. According to these results, the co-processed Manihot esculenta starch–povidone excipients show promise as potential ingredients for modified-release tablet formulations.

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