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A Research Article on- Co-Processed Excipients by Preparing Sodium Alginate Microbeads Through Inotropic Gelatin Method

Dr. Quazi Imaduddin[1]; Shaikh Mohiuddin[2]; Priyanka Kantaram Sonawane[3]; Aashu Sabhapati Yadav[4]

[1]Principal, U.B.K.W. T'S Vastanvi College of Pharmacy, Kunjkheda Taluka: Kannad Dist. Aurangabad, Maharashtra 431103.
[2]Professor of Biotechnology, U.B.K.W. T'S Vastanvi College of Pharmacy, Kunjkheda Taluka: Kannad Dist: Aurangabad, Maharashtra 431103.
[3,4]B. Pharm Students, U.B.K.W. T'S Vastanvi College of Pharmacy, Kunjkheda Taluka: Kannad, Dist. Aurangabad,
Maharashtra 431103.

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Abstract: The research article is presented to give complete research and explanation on the development of excipients and microbeads preparation with the help of excipients, and also the approaches involved in similar excipient development. As per the scientist's research, a single element of excipient can't give the specific or sufficient performance in the production of a product, and also for manufacturing, so they increase the attention on the product by multiplying the excipients in production. They make the production expensive with their cost, production, manufacturing, packaging, etc. The microbeads are small in size, and they are affected in various ways. The microbeads change their colour according to the ingredient used for production.

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I. INTRODUCTION

The scientists have researched that single-element excipients cannot always give the specific performance to allow certain active pharmaceutical constituents to be formulated or manufactured. The excipients' sedulity to date has been an extension of the food sedulity. Excipients are also the manufactured product of the food industry, used to maintain a good safety profile. Pharmaceutical excipients are any substance other than the active medicine product with has been meetly estimated for safety and is included in a medicine delivery system to either aid processing of the system during manufacture or cover, support, or enhance stability, bioavailability, or patient adequacy or help in product identification or enhance any other trait of the overall safety and effectiveness of the medicine product during storehouse and use. [1]

- *Factors Driving the Search for New Excipients:*

The growing trend in the past decades has been to use of direct compression and the desire to have a multi-purpose padding binder that can serve as a substitute for processed two or more excipients. The speed of the tabletting machinery is being increased, excipients are used to offer the best compressibility and least variance of weight, especially sudden dwell times, and particle drippers. The ability to modulate the solubility, permeability, or stability of drugs is desirable. Escalating excipients' effectiveness in overcoming decomposition, solubility and bioavailability issues. (2)

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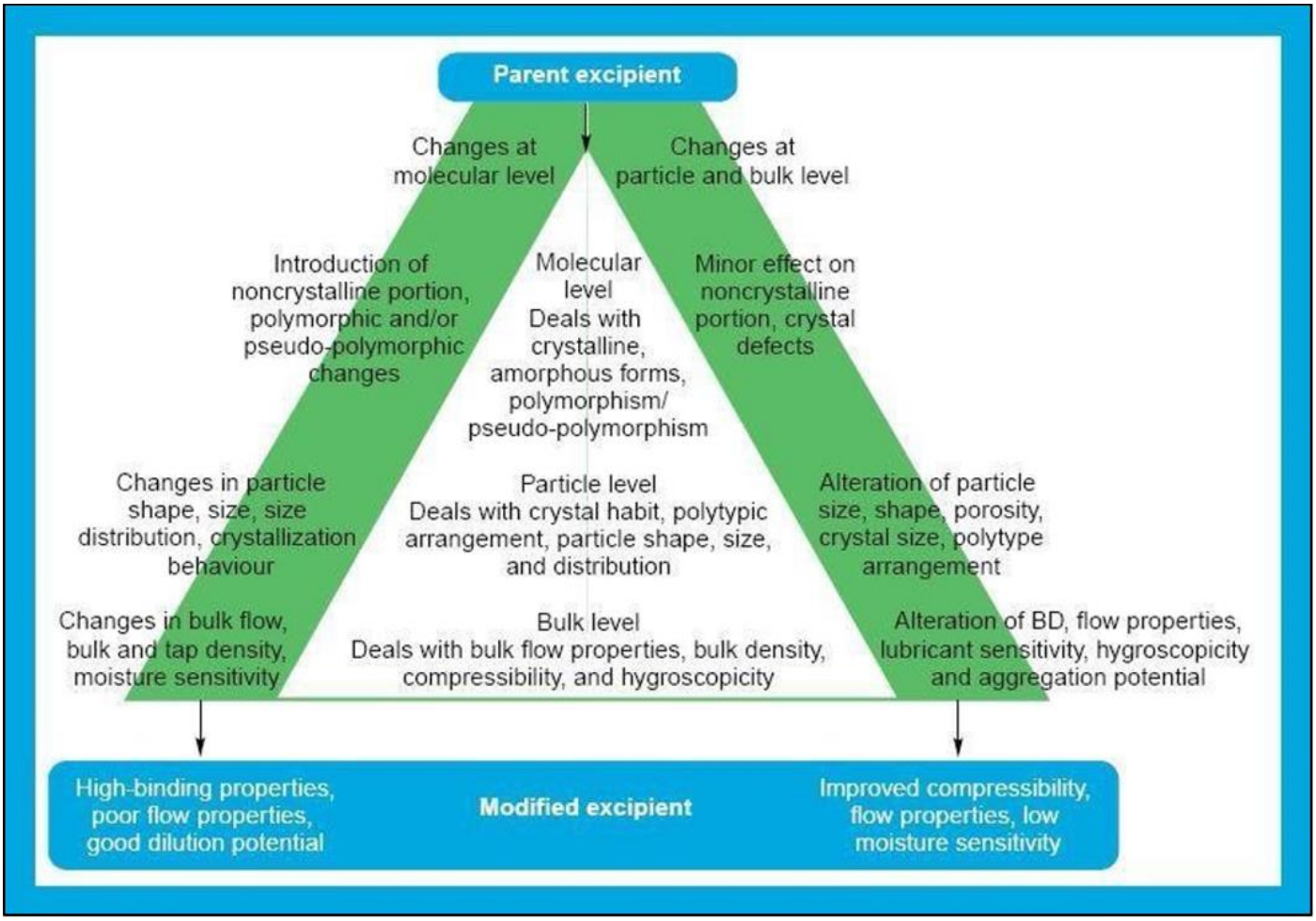

Fig 1 Parents Excipient [3]

II. DEFINITION

➢ *Excipients*

Excipients play a major part in formulating a dosage/lozenge form. [4] The International Pharmaceutical Excipients Council (IPEC) defined excipients as substances other than the API that have been properly evaluated for safety and are purposefully included in the medicine delivery system. Save, support or enhance stability, bioavailability, patient adequacy or performance of technological function. Ameliorate in product identification or enhance any other quality of overall safety [4]

- *Types of Excipients: [5]*

✓ Binders: - Binders serve as the adhesive that cohesively amalgamates products or materials to create granules.
✓ Fillers / Diluents: - Diluents, fillers, or padding are therapeutic substances devoid of pharmacological action, nevertheless essential in pharmaceutical compositions.
✓ Disintegrants and super-disintegrants: - Disintegrants are substances included in tablets and some repurposed drugs to facilitate the fragmentation of tablet and capsule masses into small particles in a dry environment.
✓ Lubricants: - Lubricants are excipients used to facilitate a smoother procedure.
✓ Glidants: - The formulation incorporates the glidant to improve the tablet core mixture's flowability.

➢ *Co-processed excipients: [6]*

A co-processed excipient is a mixture of two or further compendial or non-compendial excipients planned to physically modify their parcels. Numerous different co-processing modes may be used as spray drying, milling, melt extrusion, and granulation. The main end of co-processing is to gain a product with added value related to the rate of functionality. [4]

- *Classification of Co-Processed Excipients: [4]*

✓ Single Entity Excipients
✓ Mixture or Blends of Multiple Excipients
✓ Novel Excipients or New Chemical Organisation
✓ Co-process Excipient

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III. OBJECTIVES OF CO-PROCESSED EXCIPIENTS

- ➢ Co-processed excipients address the shortcomings linked to the utilisation of standard-grade excipients.
- ➢ The composition is built upon extensive data about co-processed excipients, which includes, among other things, data on their classifications, varieties, methodologies, limitations, physicochemical properties, ideal conditions, pros and cons, drugs on the market, and evaluation of these excipients.
- ➢ Providing a thorough overview of recent developments in excipient technology and the approaches utilised to produce comparable excipients is the primary goal of the content.
- ➢ The excipients are crucial in the formulation of a lozenge.

IV. CHARACTERISTICS OF SOME OF THE EXAMPLES OF CO- CO-PROCESSED EXCIPIENTS: [7]

➢ *Calcium Chloride*

- **Formula:** -$CaCl_2$
- **Colour:** - White
- **Odor:** - Odourless
- **Taste:** - Salty Taste
- **Molecular Weight:** - 111 g/mol

Fig 2 Calcium chloride

➢ *Sodium Alginate: [7]*

- **Formula:** - (C6H7NaO6) n
- **Colour:** - yellowish Brown Coloured PowdeR
- **Odour:** Odourless
- **Taste:** - Tasteless
- **Molecular Weight:** - 216.121 g/mol

Fig 3 Sodium alginate

V. NEED OF CO-PROCESS EXCIPIENTS: [4]

- ➢ The increasing use of the direct compression process requires an optimum padding/filler-binder which can replace two/or more excipients.
- ➢ The ability to alter solubility, permeability or stability.
- ➢ The ability to control solubility, permeability or stability. To address the concerns of flowability, compressibility, and the possibility of decomposition. Better use of excipients: the new trend of coming up with an ideal filler binder that would be able to substitute two or more excipients. The trial of the new operations of the provident excipients is cost-effective and time-saving as compared to the new development.
- ➢ The number of real excipients with some desired properties pertinent to some formulations or phrases.
- ➢ Novel medications are under evaluation for their compatibility with excipients.

➢ *Physical mixture and co-processed excipients differences[1]*

- Physical fusions, as the name suggests, are simple combinations of two or more excipients that are usually processed in a short period and without intense shear.
- Co-processed excipients Co-processed excipients are mixtures of at least two excipients that ensure performance advantages that would not be attained by physical blending of the corresponding excipients alone.

VI. SOURCES OF NEW EXCIPIENTS: [1]

The procedure of co-processing is based on the novel idea of two or more excipients which interact at the sub-microscopic flyspecking location, the ideal of which is to provide a communality of behavior. The emptiness of many excipients in co-processing provides numerous opportunities to create customizable excipients of the specification of excipients requirements, or to contribute to attaining the preferred attributes of excipients.

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Table 1 A variety of particle characteristics that impact the efficacy of excipients.

Particle property	Excipient functionality
Enlargement of particle size	Flowability, compressibility
stricting particle size distribution	Segregation potency
Enlargement of particle porosity	Compressibility, solubility
Surface roughness	Flowability, Segregation potency

VII. PRINCIPLE OF COPROCESSING: [1]

The intrinsic solid-state characteristics of the particles, like morphology, particle size, shape, surface area, porosity, and density, affect the excipient functions of flowability, compactability, dilution potential, disintegration potential and lubricating potential. The confidence of a new excipient should start with a flyspeck design that is in place to provide the necessary functionalities. Nevertheless, flyspeck engineering of one excipient will provide very little functionality improvement.

- *Standard Excipients:*

Are defined as compendial or non-compendial substances that are neither mixed excipients nor co-processed excipients. They may contain other factors, including attendant factors, residual processing aids and/or complements.[1]

- *Mixed Excipients:*

A mixed excipient is defined as a simple physical mixture of two or further compendial or non-compendial excipients produced using a low- to medium shear process where the individual factors are mixed but remain as separate chemical realities, i.e. the nature of the factors is not chemically changed. Mixed excipients may be either solid or liquid.[1]

- *Co-processed Excipients:*

A co-processed excipient is a combination of two or further compendial or non-compendial excipients designed to physically modify their parcels in a manner not attainable by simple physical mixing and without significant chemical change. Numerous different coprocessing styles may be used, including standard unit operations such as granulation, spray drying, melt extrusion, milling, etc. [1]

VIII. REVIEW OF LITERATURE

Several Pharmaceutical journals were searched to know about work done and latest development related to the present study. some of the research work and findings have been reported below.

- *B. Mamatha et al. (2017):*

The main aim of the current review article is to provide a complete overview of recent development in excipient technology and the approaches involved in the development of such excipients.

- *Sravya K et al. (2021):*

Excipients with only one component don't always work well enough to facilitate the formulation or production of certain active pharmaceutical components, and developing novel excipients is costly due to the need to conduct toxicity studies as well.

- *S.B. Pawar et al. (2019):*

Excipients play an important role in formulating a dosage form. In recent years, drug formulation scientists have recognised that a single component excipient does not always provide the requisite performance to allow certain active pharmaceutical ingredients to be formulated or manufactured adequately.

- *Mukesh Mohite et al. (2020):*

There isn't a single component here that can be used to prepare an active pharmacological component for distribution to a specific location.

- *Zaidul Islam Sarker et al. (2022):*

Incorporating active medicinal compounds into a carrier material is the job of a pharmaceutical excipient. The selection of excipients is centered on their desired qualities.

- *Paka Bhavana et al. (2023):*

The following study aimed to characterise a range of co-processed excipients that may prove suitable for dispersible tablet formulation prepared by direct compression.

- *Anand Gaurav et al. (2018):*

This study aims to talk about how co-processed excipients are becoming more popular in the pharmaceutical industry and how they will likely continue to be in the future.

IX. THE STAGES INVOLVED IN THE CO-PROCESSED EXCIPIENT: [4]

- An accurate investigation must first identify the excipient group before co-processing can begin.
- The functionality and material properties are required.
- Figure out how much of each colored excipient to use.
- Calculate the approximate size of the flyspecks required for coprocessing.
- Choosing a drying method that works, such spray or flash drying
- A schematic illustration of the co-processing system is shown in the figure.4

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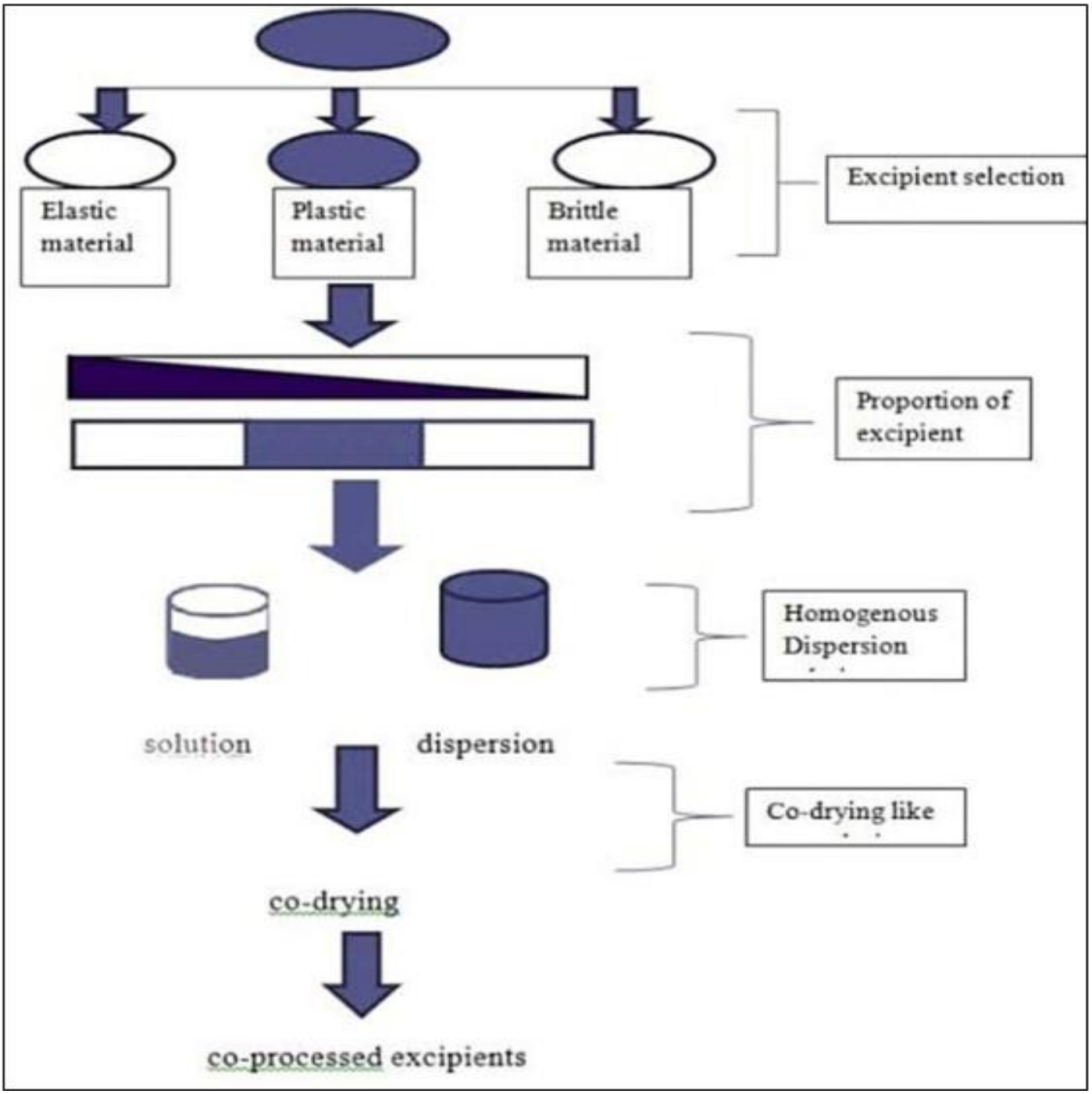

Fig 4 Schematic stages involved in the co-processed excipient

X. TYPE OF CO-PROCESSED EXCIPIENTS: [4]

- Single entity excipients.
- Mixtures/blends of multiple excipients.
- Novel excipients or new chemical Organisation.
- Co-process excipients

➢ *Single entity excipients:*

It is defined as excipients containing one component/element, which is the primary component/element called a single entity excipient.

➢ *Mixture/blends of multiple excipients:*

Simple physical mixtures/fusions of two or compendial /non-compendial excipients by means of a low to medium shear process, where the individual factors are mixed without significant chemical change of the solid mixture/ blends, individual excipients remain physically separate at t h e particulate position.

➢ *Novel excipients or new chemical entities:*

It is defined as excipients that are chemically modified to form new/novel excipients. These are generally not listed in the FDA inactive component database. The new excipient means any inactive component that is deliberately added to remedial and individual products.

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➢ *Co-process excipients:*

co-process excipients are a combination of two or further compendia or non-compendia excipients designed to physically modify their parcels in a manner not attainable by simple physical mixing and without significant chemical change. Numerous different co-processing methods/styles are included in pharmaceutical expression development, such as spray drying, solvent evaporation, crystallisation, melt extrusion and granulation/ agglomeration time.

➢ *Advantages of Co-Processed Excipients: [4]*

- Enhancing flow characteristics via the regulation of ideal particle size and size distribution.
- Enhance compressibility, dilution capacity, fill weight consistency, flow characteristics, and lubricant responsiveness.
- It may enhance tablet hardness and reduce disintegration time.

➢ *Methods of Co-Processing: [2]*

- Spray Drying process
- Solvent Evaporation Process
- Crystallisation Process
- Melt Extrusion Process
- Granulation/agglomeration Process

➢ *Spray Drying Process:*

Spraying the feed into a hot drying medium allows it to transform from a fluid condition into dried particle form in this manner. This process of flyspeck processing and drying is ongoing at all times.[2]

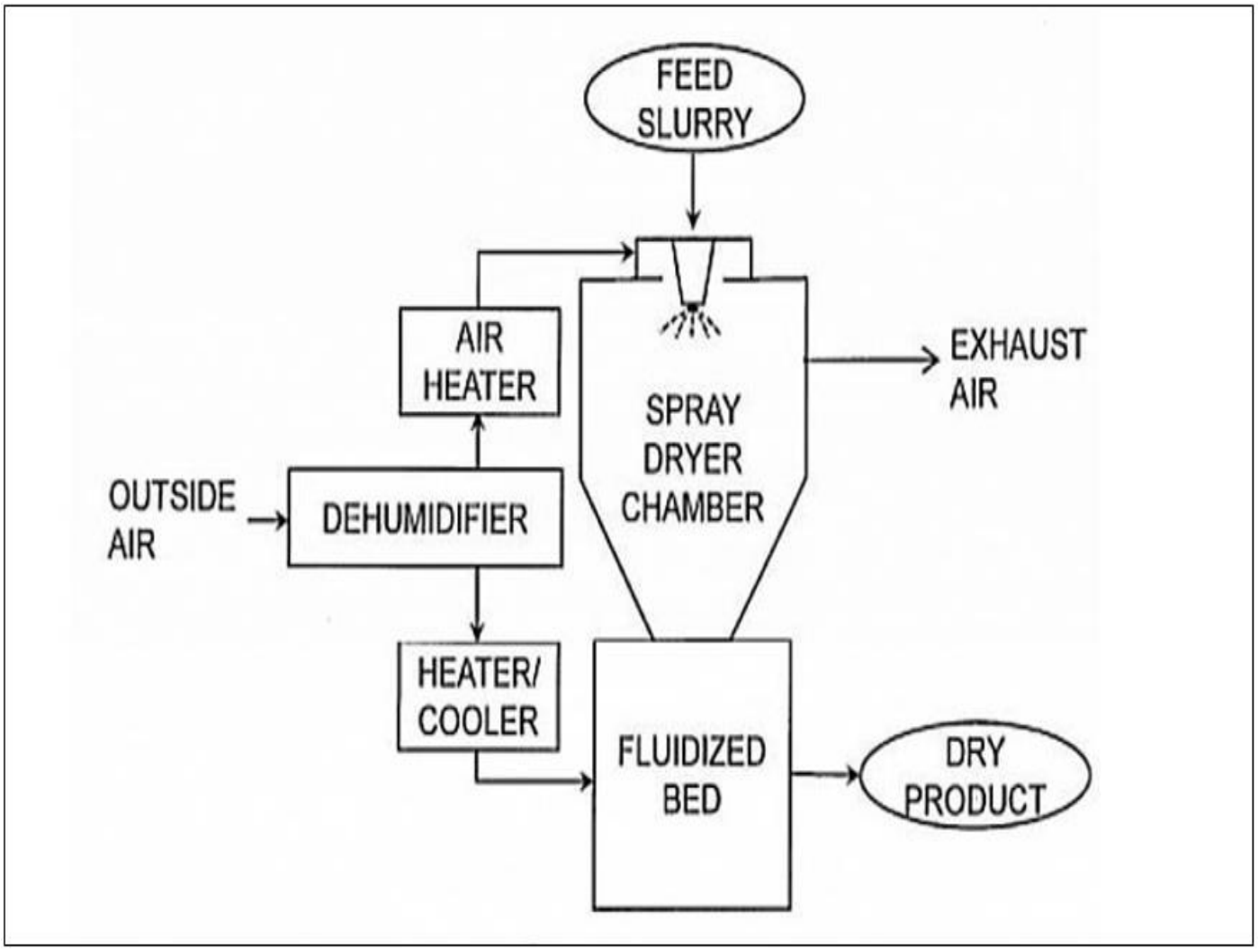

Fig 5 Spray Drying Method

➢ *Advantages of spray drying: [4]*

- Crushability and hardness are both enhanced.
- The disintegration time is reduced and the machine tabletting speed is increased.

➢ *Solvent Evaporation Process:*

To dematerialise the detergent, the mixture is heated (if needed). Previously, once the detergent has faded, the temperature of the liquid vehicle is lowered to ambient temperature (if necessary) while the agitation is continuing.

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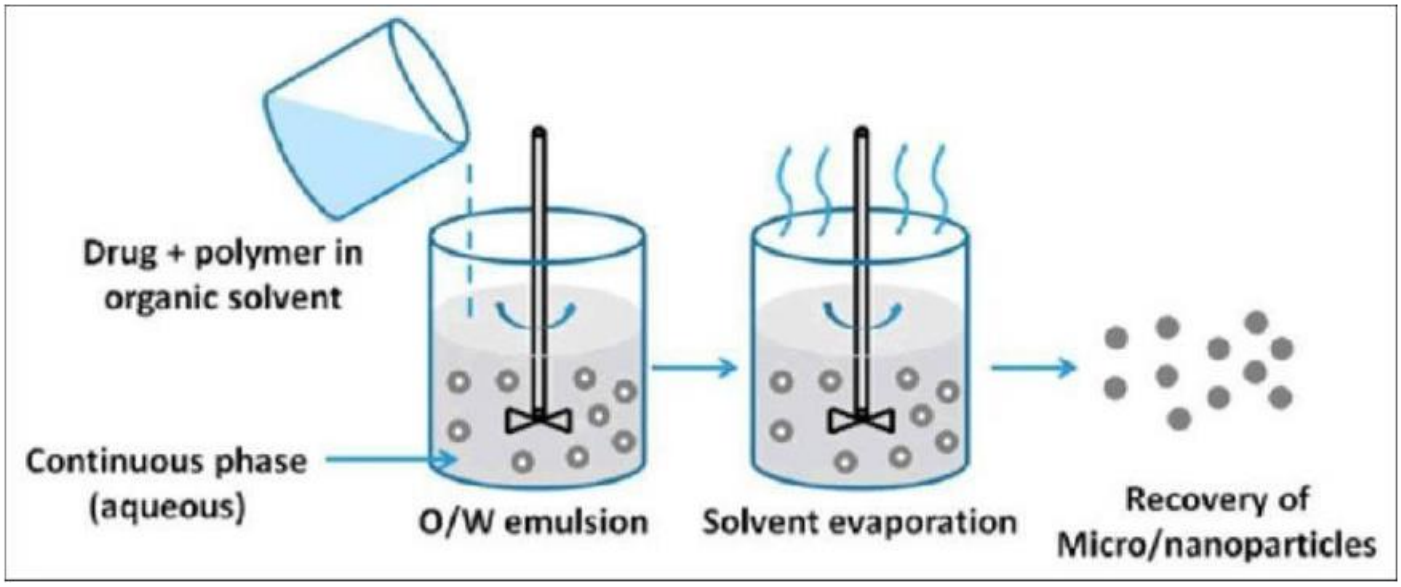

Fig 6 Solvent Evaporation Process

➢ *Crystallization Process:*

Crystallization is the process by which solid crystals are created from a solution, melt, or, less often, straight from a gas. Crystallization is a chemical solid-liquid separation method whereby the mass transfer of a solute from the liquid phase yields a pure solid crystalline form. [2]

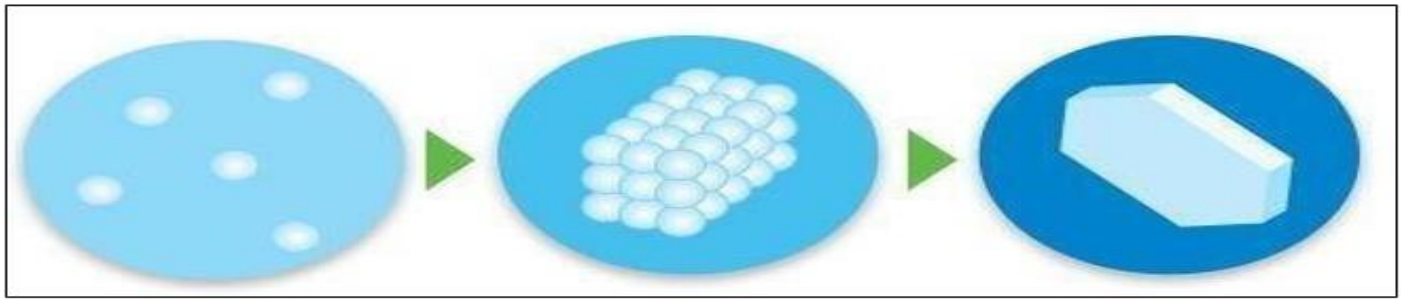

Fig 7 Crystallisation Process

➢ *Melt Extrusion Process:*

Melt extrusion is a method for producing tiny beads or pellets from a molten substance that is forced through an extruder. [2]

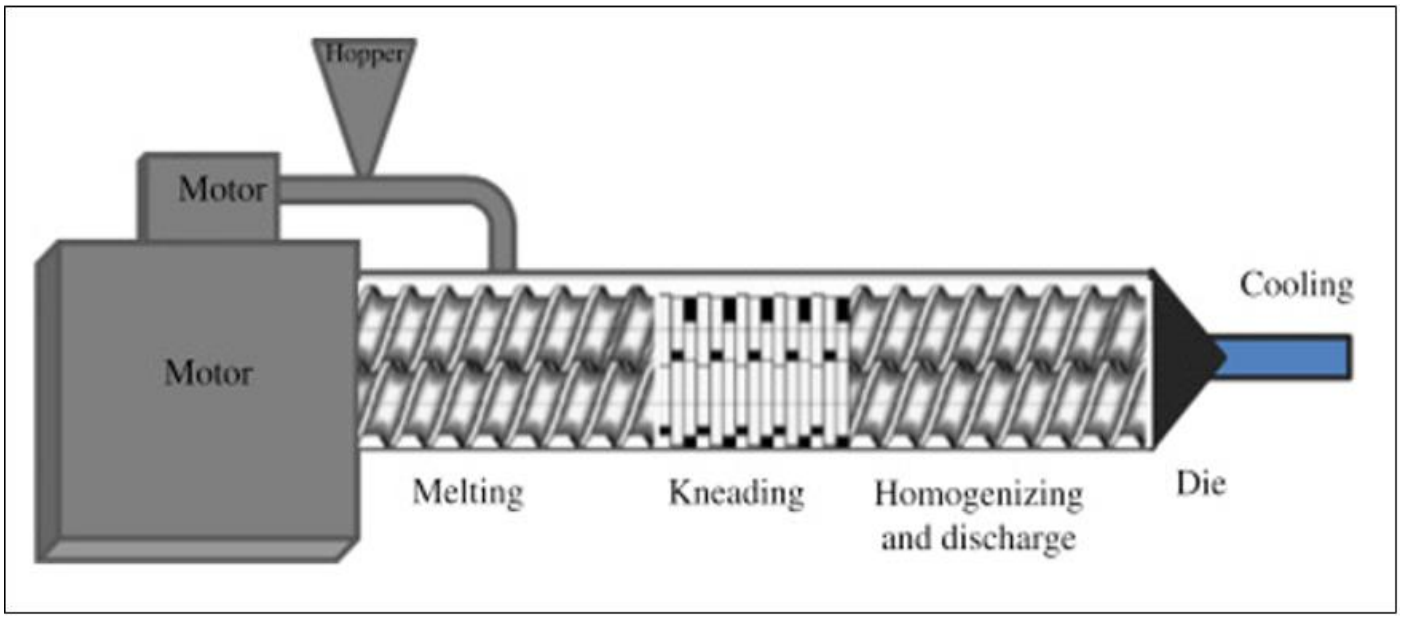

Fig.8 Melt Extrusion Process

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➢ *Advantages [4]*

- Excellent repeatability.
- Complex and elaborate forms are feasible.
- The time needed is reduced.

➢ *Disadvantages [4]*

- The cost of equipment and dies is elevated.
- The minimum economic length is high.

➢ *Granulation/agglomeration Process:*

The formation of grains via crystallisation or moulding is called granulation. The size of granules typically falls between the range of 0.2 to 4.0 mm, which is determined by their utilisation in the posterior region. Reverse "Agglomeration": Technologies that change product packages are excellent instruments for aggregation processes or, more generally, particle size blowup. It is common practice to agglomerate powders in order to improve their wettability, flowability, bulk density, and overall product look. When it comes to co-processing, wet granulation is preferred.[2]

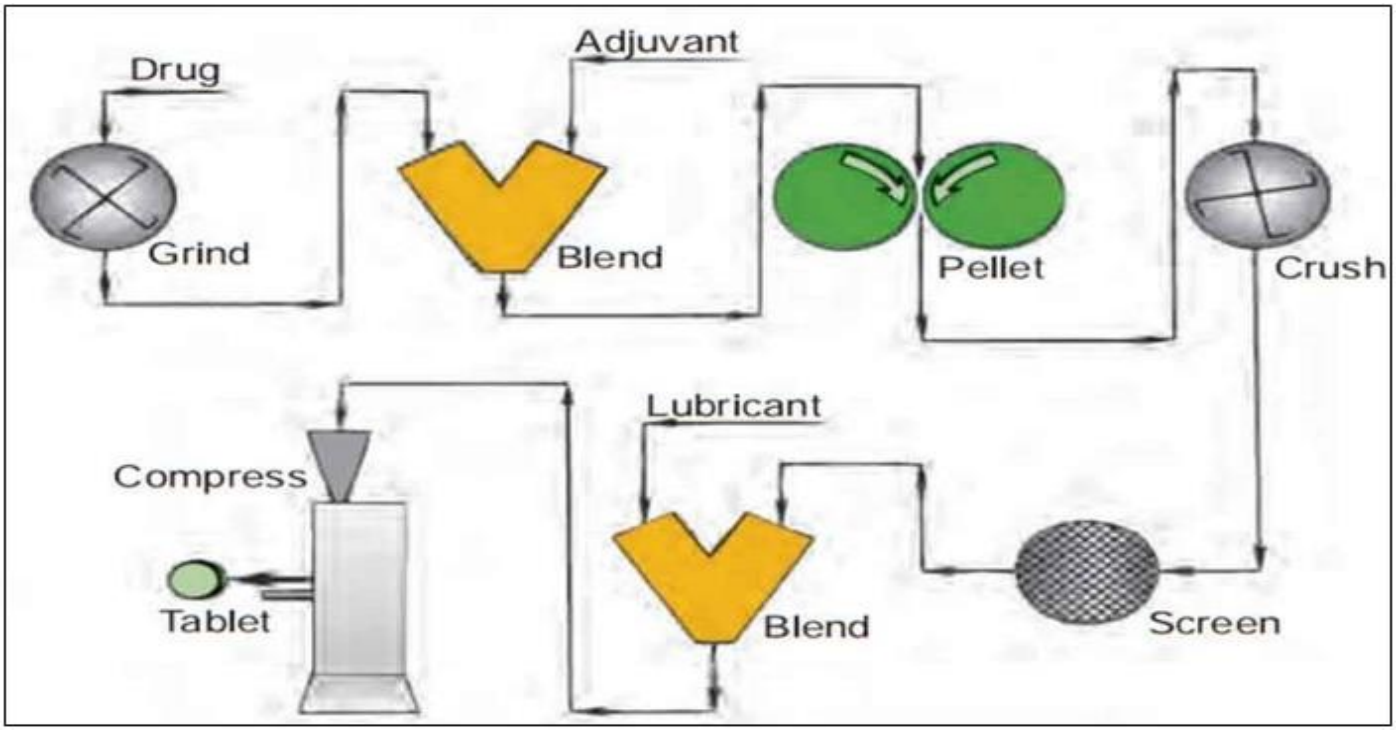

Fig 9 Dry Granulation Process

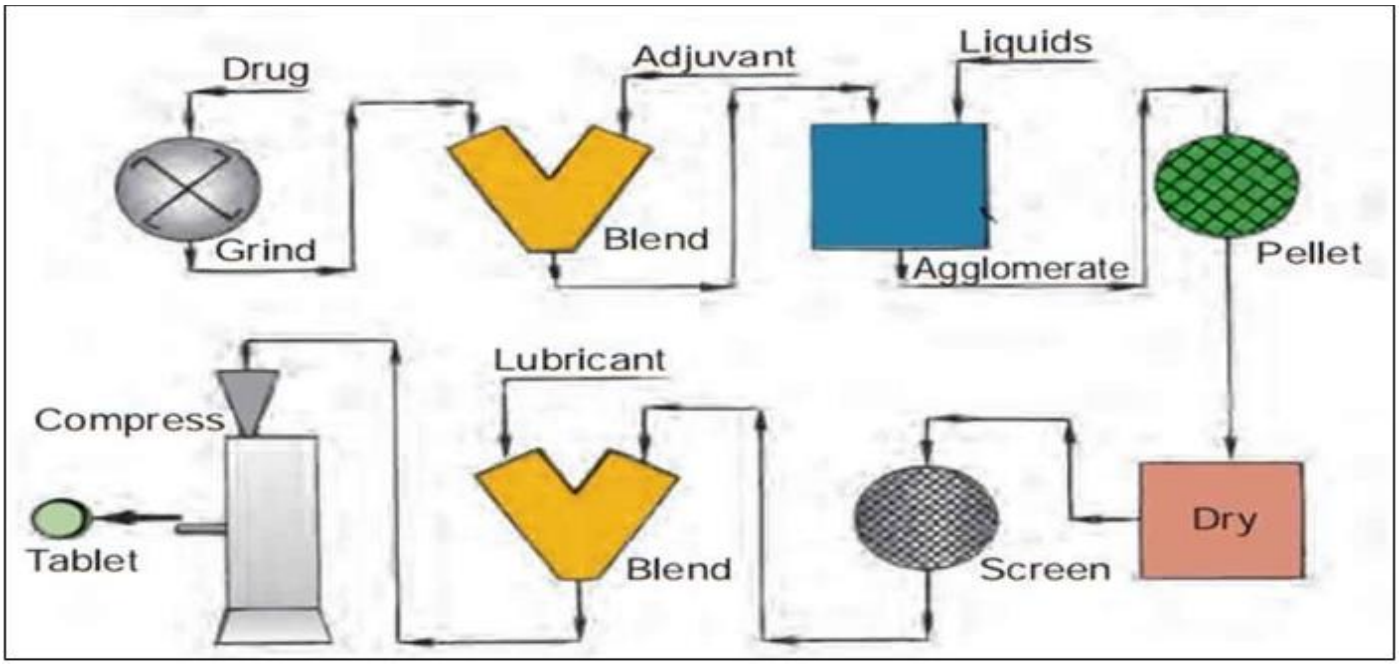

Fig 10 Wet granulation Process

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➢ *Advantages: [4]*

- It has a short processing time,
- doesn't need water or any other solvent,
- can be used with standard machinery.

XI. PHYSICOCHEMICAL PROPERTIES OF CO-PROCESSED EXCIPIENTS: [1]

➢ *Improved flow properties:*

Better inflow parcels of coprocessed excipients are achieved without the use of glidants by controlling the appropriate particle size and particle-size distribution. Researchers looked the SMCC and MCC's volumetric inflow parcels side by side. [1]

➢ *Improved compressibility:*

Because direct compression tabletting increases flow parcels and compressibility biographies netively and forms a padding/filler-binder excipient, coprocessed excipients have seen extensive application in this technique. [1]

➢ *Better dilution potential:*

An excipient's dilution potential indicates how well it may be mixed with other substances while maintaining its compressibility. For excipients to maintain excellent contraction even when combined with an agent that is not compressible, as is often the case with active medicinal compounds, the excipients themselves need to have greater compressibility characteristics. [1]

➢ *Fill weight variation:*

As a rule, direct compression accoutrements have large fill-weight variations because of poor input parcels; nevertheless, co-processed excipients exhibit fewer fill-weight variation issues than simple fusions or parent accoutrements. [1]

➢ *Reduced lubricant sensitivity:*

Due to the creation of freshly exposed surfaces during compression, which breaks up the lubrication network, the considerable volume of brittle material, such as lactose monohydrate, gives poor lubricant sensitivity. [1]

XII. LIMITATIONS OF COPROCESSED EXCIPIENTS: - [2]

➢ *Fixed Ratio:*

One major drawback of co-processed excipient admixtures is that they have a set rate of excipients. When creating a novel formulation, this rate may not be the best option for the active pharmaceutical ingredient (API) and the dosage per tablet. [2]

➢ *High Cost:*

Technical items made using proprietary procedures like as spray drying, fluid bed drying, roller drying, etc., are known as directly compressible co-processed excipients. To that end, the finished goods are priced more than the individual components. [2]

➢ *Dilution Potential Up to 40%:*

For 500 mg of medication, the final tablet would weigh more than 1.3 grams due to the fact that most directly compressible co-processed excipients can accommodate up to 40% of the poorly compressible active ingredients. This makes the tablet size large and may cause difficulty in swallowing. An example of this would be acetaminophen. [2]

➢ *Lack of Pharmacopoeial Acceptance:*

The pharmacopoeia does not recognise co-processed adjuvant as a valid substance. Until a hybrid padding/filler binder shows substantial improvements in tablet contraction compared to physical excipient fusions, it will not be adopted by the pharmaceutical industry. [2]

XIII. EVALUATION PARAMETERS OF CO-PROCESSED EXCIPIENT:

➢ *Solubility:*

The solubility of the co-processed excipient was evaluated in water, aqueous buffers at pH 1.2, 4.5, and 7.4, as well as in organic solvents including alcohol, chloroform, and petroleum ether.[2]

➢ *pH:*

The pH of a 1% w/v slurry was assessed.[2]

➢ *Melting Point:*

The melting point was ascertained using a melting point device.[2]

➢ *Porosity:*

A mercury porosimeter is used to measure the total intra-particle porosity, pore area, and distribution of pore sizes.[2]

➢ *Particle size analysis:*

The sieve analysis method is used to analyze the particle size of co-processed excipients.[2]

➢ *Loss on Drying (LOD):*

A Petri plate containing a sample of the co-processed excipient is heated to 100 °C for three hours in a hot air oven or Roster.[2]

➢ *Compatibility of Co-Processed Excipient:*

The hydraulic press employs flat face punches to compress the sample at forces of 0.5, 1.0, 1.5, 2.0, and 3.0 tons. A hardness tester measures the hardness of each compact.[5]

➢ *Moisture Absorption:*

The hygroscopic nature of the new excipient prepared was evaluated by moisture absorption studies in a closed desiccator at 84% relative humidity and room temperature. [2]

➢ *Angle of repose:*

Angle of repose is a property linked to inter-particulate disunion or movement resistance between particles (United States Pharmacopoeia, 2016). It facilitates the assessment of

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the flow characteristics of the granules.[5]

➢ *Sieve analysis:*

A collection of stainless-steel sieves with openings varying from 0.025 to 0.800 mm was positioned on a vibrating sieve shaker to ascertain the particle size distribution. The change in weight of the retained bulk was computed for each filter. [5]

- *Friability test:*

The friability test is performed using a friabilator, where the granules are rotated for 4 minutes or 100 revolutions. The weight of the granules is measured before and after the test, and the percentage of friability is determined using the formula provided below [5]

$$\%\ Friability\ = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

- *Swelling index:*

The initial volume was obtained by placing a specific amount of powder into a graduated cylinder. Then, the necessary volume of water was added and the mixture was shaken well. After allowing it to stand for 24 hours, the volume of the powder was measured. This measurement is used for calculation as described in[5]

$$Swelling\ Index = \frac{Initial\ Volume - Final\ Volume}{Initial\ Volume} \times 100$$

- *Loss on drying:*

One gram of powder was subjected to heating in a hot air oven at 100°C for 1 hour. After this, the weight of the powder was recorded. The calculation is performed as follows.[5]

$$Loss\ Of\ Drying\ = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

XIV. PREPARATION / PRACTICAL OF MICROBEADS BY USING VARIOUS CO-PROCESSED EXCIPIENTS: -

➢ *Instruments Required:*

Table 2 Instruments Required

SR.NO	INSTRUMENTS
1.	Beakers
2.	Filter paper and filter stand
3.	Spatula
4.	Injections
5.	Mortar pestle and weight balance
6.	Measuring cylinder
7.	Fennel
8.	Zip-top bags
9.	Glass rod

➢ *Chemicals Required: -*

Table 3 Chemicals Required

Sr. No	Ingredients	Formula	Quantity	Used/Action	Image
1.	Sodium Alginate	(C6H7NaO6)n	3%	Stabiliser / Thickening Agents	

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2.	Calcium Chloride	CaCl2	3%	Stability, Cross-linking, Size of microbeads	
3.	Paracetamol	C8H9NO2	650mg	Analgesic and Antipyretic, Active Ingredient Drug (API)	
4.	Distilled Water	H2O	100ml	Remove impurities, Preparing Reagents and Solutions	

➢ *Theory of Microbeads:* [15]

Microbeads are solid, particulate carriers that flow freely and are nearly spherical, ranging from 0.5 to 1000µm in size. They contain medicinal substances in either crystalline or powdered form. These microbeads, as the name suggests, are designed to offer multiple methods of drug release, either immediately or over time, without leading to significant side effects. [11] The globules can be formulated to incorporate medications and continue functioning effectively in physiological environments. This design helps reduce side effects by ensuring that the systemic drug levels remain low while achieving therapeutic effectiveness at the targeted location.[15]

➢ *Techniques of Microbeads: [15]*

- *Ionotropic Gelation Method*

The source of cross-linking ions differs across various methods. In one approach, the cross-linking ion is placed externally, while in another, it is integrated directly into the polymer structure. There are two types of ionotropic gelation techniques: [15]

✓ External Gelation
✓ Internal Gelation

Table 4 Microbeads of Various Drugs, Polymers, Methods, and Importance [15]

Sr. No	Type	Drug	Polymer	Method	Significance
1	Microbeads	Ibuprofen (Anti-Inflammatory)	Sodium alginate	Ionotropic gelation method.	Higher drug entrapment and delayed release characteristics were demonstrated by prepared Rioprostil microbeads.
2	Microbeads	Norfloxacin (Antibacterial Drug)	Sodium Alginate and pectin	Ionotropic gelation method	An increase in the sodium alginate % was associated with sustained release.
3	Microbea d	Paracetamol (Analgesic and Antipyretic)	Sodium Alginate and Calcium Chloride	Inotropic gelatin method	To achieve the immediate release of paracetamol from alginate beads at acidic pH

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➢ *Procedure:* [16]

- Take 3% Sodium alginate powder into a beaker and add 100 ml of water to it, and stir it well until the powder is dissolved in the water.
- Take in another beaker 3% Calcium chloride and add 100 ml of water into the CaCl2, dissolve it well until it dissolves into water.
- Then drop the alginate solution into CaCl2 using an injection or a dropper
- Then filter the solution of Calcium and alginate microbeads using filter paper
- The obtained extract is the microbeads, which are then dried for at least 10-30 minutes to get them harden and reduce their size
- After they are dried, they reduce their size and then wash them, the microbeads change their colour from white to yellowish and microbeads are formed. [16]

XV. OBSERVATION OF MICROBEADS:

Fig 11 Microbeads before Drying

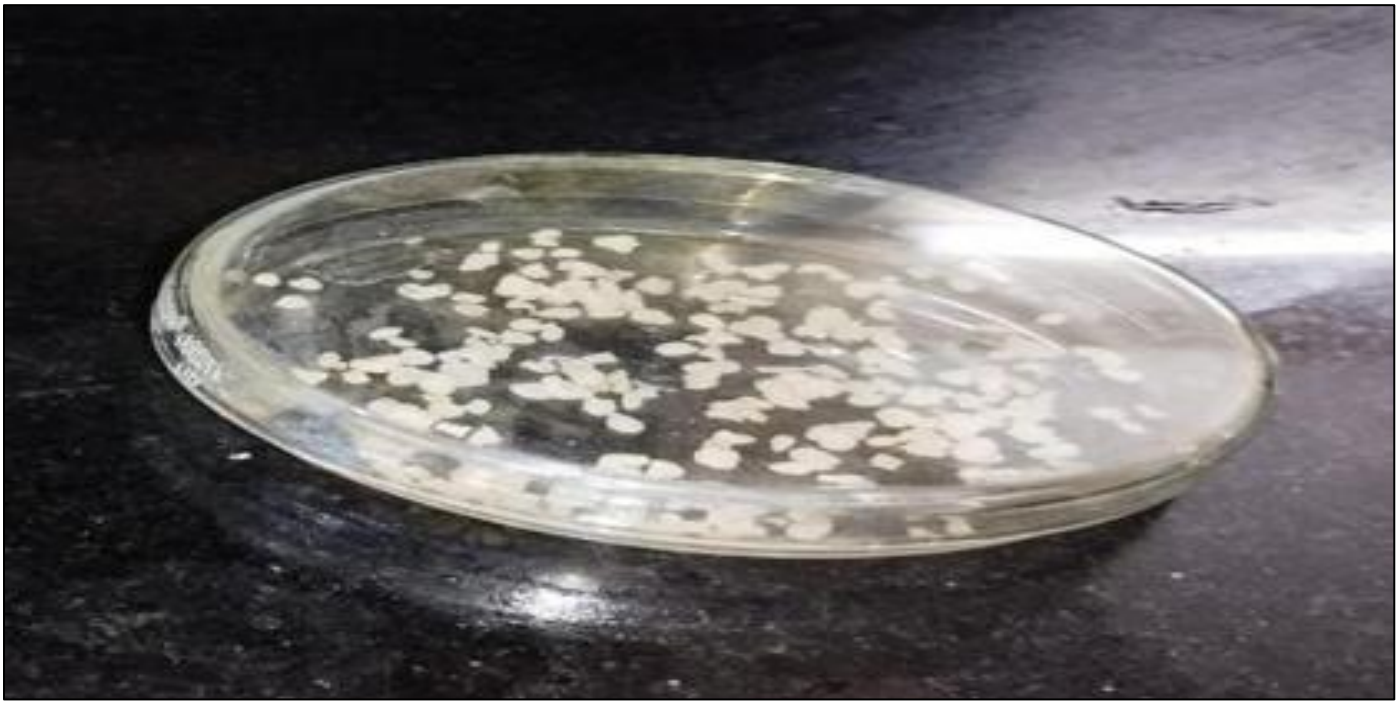

Fig12 Microbeads after drying

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Fig 13 Microbeads after drying change their colour

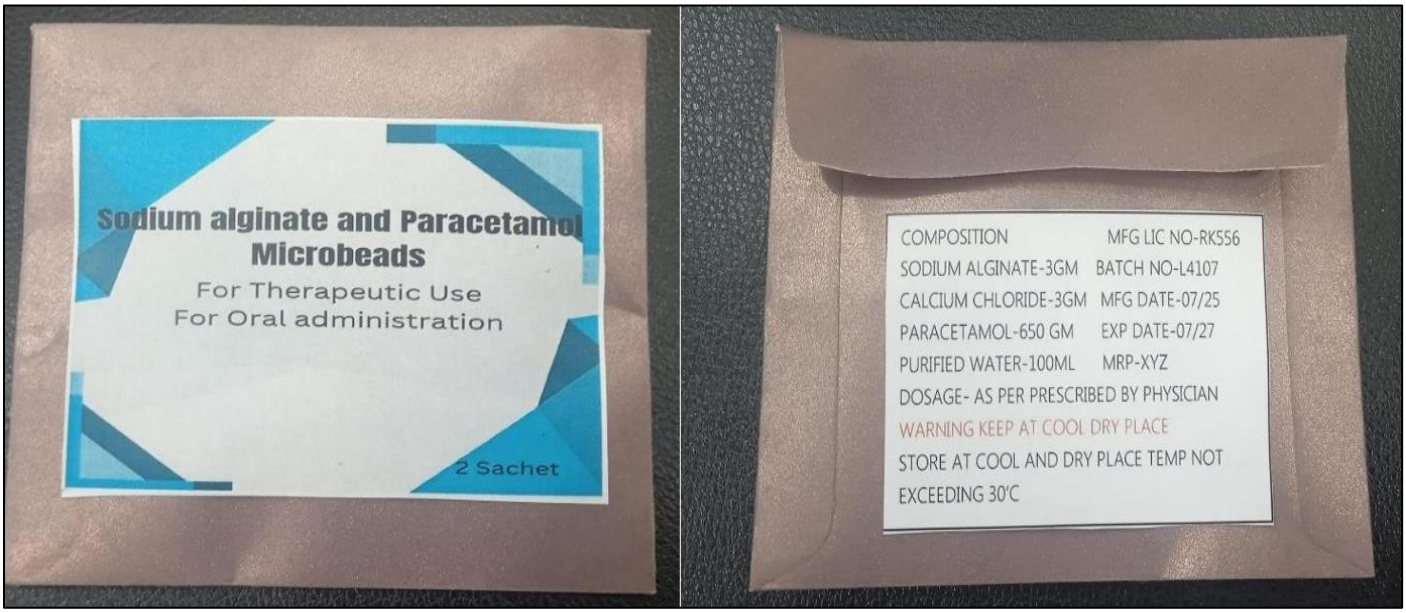

Fig 14 Final Packaging of Microbeads

XVI. EVALUATION PARAMETERS FOR MICROBEADS

➢ *Solubility:*

The nature of sodium alginates is water-soluble, but when crosslinked with calcium ions (Ca^{2+}), it forms insoluble calcium alginate gel beads.

➢ *Microbeads Solubility:*

- In Water:
- The beads do not dissolve in plain water but swell slightly.
- In Acidic Medium (e.g., pH 1.2)
- They may shrink or remain intact due to the low solubility of calcium alginate in acid.
- In Basic Medium (e.g., pH 7.4)
- They may swell or erode depending on the formulation

➢ *Evaluation of pH: -*

Sodium alginate is itself slightly basic, but when crosslinked with calcium (as in beads), the pH is usually neutral to slightly acidic; the pH is 7.4

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➢ *Loss on Drying: -*

$$Loss\ Of\ Drying = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

2 mg– 1.80mg

Loss of drying = _____ ×100

2mg

Therefore, Loss on drying = 10

➢ *Swelling Index: -*

$$Swelling\ Index = \frac{Initial\ Volume - Final\ Volume}{Initial\ Volume} \times 100$$

250 – 100

Swelling index = _____ ×100

250

Therefore, Swelling index = 60

➢ *Melting Point: -*
The melting point of microbeads is 2100 °C- 2800 °C

➢ *Particle size analysis: -*
The size of the particle is approximately 474- 564 µm after passing through sieve number 23.

XVII. RESULT OF MICROBEADS

We have prepared microbeads using co-processed excipients, and the details are presented in the table below:

Table 5 Result of Microbeads

Sr.no	Parameter	Result
1.	Solubility	Soluble in water
2.	Evaluation of pH	7.4
3.	Loss on drying	10
4.	Swelling index	60
5.	Melting point	210^0C- 280^0C
6.	Particle size analysis	474-564 µm Sieve no.23

XVIII. CONCLUSION

Co-processed excipients are crucial for ensuring the stability of a formulation, as they enhance the drug delivery system with improved physical, chemical, and mechanical properties. These excipients also address challenges related to parameters such as disintegration and dissolution. However, co-processed excipients are expensive, which contributes to the increased cost of the final product. Microbeads also play a vital role in drug delivery systems. Due to their small size, microbeads can display a specific colour depending on the ingredients used. As observed in the experiment, the presence of sodium alginate caused the microbeads to change to a yellowish-brown colour.

FUTURE TREND:

It's prognosticated that the development of knitter-made designed excipients complying with safety, performance, and non-supervisory issues is a current and unborn trend in excipient technology. [8] There may also be somehow change in preparation of microbeads.

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REFERENCES

[1]. World journal of pharmaceutical research co processed Excipients article Volume 6, 2017, pg. no. 1-2, by B Mamatha, D. Srilatha

[2]. Journal Of Chemical and Pharmaceutical Research, **2021**, 13(9):01-10 Sravya K, S Venkateswara Rao, K Padmalatha.

[3]. A Review: Co-processed Excipients-An Alternative to Novel Chemical Entities PD. Chaudhari, AA. Phatak and Ujwala Desai.

[4]. Review On Novel Pharmaceutical Co-Processed Excipients, Volume 2, 2019, pg.no 14- 15, by S.B. Pawar, S.P. Ahirrao,S.J. Kshirsagar.

[5]. Co-processed Excipients: A Revisit of Its Development In the Past Two Decadesl;A Review, 2022, by Liew Kai Bin, Hii Shou Hui, A.B.M. Helal Uddin, Zaidul Islam Sarker, Chew Yik Ling.

[6]. Co-Processed Excipients-A Review, Volume 5, 2020, pg.no 88, by Mukesh Mohite, Sayli Sarnaik, Akshay Lingayat.

[7]. Handbook of Pharmaceutical Excipients Fifth Edition, 2006, by LY Galichet, NA Armstrong.

[8]. Co- Processed Excipients for Dispersible Tablets – Part 2: Patient Acceptability Karolina Dziemidowicz, Felipe L. Lopez, Ben J. Bowles, Andrew J. Edwards, Terry B. Ernest, Mine Orlu, And Catherine Tuleu.

[9]. A review on co-processed excipients used in direct compression of tablet dosage form, 2023,23(01), pg.no. 216-217, by Paka Bhavana and M Sunitha Reddy

[10]. A Review on co-processed excipients: Current and future trend of excipients technology, Volume 11,2018, pg.no 7, by Liew Kai Binab, Ananad Gaurav, Uttam Kumar Mandal

[11]. Evaluation of co-processed excipients used for direct compression of orally disintegrating tablets (ODT) using novel disintegration apparatus witold brniakl, Renata Jachowiczl, Anna Krupal, Tomasz Skorka, and Krzysztof Niwinski.

[12]. Co-processing of small molecule excipients with polymers to improve functionality Prashant kumar K. Parmar, Srilaxmi G. Rao and Arvind K. Bansal

[13]. Review on Preparation and Characterization of a Novel Co-Processed Excipients of Chitin and Crystaline Manitol.

[14]. Preparation of co-processed excipients for controlled-release of drug assembled with solid lipid Nanoparticles and direct compression materials luis Eduardo serrano-mora, Maria L Zambrano- Zaragoza.

[15]. A review on micro beads: Formulation, technological aspects, and extraction GSC Biological and Pharmaceutical Sciences, 2024, 26(02), 059–066 Shaik Khaja Moinuddin, Pradeep Kumar M, Sandeep Kumar G, Perugumi Ramya, Konda Sravya Sree and Kavya K

[16]. Diclofenac sodium Microbeads for Oral Sustained Drug Delivery, International journal of Pharmaceutical Technology and Research. 2009; 1(9): 317-327. Manjanna KM, Shivakumar B and Pramodkumar TM.

[17]. Formulation and Evaluation of Microbeads for Colon Targeted Drug Delivery Using Natural Polymer by Yashika Uniyal, Manoj Kumar Sarangi and Kriti Dabral wjpmr, 2019,5(7), 153-163