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Review Article

Recent Advancements in Pellets by Extrusion Spheronization

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ABSTRACT

Pellets are the multi-unit dosage form which offers many advantages compared to single unit dosage form. Pelletization is an agglomeration process in which fine powders or granules of bulk drugs and excipients into small, free flowing, spherical or semi-spherical units, known as pellets. Pellets typically range in size from 0.5 mm to 1.5 mm. The methods of pelletization include drug layering, Extrusion-Spheronization, Cryopelletization, Compression, Balling, Hot-Melt Extrusion Technology, Freeze Pelletization and Spray-drying & Spray-congealing. Among which extrusion spheronization is widely as it has several advantages such narrow particle size dispersion, flowability, high yield, and excellent process repeatability. The method of preparation of pellets involves following steps i.e. granulation, extrusion, spheronization, and drying. The extruders used in the extrusion process include axial, radial, dome, rotary cylindrical, and ram extruders, etc. Recent advancement in pellets include target specific pellets, floating pellets, self-emulsifying pellets, mouth in melt pellets, protein pellets.

INTRODUCTION

oral solid dosage forms with modified release profiles include two broad categories single unit dosage forms and multiple-unit dosage forms which include granules, pellets or even mini-tablets. Pelletization can be defined as an agglomeration (size- enlargement) process that converts fine powders or particles of bulk drugs and excipients into agglomerates with relatively narrow size range known as pellets[2]. In the pharmaceutical industry, pellets can be defined free flowing, spherical particulates made of drug and pharmaceutical excipients.[3] Pellets range in size generally between 0.5mm to 1.5mm and are largely preferred for oral route of drug delivery.[4] Because of their narrow size distribution, regular shape and reproducible particle surface, a low porosity (about 10 %). the higher density compared to the granules, relatively spherical shape, low friability and free flowing properties;

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they are widely used in multiparticulate systems[5]. Pellets are commonly filled into hard gelatin capsules but it can also be compressed into tablets.[6] The pellets offers some important pharmacological as well as technological advantages over conventional single-unit solid dosage forms, like their smaller size of pellets can rapid stomach clearance, less intra and inter-subject variability in gastric emptying times, homogenous drug distribution in gastrointestinal tract can reduce the risk of side effects due to high concentration of drug in a particular area, maximize drug absorption and reduce the plasma peak fluctuations, and good flow properties with narrow size distribution, better in vivo and in vivo dissolution performance, the risk of dose dumping is reduced, decreased potential irritations in the GIT[7,8]. The different techniques for producing pellets include hot-melt extrusion and extrusion-spheronization, powder layering, solution/ suspension layering, agglomeration in roto granulators or roto processors, compression, spray drying, or spray congealing Extrusion-spheronization is the method of choice because this technique has several advantages such as preparation of spherical pellets with uniform size and high-drug loading (up to 90%) at a moderate cost using minimum excipients. easy and timesaving process.[9,10]

Advantages of Pellets:[11,12,13]

- Optimized therapeutic effect achieved by combining multiple release rates of a medication in a single dosage form.
- There is a high degree of flexibility to the design and development of the dosage form.
- The technology enables the controlled release of the medicine.
- It reduces the risk of side effects while maintaining the drug's bioavailability.
- Prevents the high concentration of a substance within a specific area.
- Reduced risk of dose dumping.
- It Slows the rate of gastric emptying which minimize the inter and intra subject variability in the plasm concentration profile.
- Pellets are ideal for film coating and other processes, because of a low surface area to volume ratio
- Capsules filled with pellets ensure consistent and accurate fill weights.
- Pellets can be used to combine drugs that would otherwise be incompatible.
- Pellets do not generate dust, making them safer and easier to handle.
- Pellets enable the segregation of incompatible ingredients into different layers distributed throughout the pellets.
- Pellets remain intact during transit and storage.
- Pellets resolve issues commonly faced with conventional tablets or crushed tablets.
- Used to mask an unpleasant taste of drugs.
- Coated pellets improves initial acceptance among the patient's and produces a sustained release of the drug.
- Due to their small size, Pellets can be easily dispersed in the G.I.T, they also have a large surface area of absorption and lower the fluctuations of peak plasma levels.

Disadvantages of Pellets: [11,14]

- The filling cost of capsule with pellets is high.
- Compressing pellets into tablets is challenging due to their rigidity, which is why they are often delivered in hard gelatine capsules.
- Pelletization requires advanced and specialized equipment, which increases manufacturing costs.
- Controlling the manufacturing process is complex due to the numerous process and formulation variables involved.

- The production process is difficult to control due to several critical process parameters.

Ideal Properties of Pellets: [12,15]

- Spherical shape and smooth surface is a desired characteristics of pellets.
- The particle size range should be narrow as possible, with the optimum size range between 600 and l000 microns.
- The amount of the active ingredient in pellets should be maximum in order to maintain size of pellet.

Theory of Pellet Formation and Growth:

The mechanism for formation and growth of pellets are essential for selecting the pelletization procedure. A mechanism for the formation of pellets has several theories, some of them are derived from research while others are postulated from visual observations. Pelletization process mainly includes nucleation, transition and ball growth.

The pellet formation and growth includes the following steps:

1) Nucleation
2) coalescence
3) layering
4) Abrasion transfer.[16]

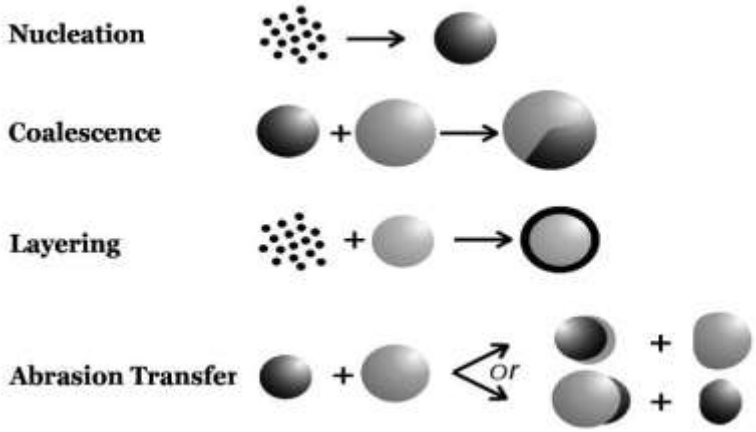


Fig 1: Pellet Formation and Growth

1. Nucleation:

Nucleation is a common stage in all Pelletization processes and occurs whenever a powder is wetted with solvent system. An individual primary particle is drawn together to create an air-water-liquid nuclei system, being held together by liquid bridges. The bonding strength is improved by reduction of particle size[17]. The size, rate and extent of nuclear formation are influenced by factors such as sizes of primary particles, moisture content, viscosity of binding particles, wet ability and the process parameters, such as tumbling and drying rate. The crucial aspect of this process is that the mass and quantity of nuclei vary with time. Nucleation followed by a transition phase where coalescence and layering are the growth mechanism affecting the transition region. This phase is characterized by elimination of fines as a result of coalescence between the primary particles with the formed nuclei. The produced nuclei would consolidate under the influence of the externally applied mechanical forces and acquire sufficient strength to resist further breakdown and will be able to grow into bigger agglomerates.[18]

2. Coalescence:

Coalescence is the formation of large sized particles by random collision of well-formed nuclei, the mechanism requires slight excess moisture on the nuclear surface[17]. Without a minor excess of moisture, coalescence needs additional mechanical stress. The number of nuclei is reduced during this phase while mass of the remains constant during this phase[19].

3. Layering:

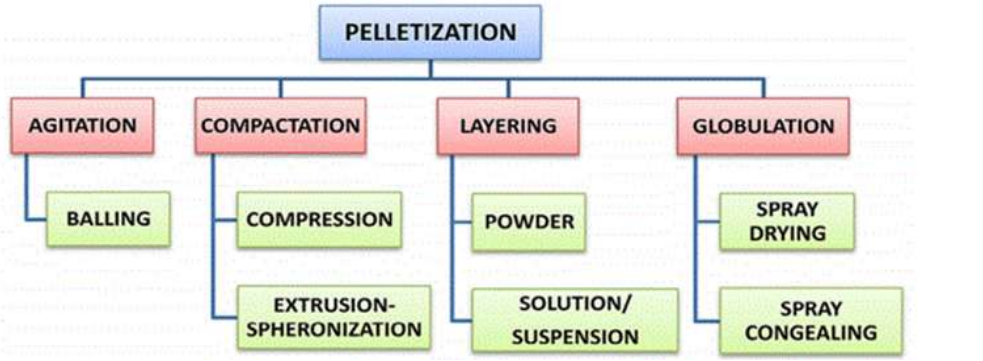
The process of layering requires gradual growth along with bypassing additions of fragments and fine particles onto the already existing nucleus. In the layering step, the number of particles remains same but the total mass in the system increases due to increasing particle size as a function of time[16]. The fragments or fine particles are formed through particle size reduction mechanism like attrition, breakage and shatter. The fines and fragments that are produced through size reduction is captured by large pellets. Production of fines and subsequent coalescence and layering continues until the number of coalescence declines rapidly, thereby leading to a reduction in the rate of growth of the pellets. At this point the third phase, the ball growth region, is reached[17].

4. Abrasion transfer:

The factors affecting the slow growth of agglomeration in ball growth phase is the abrasion transfer which involves the transfer of material from one granule to another without any preference in either direction[17]. The particles are constant in their total particle number and mass. As long as the conditions for the transfer of material exist particles continuously fluctuate in size[19].

Pelletization Technique:

Depending on the type of equipment and processes selected, there are several techniques for production of pellets. Various techniques deal with the systematic breakdown of the various processes within pelletization. These phenomena can be categorized into the following types.[20]



- **Agitation**

During agitation, the appropriate amount of liquid is added to convert finely divided particles into spherical particles by means of a continuous rolling or tumbling motion. The liquid can be added before or during the agitation stage. Pans, discs, and even mixers are capable of performing the balling process and subsequently creating pellets. [21]

- **Compaction**

A compaction is a type of pressure agglomeration in which drug particles or granules are mechanically forced together with or without formulation aids to generate pellets of well-

defined shape and sizes[21]. In the compaction process, the drug particles are prepared by using either wet granulation or dry blending process. Under higher pressure, the particles are forced against each other resulting in elastic and plastic deformation. In extrusion spheronization, an agglomerate is produced due to a binding liquid, and then the mixture is processed in the extruder to produce high-density extrudates. These extrudates are finally converted to pellets on spheronizer[22].

- **Drug Layering**

With layering, the process of pelletization is achieved by adding portions of substrates composed of drug solution, however, the preceding material must be crystals or granules or even other inert starting substances[23]. In the process of stacking powder, a binders solutions sprays onto the nucleus first, then the powder is added. A revolving pan or disc contains moist nuclei that tumble around, picks the powders particle, & produce layer are tiny particle that sticks one another and the nucleus thanks to capillaries force created liquids phases. More powder is continuously layered over the nuclei while more binding liquid is sprayed, continuing until the appropriate pellet sizes are attained[21]. In suspension or solution layering, drug particles in the form of solutions are either dissolved in, or suspended into the binding liquids These powders are then sprinkled on the core and subsequently dried. The ability of a liquid to spread is limited and depends on wettability, material properties, droplet dynamics, and shells wetting and shedding behaviors[22].

- **Globulation**

Globulation is a means of producing spherical pellets core from liquid materials such as melts, solutions or suspensions that incorporate drugs and polymer by atomization. The atomized droplets are exposed to a hot gas stream during spray drying for the evaporation of liquid and transform them into solid particles. The evaporation process involves e heat and mass transfer, which depends upon several factors like humidity, temperature, and transport properties of air which is surrounding a droplets. The airborne droplets must be cooled below the melting point of the solid vehicle. A most important requirement in this process is that the substances having a small melting point area or sharp melting point[22].

Extrusion-Spheronization

The extrusion—spheronization technique is the most commonly used method for production of pellets. This process was first reported by Reynolds and by Conine and Hadley[23]. This method can be applied for making conventional, controlled or modified release dosage forms. In order to ensure a uniform coating and free-flowing properties a constant smooth surface with a restricted size distribution is needed. This method produces uniformly sized pellets or spheroids with high drug loading capacities. Extrusion Spheronization is a multi-step process that produces uniform spherical particles that is referred as spheroids, pellets, beads or matrix pellets depending on the material and the procedure employed during pre-consolidation. The design of good extrudates is such that they are produced in regular shapes that can be pelletized within a desired size range, satisfying controllable dimensions and attributes so that the extrudates are readily sub divided into segments of desired size. When one wants to have dense, spherical pellets of uniform size and shape with high drug loading for controlled-release oral solid dosage forms with a minimal number of excipients, wet mass extrusion also known as cold-mass extrusion became known as the preferred method[19].

Extrusion spheronization mainly involves four steps: -

• Granulation
• Extrusion
• Spheronization
• Drying of pellets [24]

Granulation

a. **Dry Mixing:** Dry mixing of components is performed to create uniform distribution of powder by homogeneous dispersion and is accomplished with top drive twin shell, blend, planetary, high speed, and tumbler mixers.

b. **Wet granulation**: It is done to produce adequate plastic mass and achieve successful work for extrusion, using standard procedures and equipment as in wet granulation [17].

During this step, the evaporation of fluid phase should be minimized. This could be a problem with the high shear mixture which produces large amount of heat. The rise in temperature will lead to evaporation of the granulating fluid, which will influence the extrusion behaviour of the wet mass. Lowering the temperature of the granulation bowl may help fix this issue. During granulation there is a homogenous distribution of the liquid phase throughout the granulated mass[23].

Extrusion

Extrusion is a process where pressure is applied to a wet mass until it passes through the calibrated openings of a screen or die plate of the extruder and further shaped into small extrudate segments. The extrudates must have sufficient plasticity in order to deform, but excessive plasticity can cause sticking of extrudates. The diameter of the segments and the final size of the spheroids depend on the diameter of the openings in the extruder screen[12].

Extruder

The extruder name itself implies that it is used to develop sufficient pressure to force the material to flow into uniform openings that produce the extrudate[24].

The extruder is mainly classified into four categories:

- Screw type extruder (Axial or end plate, dome and radial extruder)
- Gravity feed extruder (cylinder roll or gear roll extruder)
- Sieve and Basket feed extruder
- Piston feed extruder (ram extruder)
- Screw type extruder

- **Screw extruder**

The screw extruder consists of one or two (twin - screw) feeding the wet mass to an axial or radial extrusion screen. In the axial type, the screen is positioned at the end of the screw, while in radial type the screen is placed around the screw, discharging the extrudate perpendicularly to the screws axis[23].

- **Gravity feed extruder**

Gravity feed extruders include rotary cylinder and rotary gear extruders, which primarily differ in the design of their two counter rotating cylinders. In the rotary cylinder extruder, it contains pressure roller solid cylinder that works alongside one rotating hollow perforated cylinder. In rotary gear extruders, two hollow counter rotating gear cylinders with counter board holes are used[23].

- **Sieve and Basket feed extruder**

In sieve and basket extruders, a screw or gravity feeds the granulate into the extrusion chamber

where a rotating or oscillating device pushes the plastic mass through the screen.[23]

- **Piston feed extruder**

Piston feed extruders are considered to be some of the oldest extruders and in these devises, a piston moves forward and displaces material, forcing it through a die at the end. Ram extruders are preferentially used in the development phase, because they can also be used to measure the rheological properties of the formulation[23].

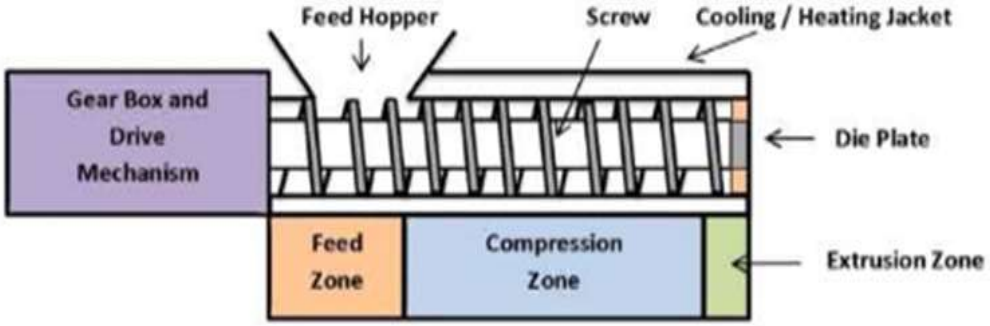


Fig: Axial type screw extruder

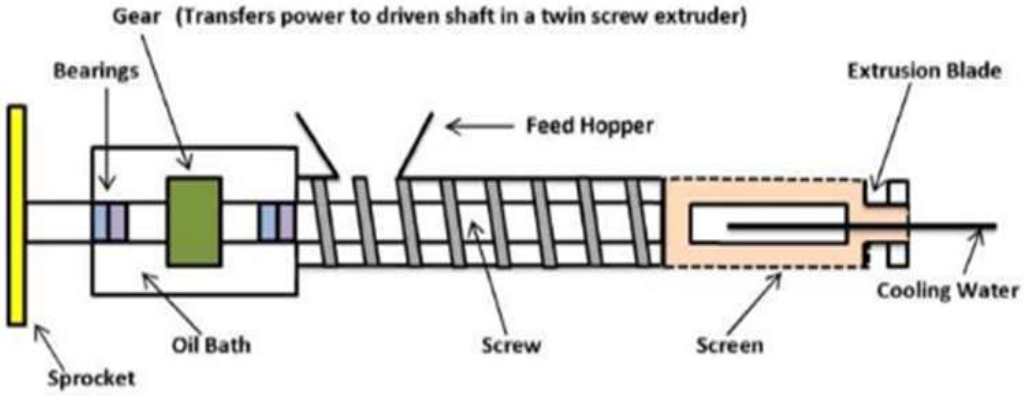


Fig: Radial type screw extruder

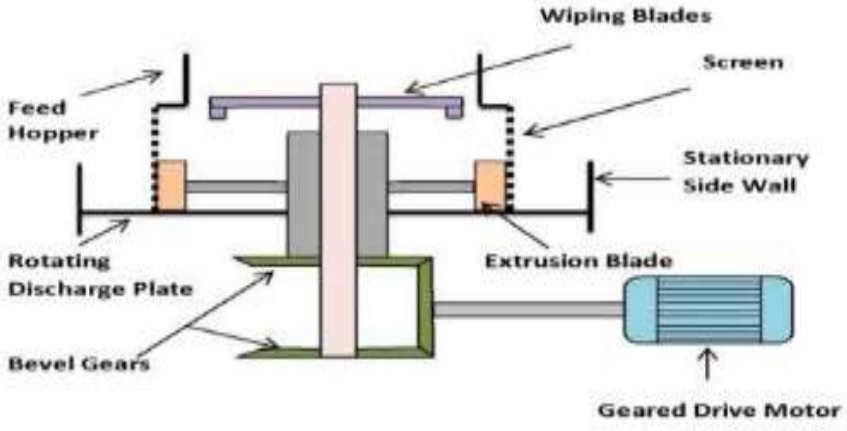


Fig: Gravity feed extruder

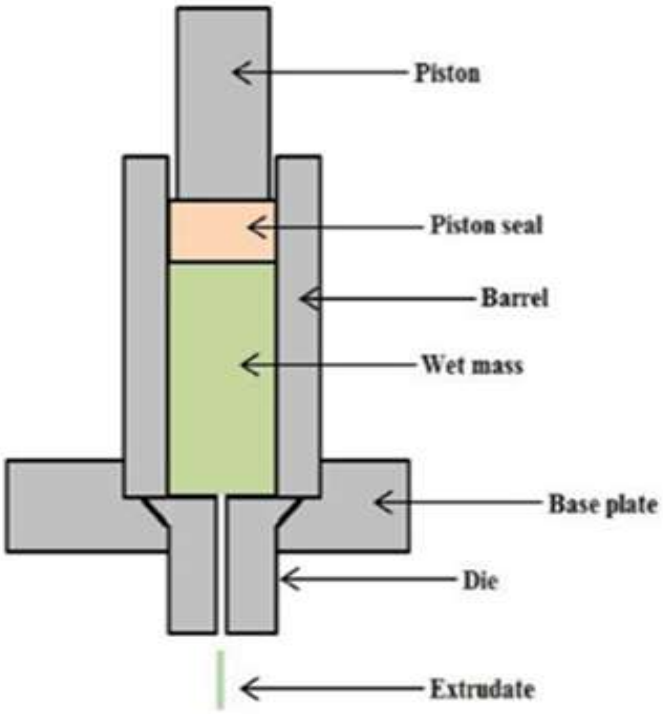


Fig: Ram extruder

Spheronization

This technology emerged with Nakahara's spheronization technology back in 1964. A spheronizer also known as merumerizer consists of a static cylinder and a rotating friction plate[25]. It is known that extruded particles which are cut down to size will gradually form perfect spheres and so, the shaping process is undergo plastic deformation. Extrudates are broken into nearly uniform lengths, all three dimensions of agglomerate are determined and spheres with uniform diameter are obtained. In spheronization process, different stages can be distinguished depending on the shape of the particles, i.e., starting from a cylinder over a cylinder with rounded edges, dumbbell shape and elliptical particles to eventually perfect spheres.[26] The most important part of spheronizer is the friction plate and a rotating disk which have a grooved surface in order to increase the frictional force. This grooved surface has two types of geometry, a cross-hatch geometry in which the grooves form right angles and a radial geometry in which a radial pattern is used. The duration of spheronization is usually 2-20 min and highly spherical pellets requires a rotational speed of 200-400 rpm of the friction plate.[23]

Drying of pellets

To achieve the desired value of moisture content, a drying stage is needed. To achieve the desired value of moisture content, a drying stage is needed. The pellets can be dried at room temperature or at elevated temperature in a tray drier/ oven or in a fluidized bed drier.[25]

Screening

To achieve a desired size distribution, screening processes may be necesary, for which sieves are employed. Regarding pellets formed by extrusion-spheronization, sieving is an essential step post-

manufacture in order to avoid pellets with high size polydispersity index.[25]

Characterization of Pellets:

- **Particle size distribution:**

The particle sizes of the formed pellets are to be measured using an optical microscope with ocular and stage micrometer where the particle size distribution can be calculated. The 'Wesmox model' with a magnification of 45x may be used. The particle size distribution study can also be done by 'Sieve Analysis' technique by using a set US standard sieve of different mesh size known as different sieve numbers with a pellet of the load of 10 gm. The sieve set is to be mechanically shaken for 10 min, total net weight of pellets retained on each sieve was determined and these values are used for calculating particle size distribution.[25]

- **Surface area**

The surface area controls the various characteristics of pellets which includes the pellet's size, shape, porosity, and surface roughness which can be characterized by different techniques like Gas absorption, Air permeability.[26]

❖ **Air permeability**

The air permeability techniques are commonly employed in the pharmaceutical industry for specialized surface measurements, particularly where batch-to-batch fluctuations must be controlled. Fisher sub-sieve sizer is a commonly used device. The surface area of a substance acts as the primary barrier to the passage of a fluid, such as air, through a plug of compacted material. sieve analysis data is used to estimate the specific surface area of uncoated drug granules [24]

❖ **Gas absorption**

The gas absorption is commonly known as the BET method which was developed by Brunauer, Emmet, and Teller (1937). This method was carried out by placing the sample in the chamber and air was evacuated within it. In this method the volume of nitrogen is used which is absorbed by the substrate in the evacuated glass blub and it is measured at different pressures.[24]

- **Porosity**

The formation and erosion of pores in the pellets profoundly affect the drug release profile. . The Scanning Electron Microscopy (SEM), mercury porosimetry and combination of optical microscopy with scanning electron microscopy used together. [26]

- **Density**

Bulk density and tap density of the pellets are used to determine the uniqueness of particle size distribution of the pellet.[21]Changes in the formulation of method can modify the density of pellets, which can have an impact on other processes parameters such as capsule filling, coating, and mixing. The bulk density of the pellets is obtained using an an automated tapping machine. True Density describes the compactness of a substance. True density is a term that describes the degree to which a substance is compacted or densified.[24] The bulk density is determined by the following formula.

$$Bulk\ density = \frac{M}{V}$$

Whereas
'M ' is the exact numbers of pellets in the measuring cylinder
' V ' is the volume occupied by the pellets without disturbing measuring cylinder.

Tap density is determined by the following formula.

$$Tap\ density = \frac{M}{V0}$$

Whereas,

'M' is the exact quantities of pellets in measuring cylinder

'V_o' is the final volume after tapping.[21]

- **Hardness and friability**

These operations make hardness and friability testing essential for transport storage and coating. To measure the hardness, Kaul's Pellet Hardness Test was used. The tablet friabilator Erweka type was used for abrasion testing, which was done over a fixed period with glass beads. [26]

- **Tensile strength**

The tensile strength of pellets is measured by an apparatus with 5kg load cell, where the pellets are pulled under strain until failure to observe collapse. The tensile strength is calculated and load is recorded by applying the value for failure load and by using the pellets radius.[24]

- **Angle of Repose**

The angle of repose is used to obtain the flow properties of powders, granules, and pellets. The measuring technique known as the fixed funnel method is useful for measuring the angle of repose. The pellets are poured into the funnel until the summit of the cone made by the pellets just grazes the tip of the funnel's pipe.

The following formula is used to determine the angle of repose. Whereas

$$Tan\ \theta = \frac{h}{r}$$

Whereas
θ is the angle of repose
h is the height of the cone,
r is the radius of the cone base [21]

Recent Advancement in Pellets

- **Target Specific Pellets**

Pellets are of particular used as cores in the manufacture of coated oral delivery systems due to their spherical or pseudo-spherical shape, consistent size, and smooth surface.[23] Pellet formulations for colon administration is coated with enzymatically degradable, pH-sensitive, or time-controlled polymer coatings. Colon delivery methods based on coated pellets have been developed to take advantage of physiological pH fluctuations in the small and large intestine, to be enzymatically degraded by the colonic microbiota, or to delay the onset of release dependent on the time it takes for dose forms to reach the colon.[27]

- **Floating Pellets**

The main principles of Gastro retentive floating pellets is to extend the residence duration of the medicine and release it in a regulated manner. Due to low bulk density of the floating pellets they float on the gastric environment for a longer period and increase the bioavailability of the drug.[11]

- **Self-Emulsifying Pellets**

Self-emulsifying pellets is efficiently produced by extrusion/spheronization method. The SE pellets that were produced were uniform in size, spherical in shape, and hard enough. The self-emulsifying properties of pellets were found to be intact. After self-emulsification in water, the droplet size

distribution of the SE pellets was nearly equal to that of the liquid SEDDS, and in vitro dissolving performance was compared for the liquid SEDDS and SE pellets, both of which were significantly greater than conventional tablets[23]. In such system, the lipophilic drug is presented in solution, in small droplets of oil, leading to the elimination of the dissolution step which can be the rate-limiting step.[11]

- **Pellets as Proteins**

Protein-based therapeutics such as vaccines, antigens, and hormones have become more popular, but limitations in biology limit the development and production of protein pharmaceuticals. The rapidly expanding pharmaceutical business is constantly looking for new active compounds to produce, which necessitates the development of an appropriate dosage form capable of properly delivering those molecules in the body.[23] The use of pellets as a means for drug delivery offers biopharmaceutical advantages and overcomes the limitations of therapeutic proteins. Extrusion spheronization is the most commonly used method to produce multiparticle delivery systems for the oral administration of therapeutic enzymes and other proteins with high-retained activity.[29]

- **Melt in Mouth Pellets**

Currently, the application of mouth melt pellets has increased due to the ease of drug bioavailability because the pellet can be consumed without water, they melt in the saliva and drug is dispersed or dissolved in the saliva and makes the drug available to the systemic circulation for its therapeutic activity.11These mouth-dissolving pellets can include a wide range of medications and nutraceuticals, resulting in improved patient compliance and a competitive advantage in therapeutic categories where similar products are available.[23]

- **Coating of Pellets**

Recent advancement in pellet technology primarily circle around the improvement of coating methods. The spherical pellets can be coated with rate-controlling polymers or compressed into tablets to achieve delayed-release, extended-release, and targeted-release profiles, new techniques are being developed, which offer enhanced flexibility and a higher degree of stability.[24]

Techniques of Pellet Coating:

Three different spray patterns are used for pelletization:

a) Top Spray Coating:

This process is used for general coatings right up to enteric coating. With top spray Coating in the fluid bed (batch and continuous), particles are fluidized in the stream of heated air which is introduced into the product container through a base plate. The coating liquid is sprayed into the fluid bed from above counter currently through a nozzle against the direction of air flow. Drying takes place as the particles continue to move upwards in the air flow. Small droplets and a low viscosity of the spray medium ensure that the distribution is uniform.[11] This is suitable for protective or colour coatings where the product throughput rates are high. in this method, the product is continuously fed into one side of the machine, and by means of air flow is transported forward via the sieve bottom. the dry coated particles are extracted continuously.[14]

b) Bottom Spray Coating

- **Wurster Coating:**

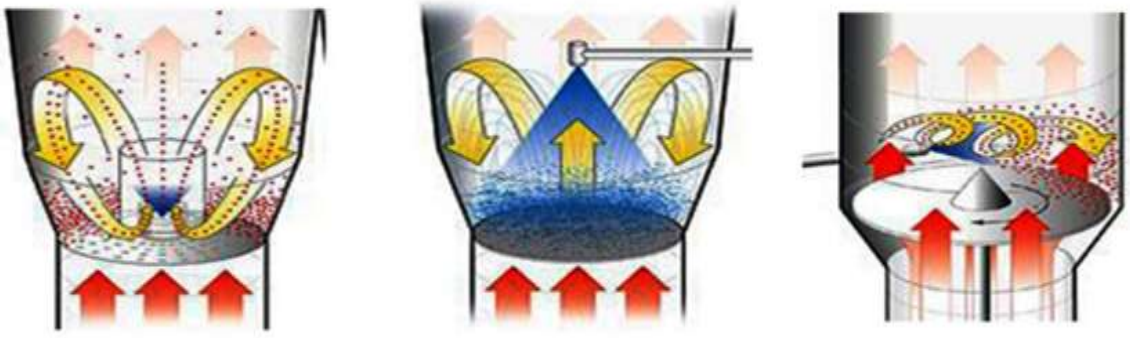
This process is commonly used to produce the controlled release of active ingredients. In the Wurster coating approach, the outer surface is completely bound by the minimum coating substance. The spray nozzle is fitted in the base plate resulting in a spray pattern concurrent with the air feed. A Wurster cylinder with a base plate having differently shaped perforations is ever used. As the particles to be coated flow through the spray cone, they are accelerated in the Wurster tube. The particles move to the top, get dried and are able to fall back to the base plate outside the Wurster tube. Outwardly, they are guided back into the tube where, through circulation, they are re-accelerated by spray. They, therefore, achieve a highly uniform film on differently sized particles.[14]

- **Continuous Fluid Bed:**

This process is suitable for protective or colour coatings in applications with throughput rates are high. The apparatus is designed in such a manner that continuously feeds the product into one side of the machine and through an air flow delivery is advanced via the sieve bottom. depending on the application, the system is sub-divided into pre - heating zones, spray zones, and drying zones where coating liquid is sprayed from below in the form of a bottom spray. the dry and coated particles are continuously extracted.[11]

c) Tangential spray (rotor pellet coating / centrifugal fluid bed granulator)

The operational principle includes centrifugal force, fludization air velocity and gravitational force. In this process the cores are placed on the turntables and hot air is blown upward between the turntables and the granulation area.[16] The passage of air causes the cores to roll on the turntables (spiral motion). Simultaneously, the coating solution is sprayed onto the rotating cores using a pump and spray gun. The process involves the concurrent application and drying of successive layers, repeated until the desired coating thickness or granule size is achieved. The product is set in spiral motion by rotating base plate and spray nozzle is arranged tangentially to rotor disc[11]. The degree of mixing depends on fludization air volume, air temprature, air velocity, slit width, bed size, disc speed determines yield and quality of final pellets. This method is suitable for Film coating, enteric coating, delayed release and hot-melt coating, sugar coatings, modified release.[16]



A **B** **C**

A: Bottom Spray, B: Top spray, C: Tangential spray

CONCLUSION:

In The Past Few Decades Pelletization Technology Has Gained An Increased Interest Within The Pharmaceutical Industry Because Of Its Simple Design, High Efficiency Of Producing Spherical Pellets & Fast Processing, drug stability, controlled release, and enhanced patient compliance. Development of pellet via extrusion spheronization can be a efficient, effective and efficient method for formulation of pellets as it produces pellets with narrow particle size dispersion, flowability, high yield, and excellent process repeatability. The future prospects of pellets dosage forms are promising, with continued advancements expected in the field of pharmaceutical technology. This includes the development of novel pellet formulations for personalized medicine, targeted drug delivery, and improved bioavailability.

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