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REVIEW ON FLUIDIZED BED PROCESSOR TOOLS, TECHNOLOGY AND APPLICATION IN PHARMACEUTICAL INDUSTRY

Miss. Charoskar S. S, Prof. Surawase R. K, Mr. Zalte A. J

Department of Pharmaceutics, Loknete Dr J. D. Pawar college of Pharmacy, manur

ABSTRACT -:

The pharmaceutical industry has found use for the fluidized bed processing technology. 1950 saw the creation of the fluidized bed processor. The newest and most promising area of pharmaceutical science at the moment is formulation development. With its cutting-edge methods, it is successfully grabbing the market today and keeping up with current developments and trends. The purpose of this review is to examine some general aspects of fluid bed granulation and certain widely used methods in the pharmaceutical sector. For granulation agglomeration, stacking, and coating of a wide range of particle sizes, fluidized bed technology is employed. The method can also be applied to the drying procedure. The three fluid-bed process patterns can be divided into three categories based on where the spray nozzle is located, i.e. top spray, bottom spray, or tangential spray.

KEYWORD -: Fluid Bed Processor Parameter , Palletization, Granulation Parameter, Wurster-Fluid Bed Coating, Human Machine Interface

Introduction -:

The fluidized bed processor (FBP) isz a key technology used in pharmaceutical manufacturing today. Fluidized bed systems initially were used as a straight forward but very efficient dryer, but with the addition of a spray nozzle, they promptly transformed into granulators. The main concept of an Fluidized Bed Process or granulation is to spray a granulating solution on to the suspended particles. which then would dry quickly in the air suspended above it. A batch can be quickly dried and granulated using this procedure. The fluid bed top spray method is used in addition to granulation for tableting. This results in granules that are extremely dispersible and have a porous structure that improves wettability. These granules are employed in food, nutritional, and chemical goods. The principle involved in such techniques may be either by bottom spray or top spray or tangential spray process

Concept of fluidization -:

The fluidized bed shows the following properties:

- Lighter particles float on top of the bed
- The beds have a static pressure head due to gravity.

 It has a zero angle of repose.

Drying, chilling, agglomeration, granulation, and coating of particle materials are all steps in the fluidized bed processing process. It is perfect for a variety of products that are both heat-sensitive and heat-resistant. A fluidized state is created by moving a gas (often air) through a product layer at a predetermined velocity to establish uniform processing conditions. The fluidization gas, which provides heat for fluid bed drying, need not be the only source. Tubes or panels submerged in the fluidized layer may introduce heat. In fluid bed cooling, heat is removed by using cold gas (air). The process of coating an object in a fluidized bed involves introducing a coat to cover the target object in order to either protect it or change its behaviour. A fluidized bed coating technique called multiparticulate coating involves coating the bed with solid particles. In this method, a coating material solution is sprayed onto the surface of fluidized solid particles to deposit a layer. The deposited solution is dried using the fluidizing gas to create a coat on the particle or multi-particle surface. Because of their high energy and mass transmission, modified fluidized beds are being employed for coating.(Remington JP. & Remington et al.,2006)

PRINCIPLE OF FLUIDIZATION

The principle of fluidization is when a gas is sent through a nozzle with a velocity of greater than the settling velocity of particles or solids, the particles tend to suspend in the air provided and continue in the stream of upward gas. When the particles are reaching to the top of the equipment, they tend to gravitational pull and so fall down and the process is suspending continues. This process is called as fluidization of suspended particles.(Räsänen E et al.2004,Pusapati RT, Rao TV et al.,2014)

Fig. No. 1: Indicating and Control Elements of FBP.

1.Dial Gauge -:

Method selection-:

- end play
- distance versus radius.

1) End play or float

practically all machines that beat journals or sleeves feature some sort of end play or float. If enough force can be given to the end of the shaft while it is rotating to keep it firmly seated against the thrust bearing or plate, it is deemed controllable. However, applying pressure to the shaft of huge machinery or machinery that needs to be electrified and "bumped" to obtain the desired rotation is frequently challenging and/or risky. The indication reversal approach must be utilised in these circumstances since float has a minimal impact and makes it impossible to obtain correct face readings.(Piotrowski J et al..,2006, Boyes W.et al.,2009)

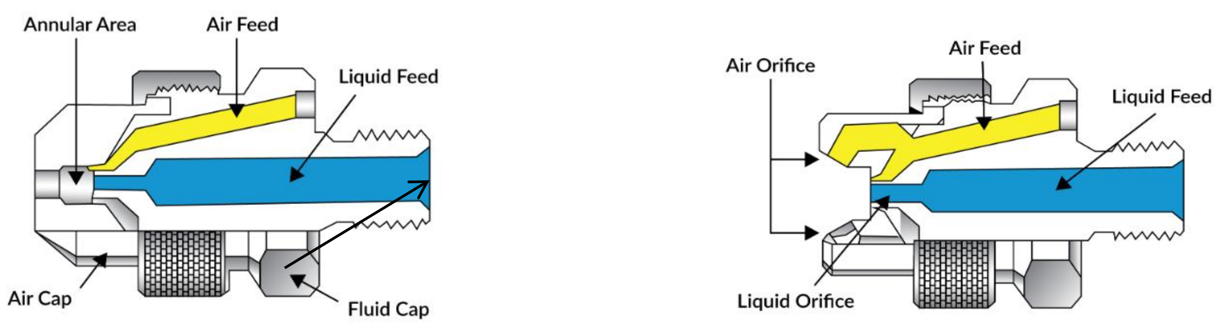
2) Distance versus radius -:

There is a choice of which approach to employ if float is controllable. The following rule determines the appropriate approach when there is a choice: The indicator reversal method should be utilised if the distance between the points of contact of the two dial indicators set up to take rim readings for the two-indicator method is greater than half the diameter of travel of the dial indicator set up to take face readings.(Piotrowski J et al..,2006, Boyes W.et al.,2009)

Fig. Dial Gauge

2.Atomization Air Nipple -:

Air atomizing nozzles **atomize fluids by combining liquid and compressed air/gas at low pressures to form a very fine spray**. They can create either a fan or cone spray pattern depending on the design of the nozzle. There are two methods of mixing fluid and air: internal and external. (Fernando RH et al.,2001, Zbicinski I. et al.,2022)



Internal Mixing -: Liquid and air streams come together inside the nozzle and are mixed, and they exit through the same orifice. The streams are not independent; airflow changes will affect the liquid flow. Not suitable for viscous liquids above 200 cP.

External Mixing-: The air and liquid streams exit the nozzle independently through each orifice. Air and liquid flow rates can be independently controlled, allowing precise fluid metering. Suitable for all liquids, including viscous liquids above 20

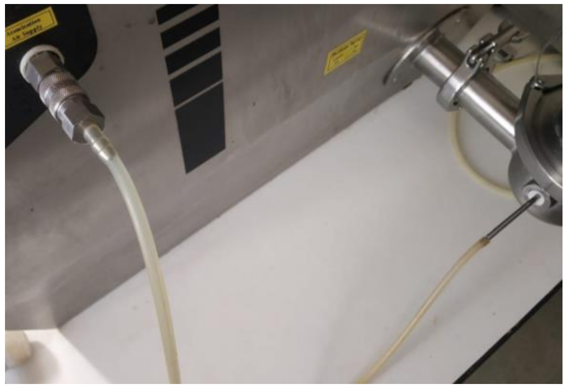


Fig. Atomization Air Nipple

3.Control Switch (Regulator) for inlet airflow & atomization air –:

Pneumatic systems employ flow control valves to manage the compressed air flow rate. The speed of the pneumatic cylinder can also be directly controlled by adjusting the flow rate. Fu Throttling refers to a slowing down or dampening process.[11,12] Throttling refers to a slowing down or dampening process. Thus, a throttling valve reduces the air flow's velocity. This is accomplished by changing the flow rate by turning a control knob to alter the height of the throttling needle over its nozzle. The equivalent cylinder chamber will fill less quickly when the flow is decreased, which results in a slower cylinder movement.

Fig. Control Switch For Inlet Airflow And Atomization Air

4. HMI (4”Human Machine Interface)-:

Siemens' 12 inch HMI panel serves as the operator panel unit. There are two levels of passwords required to access the panel, which are engineer level and operator level for operation and process management, respectively (data setting & modification). The control system and HMI showing-able are developed with interlocks and alarms. It is designed to have a specific page on HMI logging historical alarms. The HMI has an A4 printer nearby for printing process/data and alarms. . Top brand devices are used in the main apparatus. It is compatible with the Profinet (Industrial Ethernet) interface of SCADA (supervisory control and data acquisition)systems. When the pressure in the filter chamber and spray chamber exceeds the set value, it is necessary to increase the bag shaking time or frequency in order to maintain constant pressure. When the pressure in the spray chamber and base exceeds the set value, it is necessary to increase the fan speed or open the air door simultaneously in order to lose the material, to maintain constant pressure. It must have readily available emergency buttons. It is essential safety equipment in compliance with the norms and laws on labor protection to have an isolation module equipped with electrical standard wiring. cabinet for electric controls all of the equipment in the electrical cabinet, together with the cables and wires, must be properly tagged and labelled. Any cables used to link sensors, motors, and drives to the outside world must be insulated. The weak energy is shielded by the ground while the powerful electricity is separated. The operator can adjust the inlet temperature, choose the duration of the filter bag shaking, start and stop the blower motor, raise and lower the product chamber, check the exhaust temperature, and more from the control panel. Choosing a Programmable Logic Controller automated control system improves the effectiveness of controlling the drying process . (Eljabiri O. et al., 2014, Easton G et al.,2016, Sun Q & Zhang M et al..,2019)

Fig. HMI (Human Machine Interface)

5.Filter Bag & Housing Assembly-:

The filter bag and filter housing assembly are crucial components of fluidized bed machinery. The number, design, size, form, and other details of filter bag housing are covered by manufacturer patents. The filters are cleaned using the filter shaking device and the filter below off device. These are constructed from a variety of textiles and materials, including cotton, nylon, polyester, satin, and polypropylene. These can support hot air at high pressures and at high flow rates. The required factors, such as retention micron, static change, and air permeability, are taken into consideration during the manufacture of fluidized bed processor filter bags. As they are produced in accordance with specifications and are routinely inspected to ensure that they satisfy standards of quality, fluidized bed processor filter bags are both affordable and long-lasting. The finger-like form of fbp finger bags increases the efficiency of their surface area. Drying process in fbp depends upon the moc (Management of Change) of the finger bags. (Hovmand S. et al.,2020)

Fig. Filter Bag And Housing Assembly

6. Expansion Chamber -:

The expansion chamber is attached to the supporting column for the machine, which is fastened to the floor with bolts. The sight glasses are designed for monitoring the drying process visually. Numerous spray gun ports are evenly spaced out around one circle of the expansion chamber. expansion chamber is made up of hard glass containing sugar sphere or pellets.

Fig. Expansion Chamber

7. Product container -:

The product container should be made of polished stainless steel of the highest quality and be the appropriate size and form. A screen of the appropriate size needed to catch the product should be kept in the bottom portion. Additionally, it might have nozzles that spray fluid from below, choppers to break up granule lumps during processing, and specific film-coating partitions**.** This container, as its name suggests, contains damp material that needs to be dried. The high shear mixer typically produces wet grains. The product container has a transportable trolley included. It may occasionally be removed from the fluidized bed dryer and wheeled to the following piece of machinery, such the lifting column. The bottom mesh/distributor plate of the product container is another crucial component. SS clamps are used to secure it.

Fig. Product Container

8.Lower plenum -:

Transferring air up the main tower is made easier by the plenum chamber. The product chamber and the bottom chamber are interlocked before production begin. A rubber tube that transports the clean, hot, and dry air connects the base component to the AHU (Air handling unit) unit. When closed, a butterfly valve along the air input tube prevents air intake. The input air plenum is another component of the base portion. Transferring air up the main tower is made easier by the plenum chamber. The product chamber and the bottom chamber are interlocked before production begins. An inflated gasket seal guarantees that the connection is leak-free and airtight.(Frey C.et al.2023)

Fig. Lower Plenum

9.Nozzles Spray -:

Typically, hot-melt material, solutions, dispersions, and solvents are sprayed into the fluid bed using two-fluid nozzles. In Figure, a typical two-fluid nozzle is shown. Due to their limited use in the food sector, other designs, such as an annular, radial spray pattern, have been disclosed and configured into fluid-bed systems, but they will not be covered in this article. The sprayed substance is pumped through the nozzle tip as one of the fluids in a normal two-fluid nozzle. The second fluid, usually air, is forced through the coaxial channel that surrounds the nozzle tip to atomize the liquid as it emerges under pressure from a dried, compressed air supply. The degree of atomization is controlled by nozzle design, air volume, and air velocity. Nozzle tips differ according to their inside and exterior diameters, inside diameter of cap orifice, length above cap, and direction of air channelling before cap exit. The average range of atomized droplet sizes is 5 to 100 m. The majority of the time, parameters can be changed to produce a droplet size distribution with a median diameter of 8 micrometres or higher. The spray rate, viscosity, and nozzle design limitations all affect the final dispersion. When coating individual particles in a Wurster coater, droplet size might be a crucial component even if the purpose of granulation work is to create larger agglomerates. Speed of drying, as well as core particle size and integrity, are the main issues. Figure represents a theoretical evaluation of the available surface area for water droplet sizes ranging from 5 to 50 m.(Wang H et al.. 2021,Aguilera-Chávez SL et al..2022, Frey C.et al.2023)

Fig. Nozzle Spary

10. Port For Top Spray Nozzle -:

In order to reduce agglomeration, the expansion chamber is prolonged, allowing powder to be fluidized for longer while moving more quickly. The conical shape of the expansion chamber allows for a consistent slowing of the air stream. There is a bigger filter housing. Its design enables shaking the fines back into the bed without stopping fluidization, which lessens agglomeration tendencies. The coating materials are impinged on the fluidized particles only a short distance from the nozzle, which decreases droplet spray-drying and allows for a longer following drying of the coated particles. The nozzle is kept low in the expansion chamber. Top spray coater is used to apply aqueous and organic solvent based film coating § Controlled release coating § Hot melts on granules & small particles .(Fries L.et al..2011,Gryczka O et al..2008, Frey C.et al.2023)

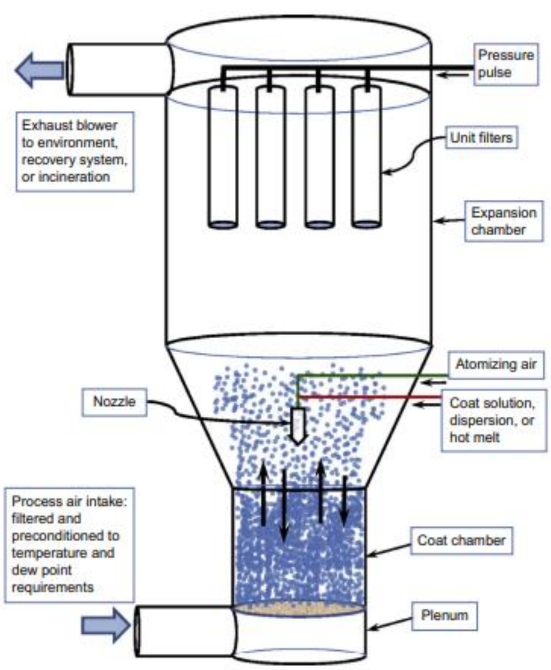


Fig. Top-spray nozzle

11. Temperature sensor-:

Inlet process air temperatures for fluid bed coating in food applications typically range from near ambient to 210F. The product chamber's input temperature is measured in the plenum area directly beneath the base plate. The setting of the input temperature is influenced by a variety of factors, including the solvent vehicle's (volatility), the properties of an ingredient's stability, process considerations (such as electrostatic cling), and core or coating characteristics, such as a glass transition temperature or melt point. Fluidized beds are only exposed to the inlet temperature close to the base plate because the temperature quickly changes after passing through the plate to temperature conditions inside the coating unit. The outside temperature and any gains or losses from it, the volume of air flowing through it, and any evaporative cooling or hot-melt warming from the coating material that was sprayed on all have an impact on the temperature inside the unit. In the absence of any limiting factors, inlet temperatures for evaporative processes are created to deliver an appropriate drying capacity without spray drying coating prior to particle contact. The intake temperature is often adjusted lower than the melt point of the melt substance in order to allow hot-melt coatings to solidify on particle surfaces. Additional critical temperatures include the bed (product) and outlet temperatures. The bed temperature is measured at the exterior of the fluidizing bed, and the outflow temperature is measured at the exterior of the expansion chamber. The setup of the equipment and the process settings determine how much (usually only a few degrees) the temperature at the bed and outflow varies.(Frey C.et al.2023, Burggraeve A.et al..2013, Wang H et al.. 2021)

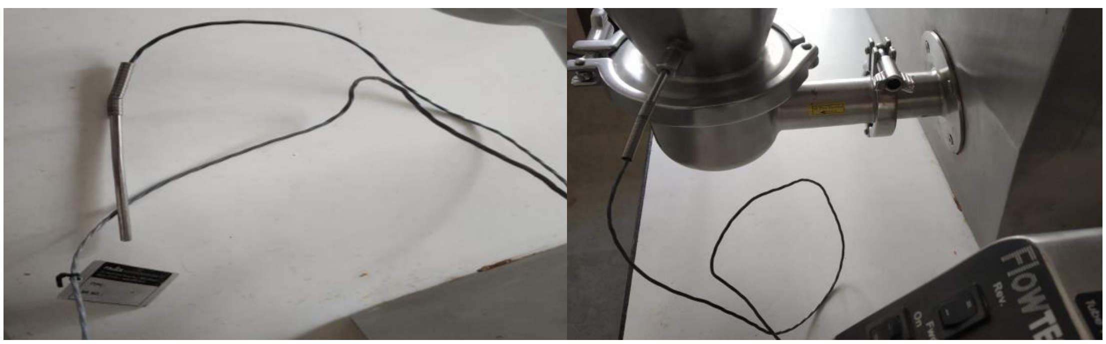


Fig. Temperature sensor

12.Port for bottom spray nozzle-:

The cylindrical product container used by this coater has perforated plates. A second cylinder (coating partition) is present in the container and is elevated just above the perforated plate. A nozzle for dispensing the coating solution is located in the center of the plate beneath this divider. The perforated plate is made with large holes under the coating partition and smaller holes throughout the rest of the plate, with the exception of one ring at the edge with larger holes. For sustained release coating, bottom-spray coating is widely utilised because it produces a high-quality, reproducible film with well ordered particle flow. Solvents, aqueous solutions, emulsions, suspensions, films, and hot melts can all be handled using this procedure. It coats small particles, pellets, and tablets in batches ranging in size from a few 100 gm. to 600 kg.(Fries L.et al..2011, Chan L.W. et al.2006, Frey C.et al.2023, Burggraeve A.et al..2013)

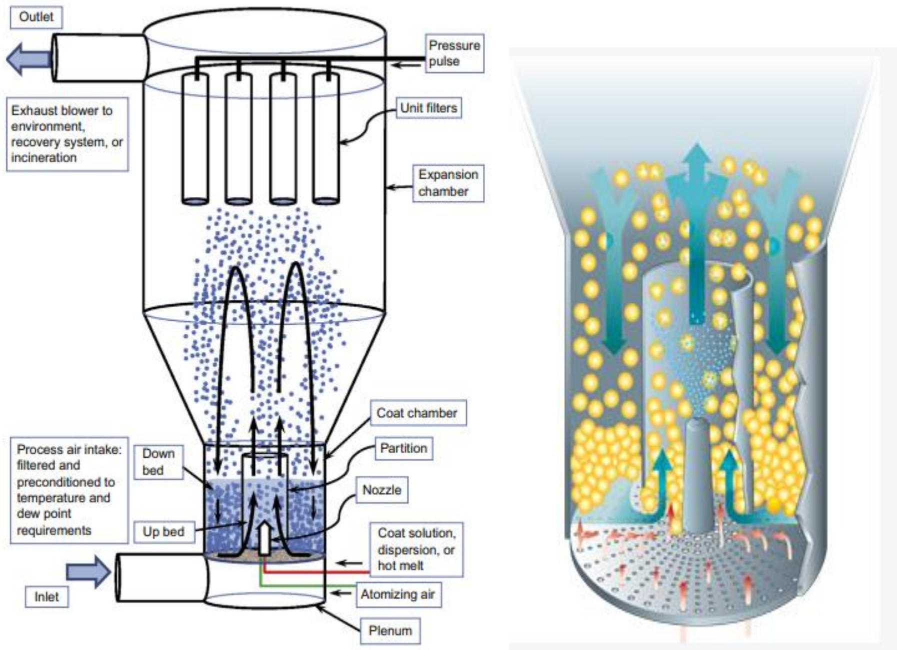


Fig. Port For Bottom Spray Nozzle

13. wurster (bottom spry) fluid bed coating -:

The Wurster method is acknowledged as the most effective fluid bed method for coating certain particles. The possibility of particle aggregation and attrition is reduced by the upward migration of particles at low population density along with spray direction and rapid drying. This system can be set up and operated to granulate material in addition to coating, producing goods that are comparable to those made by other fluid bed processes. The fluidization plate at the bottom of the particle bed causes a differential air flow, which is one of the characteristics of the Wurster fluid bed coating system shown in Figure. This disparity causes air in the "up bed" or "coating zone" to travel quickly upward at the same time as the upward spray direction. Since the air velocity in this area is far higher than what is necessary to fluidize the particles, particles are rapidly propelled upward alongside spray. In the middle of this up bed area, the nozzle is positioned at the base of the bed. The increase in cross-sectional area causes particles to slow down as they go from the up bed region into the expansion chamber. When they slow down, they land in the area known as the "down bed," which encircles the up bed region. The process air in a system that is correctly built and operated is enough to sustain fluidization in the down bed region while also accelerating particles through the up bed zone. Due to a smaller particle population at the base of the fluidizing down bed region, the air flow takes the route of least resistance into the up bed region; as a result, particles close to the down bed base are moved inward to feed into the up bed region. In an ideal arrangement and batch loading, particles complete a cycle once every 6 to 10 seconds. Until the desired coating or qualities are obtained, the process is continued.(Frey C.et al.2023, Burggraeve A.et al..2013)

Theory of Fluidization -:

- ✓ **Static bed** : When the velocity of the suspending air is low, no air suspension of particles occurs because the supplied air travels through the vacuum areas of the bed without disturbing the particles.
- ✓ **Expanded bed** -: The bed expands in the stream when the air flow rate is intermediate; this is known as an expanded bed.
- ✓ **Mobile bed** -: The particle bed is swept to the top of the vessel when the air stream is very high, or moving at a high velocity. It is referred to as a mobile bed.
- ✓ **Bubble formation** -: The bed expands and bubbles start to develop as the velocity rises.
- ✓ **Pneumatic transport** -: This occurs as the air speed continues to rise, which causes the particles to be blown out of the stream.(Pusapati RT ,Rao TV et al..2014)

Application of fluidized bed processor -:

- **Fluid bed Drying** -: Solids can be dried extremely well using fluid bed drying. Every single particle's whole surface is drained of liquid during the fluidization process. Excellent heat exchange and the perfect drying time are benefits.
- **Fluid bed Granulation/ Agglomeration** -: A contemporary technique for making granulates from powder using liquid bridges is agglomeration in the fluid bed. The liquid that is sprayed may be water, an organic solvent, or another binder. The wet powders are either dried or chilled. The agglomerates are thus loose, have a low bulk density, and are exceptionally soluble in water.
- **Powder coating / particle coating** -: The use of protective films in modern film coating allows for the selective manipulation of product properties. During coating, a very consistent coating material application is crucial. The coating must offer a complete seal that is free from tearing or mechanical damage. A technically challenging procedure with a very broad range of applications is film coating.
- **Pelletizing** -: Pelletizing involves mixing and moistening powder. A solvent or binding agent may also be included at the same time. Agglomerates formed by the centrifugal force are spheronized into homogenous, dense pellets. Direct pelletizing or stacking can be used to achieve specific product properties.(Pusapati RT ,Rao TV et al..2014)

Advantages of fluidized bed processor -:

- A quick mixing process, constant temperatures, and concentrations.
- By responding slowly to changes in operating circumstances and resisting rapid temperature changes, exothermic processes prevent thermal runaway.
- acceptable for both big and small activities.
- Smaller surfaces are needed because of the high rates of heat and mass transmission.
- Air drying and the solid material are in opposition to one another.
- It is possible to carefully de-dust the solid material while it is drying and cooling.
- Due to heat recovery based on recirculating the cooler exhaust air, dryer-cooler types provide a reduced fuel need. (Räsänen E et al.2004, Pusapati RT, Rao TV et al.,2014, Aleksić I et al.,2014)

Disadvantages of fluidized bed processor -:

- Fine particle beds that bubble up are less effective and more unpredictable.
- As a result of the intricacy of fluidized bed behaviour, scaling up from smaller scale to industrial units frequently presents challenges.
- Breaking apart of particles is widespread.
- Particle collisions cause the walls of vessels and pipes to deteriorate.
- irregular flow patterns (difficult to predict)
- Fine particle beds that bubble up are more unpredictable and less effective.(Räsänen E et al.2004, Pusapati RT, Rao TV et al.,2014, Aleksić I et al.,2014)

Processing parameter -:

1) **Drying parameters**-:
   - ✓ **Temperature** :As incoming air temperature rises, drying rate increases. This needs to be closely watched because as the temperature of the inlet air rises, the exposure of the thermolabile chemicals degrades.

- ✓ **Humidity** : Moisture content is crucial for the compound to dry out. When opposed to when the intake air has high humidity, the drying process is completed more quickly when the inlet air has lower humidity.(Teunou E et.al.,2002)

2) Granulation Parameter

- ✓ **Position of nozzle** : For better drying, the location of the nozzle should be changed based on the height of the bed.
- ✓ **Spray rate** :The spray rate should be set to its ideal level to avoid over-granulation.
- ✓ **Spray pressure** : Continuous pressure monitoring is necessary because changes in pressure can result in inappropriate drying and granulation processes. (Pusapati RT, Rao TV et al.,2014, Teunou E et al.,2002)

3) Coating parameter

- ✓ **Distance of spray nozzle** : The distance of the spray nozzle is crucial in determining the coating process since a greater distance causes the coating solution to evaporate, while a smaller distance causes over-wetting of the particles or dosage forms.
- ✓ **Droplet size** : The effectiveness of coating is inversely related to droplet size. The homogeneity of coating of the fluid increases with decreasing droplet size.
- ✓ **Spray rate** : Neither too fast nor too sluggish of a spray rate is acceptable. To achieve superior coating, the spray rate must be kept at its ideal level.
- ✓ **Spray pressure** : Coating solution atomization is influenced by spray pressure.
  The equipment's moisture causes hygroscopic materials to deteriorate. It is important to thoroughly dry the coating solution to ensure a uniform coating. Therefore, it is important to monitor the temperature for a better coating solution. The duration of drying also significantly affects the coating process. The coating layer may become brittle as drying time increases, which might cause processing issues. Additionally, if the coating layer is not sufficiently cured, doublets and triplets may form as a result of the tablets clinging to one another.(Pusapati RT ,Rao TV et al..2014, Aleksić I et al.,2014)

Application -:

1)For enteric release, barrier films, and flavour masking on particles and tablets, top-spray fluidized bed coating is used. For sustained release and enteric release, bottom spray coating is employed, while tangential spray coating is used for SR and enteric coating items.

2) For coating powders, grains, tablets, pellets, and beads suspended in an air column, fluidized The three varieties (Top spray, Bottom spray, and Tangential spray) are primarily utilised for

3) The three varieties (Top spray, Bottom spray, and Tangential spray) are primarily utilised for polymer film coatings that are based on aqueous or organic solvents.

4) Fluidized bed dryers are used to dry a variety of products, including coal, fertiliser, plastics, tablets, powders, and granules.

5) Pharmaceutical powders are granulated using this procedure.

(Santhoshkumar S et.al.,2017, Shekade SV et.al.2015)

Conclusion -:

In the pharmaceutical sector, fluidized bed processing technology has become the most popular technique. In comparison to other methods of coating and drying multiparticulate materials, fluid bed processors have significant benefits. High thermal efficiency drying and coating are made quick and simple by fluidization. So the pharmaceutical business is currently seeing excellent outcomes from fluidized bed processing technologies.

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