RJC
http://www.rasayanjournal.com

RASĀYAN J. Chem.
Vol.2, No.2 (2009), 447-450
ISSN: 0974-1496
CODEN: RJCABP

FLUIDIZED BED PROCESSING FOR MULTIPARTICULATES

Vipin Saini
B.R. Nahata College of Pharmacy, Mhow Neemuch Road, Mandsaur (M.P.) 458001
Email: singhvipins31@rediffmail.com

ABSTRACT

World wide in pharmaceutical industry, fluid bed processing technology emerged as useful application. Batch type fluid processes are using in pharmaceutical industry since 30 years. Originating in Europe, this technology gradually found its way into U.S. manufacturing facilities, beginning with the use of fluid bed dryers. The earliest fluid bed dryers were a cabinet type construction with a simple cylindrical product container which was located on exhaust air filter. Even with such an elementary design, it was apparent that new methods showed great superiority over conventional tray drying techniques. This attracted a great deal of interest within the pharmaceutical industry which leads to improvements in the design and additional features were soon developed. This gave rise to applications other than drying of granules like spray agglomeration, coating of spheroids, particle coating and powder coating. Now fluid bed process technology plays a wonderful instruments /machines to manufacture and coating of multiparticulates.

Keywords: Fluidized bed coaters; Coating process

INTRODUCTION

Fluidized bed processing involves drying, cooling, agglomeration, granulation and coating of particulates materials. It is ideal for a wide range of both heat sensitive and heat resistant products. Uniform processing conditions are achieved by passing a gas (usually air) through a product layer under controlled velocity conditions to create a fluidized state. In fluid bed drying, heat is supplied by the fluidization gas, but the gas flow need not be the only source. Heat may be introduced by tubes/panels immersed in the fluidized layer. In fluid bed cooling, cold gas (air) is used to remove heat. Fluidized bed coating is a process that takes place inside a fluidized bed whereby a coat is introduced to cover the intended object in order to protect it or modify its behavior [2,3]. Multiparticulate coating is a form of fluidized bed coating involving the coating of solid particles inside the bed.In this process, a layer is deposited onto the surface of fluidized solid particles by spraying with a solution of the coating material.The fluidizing gas is also use to dry the deposited solution to form a coat on the surface of the particle/multiparticulates.Today modify fluidized beds are used for coating because of their high energy and mass transfer [4,5]. The improvements made in the original fluid bed dryers led to the following machines based on fluid bed technology –

1. Tangential spray or centrifugal fluid bed granulator, 2. Double-walled centrifugal granulator,
3. Wurster coating process equipment

Tangential spray or centrifugal fluid bed granulator

This equipment was originally developed to perform granulation processes and was later expanded to perform other unit operations including the manufacturing and coating of multiparticulates and is used in powder layering and solution/suspension layering pelletization technique. The basic operational principle includes centrifugal force, fluidization air velocity and gravitational force. During a layering process, these three forces act to generate a spiral rope like motion of the particles in the product bed. It contains rotating disc, which create centrifugal force that pushes the particle outward to the vertical wall of the product chamber or stator.The fluidization air generates a force that carries the particle to vertical along the wall of the product container into the expansion chamber. The partical lose their momentum and cascade down towards the center of the rotating disc owing to gravitional force. Besides rotating disc, the other unique feature of the centrifugal equipment is the spray method. During layering the liquid is sprayed tangentially to and concurrent with partical movement.The degree of mixing depends on the fluidization air volume, velocity, the slit width, the bed size and the disc speed. These variables, as well as liquid and powder application rate, atomization air pressure, fluidization air temperature and degree of moisture saturation determine the yield and quality of pellets [6,7].

Double-walled centrifugal granulator

It is more or less similar to tangential spray or centrifugal fluid bed granulator in terms of principle and design .It is double walled and the process is carried out with the inner wall in the open or closed position. For example, with powder layering the inner partition is closed,so that simultaneous application of liquid and powder could proceed until the multiparticulates have reached the desired size. The inner wall is then raised and the spheres enter into the drying zone. The pellets are lifted by the fluidization air up and over the inner wall back into the forming zone.The cycle is repeated until the desired residual moisture level in the pellet/ multiparticulates is achieved[8].

Wurster coating process equipment

Wurster coating process equipment was invented three decades ago and had elaborated design modifications,refinements into ideal equipment for the manufacture of multiparticulates by solution/suspension layering.The high drying efficiency inherent in fluid-bed equipment, coupled with the innovative and efficient design feature of the wurster process, proved to be predictable and economically feasible pelletization equipment.The most important characteristic that make out wurster equipment from other fluid bed equipment are the cylindrical partition located in the product chamber and the configuration of the air dispenser plate, known as the orifice plate. The latter is configured to allow most of the fluidization or drying air to pass at high velocity around the nozzle and through the partition, carrying with it the particles that are being layered on.Once the particle exits the partition, they enter the expansion chamber, where the velocity of the air is reduced below the entrainment velocity and the particle fall back to the area surrounding the partition (down bed). The down bed is kept aerated and the particle from the down bed are then transported horizontally through the gap between the air distributor plate and the partition by the suction generated by the high air velocity that prevails around the nozzle and immediately below the partition.The spray direction is concurrent with the particle movement and particle motion is well structured under optimum conditions, uniform layering of the drug substance is consistently achieved.

There are a number of possible processes that can take place inside the bed depending on the bed's conditions, non-pareil seed particle characteristics and the coating material used. Once the coating solution is atomized in the nozzle, the resulting droplets can be successful or unsuccessful in reaching and attaching themselves to a particle surface.The coating solution that does not attach itself to a particle is spray dried and may be elutriated out of the bed if it is light or remain in the bed if it is sufficiently heavier. The fines that remain in the bed can be joined with other spray-dried fines resulting in fines agglomeration or they can be captured by larger particles resulting in 'snow ball' growth. When an atomized coating solution successfully collides with particles, it wets their surfaces. Depending on the conditions inside the bed, wetted particles may collide and form liquid bridges between them or they can be dried resulting in a layered growth. If there is excessive wetting, many particles will form bridges between them, thus joining together to form large wet clumps which will lead to the defluidization of the bed in a phenomenon known as wet quenching. In the case of moderately wetted particles, a number of solid particles will remain joined together when their liquid bridges are dried. The continuing existence of these solid bridges will depend on their strength. If the adhesive force is strong and the solid bridges join together many particles, then these particles will remain joined and the bed will eventually collapse as it can not fluidize these large particles. This occurrence is also known as dry quenching. At the same time, if the adhesive force is strong but the solid bridges joins together only a few particles, the process will continue and the resulting product will be a few particles joined together to form larger particles (i.e. agglomeration). On the other hand, if the adhesive forces are weak, the dried solid bridges will break leaving some coating on the surface of the particles. This will ultimately lead to coated particles. The challenge in achieving a successful coating process is to ensure that the sprayed coating material reaches the particles to be coated without excessive wetting. Furthermore, one has to ensure that the liquid bridges formed by colliding wet particles will break upon drying thus allowing the coating material to remain on the surfaces of individual particles. This has to be prepared inside the bed in the presence of all three phases as time heat, mass and momentum transfers are taking place at the same time [9,10,11].

PARAMETERS CONSEQUENCE FLUIDIZED BED COATING PROCESS

Feed particle dimension

Particle size of pellets should be ideal for fluidization and coating. The very small or too large, give makes disorganized fluidizing. If too small, twinning and agglomeration of multiparticulates may occurs[12].

Spray gun parameters

Atomization of the coating solution provides an ideal solution to the problem of introducing the solution to the bed. It solves the problem of local wet quenching which may be a result of excessive wetting of particles by large coating droplets.

The position of the spray nozzle in a fluidized bed depends on the construction of the equipment, the material to be processed and obtain the desired product. A assortment of nozzle positions have been adopted in particle granulation, resulting in different products. The nozzle may be positioned above the bed (top spraying), inside the bed (submerged spraying) or at the bottom next to the distributor plate (bottom spraying). If the bottom spraying is employed in a fluidized bed, there is an increasing danger of defluidization by wet quenching. The bottom spraying design is normally modified to move particles through the spraying zone as quickly as possible. This is accomplished in a variety of ways, including the use of a draft tube and unequal fluidization in the wurster design as well as using spouting gas in a spouted fluid bed. Recent developments allow the use of multiple nozzles bottom spraying. The top spraying can easily be accompanied by extreme spray-drying and elutriation of the coating material. However, this may be preferable to the increased danger of wet quenching associated with submerged spraying. The particle wet ability and coat drying varies with different coating materials. Nozzle diameter plays a important role on coating, the increase in load in fluidized bed coater require an increased diameter of nozzle and for more viscous solutions, need to use bigger nozzle diameter[13].

Coating solution

In the early days organic solvents were used in the preparation of coating solution.They allowed fast coating at relatively low fluidization gas rates and temperatures, but their use has declined because of the stringent regulations on industrial hygiene, the working environments and safety measures required during their use. Now, there has been an increasing use of aqueous solutions to replace the organic solvents and these require higher fluidizing air capacities and heating systems. The concentration of the coating solution is limited to the range where the solution remains spray able[14].

Coating thinness and consistency

Coated particles used in controlled release application, the quality of the coating must be strictly controlled. This is done by establishing the most advantageous operating condition for a particular coating material and seed particle. An ability to monitor the thinness and consistency of the coating between particles and within an individual particle is crucial in assessing the suitability of any position of process conditions.

Particle circulation

Fluidized-bed coating machine had an inner cylinder (known as draft tube) to expand the particle movement inside the bed. The spray nozzle is located at the bottom centre of the distributor plate.The movement of the coated particles is in the same direction as the fluidizing gas. The congregation resulted in a draft movement of particles which improved particle circulation but reduced the overall assimilation.

Temperature and wetness distributions

In fluidized bed coating process heat and mass transfer must take place for the particles to be coated. The temperature and wetness readings are indicators of these transfers.The variety, superiority and thinness of any coating is resolute by among other factors.The temperature and wetness in the spraying section and in the rest of the bed there was an inverse proportionality between the size of the agglomerates and difference between the inlet dry bulb temperature and the outlet wet bulb temperature.

Spray velocity

The spray velocity at which the polymer solution or dispersion is functional to a solid substrate is crucial and important processing factor. Aqueous film coating requires the uniform application of a polymeric film to the substrate surface and a well-controlled evaporation of water from that surface. The air quantity, temperature and dew position will combine to decide the drying ability.

Dewdrop magnitude

The crucial processing feature to control in the application of polymeric film coats is the mean dewdrop magnitude. In order for consistent, accurate and emaciated film formation to occur on the substrate surface, the polymer solution or dispersion must contact all surfaces consistently and evaporate quickly. This can be proficient by breaking the liquid into small droplets, with the use of two-fluid atomizers, hydraulic nozzles or ultrasonic nozzles. The dewdrops are formed by the shearing action of pressurized air on an emerging column of polymer liquid. These dewdrops are sprayed in either a conical pattern into the fluidized air or onto the tablet bed from the atomizing nozzle onto the substrate surface where they spread and evaporate to their solid constituents. Some dewdrops may contact the multiparticulates and dry before complete coalescence or film formation occurs. Large droplets will devastate the evaporative aptitude of the system causing over wetting. This may lead to sticking of multiparticulates in pans or agglomeration or loss of fluidization in air suspension coaters. As a result, it is enviable to control droplet diameter to optimize the process.The atomization air pressure delivered to the nozzle determines the dewdrops size of the liquid spray.

CONCLUSION

Fluid bed processor offers important advantages over other methods of coating and drying of multiparticulate materials.Multiparticulates fluidization gives easy materials transport, high rates of coating and drying at high thermal efficiency while preventing overheating of individual particles.So, today fluid bed processors with capacity of handle a variety of applications using one single mainframe and suitable change parts are becoming common all over the world.

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(Received: 2 May 2009 Accepted: 31 May 2009 RJC-383)