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Advanced Technology in Wurster Coating

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Abstract

Among the pelletization techniques available at present, the Wurster process is a production method of great interest as it offers various advantages in single equipment. Continuous process, less manual interruption and batch- to-batch reproducible assurance are some advantages of Wurster-based pellet coating. Many scientists have no clarity on “Is the process scalable?” due to ‘n’ the number of process variables involved. There are five sets of process variables affecting the quality of pellets - Equipment variables, Coating liquid preparation variables, preheating variables, spraying variables and drying variables involved in the Wurster-based coating process. Many of them have medium and high risk. The risk needs to be reduced by studying the variables at the lab level during development using the quality by design (QbD) approach and experimental design software. Wurster basted coating process scale up possible based on complete optimization of process variables, understanding of risk associated with variables and implementation of scale-up factor calculation provided by vendor. Lab scale and commercial scale Wurster should be linear and preferably of the same manufacturer is the key to the successful implementation of scale-up factor.

Keywords: pelletization techniques, Wurster process, quality by design.

Introduction

In recent years, a continuous interest has been focused on the development of formulations using multi-particulate systems, offering various advantages over single dosage forms, namely, improved bioavailability (Abdul S et al., 2010, Mohamad A et al., 2006) easy administration for elderly people and children (Varum FJ et al., 2011). These include the flexibility of blending different release profiles, reproducible gastric residence time, low risk of dose dumping, and low risk of high local drug concentration in the gastrointestinal tract (Pan X et al., 2010, Tuleu C et al., 1999), low intra- and inter-subject variability in plasma levels and bioavailability (Dey NS et al., 2008), reduction of irritation of the gastric mucosa due to drug degradation of simple units (Abdul S et al., 2010, Bhad ME et al., 2010) and divided into desired dose strengths without formulation changes (Deb R et al., 2013). Pellets are flexible intermediates that can be filled into capsules, compressed into tablets, added in suspension or made lyophilized tablets. Commercially, there are three most accepted pelletization technologies i.e. Suspension/solution loading, powder loading and extrusion-spheronization. However, suspension/solution loading is the most accepted technology at the industry level due to continuous process, less manual interruption and batch-to-batch reproducible assurance.

Successful pellet coating process optimization at lab level using small capacity Wurster is half the work done. Successful scale-up of the Wurster-based coating process at a commercial scale is a challenging task.
The present review focuses on process variables involved in the coating process and challenges in the scale-up of pellets from lab scale to industrial scale batch to get consistent results.

Mechanism of Wurster coating process

The Wurster process is widely used in the pharmaceutical industry powder coating and pellet coating. The Wurster containers are available in the size 100-500g to 800 Kg batch size can run. The Wurster process is used commercially for particle coating from less than 100 µm to tablets. The coating chamber of Wurster is typically slightly

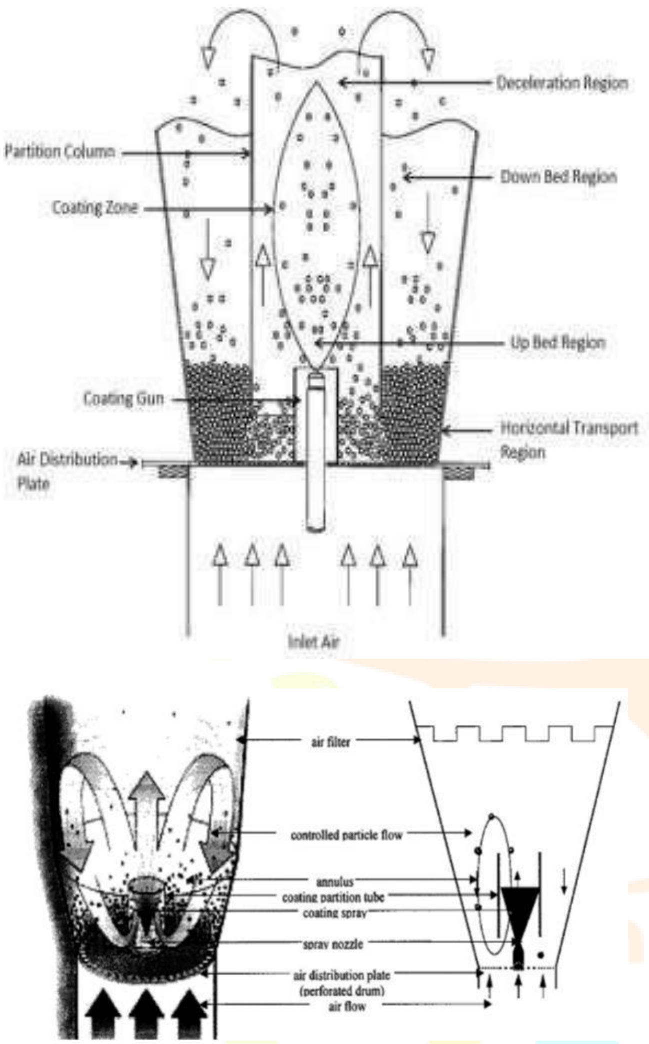


Figure 1: Schematic presentation of the Wurster process

conical, and houses a cylindrical partition about half the diameter of the bottom of the coating region. At the bottom region, air distribution plates (ADP) also known as orifice plates, are accommodated. ADP is divided into two regions. The open area of the plate that is under the Wurster column is more permeable to allow more air volume and air velocity transport parallel to airflow. As inlet air accelerates upward, particles pass a spray nozzle that is mounted in the centre of this up-bed ADP. The nozzle is a binary type - one port of nozzle is for liquid while the other is for atomized air at predecided volume and pressure. The spray pattern is in a solid cone of droplets, with a spray angle of approximately 30–50° called as coating zone. The down bed is the region outside the partition. The ADP was selected based on the size and density of the material used.

The airflow in the down bed region keeps material in suspended form and drawn horizontally into the gap at the base of the partition. The height of the column controls the rate of substrate flow horizontally into the coating zone. During coating in progress, the mass increased gradually so the height of the column increased to achieve the desired pellet flow. Above the product container is the expansion area, which is typically conical to allow for decreasing air and particle velocity.

All fluidized-bed techniques are known for high rates of heat and mass transfer, and the Wurster process is very effective in this regard. Highly water-soluble materials can be coated using water-based applications without concern for core penetration. Droplets applied to the surface spread, and form a continuous film and rapidly dry. After an initial coat has been applied, increase the spray rates. Films formed from organic solvents base coating are high in quality, because the formed droplets impinge on the substrate very quickly, minimizing the potential for spray drying of the film (Qiu Y et al., 2009).

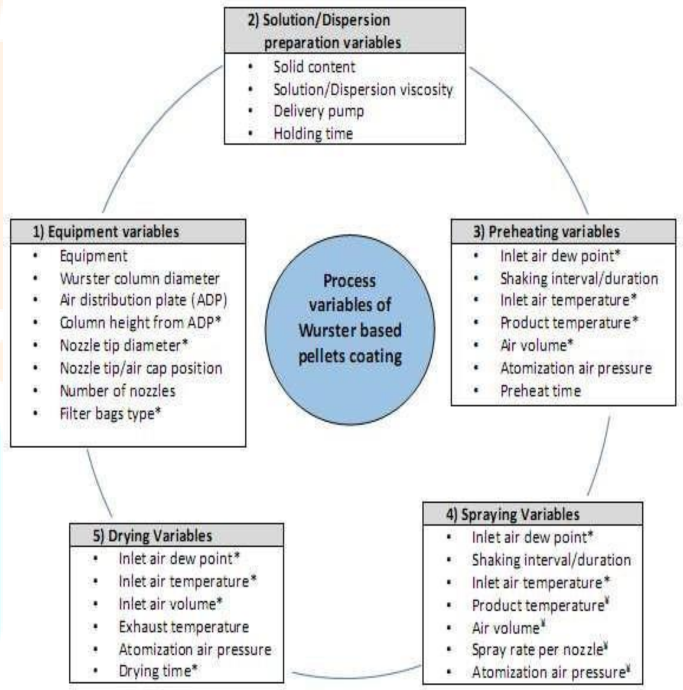


Fig.2. Process variables involved in the Wurster-based coating process (*Medium risk process variables, ¥ High-risk process variable).

Process variables involved in Wurster-based Coating Process

The Wurster process has five sets of process variables affecting the quality of pellets - Equipment variables, solution preparation variables, preheating variables, spraying variables and drying variables (Fig.2) those are discussed in detail below.

Air distribution plate (ADP)

Suitable ADP has to be selected to get consistent fluidization at minimum attrition. The fluidization volume affects particle velocity; the smaller particle requires lesser air volume to attain a certain height than the bigger particles. The air velocity and differential pressure at the air distribution plate must be almost the same. Therefore, when dealing with the smaller particles, use a plate with a lesser opening area to create resistance at the ADP to have a better distribution of the air (Shetty, 2010; Qiu Y et al., 2009). There are some recommendations for plate selection based on the size of pellets or power (Table 1).

Equipment	Pellet size in microns	Plate combination
6" Wurster	< 500 Micron	A
	250 << 1200 Micron	B
	600 << 1800 Micron	C
	> 1200 Micron and Tablets	D
For commercial models	< 300 Micron	A – I
	150 << 800 Micron	B – I
	500 << 1200 Micron	B –H
	700 << 1400 Micron	C – H
	800 << 1800 Micron	C – G
	> 1500 Micron and Tablets	D - G

Table 1. Guideline for plate selection concerning the final particle size

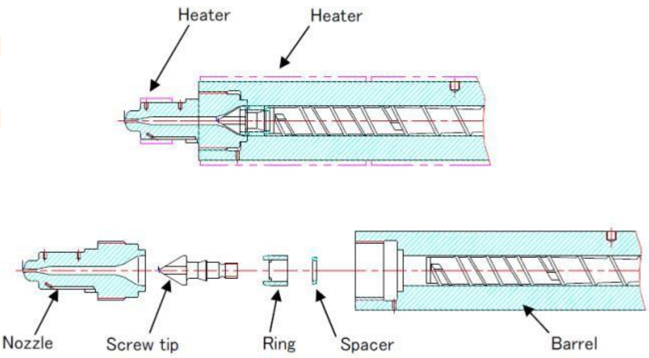
Column height

Appropriate adjustment of the partition gap ensures proper substrate circulation through the spray zone and up the partition column (Christensen and Bertelsen, 1997). The height of the column changed based on the particle properties like size, shape, flow and bulk density. It was recognized as an important factor in determining the success of coating small substrates and was found to affect the drug release profile of coated pellets (Porter and Ghebre-Sellassie, 1994). This was due to the pellets flow into the column and the exposure of pellets to the coating droplets in the spray zone (Fitzpatrick et al., 2003; Shelukar et al., 2000).

The slow and slugged form flow of particles through the column leads to an increase in agglomerates when the column gap is too more and insufficient pressure differential is created to draw particles in the column., When the gap is too small, fewer pellets draw in the column coating material loss and chances of over- wetting. Adjust the column height such that maximum pellets come in the column. Frequently change in column height is not recommended. The recommended gap for a 6" Wurster is 15-25 mm and for an 18" Wurster is 40-50 mm.

Nozzle tip diameter

For the selection of nozzle, the smaller the nozzle insert, the more consistent the will be sprayed. However, a smaller nozzle insert may cause nozzle choking. To avoid agglomeration in the wurster coater the coating fluid is to be atomized more finely than in pan coater for tablets. The nozzle must be capable of atomizing the coating fluid even if the coating fluid delivery rate is increased. Large droplets of coating fluid generated by a low-performance nozzle do not distribute evenly over the material to be coated and do not dry as quickly as smaller droplets. Very small droplets may dry quickly. Some droplets may contact with tablets or beads surface but may dry before getting spread, which will result in an irregular surface on the core material. To maintain uniform atomization when the spray rate exceeds the capacity of the nozzle large droplets of coating fluid appear along with small droplets, and large droplets result in the formation of agglomerates. To avoid agglomeration multiple unit nozzles should be used (Harlan, 2004).



Filter bags

A filter bag is used to prevent loss of material and to allow air to pass through. If the porosity is higher than optimal, the loss of material will be high. If the porosity is lower than optimal, the filter will clog and processing will be interrupted which impacts the product yield. A filter bag is selected based on the particle size of the material and previous experience. The porosity of the filter bag during coating can be examined by monitoring differential pressure.

Coating solution/suspension nature

The coating solution/suspension should have enough solid content for easy spraying. If the viscosity of the coating liquid is higher it will affect droplet size and change the pellet's surface. The ideal coating liquid velocity should not be more than 250 mPa.s.

Inlet and Product Temperature

The inlet drying air is usually heated before passing into the coating chamber to enhance the evaporation of coating material sprayed onto the cores. Control of the air temperature is important as it affects the quality of the coats formed. Generally, an excessively dry environment leads to spray drying effect and attrition while overwetting causes agglomeration (Maronga and Wnukowski, 1998). The optimal temperature allows the evaporation of solvent to take place at a rate that is sufficiently slow for adequate spreading of spray droplets and coalescence of polymer particles, and fast enough to avoid agglomeration and drug migration into the liquid layer (Yang and Ghebre-Sellassie, 1990). When the temperature of the air is too high, sprayed droplets dry quickly and do not coalesce when impinged on the core particles. This forms discontinuous coats that are rough and porous and will not impart the desired controlled release properties of a functional coat (Fukumori, 1994). The high temperatures may also cause spray drying of atomized droplets before they reach the cores, resulting in loss of coating material and thinner coats. Spray-dried coating materials may also be embedded in the film coats, disrupting the continuity (Oliveira et al., 1997; Ronsse et al., 2007). On the other hand, when the temperature is too low, a longer time is required for coat drying and this allows soluble drug to migrate from the cores into the moistened coat layer. The dissolved drug reduces the surface tension of the liquid layer, lowering the capillary forces required for the deformation and coalescence of spray droplets. Drugs embedded in the resultant coat may dissolve in contact with dissolution media, resulting in a porous and more permeable coat. If the temperature is lower than the minimum film formation temperature, coalescing would not occur, resulting in discontinuous porous films (Oliveira et al., 1997). In methacrylic acid-based coating, at higher temperatures spray gun choked frequently due to film formation of low glass transition coating dispersion. So it is recommended that run the methacrylic acid-based coating below 30°C product temperature. While in aqueous ethylcellulose-based coating requires a minimum 45°C product temperature due to the high glass transition temperature of the ethylcellulose polymer.

Air volume

Air volume is responsible for the circulation and drying of substrates during coating. Insufficient airflow may not provide sufficient drying air to circulate the substrates and remove the moisture from the deposited sprayed droplets during coating and consequently result in a high degree of agglomeration. However, excessively high airflow rates can increase attrition conditions causing erosion of friable cores or stress cracks in coats and may also augment the spray drying effect. For functional coats, this can result in loss of the desired release properties (Cole, 1995, Qiu Y et al., 2009). The suitable airflow rate is unique for each coating equipment and also depends on product characteristics such as particle density, size, and shape (Christensen and Bertelsen, 1997). For non-aqueous coating, a bubbling type of fluidization in the down bed is suggested to minimize the generation of static charge and particle friction, whereas for aqueous coating more rigorous fluidization is needed to have more drying efficiency.

Dew point

In addition to the temperature, the humidity of the inlet drying air also affects the drying of coated particles. The relationship between temperature and relative humidity or moisture content of air at different atmospheric pressures may be derived from psychometric charts (Shallcross, 1997). The humidity of air may vary from season to season or day to day. The changes in the dew point of air change the evaporating efficiency of that air. Lower humidity in the inlet air will enhance the drying capacity of air even at low temperatures but it will cause excessive static charge in the product. To eliminate static charge and process variability, the required specific and absolute level must be set at the initial stage of development itself. Too high absolute humidity will result in a depression in air temperature below the dew point, which will cause the condensation of water either on to machine or product substrate surface. It is not recommended to keep high moisture for a water-soluble substrate at the initial stage. The humidity can be increased after the initial coating because the static charge develops only once the pellets are coated with polymers (McGinity, 2002). To maintain the same environment in the Wurster chamber during particle coating in lab scale or commercial batches, run the process at dew point mode. The dew point is scale scale-independent factor.

Spray rate

In Wurster binary nozzles are used. The droplet formation, spreading, coalescence and evaporation happen almost simultaneously during the process. The spray rate depends on the core particles as well as the solution properties. The evaporation occurs by atomization air used for the formation of spray mist which increases the droplet's viscosity. In the case of solvent coating, sometimes excessive atomization pressure leads to spray drying portion of spray. The spray rate has to be adjusted according to the drying efficiency, and tackiness of the solution. To coat smaller particles we need to keep the droplet size small either by increasing the atomization pressure or by decreasing the spray rate to avoid agglomeration. At the beginning of coating the spray rate must be kept low to avoid solubilizing the core, seepage of the drug or coating polymer into another layer. Once the initial barrier is formed, the spray rate can be increased up to the optimum level. It is known that as the particle becomes bigger it can take up more droplets without agglomerating. When the particle enlargement is too high we may require increasing the spray rate in a regular interval (Swarbrick and Boylan, 1992).

High spray rates increase the propensity for agglomeration and result in the formation of less uniform coats, while low spray rates increase coat uniformity (Singh et al., 1996). Low spray rates also enable smaller spray droplets to be formed which would reduce agglomeration, especially when coating smaller substrates (Jones and Percel, 1994). However, if the spray rate is too low, fast drying of the droplets could prevent the coalescence of polymer particles, resulting in poorly formed coats (Heng et al., 1999).

Atomization air pressure

Pneumatic nozzles are commonly used for spraying coating materials in air suspension processes. These nozzles make use of air pressure to shear the coating materials into atomized droplets. Higher atomizing air pressures result in smaller spray droplets (Wan et al., 1995) and are required to prevent agglomeration, especially when coating smaller substrates (Hemati et al., 2003). When the atomizing pressure is too high, the spray droplets can be propelled away too quickly and this does not promote droplet-core contact. High atomizing air pressure also increases the attrition of cores and can produce more fines. On the other hand, low atomizing pressure causes the formation of coarse spray droplets, which dry slowly and encourage the formation of liquid bridges between the cores, leading to increased agglomeration of the substrates being coated (Heng et al., 1999).

There is an important consideration in larger capacity equipment, where there may be significant drying capacity, and the rate-limiting factor is the inability of the nozzle to atomize liquid (to a satisfactory droplet size) at the rate at which the process air may remove the resultant water vapour. The only possibility for taking advantage of the increased drying capacity is to enlarge the nozzle i.e., use more compressed air at the same pressure. A process that has excessive drying capacity, but is limited by droplet size, will result in unnecessarily hindered productivity. Upgrading to the HS nozzle, which uses substantially more compressed air at the same atomization air pressures (approximately three times the volume of the 940 series nozzle), will result in a dramatic improvement in drying capacity utilization.

Drying/curing time

The polymers dissolved in organic solvent increased the solution viscosity. During film formation, gel-like phases are created during solvent evaporation and the polymer film is formed (Fig. 3a) (Muschert S, 2008). While in aqueous dispersions, film formation is more complicated (Fukumori, 1994). Surfactants, anti- tacking agents and plasticizers are used in aqueous dispersion to improve the film nature and coating process. Plasticizers are used to reduce the minimum film formation temperature (MFT) of polymers having high glass transition temperature (Tg) (Wheatley, 1997). In aqueous dispersions base coating, polymer particles come into contact with each other and form coalescence during drying (Paeratakul O, 1993).

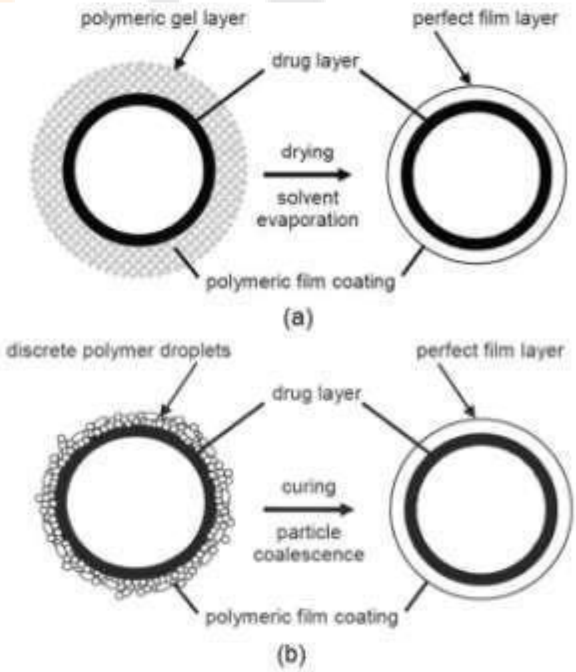


Fig. 3. a) Schematic presentation of the film-forming

mechanism from organic polymer solution b) Schematic presentation of the film-forming mechanism from aqueous polymer dispersion Usually, the coating process is performed at sufficiently high temperatures to guarantee the softness of the discrete polymer particles. The softening is related to the glass transition temperature (Tg) of the polymer (Augustine and York, 1988). A curing step (post- coating thermal treatment) is carried out after the coating process to ensure complete film formation and avoid further gradual coalescence (Harris, 1997).

Scale up process

The process parameters in the fluid beds are controllable precisely, which ensures easier optimization and reproducibility of the product quality. There are some wrong concepts related to the Wurster-based scale-up process. There are several articles available about Wurster processing, optimization and scale-up. Mehta showed little correlation between load sizes; spray rate and process time, with total spraying time increasing at every scale over five different size chambers, both single and multiple nozzles (Mehta, 1988). Other published studies, which confirm the reproducibility of the coating applied also demonstrate a processing time increase of 5x and 3.1x for two different products scaled from small scale to manufacturing scale (3kg to 180 kg).

Still question arises - "What would be the scaling up factor and consideration for reproducibility of the product quality in Wurster coating?''. The industry, which needs to scale up newly developed products from laboratory or research to manufacturing scale, must be aware of the proper designing for scaling up factors.

Currently, FDA is focusing on the Quality by Design (QbD) concept where one has to build the finished product quality attributes in the design itself. Nowadays USFDA also demanding for scientific approach for scale activity based on development batches. One of the USFDA's guides to inspections report pre/post-approval issues explained the expectations of regulatory authority on scale-up activity and said - it is important that the development and scale-up of the process be well documented so that a link between the bio/clinical batches and the commercial process can be established (USFDA, 1994).

Before attempting for successful scale-up, key variables and their effect on the output should be identified during the lab scale. If the scale-up activity starts at the stage of development itself then it will be very easy to scale up and scale out the formulation.

Wurster process has a 'n' number of variables. Some of them are easy to establish e.g. batch size, spray liquid viscosity, concentration, spray assembly setting, base plate, column height and dew point etc. Perform some trials to fix some dependent variables like air volume, atomization air pressure, spray rate, product temperature etc. It is easy to understand the variables on a small scale and it requires less time and cost. Finally, apply the design of experiments (DoE) to fix up the most critical parameters as per regulatory requirements. To minimize the number of trials further one can use statistical software like Design- Expert software (Stat-Ease, Inc., Minneapolis, MN). From the output of the statistical analysis fix up the ranges for the parameter and validate the process to check the reproducibility and freeze the parameter. Once these variables are frozen, we are left with only one unknown factor - "mass effect" due to the increase in the batch weight from the lab scale to the commercial scale. Once the parameters are studied it will be easier to compensate for the mass effect by making minor changes in the predicted parameter at pilot and commercial levels. After freezing the parameters in the lab model next step is predicting the parameter for scale-up.

Since at least 3 successful reproducible development batches are done the next step is to set up parameters for the pilot batch and also have a single Wurster. The development of the product is normally done 6" Wurster with a batch size of 0.5 to 2 kg. The Wurster column and spray nozzle are small. The Overall coating zone is small. The recommended pilot model is 18" Wurster where the Wurster column and base plate are much larger. From the lab to the pilot although there is a single spray nozzle the nozzle is much bigger and can permit a higher spray rate. The batch depth and mass flow density increase. Overall, the coating zone increases from the lab to the pilot scale. The overall coating zone will remain the same on the pilot and commercial scales except for the height of the Wurster column.

Therefore, the base area of the Wurster column plays an important role in the efficient coating. All process parameters should be proportional to the base area of the Wurster column compared with the lab model column.

All the process variables again show their significance in the scale-up model. Nevertheless, once the effect of variables is studied and understood in the lab model it will make the analysis much easier. Just like the variables remaining the same in the pilot scale also, the same process control will apply. Only the unknown factor will be the mass effect. As in the lab scale, one has to follow a sequential approach to set the parameter for the scale-up.

Linear scale-up from lab scale to pilot scale assumed that the occupancy is the same and the distribution plate in each piece of equipment is geometrically similar. Additionally, ratios of air volume to plate area and spray rate to air volume are maintained. The scale-up factor from Pam GPCG to Pam FBE 125C is approximately 9-fold based on vendor recommendation. This scale-up factor is applicable for air volume, spray rate and atomization air pressure.
The variables considered during the successful scale- up batch in Wurster are discussed below.

Batch size

The first step to designing a pilot scale-up after deciding on equipment is defining the batch size. The process parameter may change slightly depending on the batch size due to the mass effect. Set and validate the process for any change in the batch size. Keep the batch size within the recommended occupancy.
e.g. For Pam GPCG 1.1, the working volume is 2.4 litre, whereas for Pam FBE 125 it is 84 litre, i.e. 35 times. If the pilot scale-up up planned in FBE 125C then the batch size should be 35 times of batch size taken in GPCG 1.1 (Table 2). The working volume of the batch at the initial and final stages should be 20 to 100% for non-functional coating and 20 to 80% for functional coating limit.

Air volume

The fluidization pattern during processing depends on air volume. The air volume of the scale-up batch was decided based on the optimized lab scale batch. From lab to pilot scale the face velocity must be kept the same. To maintain the same velocity one must know the base plate area under the column of the lab and pilot equipment. It is expressed in the term of fluidization air volume. The following equation can be used to calculate the flow.
V2 = V1 x A2 / A1
Where, V1 =Air flow in the lab model, V2 =Air flow for the scale-up model, A1 = Base area of the Wurster column for the lab model, and A2 = Base area of the Wurster column for the pilot model.

Spray rate and atomization air pressure

The increase in the spray rate shall be always in line with the increase in the drying capacity rather than the batch size. The spray rate for a product is typically a key variable, from several perspectives. The first is economic-long processes result in high manufacturing costs. Lengthy processes also increase the likelihood of problems during the process, particularly nozzle port clogging. The spray rate is increased in relation to the increase in inlet air volume. Drying capacity is a critical component considered in scale-up activity. The drying capacity, batch size, core material and droplet size of coating liquid in the coating zone are the rate- limiting factors. That being said the inlet air humidity and temperature will remain the same for the scale- up model, the drying efficiency is increased only in terms of air volume. The spray rate can be increased in the same fold increase in the inlet air volume. spray nozzle with HS Wurster has benefits over conventional coating guns. The droplet size is large near the tip of the spray gun which formed agglomerated while by accommodating HS Wurster, the material does not come in contact with the coating gun and the spray rate can increase more. The following equation is used to calculate to predict the spray rate in the pilot model. **S2 = S1 x V2 / V1**
We can also say that S2 = S1 x A2/A1
Where, V1 =Air flow at lab model V2 =Air flow for scale up model, S1 =Spray rate in Lab model, S2 =Spray rate in pilot model
The increase in the spray rate must be compensated by the increase in the atomization air pressure to maintain the droplet size of the spray mist. To keep the droplet size the same both in 18" to 32" or more capacity Wurster is simpler due to bed height being almost the same.

Theoretical parameters

Since product temperature and dew point are the most critical factors that have an impact on the product movement as well as the release profile, during scaling up these parameters should be kept in the lab as well as the pilot model one has to keep the spray rate to atomization air volume the same.

Parameters	Units	Pam GPCG 1.1	Scale up factor	Pam FBE 125 C
Equipment Parameters				
Wurster column diameter	m	0.072	-	0.219
Wurster column height	m	0.20	-	0.36
Base plate area	m²	0.0145	-	0.1918
Suitable air distribution plate	-	B	-	B-I
Working volume	Litre	2.4	35	84
Batch size (preferred)	Kg	0.6	35	21.0
Wurster column base area	m²	0.0041	9	0.0377
Process Parameters				
Inlet air temperature	°C	26-35	-	26-35
Product temperature	°C	26-28	-	26-28
rster column height From base plate	mm	15-20	-	40-45
Inlet air volume	CFM	9	9	81
Spray rate	gm/min	10-20	9	90-180
Spray gun model	-	970/0		940-943/7-1 S91
Atomization air pressure	bar (CFM)*	1.0 (1.2)	9	2.5 (10.8)
		1.5 (1.4)	9	3.0 (12.6)
		2.0 (1.7)	9	4.0 (15.3)

Table 2. Comparative pellets coating process parameters of Pam GPCG 1.1 and Pam FBE based on scale-up factor

Normally atomization air volume should restrict the maximum pressure up to 4 to 5 bar. Higher the atomization air pressure the mechanical stress on the core will be high due to higher velocity. If someone uses higher air pressure in the lab model then during the scale either the spray rate needs to be reduced or the spray gun with a higher capacity like an HS gun can be used. Any deviation in the spray rate from the scale-up factor of airflow shall be compensated by either increasing or reducing the inlet air temperature.

Mass effects

The mass effect can't be predicted based on batch performance in small-scale equipment. The best scale- up of the Wurster process is from a 6" lab model to an 18" industrial scale model. In 6" Wurster, bed height not more than 200 mm and material fluidized up to 125 cm or less height. In the 18" Wurster, bed height is up to 600 mm, and fluidization height is up to 2 meters. Scale up from constant.

There may be some deviation in the results from the lab scale even after maintaining the parameters as per the scale-up calculations due to the mass effect. One or the other parameter may have to be changed marginally to achieve the desired release profile. The scale-up activity starts with preliminary trials with predicted parameters, analysing the results, and taking action if required to match the profile. If all the parameter and their effect on the release were understood in the lab scale, it would be easier to analyze the analytical results and vary the parameters to get the desired profile. Process validation is recommended to check the robustness of the process before filing the parameters or planning the scale-out activity.

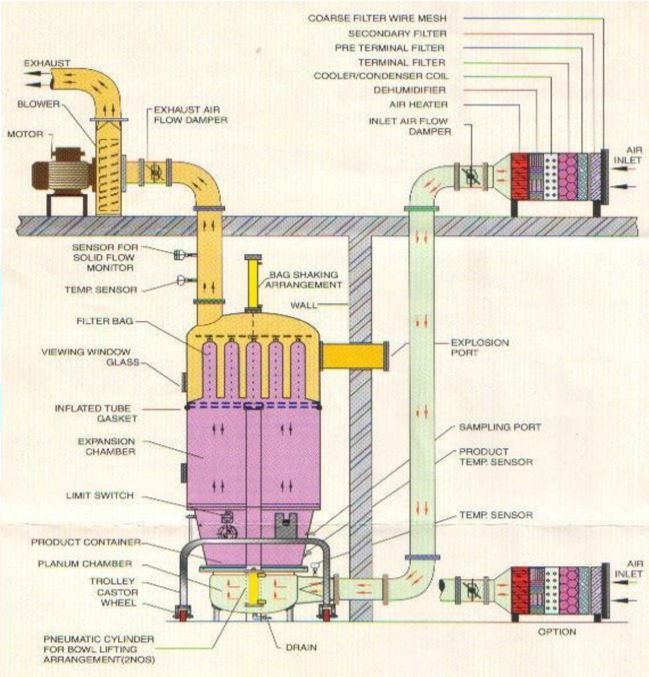
Fluid Bed Dryer

Working of a Fluidized bed dryer

A fluidized bed dryer works by passing Hot air with high pressure through a perforated bed of moist solid particles. The hot air passes at a velocity greater than the settling velocity of the particles resulting, in particles starting to suspend in the air. As the moist particle suspends in hot air, the moisture content of solid particles reduces to achieve the desired loss on drying (LOD). The drying vapours carry the vaporized liquid away from the moist solid particles. In some cases, the remaining gas is recycled to conserve energy.

Components of Fluidized-bed Dryer:

- Body Stainless steel
- Inlets Filters
- Air preparatory unit.
- Product container or Bowl.
- Expansion chamber
- Exhaust filter.
- Exhaust blower.
- Control panel (MMI).
- Air distribution plate.
- FBD bags (Finger Bags)
- Plenum
- Gaskets



SCHEMATIC DIAGRAM OF FLUID BED DRYING SYSTEM

Case study

A successful lab scale batch was taken in Pam GPCG 1.1 (6" Wurster) of pellet core of 200-300 microns which increased up to 500 microns after functional coating. If the scale-up planned in Pam FBE 125 has a single partition column, then 9 will be the scale-up factor based on the Wurster column base area comparison. Following are the values of process parameters obtained for FBE 125 C based on the scale-up factor to get reproducible results.

Conclusion

The Wurster-based coating process involves air volume, product temperature, spray rate and atomization air pressure are the high-risk process variables that can be mitigated by systematic optimization study while column height, filter bag type, dew point and drying time are medium-risk process variables that can fix during lab scale batches. Many reported difficulties in scaling up a process can be traced to improper correlation of these factors and/or to poor equipment design. The best approach to start the scaling-up activity is to collect complete information about the equipment from the manufacturer in the beginning.

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