

Precision Coating Technology for Improved Yield, Enhanced Product Quality, Reduced Process Time and Easier Scale-up.



Coating technology has many applications in the pharmaceutical industry for taste masking and drug release control. Fluid bed coating is particularly suitable for smaller particles and pellets. In this article, Harald Stahl, from Niro Pharma Systems, explains how the unique airflow within the Aeromatic-Fielder Precision Coater can provide significant improvements in coating performance and overcome many of the coat quality and scale up problems experienced with traditional coating tubes

The pharmaceutical industry has had technology that can coat particles in order to improve appearance, mask unpleasant tastes or to provide sustained release drugs for almost 50 years. However, with the dramatic rise in the number of drugs requiring this technology, and the increased cost of processing time and the compounds used, technologists are now under growing pressure to increase yield, improve coat quality and reduce process time

Coating Quality

Coating products can be expensive and the volume of product needed is inversely proportional to the particle size of the material to be coated. For example, the surface area of a 1cm cube is 6cm. If, however, that cube were made up of smaller cubes each of 1mm, the total surface area would increase ten-fold. For particles smaller than 100 microns, the volume of the coating material can easily exceed the volume of the active ingredient. Coating quality is, therefore, of paramount importance.

The problem is to coat the particle with just enough coating material to achieve the desired result, but no more. In the case of functional coatings

the coating must, also, be evenly distributed over the entire surface of the product. An uneven application can seriously affect the performance of the coat e.g. - the release profile of the drug.

One cause of uneven coating can be the failure to generate sufficient rotation (spin) of the product during the coating process. One solution to this can be to increase the airflow, however this will, in turn, increase the losses due to attrition through the generation of small, dust particles and, thus reduce yield.

Product Yield

The product yield is simply the product, which meets the required specification, produced, expressed as a percentage of the total material mass introduced to the process. The difference represents the product losses that occur during processing. In a traditional fluid bed coater, product can be lost as dust (caused by attrition of the core material or the spray dried particles) or by the agglomeration of larger, damp particles as they impact upon themselves or the equipment

Agglomeration is caused when the spray rate is too high and the product is still damp when it meets either another particle in the bed or the surface of the coater. In some systems the spray nozzle itself can also cause using a 'venturi' effect sucking particles into the zone of very high humidity around the nozzle where they can collide and agglomerate.

Again one cure for this can be to increase the airflow rate in order to keep the particles separate. However this can also increase the losses through attrition the alternative is to reduce humidity in the vicinity of the spray nozzle by reducing the spray rate, however the downside of this is an increase in the process time.

Traditional coating technology

Traditional bottom spray coating systems, such as those that have been in use since the 1950s, suffer from all these problems and more. In addition to the difficulties of agglomeration, attrition, uneven product quality and long processing times, they are also difficult to scale up from pilot to full production, they can not operate as a multi-tube systems and it is impossible to inspect the nozzles for agglomeration during processing. All of these failings have been addressed in the new breed of coating technology from Niro Pharma Systems, the Precision Coater.

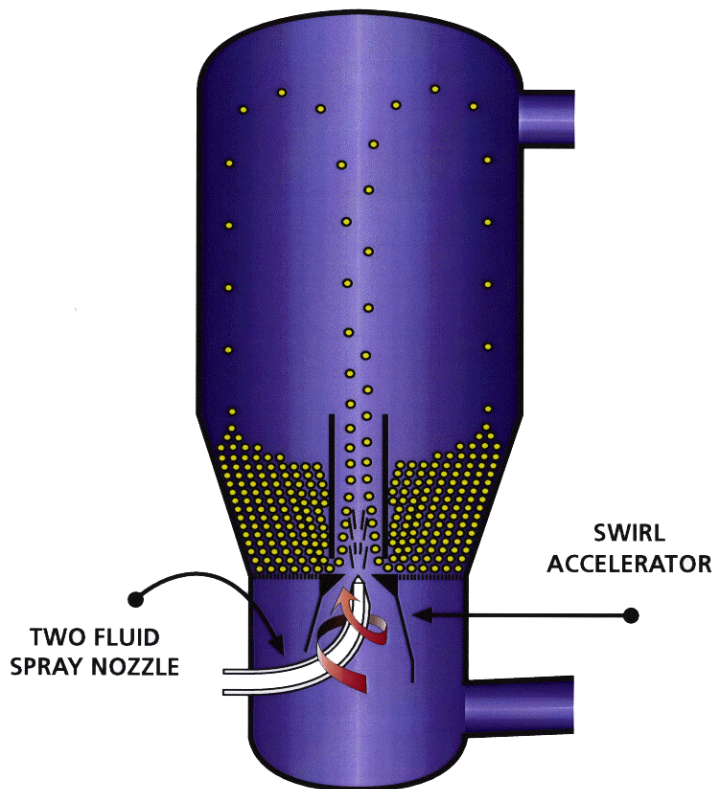
How the Precision Coater Works

The key element of the new Precision Coater is the Swirl Accelerator that controls accurately the airflow properties and so the behaviour of particles flowing into the coating column.

In a traditional fluidized bed coater a large proportion of the air flows into the bed around the column, which is then fully fluidized and allows the

particles to flood into area around the spray nozzle by virtue of the hydrostatic head of the bed

However in the precision coater much more of the air is directed into the coating column via an insert plate and the swirl accelerator. This design creates a much higher process air speed adjacent to the nozzle and generates a low-pressure zone that sucks particles into the core of the coating tube. The high speed of the airflow causes the individual particles to spin allowing a much more even coating



The swirl accelerator imparts a rotational component to the air stream which when combined with the high speed of the air stream ensures that the individual particles are kept separate so that it is possible to operate a much higher humidity local to the nozzle without the risk of agglomeration.

Tests show that the high speed of the air stream also generates a much higher level of evaporation so that

particles are dry and will not agglomerate long before they return to the bed around the coating tube.

This very fast drying effect is the same process that causes clothes to dry faster on a windy day.

The system has been proved to provide an even coating of a prescribed thickness in a significantly reduced process time compared with traditional coating systems.

The use of a high speed / low pressure zone to suck the particles into the coating area, enables the multi-tube Precision Coater system to avoid dead zones with low particle flow which can be found on traditional multi-tube systems.

As a result the Precision Coater system can be scaled up from test, through pilot and up to full production using similar sized coating tubes. Configuring multi-tube production units and single column pilot scale systems to use the same air flows and patterns in the coating tube can

eliminate many scale up difficulties experienced with systems which have much larger coating tubes in production units.

In the event of a spray nozzle problem during processing the unique design of the Precision Coater allows the whole nozzle assembly to be removed, cleaned and replaced without stopping the process and thereby allows minimum production time and top quality production

Conclusion

The Precision Coater provides higher yield through reduced agglomeration and attrition; it improves productivity by coating and drying product faster; and it significantly improves product quality by ensuring a coating of uniform thickness for optimum clinical effectiveness. It is ideal for uses in coating particles from 50 microns to 3mm diameter. Niro Pharma Systems believes that no other product currently available is better suited to the industry's need for a highly effective coating system with excellent scale up characteristics.

For further information please contact:

Dr Harald Stahl

Senior Pharmaceutical Technologist

Niro Pharma Systems

Email: hstalh@niropharma.com

Telephone: +49 7631 7016 14