Rotor technology for dry powder coating

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Traditionally, pharmaceutical film coating of active pharmaceutical ingredient (API) or functional excipients and polymer on to inert or active cores has been carried out by atomizing coating dispersions or solutions of varying percent solid concentrations. These coating systems are either aqueous or organic solvent based and require some considerations: APIs must be stable in dispersing solvents, need for a common solvent to dissolve/disperse API and excipients, solids must remain homogenously dispersed or dissolved throughout the coating process, and handling of highly viscous solutions/suspensions. In addition, such coating processes are often time-consuming as use of high amounts of coating solvents require longer drying cycles to achieve residual solvent concentration to an acceptable limit. Further, the use of large amounts of organic solvents and their expensive recovery adds a significant cost to manufacturing.

In the past 10 to 15 years, researchers and process engineers have made significant progress in developing alternate technologies to apply high API loading or functional coating with reduced amounts of coating solvents at significantly less processing times. One such process is rotor technology or rotor processor. Due to its unique design, the rotor technology offers a platform for dry powder coating, spherical granulation, and conventional solution or suspension coating.

The rotor processor is a one-pot insert where dry API coating/dry functional polymer coating, solution coating/seal coating, and drying can all be carried out stepwise without need for transferring the product to different processing equipment.

It is also possible to generate active API cores or

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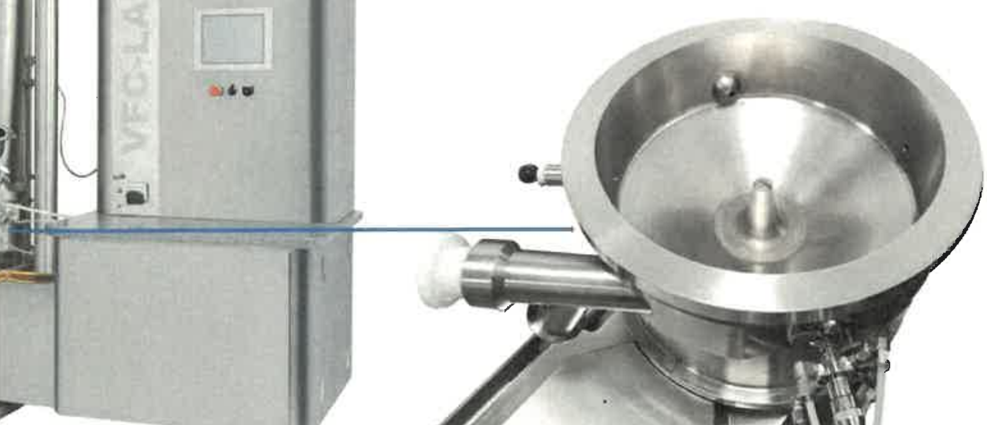

Rotor chamber

pellets through spherical granulation from raw powder blends to increase drug load followed by dry API coating and so on. Since 100% dry powder blend instead of the traditional lower % solid dispersion or solution is applied during coating, overall processing time is significantly reduced, and productivity increased.

The rotor processor includes a stationary chamber with a rotatable conical rotor or disc in which particles are circulated for coating or powder layering. The rotor has a perimeter edge spaced closely to the interior wall of the chamber. This gap or slit supplies airflow at a specific temperature. An expansion chamber provides housing for drying airflow duct for moving product inside the rotor chamber.

Over the years, the rotor technology has been evolved from flat rotor design to conical rotor to provide better product movement for efficient coating and simultaneous drying. A spray gun is mounted on the wall of the stator chamber above the slit to apply binder spray into the rotor chamber in the direction of moving particles. Similarly, a powder gun connected with a powder feeding system is mounted in the stator chamber which directs dry powder into the rotor chamber. The spray gun and powder feed system are spaced apart circumferentially to define a distinct spray zone and powder zone.

Depending on the scale of equipment (laboratory R&D versus production), number of spray and powder guns are increased in a similar order. For uniform coating or layering, compressed air is added to the powder feed line to disperse or atomize powder blend before it enters the rotor chamber. During this process, micronized API and excipient blend or dry polymer is coated successively in a layer-by-layer fashion onto the cores with help of small quantities of binder solution. The process is continued until the desired weight gain is achieved.

To improve flow ability, flow-aids are often added to the powder blend. Like other processing technologies, close monitoring and optimization of critical process parameters to achieve critical quality attributes of a final product is crucial. These process parameters include rotor speed, slit air flow and temperature, binder spray rate, spray nozzle atomization air pressure, powder addition rate, eductor air pressure to disperse powder blend, ratio of binder to powder addition rate, product temperature, drying airflow and temperature, and drying time. The dry powder coating is carried out at relatively colder temperatures compared to other coating processes. In many instances, only slit airflow is activated during the coating process to avoid unnecessary drying of substrate or cores. The ratio of binder to powder addition will depend on the type of solvent involved (organic versus aqueous), powder blend (hydrophilic versus hydrophobic),and core material properties.

The powder-coated pellets or multi-particulates are often further coated with functional polymers to achieve modified drug release or protective moisture barrier for stability. The critical quality attributes of the product will include particle size distribution, bulk density, residual solvent concentration, particle shape and morphology, content uniformity, and drug release profile.

Due to the flexibility of the rotor processor, it is possible to coat different APIs in different layers in case of chemical incompatibility. With advancement in process analytical technologies, it is also possible to monitor and control dynamic and complex processes like dry powder layering in real time.

This technology offers a great flexibility to produce immediate or modified release pellets, granules, or multi-particulates with high API loading with high efficiency and at significantly lower processing times. Based on current processing data available, this process technology is capable to achieve >500%w/w weight gain and product yields of > 95% with high bulk density. It is truly a processing blessing for product manufacturers to avoid time-consuming intermediate product transfers and storage.