

Spray nozzle design: Research by Manesty has been aimed at establishing droplet size and distribution from various gun designs

Droplet size matters

Current research on coater design highlights the important role that droplet size distribution from the spray guns can play in creating the optimum coating conditions.

Out of the many variables that influence the quality of film coated products, spray gun performance, the resulting droplet characteristics and tablet mixing in the coating drum have not until recently attracted as much attention as other process related factors.

Indeed, finding the optimum coating conditions for a particular tablet and coating material can involve a complex operation, demanding

a compromise between a whole host of variables. Even so, the six major factors that affect the efficiency of the process can be defined as: drying efficiency, spray gun type, the tablet properties, the quantity and type of coating to be applied, the duration of the process and the degree of mixing that can be achieved.

With this in mind, research by tablet coater manufacturer Manesty over the past two years has concentrated not only on establishing the connections between the type of spray gun employed and mean droplet size and distribution, but also the assessment of mixing resulting from the different baffle systems employed and its importance in today's coating processes.

Droplet size variation gives a problem during the process mainly due to the differing rates of evaporation of large and small droplets. This variation can lead in the extreme to a process showing indications of spray drying (dust formation) and over wetting (tablet picking) making optimisation of the process difficult.

The mean droplet size also has consequences in the process as well as evaporation, since the spreading on the tablet surface is critical to the

resulting film formed. Inappropriate spreading can lead to problems such as thickness variation, surface roughness, weak films and poor adhesion. Droplet size is influenced by spray gun design, atomizing air pressure and viscosity of the coating suspension.

Spray nozzle design

The research by Manesty was carried out to characterise its own spray nozzle design in terms of droplet size at a range of operating atomising and fan air pressures, while also making comparisons with two other nozzle types used in pharmaceutical film coating processes.

The Manesty nozzle was found to give the lower mean droplet size and narrow distribution. This information can now be used to predict the effect on the coated product resulting from changes in gun parameters, coating materials and spray guns of different design.

In addition, efficient mixing, undoubtedly the most important factor in the efficiency of the coating process, can save materials, energy and time. While this can often be achieved by running the pan faster, few pharmaceutical

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products to be coated have the properties to withstand this, which means that the mixing system must be designed accordingly, to avoid damage to tablets.

In the original design of the established Manesty Accelacota the conical ends of the pan were made with different angles to achieve some degree of mixing, but results were less than optimum unless the pan revolved at relatively high speeds, typically 15rpm for a 48in diameter unit. Difficulties were then encountered when friable products were to be coated.

Following considerable research into the design of mixing baffles these were incorporated in the pan and allowed speeds to be reduced – to typically 4-5rpm on a 48in unit – while still obtaining good mixing.

Efficient in smaller pans

However, further studies then showed that while these baffles gave efficient mixing in smaller pans, the same results were not obtained in very large pans. This was because the tablets lying against the surface of the pan and those on the surface of the bed moved fastest, as would be expected, while each successive layer between moved slightly slower, creating a core in which tablets circulated but dwelt for some time.

As a result, any tablets spending an appreciable amount of time in the core received less coating. Indeed, it was established that the core becomes more pronounced as pan size increases and as tablet size decreases, leading to the conclusion that any mixing system must be able to break up this core.

So the latest Manesty pan design consists of four divergent tubes (tubular baffles), mounted on opposite sides of the pan at 180deg to each other. They enter the bed gently with little mixing action as they pass through, but, as they leave the bed, tablets from the middle of the bed at one side are deposited on the surface at the other side.

Initially, the success of the system could be demonstrated in a simple fashion with the pan divided into two, down its centre line, at right angles to the axis of rotation and each side filled with different coloured tablets. The tablets could then be seen to be completely mixed in six revolutions of the pan.

This showed that good mixing can be achieved at low speeds – typically 4rpm on Manesty's latest Premier 200 coater – giving a gentle action resulting in less aggressive mixing of the product. Indeed, reductions in coating

time up to 35 per cent have been achieved with these baffles. A further baffle system was later introduced essentially for use in sugar coating but also found a use for products not suitably mixed by the tubular baffles.

However, Manesty and the School of Pharmacy and Pharmaceutical Sciences at Manchester University have recently conducted more searching tests to compare different baffle designs by assessing the colour change over time of white tablets coated with a pigmented suspension using colourimetric analysis.

Results showed that while in a Manesty XL laboratory scale coater with no baffles colour uniformity was achieved in 70 minutes, the inclusion of tubular baffles reduced this to 30 minutes. When the same experiment was carried out on the production scale Manesty Premier 200, mixing times were 40 minutes for tubular baffles and 50 minutes for the plough-share baffles.

The reasons for such a detailed study to be carried out was to accommodate recent advances in the coating process in the areas of materials and drug delivery systems. By far the most commonly used polymer in film coating is Hydroxypropylmethylcellulose (HPMC). However, incorporation of this polymer in coating formulations leads to a rise in viscosity, with the result that solid levels of 10 per cent w/w are the maximum before problems of spraying and pumping are seen.

In recent times preformulated coating formulations have become favourable allowing increases in solid content to be made. From an equipment manufacturer's point of view the increase in solid inclusion leads to a reduction in solvent to be evaporated and ultimately a reduced time for mixing, emphasising the need for efficient mixing.

Although Manesty's latest coater, the Premier, was designed from the ground up, the lessons learnt particularly with pan design from the established Accelacota have been incorporated.

Automated production

However, the Premier is specifically designed for high rate automated production and low downtime, and was developed from the outset as a clean-in-place machine. In effect, this means that the coating chamber is free of all ledges, angles and crevices while the internal geometry, seals, slopes and radii are designed for CIP routines, which can be incorporated as part of the machine's program for each product.

Two models are available, the Premier 200

with pan capacities of 125, 170 or 225 litres and the Premier 500 with three standard pan sizes of 350, 450 and 550 litres. Automated loading is possible from the rear while drum reversal provides automated unloading.

Set-up is recipe-driven and may be carried out from either the remote PC-based supervisor station or via the operator controls mounted on the machine itself. The supervisor station may also be used for creation of recipes remotely from the coater.

Software allows upgrades

Recipe programs created for each product are held by the supervisor station and downloaded to the PLC that runs the coater. Open architecture software systems are employed to allow future upgrades to be made and to provide communication links with higher level factory management systems.

The Premier was designed for lights-out operation, allowing complex coating processes to be carried out with minimum intervention by the operator – giving complete automation from product loading to discharge – and incorporates a validatable clean-in-place system.

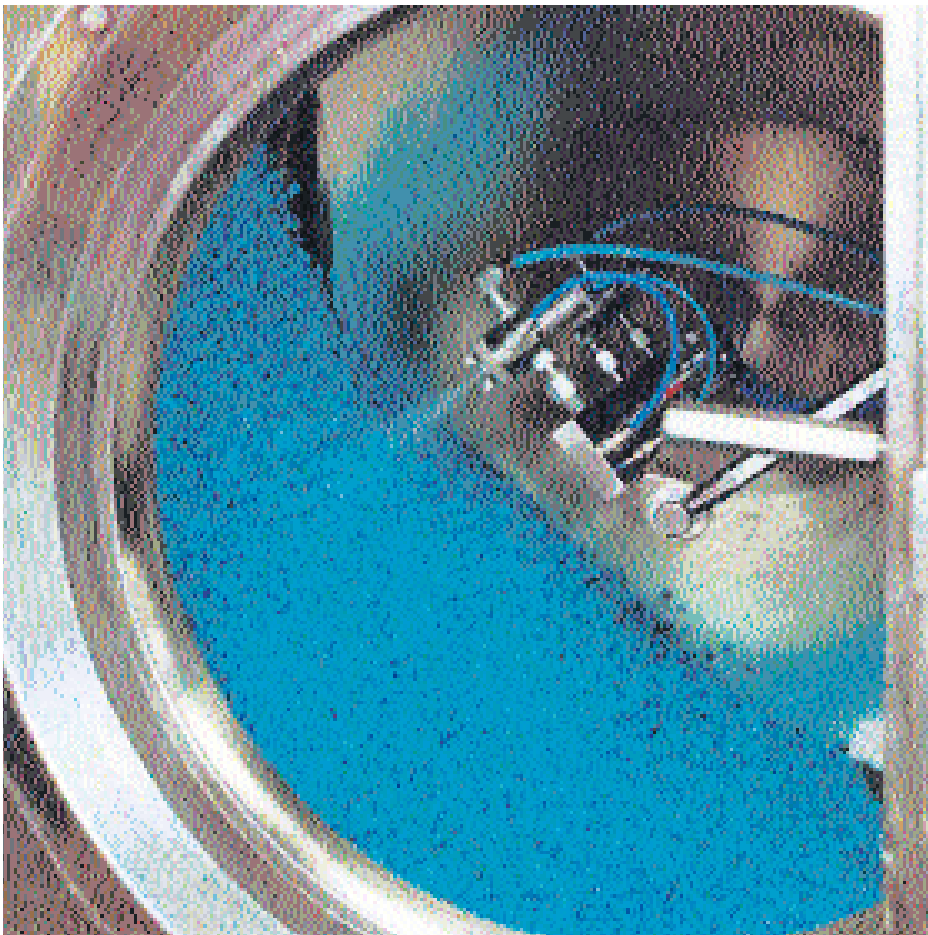
However, the high level of automation provided by the control system and the efficiency of clean-in-place is only part of the story. In terms of coating efficiency itself, derived from drum, spray and air handling equipment design, the Premier owes much to the development of the Accelacota, which remains in production.

Shortest possible time

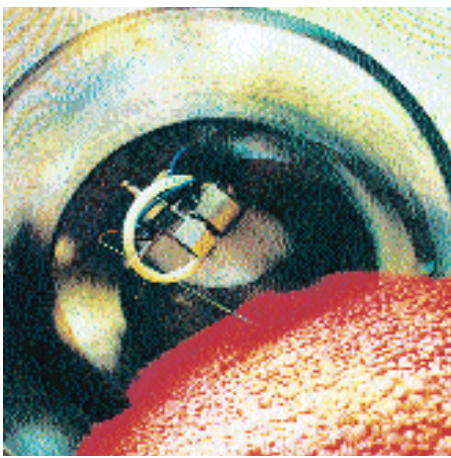
Efficiency in this case is defined as applying a complete and even cover of coating material in the shortest possible time, without waste of coating material or energy.

Traditionally the Accelacota 10 has been the laboratory and trials coater in the Manesty range. However in order to offer customers an increased level of flexibility and portability the Manesty XL was developed, providing the same functions as all Manesty production coaters but in a compact cabinet with interchangeable drums. Indeed, the facility to change the drums quickly and easily gives the Manesty XL a capacity range far greater than would be achievable with a single size.

A further feature of the XL is the option of mobile air handling equipment to allow full use to be made of the machine's portability. This provides heated filtered air to the coater and removes and filters the exhaust air in a single electrically operated unit. Being mounted on



Time to mix: *Manesty trials compared mixing times with different baffles*



Long drum: *Bohle BFC coater moves tablets up and down its length in a figure of 8 pattern*

wheels means that it can be stored away when not in use, freeing up often-valuable laboratory space. The traditional fixed ductwork between the coater and air supply has been replaced with part flexible tubing coupled with quick disconnection fittings.

The Manesty XL has been designed along similar lines to the top-of-the-range Premier coaters. This means that the cabinet is of fully welded construction with a polished internal area with automatic drain to allow easy cleaning. The same pump system – incorporated in the XL cabinet to retain mobility – is utilised and linked to the Manesty spray gun.

Due to the proposed laboratory/trials location, the user's view of the coating area becomes more important so the amount of glass on the doors of the cabinet has been increased to provide good visibility of all areas of the tablets being coated. The Manesty XL is also supplied with the same manual control system provided on both the Accelacota and Premier ranges of coaters, so enabling users to scale up trial work easily to a full-sized production environment.

Batches up to 600kg

Meanwhile, a new generation of film coaters, able to handle batches of tablets up to 600kg – so eliminating a common bottleneck in tablet production – has been launched by German manufacturer LB Bohle, represented in the UK by ACM Machinery.

The BFC machines, offering 200, 400 and 600kg capacities, use the same style of cylindrical drum first used by Bohle in its smaller capacity KOKO coaters, and now proved in production over the past five years. Since the drum is longer than its diameter, and employs two spiral vanes to move tablets up and down its length – horizontally and radially – in a figure of 8 pattern, the tablet bed can be relatively shallow, compared with a conventional format coater of the same capacity.

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This means that spraying can take place at one end of the drum, while drying air enters the tablet bed from below at the other end. Constant movement of the tablets between the spraying and drying zones is said to reduce cycle times and contribute to coating quality.

In this way, large batches can be handled without subjecting tablets to the high static loads and risk of attrition inherent in a deep tablet bed, which would be necessary on a conventional coater design.

"The thickness of a tablet bed inside a Bohle film coater for 600kg batches is as low as 300-400mm," points out the company. "This allows optimum air flow conditions to be achieved as well as handling the tablets gently."

Moving backwards and forwards

Because the tablets are moving backwards and forwards, up and down the length of the drum, only two spray nozzles are required to achieve coverage, and can be set much closer to the bed to reduce the opportunity for evaporation. The spray nozzles are self cleaning, via a patented design, with any debris removed by an air extraction system. Bohle has also designed the new 600kg capacity coater for clean-in-place.

In the Manesty and Bohle machines, perforated drums are employed to allow drying air to penetrate the cores' bed. However, the GS range of coating equipment, now supplied by the solid dose division of IMA, uses a solid wall coating pan which, with the choice of two different, but interchangeable types of ventilation system, can be used not only for film or sugar coating of tablets but also for size enlargement/coating of pellets or microgranules, all on the one machine.

The use of a solid wall pan also reduces air volume compared with perforated pan systems, which must be housed in a larger enclosure, bringing energy savings in the region of 30-35 per cent, points out IMA. The standard system for film or sugar coating consists of two parallel paddles immersed in the bed of tablets, to draw drying air entering the pan from the heater unit down through the product, before it exhausts to the dust recovery unit.

This approach is said to prevent any turbulence in the pan and provide high drying efficiency using low volumes of air, with the efficient evaporation of water based film coatings in particular offering valuable energy savings.

In film coating, constant spraying and air movement is employed. However, for sugar coating, the GS machines are equipped with an



New to the market: *Sejong SFC-150 coater introduced by Glenvale Packaging*

automatic system in which, once the bed has been raised to the correct initial temperature, the paddles rotate out of the bed and the air intake is shut down, as syrup is first sprayed and the mass then tumbled for thorough mixing.

After a pre-set interval, the paddles are moved back into the mass and the flow of drying air resumed. When the cores are sufficiently dry the process is repeated until the required build-up of coat is achieved. Typically, weight gain range goes from 50 to 100 per cent and can be achieved within a single shift operation, including polishing.

Two paddle system

The other ventilation system, based on two paddles with open ends, is used with the air flow reversed to introduce drying air into the bed of the product and is employed as an alternative to fluid bed or extrusion/spheronisation systems for enlargement/coating of pellets or microgranules. The active ingredient is introduced in either suspension or powder form, via the GS powder dosing system.

Indeed, IMA points out that powder form layering offers the advantages of shorter process times, consistent density of active ingredient, lower friability and regular spherical shape. The solid base, such as starch, is first slightly wetted for pliability and the powder then distributed across it at a measured rate by a horizontal auger as the pan rotates.

Pilot scale machines of 3, 10 and 25 litres are

available, giving results that scale up to full production equipment of 70-600 litres.

Glenvale Packaging has recently introduced the SFC-150 film and sugar coating machine from Sejong Pharmatech of Korea, available from laboratory scale up to full-scale production models. It uses a pan construction with an air-tight cover which, says the company, reduces coating and drying times, while plate type baffles attached to the wall of the coating pan allow tablets to be coated in the air shower as hot air passes through the falling tablets.

Hot air supply and exhaust are automatically controlled along with the temperature, with the supply of coating solution and atomising air operated simply by the spray control unit.

For sugar coating the hot air supply and the exhaust can be automatically controlled by the auto damper and the sequence spray – pause 1, pause 2, dry – is automatically operated by the pre-set timer. Reverse rotation of the drum is employed for discharge. ■

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