Using The GansCoater® to Improve Coating Efficiency for Pharmaceutical Enteric Tablets Intended for the Treatment of Gastroesophageal Reflux Disease (GERD)

Background

Functional tablet coating is employed in the pharmaceutical industry to alter the release profile of drug from the dosage forms. One of the most popular functional coatings is the enteric coating, which prevents the release of active from the medication until it reaches the small intestine. Hence, enteric coated tablets containing proton pump inhibitors and antacids are used for the treatment of GERD. Enteric polymers consist of acidic functional groups that are capable of ionization in the intestinal fluid, owing to which the drug releases in the intestine. Also, a seal coat applied on the tablet surface prior to a functional coat prevents any possible interaction between the tablet core and the enteric layer.

Challenge

A pharmaceutical company was facing issues including time-consuming enteric coating process, choking of the spray nozzles and requirement of additional quantity of coating solution per batch on The GansCoater® (GAC-1500) which led to escalation in the overall cost of production. Gansons proposed conducting the trial on this equipment with several modifications in the existing process parameters.

Gansons Solution

One lot of 320kg tablets (320 mg; 10,00,000 tablets) was seal coated (Tablet weight gain of 2%) using non-aqueous Instacoat™ Sol film coating system. This was followed by enteric coating using Instacoat En Super-II enteric coating system to achieve a tablet weight gain of 9 percent on the seal coated tablets. The old and modified process parameters are listed in Table 1.

Table 1: Process Parameters for GAC 1500

Parameters	Old Parameters	New Parameters
SEAL COATING		
Dosing pump rpm	100	50
Spray tube make	Silicone	Marprene
Spray rate (gm/min)	-	1200-1300
ENTERIC COATING		
Quantity of suspension/lot (kg)	216.25	176.25
Spray nozzle diameter (mm)	1.0	1.5
Number of spray nozzles	6	6
Total spray rate (gm/min)	180-210	250-320
Total spray time (hrs)	20	9
Inlet cfm	2281	4929
Inlet air temperature (°C)	45-50	45-50
Exhaust temperature (°C)	35-40	35-40
Nozzle to bed distance (cm)	15-18	15-18
Fan air pressure (kg/cm^2)	3-4	3-4
Atomization air pressure (kg/cm^2)	2-3	2-3

Observations

In the former process, the tablets were seal-coated with a non-aqueous Instacoat™ Sol system using a silicone tubing. The use of this polymeric seal coat system is known to develop back pressure during the coating process, leading to choking of spray nozzles and occasional bursting of silicone tubes. Hence, the client could not achieve the desired spray rate even at a dosing pump rpm of 100. Gansons replaced the old silicone tubes with Marprene, a thermoplastic elastomer with longer lifespan and superior burst resistance. With this simple modification, a spray rate of 1,200-1,300 gm/min could be achieved at a dosing pump rpm of 50 for the seal coating process.

Inlet air cfm is an important parameter which influences the drying of tablets by controlling the amount of air pulled through the tablet bed. The low value of inlet cfm in the former process used by the client led to improper rolling and drying of tablets in the coating pan. Also, a low spray rate with a smaller nozzle diameter led to an increase in the tablet coating time. Additionally, the low solution flow rate led to incomplete

coalescence of the polymer on the tablet surface resulting in a brittle film. Hence, the spray rate was increased from 190 to 275 gm/min, which ensured the presence of a uniform layer of the enteric polymer on the tablet surface. Spray rate was not increased beyond these values due to the possibility of over wetting the tablet surface and consequent sticking and picking issues.

The enteric coating process was completed in 9 hours compared to the former process which required 20 hours for completion. Moreover, a reduction in the quantity of coating suspension (40 kg saving) was seen in this trial. Hence, slight modifications in the process parameters were found to mitigate the customer's concerns.

Highlights

- Reduction in coating time by 55% compared to the earlier process
- About 12% savings in the quantity of enteric coating suspension
- Elimination of nozzle clogging issue
- Superior tablet quality and absence of coating defects vis-a-vis the former process

Conclusion

Functional coatings are critical to the efficacy of pharmaceutical dosage forms since slight alteration in the tablet coating parameters can have a significant impact on the dissolution profile of drugs. The high cost of these excipients necessitates that the coating process is optimized to minimize the overages. Hence, by slight changes in the coating parameters, reduction in time and coating solution wastage was achieved for the client with overall increase in productivity.

Please contact us for more information:

Global: sales@gansons.com
Europe: engineeringUK@gansons.com