Using Gansons Wurster Technology to Improve Formulation of Eudragit L 30 D-55 Delayed Release Pellets

Introduction

Fluidized bed processor coaters have been widely used in the pharmaceutical industry for coating pellets, granules and mini-tablets. They consist of a cylindrical chamber with a perforated plate at the bottom which assists in channelling the flow of the product. The products are suspended with the aid of air passing through the air distribution plate. Subsequent coating of the product occurs by the coating solution sprayed via a nozzle located at the centre of the chamber.

Enteric coating involves the use of pH dependent polymers which coat the tablets, provide a barrier to release the drug in the gastrointestinal tract and promote the release of the same in the small intestine. Eudragit L30 D-55, an aqueous dispersion of methacrylic acid copolymer, provides a stable enteric layer on the tablet surface with site specific delivery of the active in the intestine.

Challenges

A pharmaceutical company was facing difficulties such as gun choking and non-uniform coating for delayed release pellets using their fluidized bed processor coater. Gansons proposed performing the customer trials on Gansons fluidized bed processor coater (GFBPC) with modifications of the equipment and process parameters.

Trial Parameters

An aqueous suspension of Eudragit L30 D-55 (along with a plasticizer, anti-tacking agent, surfactant and opacifier) was sprayed on seal coated pellets (400 gm) to achieve a final weight gain of 32%. A small quantity of colour was added to the suspension to ascertain the uniformity of the applied coat. The modified process parameters using the GFBPC are listed in Table 1.

Table 1: Process and Equipment Parameters for GFBPC

Parameters	Client Parameters	Gansons Parameters
Product Temperature (°C)	31-35	28-29
Spray Pump rpm	1.0	2-3
Blower rpm	1,200	1,200-1,700
Atomization	1.6	0.8-1.2
Column Height (mm)	12-15	18

Gansons Solution

The spray nozzle was validated by verifying the spray pattern of water and the column height was adjusted to 18 mm before commencement of pellet coating. The column height is an important parameter to ensure successful coating and ensures proper product circulation as well as exposure of pellets to the coating solution in the spray region.

Minimum film formation temperature (MFFT) is the temperature at which polymer coalesces and forms a thin and uniform film on the pellet surface. The product temperature was set in the range of 26-30°C during the coating process as Eudragit L30 D-55 has a low MFFT. The product temperature set by the client was >30°C, which led to non-uniformity in the enteric coating.

The blower rpm using the Wurster process varies depending on the size and shape of the pellets and was adjusted to 1,500 rpm for the current process. Proper adjustment of rpm is critical to obtain the appropriate venturi pattern and it must be increased gradually with advancement in the process to ensure proper flow of pellets and uniform coating.

The value of atomization was tweaked in the range of 0.8-1.2 compared to the former process. Higher value of atomization leads to spray drying of the coating solution and is a contributing factor for variation in amount of coating material deposited on the pellets.

The above changes in process parameters led to uniform pellet coating compared to the former process with reduction in coating time as shown in Figure 1.

Figure 1: Uniform Enteric Coating with Gansons Process Parameters

Highlights

- Uniform coating of pellets after visual inspection
- Reduction in process time by 20% compared to the former process
- Absence of nozzle choking during the entire coating process

Conclusion

The coating uniformity is a critical attribute for delayed release formulations as it governs the target potency and drug release in the intestine. Moreover, precise control of atomization and particle circulation is required to obtain high coating efficiency. Hence, understanding the key variables which impact the desired properties of the dosage forms can minimize errors and ultimately improve productivity for pharmaceutical companies.

Please contact us for more information:

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