

Coating of Inert cores for a Gastro Resistant Coating

The Process...

Raw material from the customer consist of small particles (under 1µm) made of a co-precipitated of Silica and Mesalamine.

A) Powder composed of particles of this size are difficult to fluidize and handle properly without forcing it against the filters or walls of the Fluid Bed Dryer, leading to material loss and low yield.

B) Particles of this size have a high exposed surface area, requiring a significant amount of coating material.

To overcome these challenges, a two-step process was implemented:

1. Layering the raw material onto inert cores made of sugar – This increases the substrate size, allowing a proper movement of the product to coat and reducing the exposed surface area and, consequently, the amount of coating material required to achieve gastro resistance.
2. Coating the pellets with Eudragit® S100 – This step ensures the necessary gastro resistance, preventing the formulation from dissolving in the stomach.

General Information...

Process Equipment:

- ✓ FC-LAB 3 with Granurex® GXR-35 Rotor
 - Solution Gun
 - Powder Feeder Gun
 - Pleated Polyester Filters
- ✓ K-Tron Precision Powder Feeder
- ✓ QICPIC Particle Size Analyzer

Powder Layering...

Batch Size:	1000 g
Solution:	HPMC E3
Airflow:	5-11 cfm
Rotor Speed:	250 rpm
Eductor Air Pressure:	21 psi
Spray Air Pressure:	18 psi
Slit Air Temperature:	29.1-58° C
Product Temperature:	18-25° C
Solution Flowrate:	7-10 g/min
Powder Rate:	7-10 g/min
Total Powder Applied:	300 g

Suspension Coating...

Batch Size:	1300 g
Solution:	Eudragit S100
Airflow:	15-17 cfm
Rotor Speed:	250 rpm
Spray Air Pressure:	21-25 psi
Slit Air Temperature:	48-51° C
Fluid Bed Drying Air:	49-55° C
Product Temperature:	23-33° C
Solution Flowrate:	7-17 g/min
Total Solution Sprayed:	2330 g
Spray Time:	162 min

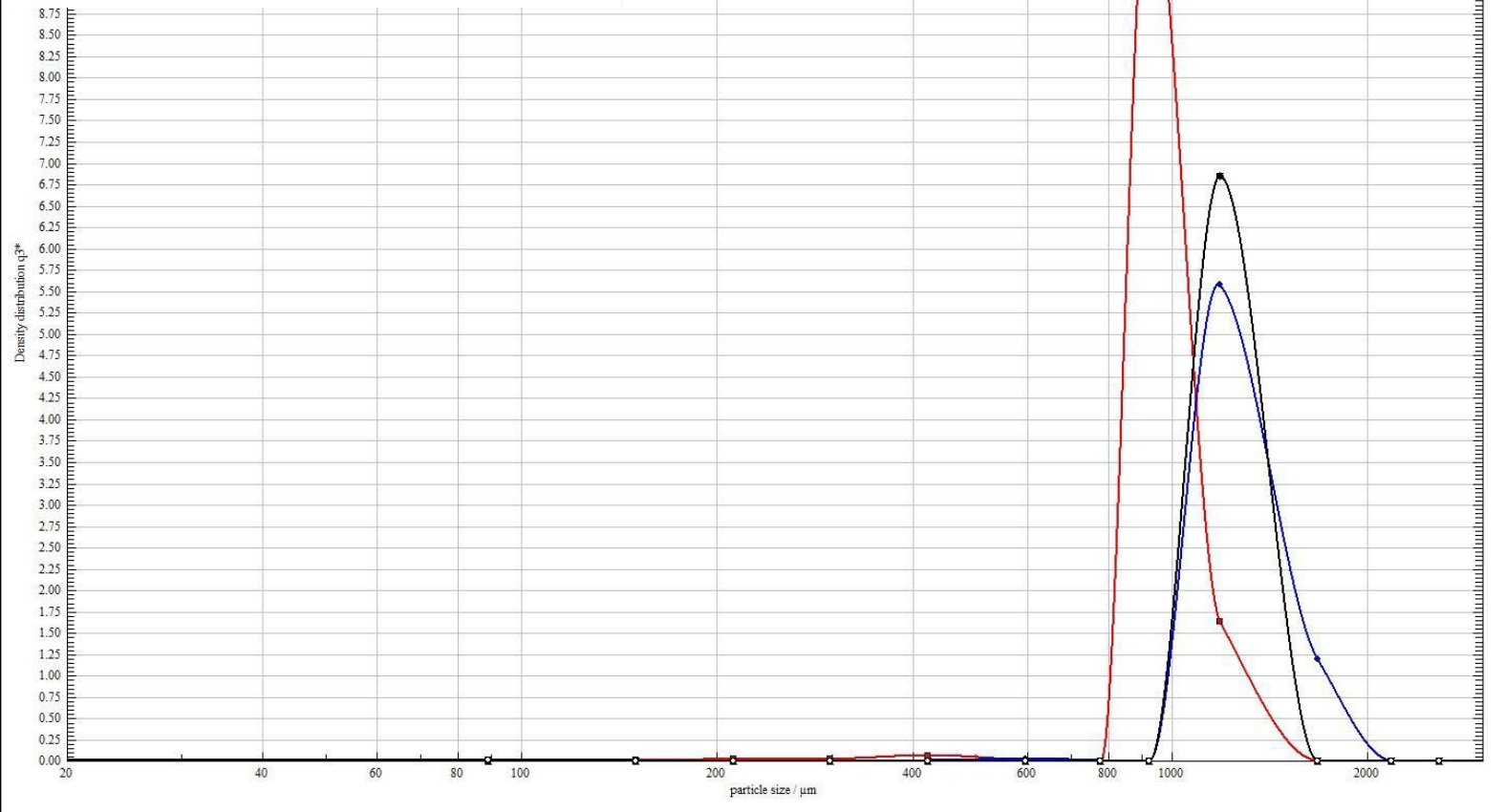
The Conclusion...

- 1) The most critical process is the layering step, the loading of the raw material on the sugar beads, the process requires a fine balance between the powder and solution addition to avoid agglomeration or heavy powder loss.
- 2) The HPMC solution diluted at 2.5 % along with adding 2g of talc worked due to the lower stickiness, allowing for a wider range of parameters and without causing agglomeration and sticking on the walls of the chamber.
- 3) The coating step was performed at a conservative solution flow rate as precaution, but considering the behavior of the product and the set parameters, increasing solution delivery rate (which would decrease the length of the process) is achievable.



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Product	D10 μm	D50 μm	D90 μm
—■— Cores, Uncoated	866.97	947.39	1232.15
—▼— Cores, With Powder at 120 min	1039.99	1199.99	1360
—●— Cores, with Powder and Soutlion at 157 min	1047.47	1244.23	1672.71



Pellets, Uncoated



Pellets, Coated for 150 min

