



SURETERIC[®]
AQUEOUS ENTERIC COATING SYSTEM

Technical Data Sheet
Coating Applications

Delayed Release Coating of Aspirin Granules with Sureteric[®]

Purpose:

To evaluate Sureteric, as an aqueous, delayed release coating for granules in pilot and production scale fluid bed equipment.

Methods:

Several trials have been conducted in both Glatt and Aeromatic fluid-bed equipment utilizing the Wurster process. Aspirin granules (40 mesh) were used as a substrate for all of the coating trials. In each case, a 1-2% weight gain of an Opadry[®] (YS-2-7013) as a subcoat was used prior to the Sureteric application. Typical coating conditions for the application of Sureteric are reported in Table 1 below:

Table 1. Coating Conditions for the Application of Sureteric

| Specification | Glatt GPCC-3 | Glatt GPCC-60 HS | Aero MP-2 |
|-----------------------|------------------|------------------|------------------|
| Bed Charge | 2-3.0kg | 50.0kg | 15.0kg |
| Sureteric % solids | 15.0 | 15.0 | 15.0 |
| % Weight gain applied | 20.0 | 20.0 | 20.0 |
| Spray nozzle | Schlick 1.2mm | Schlick "04" | Schlick 1.2mm |
| Plate | "C" | "B" | 8% |
| Inlet air temp °C | 60-65 | 65-75 | 65-70 |
| Exhaust air temp °C | 35-40 | 30-35 | 30-35 |
| Spray rate g/min | 20-25 | 275-350 | 65-75 |

Process Considerations:

In the Wurster process, the spray nozzle and a portion of the liquid feed line are placed in the supply plenum directly within the source of heated process air. Care must be taken not to stop the flow of Sureteric suspension without clearing the feed lines and nozzle. Typically, this can be accomplished by disconnecting the liquid feed line from the nozzle with the atomization air still turned on. This will allow any Sureteric remaining in the nozzle to be aspirated from the assembly by the atomizing air. If the Sureteric remains static in the nozzle under elevated temperature conditions, nozzle plugging may occur.

Dissolution Results:

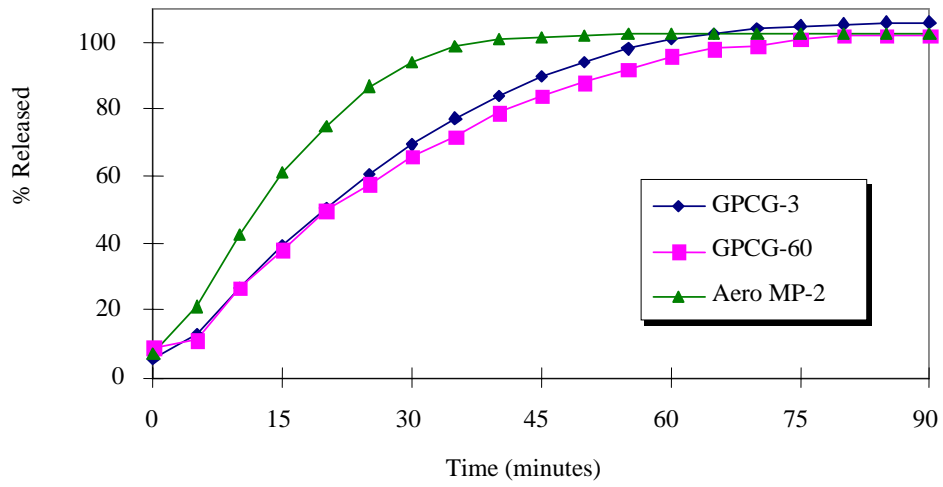
Coated granules were tested using U.S.P. Delayed Release Method I. Typically a 15-20% weight gain of Sureteric will provide enteric protection with < 10% aspirin release in 0.1N HCL over 2 hours and suitable drug release with greater than 80% release in less than 90 minutes in phosphate buffer, pH 6.8.

Table 2. Drug Release from Aspirin in 0.1N HCL

| % Aspirin released after 2 hours in 0.1N HCL (Limit <10%) | | |
|---|------------------|----------|
| Glatt GPCG-3 | Glatt GPCG-60 HS | Aero MP2 |
| 5.51 | 8.98 | 7.55 |



**Figure 1. Sureteric Coated Aspirin Granules: 20% Weight Gain.
Dissolution in 6.8 Phosphate Buffer**



Conclusion:

Successful delayed release coating of aspirin granules with Sureteric in a Wurster process has been demonstrated from pilot through production scale.

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First Published 02.1999. Revised 10.2006