MODIFIED RELEASE

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 ºC	60-65	65-75	65-70
Exhaust air temp ºC	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

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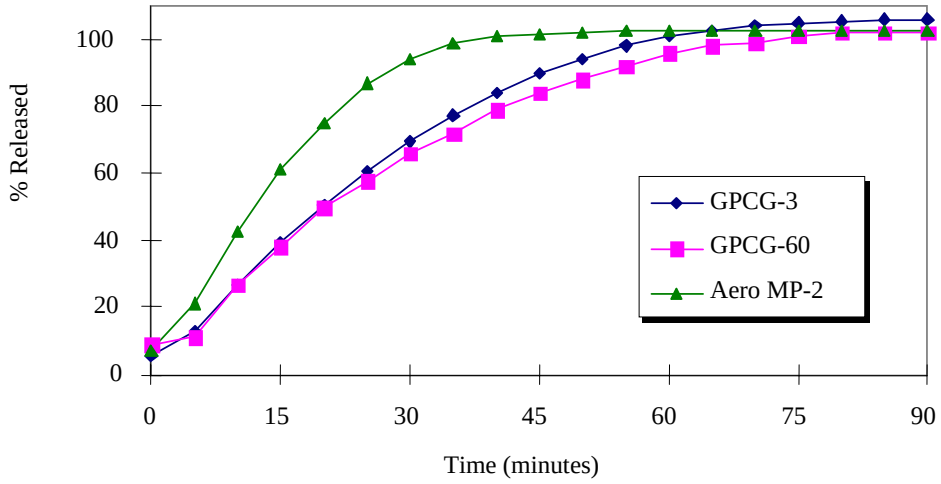
Figure 1. Sureteric Coated Aspirin Granules: 20% Weight Gain.
Dissolution in 6.8 Phosphate Buffer



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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