

AQUEOUS ENTERIC COATING SYSTEM

Technical Data Sheet Coating Application

Coating Tablets with Sureteric

Sureteric is a specially blended combination of PVAP (polyvinyl acetate phthalate), plasticizers, and other processing ingredients, specifically designed to meet the enteric coating needs of solid oral dosage forms in the pharmaceutical industry

Coating Parameter	24" Accela-Cota	48" Accela-Cota	60" Accela-Cota	
Solvent	Distilled Water	Distilled Water	Distilled Water	
Solids content (% w/w)				
Opadry [®] subcoat	15	15	15	
Sureteric [®]	15	15	15	
Opadry II topcoat	15-20	15-20	15-20	
Theoretical weight gain (%)				
Opadry subcoat	2	2	2	
Sureteric	10	10	10	
Opadry II topcoat	3	3	3	
Tablet charge (kg) ⁽¹⁾	11-13	120-150	280-320	
Inlet air temperature (°C)	75-84	70-80	70-80	
Drying air volume (m³/hr) ⁽³⁾	425+/-42	3227+/-170	4250+/-340	
Exhaust air temperature (°C)				
Sureteric	38-41	40-45	40-45	
Sub and topcoat	42-44	45-48	45-48	
Pre-warm tablet bed (°C)	45-48	45-48	45-48	
Spray equipment	2 x Binks 605	4 x Binks 605	5 x Binks 605	
Fluid nozzle (mm)	1.8 mm, Binks 66SH	1.8 mm, Binks 66SH	1.8 mm, Binks 66SH	
Air cap	External Atom., Oval	External Atom., Oval	External Atom., Oval	
Atomizing air pressure (bar) ⁽³⁾	2.4-2.7	4.0-5.5	4.0-5.5	
Pattern air pressure (bar) (3)	N/A	N/A	N/A	
Gun-to-bed distance (cm)	13-18	25-31	25-31	
Spray rate (g/min) Sureteric	60-70	400 500	700-800	
Sub and topcoat	55-60	400-500 350-450	650-750	
Pan speed (rpm)	14	4-8	3-6	
Coating Time (Hours)	17	7-0	3-0	
Opadry subcoat	0.5	1	1	
Sureteric	2	3-4	3-4	
Opadry II topcoat	1	1-1.5	1-1.5	

- 1) Maximize pan charge
- 2) Air volume may be decreased to prevent edge chipping3) Adjust to maximize efficiency



Additional Considerations

- 1. Always maintain a negative air pressure in the pan (more air out than in).
- 2. Rotate (jog) the table and bed minimally prior to constant rotation, during the spray cycle.
- 3. After start-up, allow a minimum of 15 minutes for exhaust temperature to equilibrate before making changes in fluid and/or air flows.
- 4. To maximize enteric performance and adhesion between the sub-coat and enteric interface, reduce the Sureteric spray rate by 15%, for the first 1% weight gain, if any tackiness or sticking is noticed. The delivery rate may then be increased as the cores become sealed with Sureteric.
- 5. Once Sureteric delivery has begun, maintain a constant flow. Gun needles should remain in an open position for the duration of the Sureteric application.
- 6. Immediately after applying the topcoat, tablets may be polished using powdered Carnauba wax. Apply no more than 10.0 g per 100 kg of tablets. Apply the wax without exhaust or drying air on the tablets. Run for 5 minutes at 3 rpm, then cool to room temperature with exhaust at low speed for no longer than 5 minutes.

The above parameters are recommended based on Colorcon trial data. Individual product and machine functions may create a need to alter the conditions. Please consult Colorcon if further technical advice is required.

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