PHARMACEUTICAL TECHNOLOGY REPORT



Consumer Specialties ashland.com

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Aquarius[™] Control ENA film coating systems

Reconstitution Instructions

Materials

PTR-109

- Aquarius Control ENA film coating systems (20% solids recommended)
- Water, preferably deionized or distilled, ambient temperature
- Solids: 20% recommended

Equipment

- Mixing vessel with 25–35% greater height than the liquid level; diameter of the mixing vessel should be approximately 75–100% of the height of the liquid
- Variable speed mixer (100–2000 rpm)
- Propeller stirrer

Preparation Guidelines

- 1. Weigh the required quantity of water into the mixing vessel.
- 2. Weigh out the required quantity of Aquarius film coating system.
- 3. Center the propeller stirrer in the mixing vessel so that it is as close to the bottom as possible (see Figure 1a).
- 4. Set the mixer to the fastest possible speed which maintains a vortex without drawing air into the water.
- 5. Add the Aquarius film coating system powder to the vortex as quickly as possible, avoiding flotation of the powder and increasing the mixer speed as necessary to maintain the vortex (see Figure 1b).
- 6. Maintain the mixer speed to give gentle mixing throughout the 60-minute reconstitution period (see Figure 1c).



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Figure 1. a: Propeller stirrer properly positioned in mixing vessel. b: Addition of Aquarius™ film coating system powder to the water. c: Mixing for 60 minutes

Suspension Handling

Coating suspensions made with Aquarius[™] film coating systems should be stirred throughout the coating process.

• After the dispersion, pass through a 20-mesh screen before commencing spraying.

Coating Parameters

Coating Parameters	GEA Precision Coater MP-1	
Spray gun	One Schlick 970	
Column height (mm above base)	20	
Pellet load (kg)	4	
Specific Coating Parameters	Subcoat: Aquarius Prime (10% solids)	Enteric coat: Aquarius Control ENA (20% solids)
Inlet air dew point (°C)	13.6	13.6
Inlet air temperature (°C)	65	60
Product temperature (°C)	42	39
Exhaust temperature (°C)	42	39
Atomizing air pressure (bar)	2	2
Process air volume (m ³ h ⁻¹)	70	77 (75–80)
Spray rate (g min ⁻¹)	11.5	15.8

A. Coating Pellets with Aquarius Control ENA Film Coating Systems



Coating Parameters	Vector LCDS with Schlick ABC
Number of baffles	4 (plough)
Pan loading (kg)	1.5
Coating solids (% w/w)	20
Quantity of coating suspension* (g)	500
Inlet air dew point (°C)	12.3
Inlet air temperature (°C)	50
Exhaust air temperature (°C)	37
Bed temperature (°C)	31.5
Process air volume (cfm)	60
(m ³ h ⁻¹)	100
Spray rate $(g min^{-1})$	6.5 (6.2–7.3)
Atomizing air pressure (bar)	1.6
Pattern air pressure (bar)	1.8
Pan speed (rpm)	27

Coating Softgels With Aquarius™ Control ENA Film Coating Systems

* Note: Theoretical weight gain was 5%, with samples removed at 3% and 4%

B. Coating Tablets with Aquarius Control ENA Film Coating Systems

	Bohle BTC 100	Bosch XL-Cota	IMA GS 300
Process Parameter	Coater with	150 with	Coater With
Spray guns	4 Schlick ABC	3 Opticoat	4 Schlick ABC
Gun-to-bed distance (cm)	17	15–17	17–18
Pan loading (kg)	94	120	163.2
Weight gain (% w/w; max)	10	10	10
Inlet air dew point (°C)	10	-	-
Inlet air temperature (°C)	58	58.1	63.2
Exhaust air temperature (°C)	38	44.3	42.3
Product temperature (°C)	-	38.2	40.6
Process air volume (m ³ h ⁻¹)	1500	2250	1700
Atomizing air pressure (bar)	1.5	2	2.2
Pattern air pressure (bar)	1.8	2	2.2
Pan speed (rpm)	10	8–10	8–10
Spray rate (g min ⁻¹)	300	253.5	222.5
Coating solids (% w/w)	20	20	20
Coating suspension applied (kg)	47	60	77.8
Coating process time (min)	156	241	349

Usage

The maximum solids level will not only depend on the particular Aquarius film coating system selected, but also the coating equipment (such as spray gun, pump and coating machine) used.

