# PHARMACEUTICAL TECHNOLOGY REPORT



**Consumer Specialties** ashland.com

Page 1 of 3

# Aquarius<sup>™</sup> 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).



The information contained in this document and the various products described are intended for use only by persons having technical skill and at their own discretion and risk after they have performed necessary technical investigations, tests and evaluations of the products and their uses. While the information herein is believed to be reliable, we do not guarantee its accuracy and a purchaser must make its own determination of a product's suitability for purchaser's use, for the protection of the environment, and for the health and safety of its employees and the purchasers of its products. Neither Ashland nor its affiliates shall be responsible for the use of this information, or of any product, method, or apparatus described in this document. Nothing herein waives any of Ashland's or its affiliates' conditions of sale, and WE MAKE NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS OF ANY PRODUCT FOR A PARTICULAR USE OR PURPOSE. We also make no warranty against infringement of any patents by reason of purchaser's use of any product described in this document. All statements, information and data presented herein are believed to be accurate and reliable, but are not to be taken as a guarantee, an express warranty, or an implied warranty of merchantability or fitness for a particular purpose, or representation, express or implied, for which Ashland Inc. and its subsidiaries assume legal responsibility. @ Registered trademark, Ashland or its subsidiaries, registered in various countries. TMTrademark, Ashland or its subsidiaries, registered in various countries. \*Trademark owned by a third party. © 2017, Ashland 11-2017



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<sup>™</sup> 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 <sup>3</sup> h <sup>-1</sup> )	70	77 (75–80)
Spray rate (g min <sup>-1</sup> )	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 <sup>3</sup> h <sup>-1</sup> )	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 <sup>3</sup> h <sup>-1</sup> )	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 <sup>-1</sup> )	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.

