



ACRYL-EZE®
Aqueous Acrylic Enteric System

Technical Data Sheet

Coating Parameters for the Use of Acryl-EZE® to Provide Enteric Protection to Tablets

Acryl-EZE is a fully formulated, dry acrylic-enteric coating system, dispersible in water, for the application of a delayed release film coating to solid dosage forms such as tablets, granules and beads.

Combining the benefits of a fully formulated coating system with a globally accepted delayed release polymer, Eudragit® L100-55, Acryl-EZE is readily dispersible in water for easy application. The coating system can be pigmented to meet marketing requirements and provides consistent, reproducible delayed release profiles.

The coating parameters which are recommended for use with Acryl-EZE are based on Colorcon trial data. Individual product and machine functions should be taken into account and conditions altered as required. For further technical advice, please contact your Colorcon Technical Representative.

Coating Parameter	O'Hara 24" Pan	O'Hara 30" Pan	O'Hara 48" Pan	Accela-Cota 150	Accela-Cota 60 DXL
Solvent	Distilled Water	Distilled Water	Distilled Water	Distilled Water	Distilled Water
Solids content (% w/w)	20	20	20	20	20
Theoretical weight gain (%)	7-10	7-10	7-10	7-10	7-10
Tablet charge (kg)	15	40	140	120	360
Inlet air temperature (°C)	55	46	53	53	54
Drying air volume (cfm)	250 (425 m ³ /hr)	550 (935 m ³ /hr)	1530 (2600 m ³ /hr)	1530 (2600 m ³ /hr)	4000 (6800 m ³ /hr)
Tablet surface bed temperature (°C)	29-35	29-35	29-32	29-35	29-36
Exhaust air temperature (°C)	32-34	30-35	34-38	36-38	37-40
Pre-warm tablet bed (°C)	34-36	34-36	34-36	34-36	34-36
Spray equipment	2 X SSVAU	2 X SSVAU	4 X SSVAU	4 X Manesty	5 X JAU
Fluid nozzle (mm)	1.5	1.5	1.5	1.2	1.5
Air cap (mm)	3.3	3.3	3.3	4	3.4
Atomizing air pressure (1) (psi)	35 (2.4 bar)	45 (3 bar)	40 (2.8 bar)	45 (3 bar)	50 (3.6 bar)
Pattern air pressure (1) (psi)	35 (2.4 bar)	40 (2.8 bar)	30 (2.1 bar)	35 (2.5 bar)	N/A
Gun-to-bed distance (inches)	5.5-6 (14-15 cm)	7-7.5 (18-19 cm)	8-8.5 (21-23 cm)	9-9.5 (23-24 cm)	10-12 (25-30 cm)
Spray rate (g/min)	55-60	115-120	350	320	500-600
Baffles	2	2	4	4	4
Pan speed (rpm)	12	8	6-8	7	3.5-4.5

(1) Adjust to maximize efficiency

Acryl-EZE is reconstituted to 20% w/w solids dispersion for use. Recommended weight gains of Acryl-EZE are 7% to 10% for delayed release performance depending on the core. A sub-coat may be required to separate alkaline drugs from the enteric polymer or to strengthen the dosage form prior to enteric coating.

A top-coat may be used for additional gloss or to aid in printing.

World Headquarters

Colorcon

415 Moyer Blvd., P.O. Box 24, West Point, PA 19486-0024

Tel: 215-699-7733 Fax: 215-661-2605 Web Site @<http://www.colorcon.com> E.mail: modified_release@colorcon.com

Locations	Telephone	Facsimile	Locations	Telephone	Facsimile
<i>United States</i>			<i>Asia/Pacific</i>		
Santa Ana, California	714-549-0631	714-549-4921	Singapore	65-6438-0318	65-6438-0178
Indianapolis, Indiana	317-545-6211	317-545-6218	Nishiyama, Japan	81-5-4465-2711	81-5-4465-2730
Humacao, Puerto Rico	787-852-3815	787-852-0030	Shanghai, China	86-21-5442-2222	86-21-5442-2229
Quebec, Canada	514-337-8341	514-337-9159	Goa, India	91-832-288-3434	91-832-288-3440
			Seoul, Korea	82-2-2057-2713	82-2-2057-2179
<i>Europe</i>			<i>Latin America</i>		
Dartford, Kent, England	44-1322-293000	44-1322-627200	Buenos Aires, Argentina	54-11-4552-1565	54-11-4552-3997
Massy, France	33-1-6447-9750	33-1-6932-5983	Cotia, Brasil	55-11-4612-4262	55-11-4612-3307
Idstein, Germany	49-6126-9961-0	49-6126-9961-11	Bogota, Colombia	571-418-1202	571-418-1257
Gallarate, Italy	39-0331-776932	39-0331-776831	Santa Fe, Mexico	525-5-3000-5700	525-5-3000-5701
Budapest, Hungary	36-1-200-8000	36-1-200-8010	Caracas, Venezuela	58-212-442-4819	58-212-442-8724
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792			
Istanbul, Turkey	90-216-465-0360	90-216-465-0361			

The information contained herein, to the best of our knowledge is true and accurate. Any recommendations or suggestions are made without warranty or guarantee, since the conditions of use are beyond our control. Any information contained herein is intended as a recommendation for use of our products so as not to infringe on any patent.

© Colorcon, 2008. The information contained in this document is proprietary to Colorcon and may not be used or disseminated inappropriately.

Acryl-EZE[®] is a registered trademark of BPSI Holdings LLC.

EUDRAGIT[®] is a registered trademark of Röhm GmbH

mr/acryl-eze/coating_params/03.08_rev3