

Coating Parameters – Ethanol/Water Solvent Solution

FOR FORMULATIONS BASED ON HYPROMELLOSE PHTHALATE (HPMC-P)

Opadry® Enteric is a fully formulated, delayed release coating system for pharmaceutical solid oral dosage forms applied by hydro-alcoholic processing techniques. The coating parameters listed in the table below are based on Colorcon data for Opadry Enteric (920 Series) formulations using an ethanol/water solvent solution**. Individual product and machine functions should be taken into account and process parameters adjusted as required.

Opadry Enteric should be applied over tablets seal-coated with a 2%WG of Opadry® (03K19229).

Pan Type		Fully Perforated Side Vented Coating Pan		
Pan Diameter	cm	38.1	60.96	122
	in	15	24	48
Solution Preparation				
Solvent		** ETOH / H2O		
Solids Content	% w/w	12.5	12.5	12.5
Run Objectives				
Theoretical Weight Gain	% w/w	8 – 12	8 – 12	8 – 12
Tablet Charge	kg	1.5 - 3.0	12 – 15	120 – 160
Gun Configuration				
Example Spray Gun	Type	Schlick 931/7-1 S22	Schlick 931/7-1 S35 (ABC)	Schlick 931/7-1 S35 (ABC)
Number of Guns	guns	1	1 – 2	3 – 4
Nozzle Diameter	mm	1.2	1.2	1.2
	in	0.05	0.05	0.05
Gun to Bed Distance	cm	10	17	25
	in	4	7	10
Gun to Gun Distance	cm	N/A	10	15
	in	N/A	4	6
Atomizing Air Pressure	bar	1.4	1.4	1.7
	psi	20	20	25
Pattern Air Pressure	bar	1.4	1.4	1.7
	psi	20	20	25
Process Parameters				
Drying Air Volume	cu.m/hr	250 – 290	424 – 470	2300 – 3060
	cu.ft/min	147 – 175	250 – 275	1350 – 1800
Pan Speed	rpm*	18	14	7
Pre-warm Tablet Bed	°C	33 – 36	33 – 36	33 – 36
	°F	91.4 – 96.8	91.4 – 96.8	91.4 – 96.8
Inlet Air Temperature	°C	36	36	36
	°F	96.8	96.8	96.8
Tablet Bed Temperature	°C	31 – 33	31 – 33	31 – 33
	°F	87.8 – 91.4	87.8 – 91.4	87.8 – 91.4
Spray Rate	g/min	22 – 25	48 – 52	250 – 340***
Approximate Coating Times	min	44 – 195	195 – 338	374 – 550***
*Pan speed should be set so that even mixing of the bed occurs. This will be influenced by tablet size, shape, friability and baffle type in the pan. ** Ethanol/Water mass ratio 80/20*** Estimated				

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For more information, contact your Colorcon representative or call:

North America	Europe/Middle East/Africa	Latin America	India	China
+1-215-699-7733	+44-(0)-1322-293000	+54-1-5556-7700	+91-832-6727373	+86-21-61982300

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