

Coating Parameters - Clear (PVA-based) Formulations

Opadry® II, high performance film coating systems, are dry blends containing a combination of excipients for the aqueous film coating of pharmaceutical solid dosage forms. The coating parameters listed in the table below are based on Colorcon data for Opadry II clear (PVA-based) formulations. Individual product and machine functions should be taken into account and conditions altered as required.

Fully Perforated Side Vented Pan						Conventional Pan
Pan Diameter	cm	38.1	60.96	122	152.4	40.64
	in	15	24	48	60	16
Solution Preparation						
Solvent		Purified Water	Purified Water	Purified Water	Purified Water	Purified Water
Solids Content	% w/w	8	8	8	8	8
Run Objectives						
Theoretical Weight Gain	% w/w	1	1	1	1	1
Tablet Charge [†]	kg [†]	1.5 - 3.0	12 - 15	120 - 160	320 - 350	3
Gun Configuration						
Example Spray Gun	type	Schlick 931/7-1 S22	Spraying Systems 1/8 VAU	Schlick 931/7-1 S35 (ABC)	Manesty	Schlick 970/7-1 S75
Number of Guns	guns	1	1 - 2	3 - 4	5 - 6	1
Nozzle Diameter	mm	1.2	1.2	1.2	1.2	1.2
	in	0.05	0.05	0.05	0.05	0.05
Gun to Bed Distance	cm	10	17	25	25	15
	in	4	7	10	10	6
Gun to Gun Distance	cm	N/A	10	15	15	N/A
	in	N/A	4	6	6	N/A
Atomizing Air Pressure	bar	1.4	1.7	2.5	2.6	1.4
	psi	20	25	36	36	20
Pattern Air Pressure	bar	1.4	1.7	2.5	2.5	1.4
	psi	20	25	36	36	20
Process Parameters						
Drying Air Volume	cu.m/hr	250 - 290	424 - 470	2300 - 3060	5440 - 6630	140
	cu.ft/min	147 - 175	250 - 275	1350 - 1800	3200 - 3900	80
Pan Speed*	rpm*	18	14	8	6	20
Pre-warm Tablet Bed	°C	45 - 50	45 - 50	45 - 50	45 - 50	45 - 50
	°F	113 - 122	113 - 122	113 - 122	113 - 122	113 - 122
Inlet Air Temperature	°C	60	65	65	65	65
	°F	140	149	149	149	149
Tablet Bed Temperature	°C	45 - 48	45 - 48	45 - 48	45 - 48	45 - 48
	°F	113 - 118	113 - 118	113 - 118	113 - 118	113 - 118
Spray Rate	g/min	12 - 20	40 - 60	260 - 430	650 - 750	12
Approximate Coating Times	min	15 - 20	30 - 40	45 - 60	55 - 65	31

*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.

[†]Tablet charge is dependent on tablet size and shape.

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