High Performance Film Coating Systems

OPADRY[®] II

Coating Parameters – Pigmented (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 pigmented (PVA-based) formulations. Individual product and machine functions should be taken into account and conditions altered as required.

		Fully Perforated Side Vented Coating Pan				Conventional Pan
Pan Diameter	cm	38.1	60.96	122	152.4	40.64
Pan Diameter	in	15	24	48	60	16
			Solution Prepara	tion		
Solvent		Purified Water	Purified Water	Purified Water	Purified Water	Purified Water
Solids Content	% w/w	20	20	20	20	20
			Run Objective	s		
Theoretical Weight Gain	% w/w	3	3	3	3	3
Tablet Charge [†]	kg [†]	1.5 - 3.0	12 - 15	120 - 160	320 - 350	3
			Gun Configurat	ion		
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	mm	1.2	1.2	1.2	1.2	1.2
Diameter	in	0.05	0.05	0.05	0.05	0.05
Gun to Bed	cm	10	17	25	25	15
Distance	in	4	7	10	10	6
Gun to Gun	cm	N/A	10	15	15	N/A
Distance	in	N/A	4	6	6	N/A
Atomizing Air	bar	1.4	1.7	2.5	2.5	1.4
Pressure	psi	20	25	36	36	20
Pattern Air	bar	1.4	1.7	2.5	2.5	1.4
Pressure	psi	20	25 Process Parame	36	36	20
- · · · ·		050 000			5440 0000	1.10
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 Approximate Coating Times	g/min	12 - 20	40 - 60	260 - 430	650 - 750	12
	min	18 - 23	38 - 45	55 - 70	70 - 80	38
*Pan speed shou	uld be set so	-	the bed occurs. This w type in the par ge is dependent on ta	l		, friability and baff



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