

Table 1: Typical potential critical process parameters

Process Step	Type (Examples)	Potential Critical Process Parameters	Potential Critical Quality Attributes
Mixing/lubrication	Bin blender (e.g., Servolift, Galley, Matcon, Bohle)	<ul style="list-style-type: none"> • Mixing time • Speed • Order of addition • Change in direction • Holding time (for final blend) • Load size 	<ul style="list-style-type: none"> • Homogeneity, potency • Particle size distribution • Bulk density or Specific volume • Moisture (in case of Osmotic blend) • Compactability • Bulk Flowability

Process Step	Type (Examples)	Potential Critical Process Parameters	Potential Critical Quality Attributes
	Planetary blender (e.g., Herbst, AMF, Hobart)	<ul style="list-style-type: none"> • Mixing time • Speed • Impeller configuration • Order of addition • Change in direction • Holding time (for final blend) • Load size 	<ul style="list-style-type: none"> • Static Charge
	Tumble blenders (Double cone blender and PK-V-blender)	<ul style="list-style-type: none"> • Mixing time • Speed • I-bar speed (if used) • Order of addition • Holding time (for final blend) • Load size 	
	High shear blender (e.g., Diosna, Collette Gral, Fielder Spectrum)	<ul style="list-style-type: none"> • Impeller mixing time • Impeller Speed • Chopper mixing time and speed • Order of addition • Holding time (for final blend) • Load size 	
Granulation binder preparation	Stirring vessel for binder solution	<ul style="list-style-type: none"> • Mixing time • Speed • Temperature • Holding time 	<ul style="list-style-type: none"> • Homogeneity of solution (clear)
Dry granulation	Roller compactor (e.g., Bepex & Frewitt, Fitzpatrick Chilsonator, Gerteis, & Vector)	<ul style="list-style-type: none"> • Compression force • Roll speed • Roll force • Screen size and type • Feed rate • Type of roll used • Temperature • Roller gap width • Tamp to Feed (auger ratio) 	<ul style="list-style-type: none"> • Moisture content • Bulk density • Particle size distribution • Ribbon solid fraction • Ribbon tensile strength • Compressibility

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Process Step	Type (Examples)	Potential Critical Process Parameters	Potential Critical Quality Attributes
	Dosing disc (e.g., Bosch GKF)	<ul style="list-style-type: none"> Machine settings (vacuum, pressure, etc.) Encapsulator speed Dosing disc size Holding time Tamping pins and settings 	<ul style="list-style-type: none"> Weight variation Visual inspection Dissolution Microbial (if applicable)
	Dosator (e.g., MG2 G 120, Zanasi)	<ul style="list-style-type: none"> Machine settings (powder bed height, vacuum pull, etc.) Encapsulator speed Holding time Dosator height 	
Laser drilling	Lumonics Laser Drill	<ul style="list-style-type: none"> Pulse on time Hole position Eject delay 	<ul style="list-style-type: none"> Orifice size Orifice location Visual inspection
Film Coating	Perforated pan (e.g., Glatt, Vector, Accela-Cota)	<ul style="list-style-type: none"> Coating pan settings Outlet air temperature Spray rate Spray air pressure/pattern 	<ul style="list-style-type: none"> Visual inspection/Elegance Dissolution Moisture content Microbial (if applicable)
Film Coating (continues)	Fluidized bed (e.g., Huttlin HKC)	<ul style="list-style-type: none"> Nozzle size Gun angle Distance between guns Distance of the guns to the tablet bed RPM Quantity of suspension/solution Holding time 	
Coating solution/suspension preparation	Stirring vessel	<ul style="list-style-type: none"> Mixing speed Mixing time Temperature Order of addition Holding time 	<ul style="list-style-type: none"> Viscosity Specific gravity Microbial Homogeneity of suspension (free of agglomerates)
Membrane Coating	Perforated pan (Vector Hi-Coater)	<ul style="list-style-type: none"> Load size Gun to bed distance Inlet Air Flow Exhaust temperature Spray rate Pan speed 	<ul style="list-style-type: none"> Coating weight gain Thickness Visual inspection Dissolution point or profile Moisture content Degradants Microbial (if applicable)