TABLETS & HARDGEL CAPSULES

S.No.	Unit Operations	S.No.	Critical Process Parameters	Critical Quality Attributes
1.	Dispensing	1	Choice of balance	Quantity of material as per formula
		2	Calibration status	Quantity of material as per formula
		3	Daily checking of balance	Quantity of material as per formula
		4	Verification of material during dispensing.	Identity
2.	Sifting	1	Size of the sieve	PSD
		2	Geometrical mixing	BUA
3.	Milling in comminuting mill	1	Size of the screen	PSD
		2	Type/speed of the blade	PSD
		3	Feed rate of material	PSD
4.	Binder preparation	1	Granulation fluid mixing time	Uneven hardness
		2	Granulation fluid mixing speed	Uneven hardness
		3	Granulation fluid amount	Hardness, Friability, Dissolution
		4	Granulation fluid temperature	Relative impurities
5.	Wet Granulation	1	Granulation fluid addition rate	Hardness, Friability, Dissolution
		2	Dry Mixing time	BUA
		3	Wet Mixing time	Hardness, Friability, Dissolution
		4	Impeller sped	Hardness, Friability, Dissolution
		5	Chopper speed	Hardness, Friability, Dissolution
		6	Ampere load	Hardness, Friability, Dissolution
6.	Fluid bed drying	1	Supply air flow rate	PSD, LOD
		2	Supply air dew point	LOD, moisture content
		3	Drying Time	LOD, moisture content
		4	Inlet temperature	LOD, moisture content, RI
		5	Outlet temperature	LOD, moisture content
7.	Sizing in OG	1	Screen size	Granulometry
		2	Feeding rate of granules	Granulometry
		3	Oscillation rate	Granulometry
		4	Sizing time	Granulometry
8.	Blending/Lubrication	1	Occupancy	BUA, Assay
		2	RPM of blender	BUA, Assay
		3	Blending time	BUA, Assay
9.	Sampling of granules	1	Selection of sampler	BUA, Assay
		2	Sample container	Relative impurities
		3	Sample storage	Relative impurities
10	Roller compaction	1	Selection of roller	Granulometry
		2	Roll speed	Granulometry
		3	Fed screw speed	Granulometry
11	Tray drying	1	Inlet air temp.	LOD, Moisture content, RI
		2	Inlet dew point	LOD, Moisture content
		3	Drying time	LOD, Moisture content
12	Compression	1	Turret RPM	Weight variation, Hardness, dissolution
		2	Main compression force	Thickness, Hardness, dissolution

		3	Pre-compression force	Thickness, Hardness, dissolution
		4	Dwell time	Thickness, Hardness, dissolution
		5	Feeder speed	Weight variation, Hardness, Thickness
		6	Upper punch entry	Hardness, Thickness
		7	Tooling type used	Hardness, dissolution
		8	Verification of tooling before use.	Product mix-up
13	Coating suspension preparation	1	Stirrer Mixing speed	Viscosity, appearance of tablets, disso. pattern in case of functional coating
		2	Stirrer Mixing time	Viscosity, appearance of tablets
		3	Milling time in colloidal mill.	Viscosity, appearance of tablets
14	Coating	1	Coating suspension spray rate	Weight gain, DT in GF
		2	Atomization air pressure	Appearance
		3	Pan RPM	Appearance
		4	Pre heat time	Appearance, RI
		5	Inlet air velocity	Appearance
		6	Inlet air temperature	Appearance, RI
		7	Product bed temperature	Appearance, RI
		8	Gun to bed distance	Appearance
		9	Number of guns	Appearance
		10	spray nozzle diameter	Appearance
15	Inspection	1	Sample inspection (decision for inspection)	Appearance defects
		2	Sorting of rejected tablets/ capsules	Appearance defects
16	Extruder process	1	Scraper adjustment	PSD
		2	Roller RPM	Dissolution
		3	Sieve size	PSD
17	Capsule filling in AF-40	1	Room condition	Brittleness, stickiness
		2	machine SPM	Weight of capsule
		3	ECS voltage set up	Empty capsule in filled capsules
		4	Locking plate adjustment	Lock length, denting, telescopic
		5	Function of NFD	All cqa
		6	powder tub vacuum	Dissolution, DT, weight variation.
		7	Air pressure in locking plate	Lock length
		8	Metal detector	Contaminated product
18	Capsule filling in SA-9	1	Selection of table speed	Weight variation, disso.
		2	Auger speed	Weight variation, disso.
		3	Powder level in hopper	Weight variation
		4	Air pressure in locking plate	Lock length, denting, telescopic
19	Polishing of capsules	1	Polishing unit speed	Appearance
		2	Vacuum or DEX	unpolished capsules
20	Sampling of tablets/capsules	1	Sampling method	Product OOS
		2	Sample storage condition	Relative impurities
21	Storage of bulk	1	Storage container	LOD, moisture content, friability
		2	Storage condition	Relative impurities, LOD, moisture

				content.