

Guidance Number:
025

Table I: Swab locations for Drug Product Equipment

Equipment Use	Common Swab Locations for Validation	Visual Inspection Locations During Validation
<ul style="list-style-type: none"> • Mills (particle reduction) • Impact (e.g. Fitzmill) • Fluid energy (e.g. Alpine jet) • Impeller (e.g. Quadro- Comil) • Other (cutting, tumbling) 	<ul style="list-style-type: none"> • Hopper/Auger feed • Milling chamber • Discharge chute • Milling blades (if feasible) or hammers • Blade axel • Screen (if feasible) 	Complete disassembly of all product contact parts – Inspect all surfaces
<ul style="list-style-type: none"> • Separators (particle separation) • Vibratory (e.g. Russell sieve) • Centrifugal (e.g. Azo) 	<ul style="list-style-type: none"> • Sieve/screen 	Complete disassembly of all product contact parts – Inspect all surfaces
<ul style="list-style-type: none"> • Blenders and Mixers • Tumble (V , double cone, bins) • Convection (ribbon, planetary, Lodige) 	<ul style="list-style-type: none"> • Chamber (Top, bottom, side) • Blade (intensifier, if feasible) • Discharge port 	<ul style="list-style-type: none"> - Inside (top, bottom, sides) - Top and bottom valves
<ul style="list-style-type: none"> • Granulators • Dry- Roller Compactor • Wet- high shear • Wet- low shear • Extruder • Fluid- bed • Spray-dry 	<ul style="list-style-type: none"> • Granulating Chamber (top, bottom) • Bars/blades/rolls (if feasible) • Entry and discharge ports 	<ul style="list-style-type: none"> • Granulating chamber (top, bottom) • Bars/blades/rolls (if feasible) • Entry and discharge ports • Filter bags of Fluid beds to be dedicated
<ul style="list-style-type: none"> • Dryers • Oven (Trays, Trucks, belts) • Fluid Bed • Spray Dryer • Rotary/paddle (e.g. tumble) • Static bed/Lyophilizer • Microwave 	<ul style="list-style-type: none"> • Chamber walls • Bowl • Mesh or trays • Agitator/paddles 	<ul style="list-style-type: none"> • Chamber walls • Bowl • Mesh or trays • Agitator/paddles • Filter bags of Fluid beds to be dedicated
<ul style="list-style-type: none"> • Unit Dosing • Compression • Encapsulation • Powder filler 	<ul style="list-style-type: none"> • Feed hopper • Discharge chute • Tooling (if practical) 	Tablet machine tooling is usually dedicated Capsule machine tooling may or may not be dedicated
<ul style="list-style-type: none"> • Mixing vessels/Mixers/Tanks • Liquid/SemiSolidTanks • Mixers 	<ul style="list-style-type: none"> • Vessel walls • Mixing shaft/blades (if practical) 	
<ul style="list-style-type: none"> • Coating • Film/sugar coating pans • Spray apparatus 	<ul style="list-style-type: none"> • Coating pan sides 	<ul style="list-style-type: none"> • Coating pan sides
<ul style="list-style-type: none"> • Printing and Drilling • Ink printing • Laser drilling 	<ul style="list-style-type: none"> • Print rollers 	<ul style="list-style-type: none"> • Print rollers

Table I: Swab locations for Drug Product Equipment (Cont.)

Equipment Use	Common Swab Locations for Validation	Visual Inspection Locations During Validation
<ul style="list-style-type: none"> • Emulsifiers/Deaeration • Dispersator • Rotor Stator • Vacuum 	<ul style="list-style-type: none"> • Rotor/stator • Interior of housings 	<ul style="list-style-type: none"> • Rotor/stator • Interior of housings
<ul style="list-style-type: none"> • Transfer/Process Piping • Liquid, semisolid, etc. • Coating lines • Granulation solution lines 	<ul style="list-style-type: none"> • Dead Legs • Transfer Manifolds • Sanitary Piping (rinse test) • Nitrogen feed lines attached to bottom/top of lines or tanks. 	<ul style="list-style-type: none"> • Dead Legs • Transfer Manifolds • Sanitary Piping • Nitrogen feed lines attached to bottom of tank transfer lines
<ul style="list-style-type: none"> • Packaging • Fillers • Pumps • Blisters 	<ul style="list-style-type: none"> • Auger feed hopper or spiral chutes • Tooling • Nozzles • Discharge area 	<ul style="list-style-type: none"> • Auger feed hopper or spiral chutes • Tooling • Nozzles • Discharge area
<ul style="list-style-type: none"> • Vacuum pumps used for drying operations • Compovac/Apovac (return loop to dryer) 	<ul style="list-style-type: none"> • None 	<p><i>Recommend installing sight glasses at Inlet and outlet piping of Vacuum.</i></p> <ul style="list-style-type: none"> • Vac Inlet & Outlet Piping
<ul style="list-style-type: none"> • Head tanks • Vessels used to store pure raw materials/reactants 	<ul style="list-style-type: none"> • Dome • Wall • Bottom Valve • 	<ul style="list-style-type: none"> • Dome and Nozzles • Interior of Bottom Valve
<ul style="list-style-type: none"> • Centrifuges 	<ul style="list-style-type: none"> • Dome • Sidewall • Bowl • Discharge Chute 	<ul style="list-style-type: none"> • Dome and Nozzles • Bowl • Discharge Chute • Agitator (if applicable) • Spray Devices
<ul style="list-style-type: none"> • Tray Dryers 	<ul style="list-style-type: none"> • Racks • Interior of Trays • 	<ul style="list-style-type: none"> • Walls & Door • Racks • Trays
<ul style="list-style-type: none"> • Tumble Dryers • Totes & Bins • Hoppers 	<ul style="list-style-type: none"> • Charging Valve or Portal • Discharge Valve or portal • Interior surface 	<ul style="list-style-type: none"> • All interior Surfaces

Table II: PK Processor/ V-Blender Sampling Locations and Rationale

Sampling Location	Active	Detergent	Micro	Rationale for Selection
Charge Chute	x	x	x	Possible humidity retention causing microbial growth
Superior wall (right side)	x	x		Difficult to clean
Interior wall (left side)	x	x		Difficult to clean
Center PK interior (close to I-bar)	x	x		Difficult to clean
PK Valve	x	x	x	Possible humidity and material retention causing microbial growth
I-bar (center)	x	x		Difficult to clean

Table III: Equipment Sampling points and Monitoring Technique example

Equipment	Product Contact Material	Part Name	Product / Non-Product Contact	Monitoring Method Technique			Sample ID #
				Active Ingredient / Detergent	Visual	Micro	
Compressing	AA	Feeders	P	Swab	Visual	Swab	1
	SS 316	Slider	P	Swab	Visual	Swab	2
	SS 316	Vacuum Duct	P	Swab	Visual	Swab	3
	SS 316	Funnel	P	Swab	Visual	Swab	4
	SS 316	“Y”	P	Swab	Visual	Swab	5
	CS	Die Table Surface	P	Swab	Visual	Swab	6
	SS 316	Fast Reject	P	N/A	Visual	N/A	N/A
	CS	Superior Guides	P	N/A	Visual	Swab	7
	SS 316	Recirculation Guide	P	N/A	Visual	Swab	8
Tablet Deduster	SS 316	Vibrator Screen	P	Swab	Visual	Swab	1
Safeline Metal Detector	SS 316	Diverter	P	N/A	Visual	Swab	1
300L Zanchetta Bin	Silicone	Stopper	P	Swab	Visual	Swab	1
	SS 316	Valve	P	Swab	Visual	Swab	2
	SS 316	Coupling	P	Swab	Visual	Swab	3
	SS 316	Inner Top Wall	P	N/A	Visual	N/A	N/A
	SS 316	Inner Bottom Wall	P	N/A	Visual	N/A	N/A
Coating	Silicone	Baffle	P	Swab	Visual	Swab	1
	SS 316L	Pan (Drum)	P	Swab	Visual	Swab	2
	SS 316L	Intermediate Hopper	P	Swab	Visual	Swab	3
	SS 316L	Charge Tube	P	Swab	Visual	Swab	4
Ackley Imprinting Machine	SS 316L	Feed Hopper	P	Swab	Visual	Swab	1
	SS 316L	Exit Hopper	P	Swab	Visual	Swab	2
	SS 316L	Discharge Chute	P	Swab	Visual	Swab	3
Inspection	SS 316L	Hopper	P	Swab	Visual	Swab	1

AA = Anodized Aluminum

SS = Stainless Steel

CS = Cast Steel or Carbon Steel