Title:	Cleaning Validation – Guidance for Swab and Visual Inspection Sampling Locations for Drug Product Equipment				
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Cleaning Validation – Guidance for Swab and Visual Inspection Sampling Locations for Drug Product Equipment

Introduction

This guidance provides recommendations related to the selection and application of swab sampling and visual inspection for various types of Drug Product equipment.

This guidance provides information on selecting the type of sampling method to use for particular types of Drug Product equipment and recommends locations for where to perform swab sampling and/or visual inspection conducted during cleaning validation.

Recommendations and Rationale

The cleaning evaluation determines the major contaminant(s) to be sampled and tested, along with the sampling locations for each equipment item. Table I below provides guidance for sampling locations for each equipment type. This table does not substitute for a thorough consideration of the design of equipment to identify those locations deemed most difficult to clean, nor does it mandate the inspection or sampling of suggested locations that would require vessel entry or require undue safety concerns based upon the design, size, or intended use of equipment.

If swabbing is used as the sampling method, product-contact surfaces should be swabbed in locations from which there is a likelihood of contamination or carryover to a subsequent product and from the most difficult to clean areas. If a rinsate method is used, a measured volume of solvent used for the final rinse should thoroughly wet all product contact surfaces, and should be circulated, where applicable, through all product contact lines before it is visually inspected or tested in the laboratory for residues. Rinsate
recovery studies can be based on worst case product groupings, and/or by grouping of worst case materials of construction.

Table II is an example on how to justify and document the rationale for sampling site selection and table III is an example of how to tabulate the sampling points and sampling methods. Consideration of locations to sample can be documented as part of the cleaning evaluation documentation (e.g. site SOP) conducted for the development of a sampling plan of the equipment system. For more guidance consult with the guidance on conducting a system design review for sample location selection and documentation.

Examples:

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

