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MAC_dosage	swab	solid	$(1 / sf_solid) * (min_td_a) * (1 / max_td_b) * (min_bs_b) * (1 / area_shared)$	based on minimum daily dose of the drug active in a maximum daily dose of the next drug product
MAC_general	swab	solid	$(1 / 1e+5) * (min_bs_b) * (1 / area_shared)$	general 10ppm limit to be considered when it is lower than dosage/toxicity based limits or when dosage/toxicity data is not available
MAC_toxicity	swab	solid	$(pde_a) * (1 / max_td_b) * (min_bs_b) * (1 / area_shared)$	based on Risk-MaPP Acceptable Daily Exposure (ADE) approach

Name	Description
Default	Recommended cleaning limit policy based on latest regulatory guideline. Acceptance limit is always equal to HBEL based limit and site acceptance limit is either based on dosage based limit if it significantly lower than HBEL or is a lower ratio of HBEL itself

Name	Description	Rank	Formula
RPN_overall	risk evaluation from multiple risk factors	1	$R1 * R2 * R3 * R4$

1 Section F4: PE Matrix

The PE (Product-Equipment) relationship is described by the table given below:

Product Id	Equipment Used	Surface Area
P1	EQ1, EQ2, EQ3	70000
P2	EQ1, EQ2	30000
P3	EQ1, EQ3	50000
P4	EQ1, EQ2, EQ3	70000

The PE (Product-Equipment) relationship is described by the table given below:

Product Id	Equipment Used	Surface Area
Equipment1	P1, P2, P3, P4	10000
Equipment2	P1, P2, P4	20000
Equipment3	P1, P3, P4	40000

ID	Name	Toxicity based MAC Swab Ex- tract	Dosage based MAC Swab Extract	General MAC Swab Extract	Site Acceptance limit MAC Swab Extract
EQ1	Equipment1	3.1111	2.0000	0.0571	1.5556
EQ2	Equipment2	3.1111	3.4286	0.0571	1.5556
EQ3	Equipment3	6.0000	2.0000	0.0571	3.0000

Name	Risk ID	Product Property	Unit	From	To	Risk Category Number
Toxicity Risk	R1	pde	mg	0	0.001	5
Toxicity Risk	R1	pde	mg	0.001	0.01	4
Toxicity Risk	R1	pde	mg	0.01	0.1	3
Toxicity Risk	R1	pde	mg	0.1	1	2
Toxicity Risk	R1	pde	mg	1	Infinity	1
Potency Risk	R2	min_td	mg	0	0.001	5
Potency Risk	R2	min_td	mg	0.001	0.01	4
Potency Risk	R2	min_td	mg	0.01	0.1	3
Potency Risk	R2	min_td	mg	0.1	1	2
Potency Risk	R2	min_td	mg	1	Infinity	1
Solubility Risk	R3	solubility_factor		0	1	1
Solubility Risk	R3	solubility_factor		1	2	2
Solubility Risk	R3	solubility_factor		2	3	3
Solubility Risk	R3	solubility_factor		3	4	4
Solubility Risk	R3	solubility_factor		4	5	5
Solubility Risk	R3	solubility_factor		5	Infinity	6
Cleanability Risk	R4	cleanability_factor		0	1	1
Cleanability Risk	R4	cleanability_factor		1	2	2
Cleanability Risk	R4	cleanability_factor		2	3	3
Cleanability Risk	R4	cleanability_factor		3	4	4
Cleanability Risk	R4	cleanability_factor		4	5	5
Cleanability Risk	R4	cleanability_factor		5	6	6
Cleanability Risk	R4	cleanability_factor		6	7	7
Cleanability Risk	R4	cleanability_factor		7	10	8

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