1 Section F1: Product Attributes Table

The product attributes are given below for Product Type: solid

Name	Product Id	API	Solubility Factor	Cleanability Factor	PDE	Min TD	Max TD	Min BS	Strength
Product1	P1	API1	1	1	0	180	360	440000	400
Product2	P2	API2	3	3	0	180	360	210000	400
Product3	P3	API3	5	3	0	300	600	200000	400
Product4	P4	API4	2	5	1	150	300	200000	400

2 Section F2: Equipment Attributes Table

The equipment attributes are given below:

Equipment Id	Equipment Name	Surface Area
EQ1	Equipment1	10000
EQ2	Equipment2	20000
EQ3	Equipment3	40000

3 Section F3: Equipment Group Attributes

The Equipment Group attributes are given below:

Name	Group Id	Product Type	Equipments
Train1	EqGrp1	solid	Equipment1, Equipment2, Equipment3

4 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

5 Section F5: Calculation Variables

The various variables used in the evaluation of the worst case limits and molecules are given in the table given below:

Name	Short Name	Unit	Description	Default Value
Body weight (for LD50 dose)	bw	kg	body weight of patient taking next product	60
Equipment Verification Period	verifyPeriod	month	The frequency at which equipment needs to be verified.	3
Modification factor	mf		Cumulative modifying factor, selected by the toxicologist. generally no more than 1000	1000
Safety Factor - Solids	sf_solid		Safety Factor for Solids drug dosage	1000

6 Section F6: MAC Formula

The below set of formula are used to calculate the MAC Limits. Please note that the MAC Surface Area is taken as the default limit here.

Name	Sampling Type	Product Type	Formula	Description
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

7 Section F7: Sampling Paramters

The Sampling Parameters used in the protocol workflow is as:

Sampling Parameter	value
swab	40
sda	20

8 Section G2: Risk Formula

Risk Priority Number(s) are defined as per the formula given in the table below:

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

9 Section H: Current Cleaning Limit Policy

Current Cleaning Limit Policy given in the table below:

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