

1 Section B: Equipmentwise MAC and Worst Products

Equipment wise worst case residue limits (MAC Surface Area) are given below:

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	3.111111111111103	1.999999999999993	0.05714285714285712	1.555555555555551
EQ2	Equipment2	3.111111111111103	3.428571428571427	0.05714285714285712	1.555555555555551
EQ3	Equipment3	5.999999999999996	1.999999999999993	0.05714285714285712	2.999999999999998

Equipment wise worst case products based on the RPN(Risk Priority Numbers) are given in the table below:

Equipment ID	Equipment Name	Worst Product by C1
EQ1	Equipment1	Product3
EQ2	Equipment2	Product2
EQ3	Equipment3	Product3

Equipment wise worst case residue limits (MAC Surface Area) for each of the cleaning agents are given in the table below:

Equipment ID	Equipment Name	methanol
EQ1	Equipment1	342.39999999999975
EQ2	Equipment2	489.142857142857
EQ3	Equipment3	342.39999999999975

2 Section C: Equipment Group Wise MAC

For the selected group, worst case limit is given below

ID	Toxicity based MAC Swab Ex- tract	Dosage based MAC Swab Extract	General MAC Swab Extract	Site Acceptance limit MAC Swab Extract
EqGrp1	3.1111111111111103	1.9999999999999993	0.05714285714285712	1.5555555555555551

3 Section G: Worst Product Selection Criteria

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 - ★ Product having the highest solubility rating will be selected as worst product.
 - ★ In case where solubility rating of two products are identical, Product having the highest Toxicity Risk category will be selected as worst product.
 - ★ In case where Toxicity Risk category of two products are identical, Product having the highest risk number as per RPN overall will be selected as worst product.

4 Section E: Calculation Methodology

The calculation Methodology is given as below:

The MAC(Maximum Allowed Carryover) limit calculations performed in this document are based on the principles outlined in the below reference documents:

- Fourman and Mullen, Determing Cleaning Validation Acceptance Limits for Pharmacautical Manufacturing Operations ...
- PDA Technical Report No. 29, Revised 2012 Points to Consider for Cleaning Validation TR29

Definition of MAC (Maximum Allowed Carryover) or Acceptable Residue Limit in the next product:

The acceptance level (i.e. concentration) of the target residue in the subsequently manufactured product may be called by different terms, but for this document that concentration will be called Maximum Allowed Carryover (abbreviated MAC).

This is an expression of the maximum concentration of residue allowed in that next product, as determined by medical, pharmacological, safety, stability and or performance issues. For chemical residues (such as the drug active or cleaning agent), this concentration is typically given as µg/g or µg/mL (or an equivalent expression depending on the units selected).

MAC is generally expressed in various forms. The terminology used in this document is given below.

MAC Surface Area = Maximum allowed residue limit in the next product batch per shared surface area across the product equipment contact surface area. This is generally expressed in mg per square inch

MAC Swab = residue concentration in the swab.

MAC Swab = (MAC Surface Area) * (Swabbed surface Area)

MAC Swab Extract = residue concentration in the swab.

MAC Swab Extract = (MAC Surface Area) * (Swabbed surface Area) / (Solvent Desorption Amount)

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