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Cleaning Validation

Practical 19 - Validation-record practical

Aim

To evaluate cleaning effectiveness using a justified residue limit and a qualified recovery method.

Principle

Cleaning validation links the product and equipment risks to a predefined cleaning process and evidence that relevant residues are controlled. Sampling location, recovery, analytical capability and dirty and clean hold conditions affect the conclusion.

A residue result must be compared with a scientifically justified limit appropriate to the product and equipment context. A convenient historical rule alone is not a sufficient toxicological justification.

Materials and Requirements

- Equipment map and approved cleaning procedure
- Justified residue and microbial requirements where relevant
- Qualified swab or rinse recovery procedure
- Selective analytical method and sampling records

Procedure

1. Define the equipment train, product sequence, worst-case rationale and the residue limits established through the approved assessment.
2. Identify difficult-to-clean locations, contact surfaces and the intended swab or rinse approach.
3. Demonstrate recovery at relevant levels on suitable representative surfaces or through the justified sampling model.
4. Perform the approved cleaning process and collect identified blanks, controls and samples at the prescribed locations.
5. Analyse using a method with adequate quantitation capability and review any recovery correction or uncorrected conservative reporting convention.
6. Calculate residue per area or other defined basis and compare all locations with the justified limits.
7. Issue a report covering process records, sampling recovery, results, deviations and the supported cleaning conditions.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Location / area	Raw residue amount	Recovery convention	Reported residue and limit
Sampling blank	Record	State	Evaluate
Recovery control	Record	Calculate	Evaluate
Worst-case location	Record	Apply justified convention	Compare
Additional location	Record	Apply justified convention	Compare

Calculations

• Residue per area = measured recovered residue / sampled area
• If validated and prescribed: recovery-corrected residue = measured recovered residue / recovery fraction

Worked Example

Illustrative measured residue is 2.0 micrograms from a 25 cm^2 area. Uncorrected result = 0.080 micrograms/cm^2.
For a validated recovery fraction of 0.80 and a protocol requiring correction, corrected residue is 2.5 micrograms, or 0.100 micrograms/cm^2.
Compare with the limit from the approved assessment; the example supplies no universal acceptable limit.

Result and Interpretation

• State recovery convention, analytical capability and each location result. A result below quantitation is interpreted with the method limit and reporting rule.

Precautions

• Select limits before generating validation data.
• Prevent contamination of blanks and swabs.
• Document actual sampled area and surface identity.
• Do not average a failing difficult-to-clean location into a passing overall mean.

Viva Questions and Answers

Why choose worst-case locations?

They challenge the cleaning process at relevant difficult points.

Why qualify recovery?

Sampling may collect only a fraction of the actual residue.

Does a low analytical value alone validate cleaning?

The process, sampling, method capability and justified limits must all be considered.

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