Summary - Rinsate and Swab Sample, Test Method Development and Validation

The guidance describes recommended approaches to develop and validate sampling and test methods for cleaning verification using rinse and swab samples.

Contents of Equipment Cleaning Analytical Method Validation Protocols should include

- Sampling Method
- Analytical Method
- Acceptance criteria including the Residue Acceptance Limit (RAL)

Method Validation
Method validation shall be performed in accordance with guidelines "Analytical methods for Equipment Cleaning".

Method Specificity
The cleaning evaluation for a given product, intermediate or drug product excipient provides the basis for the rationale of which material(s) should be tested for during the analysis.

If a specific method is being validated for a cleaning agent, the only specificity experiment typically executed is specificity from swab extractables.

Range
The method is considered valid for any RAL within the validated recovery range. If the RAL falls outside the validated recovery range, the method should be revalidated with respect to

Linearity
The lower end of the linearity study shall take into consideration the correction factor for sampling recovery, if applicable (e.g. if the RALs have a range of 4-6 ug/cm_2 and the recovery is 50 percent, the linearity study should include levels of 2-6 ug/cm_2).

Recovery Studies
Analyte residue recovery shall be challenged as part of the analytical method validation. Recovery studies should include replicate or repeatability studies to confirm reproducibility of results. Site procedures may combine recovery from the surface and recovery from the swab in a single recovery study.

Site procedures should specify a minimum percentage recovery from the surface. For recoveries greater than 100%, no recovery values are to be used as correction factors.

Qualification and Training of Swabbing Personnel

If a special swab is required for a particular product it should be documented.
• Texwipe Alpha Swabs TX761
• Texwipe, Large Alpha Swab.
• Non Woven Swabs NT2300

Swab Pre-treatment
Area Swabbed
Choose solid, flat or semi-flat surfaces when selecting swab locations, if possible. Swab locations should be chosen based upon their difficulty to clean not the difficulty to swab sample.

A template of a non-porous material can be fabricated and used as a guide to ensure the individual performing the swab sample swabs the specified area.

Swab Standard Test Procedure Content
To facilitate the transfer of swab methods between sites and to achieve a greater uniformity of test methods at all gmp sites STPs or SOPs should include:

- Swab type
- Swab technique
- Swab area
- Surface types that the recovery is applicable to
- Extraction technique

a) proving linearity of results from swabbing spiked coupons at a range of concentrations and compared to linearity of the test method, or

Equivalence of Methods Transferred Between Sites

If the validated range needs to be extended, then a separate swab linearity study should be performed by the receiving site over the required range.

Perform a recovery on 6 coupons using the receiving site's procedure.

- Calculate the mean of the 6 recovery results. If the absolute % difference between the mean recovery and that stated in the originating site's STP is not greater than 15%, then the recovery value stated in the STP will remain unchanged (e.g., if the STP states a recovery of 85%, then the receiving site

- Calculate the RSD of the 6 recovery results.

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