

CURRENT PERSPECTIVES ON CLEANING VALIDATION: TECHNIQUES AND PRACTICES ACROSS MULTIPLE SURFACE TYPES

Dr. Putchakayala Purna Chandra Rao, Srilakshmi Sadam, Botta Chinnam Naidu*, Dr. Rajesh Vooturi, Mangali Yuvaraj, Nikhil Siddamsetti

Aurigene Pharmaceutical Services Limited, Hyderabad, Telangana.



***Corresponding Author: Botta Chinnam Naidu**

Aurigene Pharmaceutical Services Limited, Hyderabad, Telangana.

DOI: <https://doi.org/10.5281/zenodo.18093828>

How to cite this Article: Dr. Putchakayala Purna Chandra Rao, Srilakshmi Sadam, Botta Chinnam Naidu*, Dr. Rajesh Vooturi, Mangali Yuvaraj, Nikhil Siddamsetti (2026). Current Perspectives On Cleaning Validation: Techniques And Practices Across Multiple Surface Types. European Journal of Biomedical and Pharmaceutical Sciences, 13(1), 33–41.

This work is licensed under Creative Commons Attribution 4.0 International license.



Article Received on 05/12/2025

Article Revised on 25/12/2025

Article Published on 01/01/2026

ABSTRACT

In the food, biotechnology, and pharmaceutical industries, cleaning validation is an essential part of quality assurance since it guarantees that manufacturing equipment is clear of residues that can contaminate later batches. The procedures and analytical techniques used to find residues on a variety of surface types, such as stainless steel, glass, rubber, acrylic, aluminum, bronze, Teflon, PVC, polypropylene, titanium, ceramic, and electro shield plates, are highlighted in this review, which offers an updated overview of cleaning validation strategies. The function of surface material in residue recovery, sampling strategies including swab and rinse methods, and the choice of suitable analytical instruments like HPLC, TOC, UV-Vis, and LC-MS/MS are all covered in the article. The significance of surface-specific recovery investigations, technique validation, and regulatory expectations are emphasized. The review's objective is to assist experts in creating reliable cleaning validation procedures that are suited to a variety of equipment surfaces.

KEYWORDS: Cleaning validation, Pharmaceutical Manufacturing, Residue Analysis, Specific surface Plates, Analytical techniques, GMP Compliance.

INTRODUCTION

Cleaning validation is documented evidence with high degree of assurance that one can consistently clean a system or piece of equipment to predetermined and acceptable limits. It is primarily applicable to the cleaning of process manufacturing equipment in pharmaceutical industry. It is an essential part of good manufacturing practices (GMP). Cleaning procedures should normally be validated. Cleaning validation should be directed to process steps where contamination of materials produces the greatest risk to active pharmaceutical ingredient quality.

The primary regulatory concern driving the need for cleaning validation in pharmaceutical manufacturing is the risk of cross-contamination either from.

1. Active Pharmaceutical Ingredients (APIs) left over from previous batches.
2. Residues of cleaning agents used during equipment cleaning.

Importance of validate Cleaning Procedures Customer requirement

Provides assurance of the safety, purity, and quality of the final product, ensuring it is free from contaminants.

Regulatory requirement

Mandatory in the manufacture of Active Pharmaceutical Ingredients (APIs) to comply with Good Manufacturing Practices (GMP) and avoid cross-contamination.

Internal control & compliance

Ensures the consistency and reliability of the cleaning process, supporting internal quality systems and regulatory audits.

Advantages of Cleaning Validation

1. Assurance of Quality & Safety: Ensures that products are free from contaminants, maintaining patient safety and product integrity.

2. Compliance with Government Regulations: Meets regulatory requirements from agencies like FDA, EMA, and ICH for GMP compliance.
3. Batch Integrity: Prevents cross-contamination between batches, ensuring consistency and reliability.
4. Equipment Reuse: Validates that equipment can be safely reused without compromising product quality.
5. Reduction in Quality Costs: Minimizes costs related to recalls, rework, and investigations due to contamination.
6. Good Business Practice: Enhances operational efficiency and builds trust with customers and regulators.
7. Fewer Batch Failures: Reduces the risk of batch rejection due to contamination or cleaning issues.
8. Cross-Contamination Control: Demonstrates control over potential contamination sources, protecting product purity.

Factors Influencing Cleaning Validation

1. Equipment Usage: Depends on whether the equipment is used daily, intermittently, or occasionally, which affects the risk of residue buildup.
2. Stage of Manufacture: Varies based on whether the cleaning is performed during the early, middle, or final stages of the manufacturing process, influencing the criticality of contamination control.

In cleaning validation, the Maximum Allowable Carryover (MACO) value is a critical parameter used to determine the acceptable level of residue from a previous product that can remain on equipment without posing a risk to patient safety. Here's how MACO is typically selected.

Steps to Select MACO Value

1. Determine the Health-Based Limit: Use toxicological data to calculate the Permitted Daily Exposure (PDE) or Acceptable Daily Exposure (ADE) of the previous product.
2. Calculate MACO Using the Following Formula.

MACO =	PDE X Minimum batch size of next product
	Maximum daily dose of next product

Where

- PDE = Permitted Daily Exposure of the previous product
- Minimum Batch Size = Smallest batch size of the next product manufactured in the same equipment
- Maximum Daily Dose = Highest daily dose of the next product

Alternative Approaches (if toxicological data is unavailable)

- 10 ppm Criterion: No more than 10 parts per million of the previous products in the next product.
- 1/1000th Dose Criterion: No more than 1/1000th of the therapeutic dose of the previous product in the maximum daily dose of the next product.

These are more conservative and less scientifically justified than PDE-based methods, but still used in some cases.

Additional Considerations

- Analytical Method Sensitivity: Ensure the method can detect residues below the MACO limit.
- Surface Area of Equipment: MACO is often converted to a concentration per surface area (e.g., $\mu\text{g}/\text{cm}^2$).
- Worst-Case Product Selection: Choose the most toxic or least soluble product for validation.

Analytical sampling techniques on cleaning validation

Swab and rinse sampling techniques, especially relevant in residue analysis for pharmaceutical cleaning validation, surface contamination studies.

1. Swab sampling

Advantages of swab sampling:

Swab sampling is good for hard to reach any areas (e.g., corners, crevices) and allows localized sampling and used on dry or wet surfaces also Suitable for low-volume residue detection.

Limitations of swab sampling

It has several limitations can affect the quality and reliability of the results.

1. Low recovery efficiency- the recovery rates significantly depending on the swab material, technique, and surface type.
2. If contamination is unevenly distributed, it can lead to false negatives.
3. Variability of results – pressure applied, number of swipes and swab orientation can affect recovery.
4. It may not detect very low level of contamination.

2. Rinse Sampling

Advantages: Rinse sampling have several advantages of cleaning validation in pharmaceutical industries.

1. It allows for the sampling of larger surface area which can be particularly useful for equipment with multiple surfaces.
2. It dissolves and carry away residues more effectively, especially for hard reach areas (Inside narrow pipes, under gaskets or seals) and crevices (small gaps, cracks) where residue can accumulate.
3. It is suitable for both chemical and microbial testing can be analyzed for chemical residues and microbial contamination using appropriate methods.

Procedure: Pipette 1mL of recovery stock solution for LOQ level and drawn as a pattern on a Glass plate, with the help of dryer dried the solution, then rinsed the plate with 50mL of diluent in 100mL volumetric flask with the help of funnel then make up with diluent and mixed well and taken the solution into HPLC vial.

1. Rinse the equipment surface with a measured volume of solvent.
2. Collect the rinse solution in a clean container.

- 3. Analyze the solution for residue content.
 - 4. Using the supernatant solution analyze using techniques like HPLC, UV, TOC, etc.
- Limitations: May dilute residue below detection limits,
Not suitable for non-soluble or sticky residues.
Less effective for specific location analysis.

When to use for swab and rinse sampling.

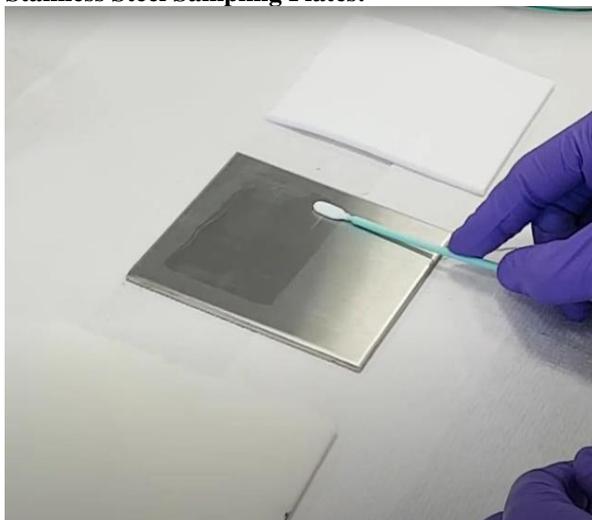
Criteria	Swab Sampling	Rinse Sampling
Small, defined area	√	X
Large surface area	X	√
Hard-to-reach locations	√	X
Soluble residue	√	√
Non-soluble residue	√	X
Quantitative analysis	√ (With validation)	√

The sequence for swab sampling shall be as follows.

Order	Sequence for swab sampling	Residue soluble in water	Residue Insoluble in water
1	Sample for Microbiological evaluation	Rinse for Chemical	Rinse for Microbial
2	Sample for Active ingredient evaluation	Rinse for Microbial	Rinse for Detergent
3	Sample for Detergent evaluation, if any,	Rinse for Detergent	Rinse for Chemical

Types of plates used in swab & Rinse techniques

1. Stainless Steel Sampling Plates:



- Material: Durable, reusable, and easy to clean.
- Use: Often used in pharmaceutical environments.
- Size: Typically defines a fixed area (e.g., 25 cm² or 100 cm²).

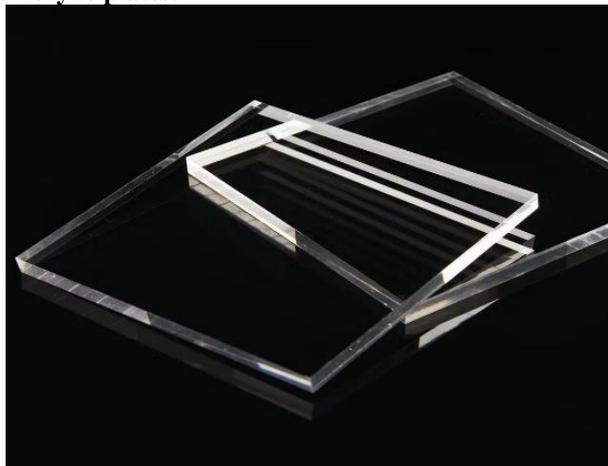
Advantages:

- Chemically Inert: Resistant to most solvents and reagents used in cleaning validation.
- Durable and Reusable: Long lifespan with proper cleaning and maintenance.
- Industry Standard: Most equipment in regulated industries is made of stainless steel, making it highly relevant.
- Smooth Surface: Promotes consistent swab recovery and reproducibility.
- Non-reactive: Minimal risk of interference with analytical methods.

Limitations:

- Cost: More expensive than disposable materials like acrylic or plastic.
- Weight: Heavier than alternatives, which may affect portability.
- Surface Uniformity: May not represent textured or irregular surfaces found in some equipment.
- Cleaning Requirement: Must be thoroughly cleaned and validated between uses to avoid cross-contamination.
- Not Suitable for All Surface Types: Cannot simulate rubber, glass, or other non-metallic surfaces.

2. Acrylic plates:



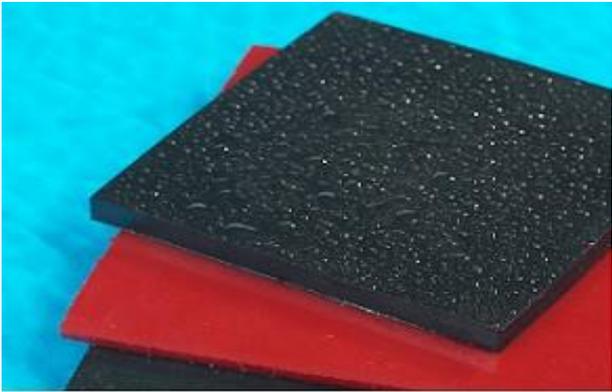
- Material: Lightweight and transparent.

Advantages

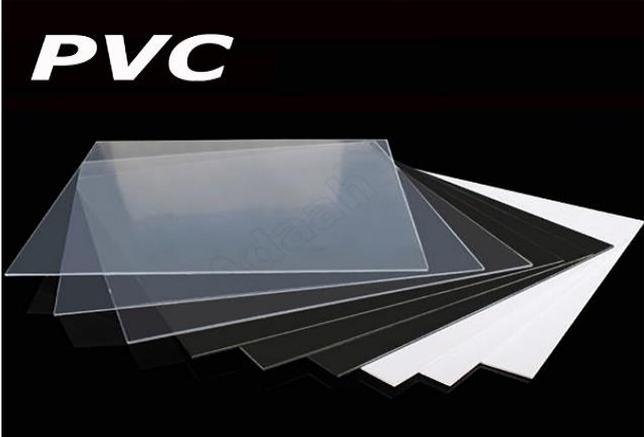
- Lightweight and transparent: Easy to align and handle.
- Non-reactive: Generally inert with most solvents.
- Cost-effective: Can be disposable or reusable.
- Customizable: Can be laser-cut to specific dimensions.

Considerations

- Ensure the acrylic does not interact with solvents or analytes.
- Validate recovery efficiency using acrylic plates.
- Avoid scratches or damage that may affect sampling accuracy.

<ul style="list-style-type: none"> • Use: Used for visual alignment and ease of handling. • Advantage: Disposable or reusable depending on the protocol. • Place the acrylic plate on the surface to define the sampling area. • Ensure it sits flat and stable without gaps or movement. 	
<p>3. Glass plates</p>  <p>Glass plates are less commonly used than stainless steel or acrylic plates in swab sampling, but they can serve specific purposes in residue analysis, particularly in controlled environments like laboratories or cleanrooms.</p>	<p>Advantages</p> <ul style="list-style-type: none"> • Chemically inert: Does not react with most solvents or analytes. • Smooth surface: Ideal for reproducible recovery studies. • Transparent: Allows visual inspection of residue or swabbing pattern. <p>Limitations:</p> <ul style="list-style-type: none"> • Fragile: Can break easily, not suitable for industrial environments. • Not suitable for equipment surfaces: Typically used in lab simulations, not in actual manufacturing areas. • Requires careful handling: Risk of contamination or injury if broken.
<p>4. Rubber Plates:</p>  <p>Rubber plates may be used to:</p> <ul style="list-style-type: none"> • Simulate elastomeric surfaces found in pharmaceutical equipment (e.g., gaskets, seals). • Evaluate swab recovery efficiency from soft or textured surfaces. • Conduct method validation for cleaning procedures involving rubber components. 	<p>Applications</p> <ul style="list-style-type: none"> • Recovery studies: Assess how well residues (e.g., APIs, detergents) can be recovered from rubber surfaces. • Training: Teach operators how to swab non-metallic, flexible surfaces. • Surface compatibility testing: Ensure solvents and swabs do not degrade rubber materials. <p>Advantages</p> <ul style="list-style-type: none"> • Mimics real-world rubber surfaces used in manufacturing. • Useful for non-metallic equipment parts. • Can be customized in shape and texture. <p>Limitations</p> <ul style="list-style-type: none"> • Porosity and texture may affect recovery rates. • May interact with solvents or analytes (e.g., leaching, adsorption). • Requires validation to ensure accurate and reproducible results. <p>Validation consideration</p> <ul style="list-style-type: none"> • Perform recovery studies specific to rubber material. • Use controls to check for interference or contamination. • Ensure solvent compatibility with rubber surface
<p>5. Aluminium plates</p>  <p>Aluminium plates in residue sampling are used similarly to stainless steel, acrylic, or glass plates, but they have specific characteristics that make them suitable applications in analytical cleaning validation and surface recovery</p>	<p>Applications</p> <ul style="list-style-type: none"> • Cleaning validation on Aluminium equipment surfaces. • Recovery studies to assess swab efficiency on metallic surfaces. • Method development for residue detection on aluminium. <p>Advantages</p> <ul style="list-style-type: none"> • Lightweight and durable: Easier to handle than stainless steel. • Chemically stable: Resistant to many solvents and reagents. • Realistic simulation: Mimics actual equipment surfaces made of aluminium. <p>Limitations</p> <ul style="list-style-type: none"> • May be reactive with strong acids or alkalis. • Surface may be more porous or textured than stainless steel, affecting recovery.

<p>studies. To define a fixed sampling area for swab collection, especially when simulating or validating cleaning procedures on aluminum surfaces commonly found in pharmaceutical or food processing equipment.</p>	<ul style="list-style-type: none"> Requires validation to ensure no interference with analyte detection. <p>Validation Considerations</p> <ul style="list-style-type: none"> Conduct recovery studies using known analyte concentrations. Ensure no leaching or adsorption from the aluminium surface. Use blank controls to check for background contamination.
<p>6. Bronze plates</p>  <p>Bronze plates are quite rare in routine residue sampling or cleaning validation procedures, but they may be used in specialized applications where bronze is part of the equipment surface such as in older machinery, decorative components, or specific industrial setups. To simulate or directly sample from bronze surfaces for:</p> <ul style="list-style-type: none"> Cleaning validation Surface recovery studies Compatibility testing with cleaning agents or solvents 	<p>Applications</p> <ul style="list-style-type: none"> Pharmaceutical or food equipment with bronze components (e.g., valves, fittings) Recovery efficiency studies for swab sampling on bronze Residue detection of active ingredients, detergents, or microbial contaminants <p>Advantages</p> <ul style="list-style-type: none"> Realistic simulation of bronze equipment surfaces Durable and reusable Can be custom machined to specific dimensions <p>Limitations</p> <ul style="list-style-type: none"> Reactive surface: Bronze may oxidize or interact with certain solvents or analytes Surface texture: May affect swab recovery efficiency Requires validation to ensure accurate and reproducible results
<p>7. Ceramic Plates</p>  <p>Best Practices</p> <ul style="list-style-type: none"> Use glazed ceramic plates for smoother, non-porous surfaces. Validate recovery efficiency with known analyte concentrations. Handle with care to avoid breakage and contamination. Ensure no leaching or adsorption from the ceramic material. 	<p>Applications</p> <ul style="list-style-type: none"> Surface Recovery Studies: Used to simulate ceramic surfaces found in certain manufacturing environments (e.g., reactors, insulators, or specialty equipment). Cleaning Validation: Evaluate cleaning effectiveness on ceramic components. Method Development: Assess swab recovery efficiency from non-metallic, hard surfaces. Compatibility Testing: Determine how cleaning agents interact with ceramic materials. <p>Advantages</p> <ul style="list-style-type: none"> Chemically Inert: Resistant to most acids, bases, and solvents. Non-porous (if glazed): Offers a smooth surface for consistent swabbing. Thermally Stable: Can withstand high temperatures without degradation. Non-reactive: Minimal risk of interfering with analytical methods. <p>Limitations</p> <ul style="list-style-type: none"> Brittle: Prone to cracking or breaking under mechanical stress. Surface Variability: Unglazed ceramics may be porous, affecting residue recovery. Limited Use in Industry: Not commonly found in pharmaceutical equipment, so less relevant for routine validation. Weight and Handling: Heavier and more fragile than acrylic or stainless steel alternatives.
<p>8. Teflon Plates</p>	<p>Applications</p> <ul style="list-style-type: none"> Surface Recovery Studies: Used to simulate Teflon-coated equipment surfaces (e.g., non-stick reactors, tubing, gaskets). Cleaning Validation: Evaluate cleaning effectiveness on non-reactive, hydrophobic surfaces. Method Development: Assess swab recovery efficiency from

 <p>Best Practices</p> <ul style="list-style-type: none"> • Use validated swabbing techniques with appropriate solvents. • Perform recovery studies to quantify efficiency on Teflon surfaces. • Avoid abrasive swabbing to prevent surface damage. • Ensure no leaching or contamination from the Teflon material. 	<p>low-adhesion surfaces.</p> <ul style="list-style-type: none"> • Compatibility Testing: Determine how cleaning agents and solvents interact with Teflon. <p>Advantages</p> <ul style="list-style-type: none"> • Chemically Inert: Highly resistant to acids, bases, and organic solvents. • Non-Stick Surface: Minimizes residue adhesion, often easier to clean. • Thermally Stable: Can withstand high temperatures without degradation. • Non-reactive: Ideal for sensitive analytical methods (e.g., LC-MS/MS, TOC). <p>Limitations</p> <ul style="list-style-type: none"> • Low Surface Energy: May result in poor swab recovery due to minimal residue retention. • Soft Material: Can be scratched or damaged during aggressive swabbing. • Not Common in All Equipment: Mostly used in specialized or coated components. • Requires Specific Validation: Recovery studies must account for low residue retention.
<p>9. PVC Plates ((Polyvinyl Chloride))</p>  <ul style="list-style-type: none"> • Chemical Resistance: PVC resists many cleaning agents (e.g., dilute acids, alkalis, alcohols), making it suitable for repeated cleaning cycles. • Non-porous Surface: Smooth and impermeable, reducing the risk of residue retention and aiding in effective swab recovery. • Cost-effective: Economical for use in mock-up studies or non-product-contact surfaces. • Ease of Fabrication: Can be cut, shaped, or drilled to simulate equipment surfaces or create custom validation setups. • Lightweight and Portable: Useful for mobile setups or temporary validation environments 	<p>Applications</p> <ul style="list-style-type: none"> • Surface Recovery Studies: PVC plates are often used as surrogate surfaces to validate swabbing techniques and recovery efficiency. • Mock Equipment Surfaces: Simulate contact surfaces for evaluating cleaning procedures without using actual equipment. • Training and Demonstration: Used in training personnel on swabbing techniques or cleaning procedures. • Barrier or Partitioning: Temporary separation of clean and dirty zones during validation sampling. • Residue Sampling Studies: Evaluate worst-case scenarios for residue retention and recovery. <p>Limitations</p> <ul style="list-style-type: none"> • Temperature Sensitivity: PVC softens above ~60°C and is unsuitable for high-temperature cleaning methods like steam-in-place (SIP). • Limited Solvent Compatibility: Not resistant to strong oxidizers, ketones, or chlorinated solvents, which may be used in cleaning. • Surface Wear: Scratches or abrasions can harbor residues and affect recovery results over time. • Regulatory Acceptance: May not be accepted as representative of actual product-contact surfaces unless justified with scientific rationale. • Static Charge: Can attract particulate matter, potentially interfering with residue analysis.
<p>10. Polypropylene (PP) plates</p>	<p>Advantages</p> <ul style="list-style-type: none"> • Excellent Chemical Resistance: Resistant to a wide range of acids, bases, and solvents commonly used in cleaning procedures. • Non-porous Surface: Smooth and hydrophobic, which helps minimize residue retention and supports effective swab recovery. • Autoclavable: Can withstand steam sterilization and high-temperature cleaning cycles (up to ~120°C). • Low Cost: Economical for use in mock studies or disposable setups. • Lightweight and Durable: Easy to handle and resistant to



impact and wear.

- **Low Moisture Absorption:** Maintains integrity in humid or wet environments.

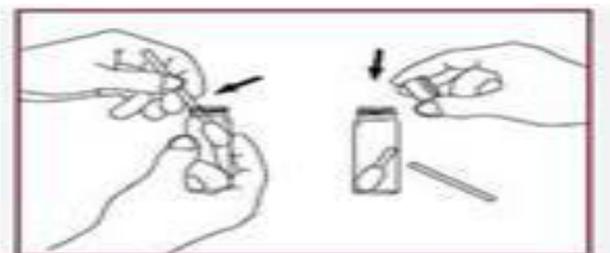
Applications

- **Surface Recovery Studies:** Used as surrogate surfaces to validate swabbing techniques and recovery efficiency.
- **Mock Equipment Surfaces:** Simulate product-contact surfaces for evaluating cleaning procedures.
- **Residue Sampling:** Useful in worst-case scenario testing for residue retention and removal.
- **Training and Demonstration:** For teaching cleaning and sampling techniques.
- **Barrier or Partitioning:** Temporary separation of clean and dirty zones during validation sampling.

Limitations

- **Limited Compatibility with Strong Oxidizers:** May degrade when exposed to agents like nitric acid or strong peroxides.
- **Surface Scratching:** Can develop micro-abrasions over time, which may trap residues and affect recovery.
- **Regulatory Acceptance:** May require justification if used as a surrogate for stainless steel or other product-contact surfaces.
- **Thermal Limits:** Though autoclavable, it cannot withstand extreme heat like metals (e.g., >130°C).
- **Electrostatic Properties:** Can attract dust or particulates, potentially interfering with residue analysis.

Swab sampling technique



Ensure the immersion of 100% swab heads into the diluent (illustrated as above image for reference purpose). In case of light sensitive molecule, ensure usage of amber colour test tubes for swab collection.

Squeeze the swab stick to the inner side of test tube/bottle in such way that the excess solvent shall be removed from swab bud. Swab pattern shall be

overlapping to the previous swab stroke and do not left any space between the strokes. Collect the swabs into the labelled test tubes/bottles corresponding to the location. Using the above pre-treated swabs, swab the surface area of 4" x 4" (using a frame/ template) in four steps as per the pattern shown below in specific locations as indicated in sampling.

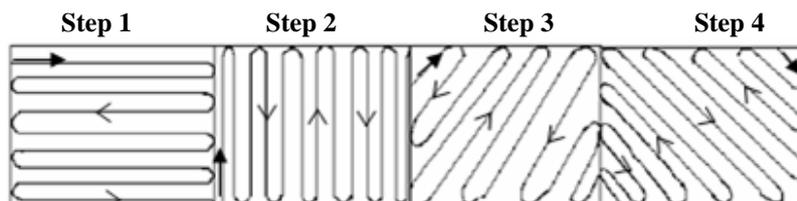


Figure 1.

Horizontal swabbing (Step 1): Swab a portion of the sampling area horizontally with one side of the swab starting from left to right and right to left from upwards to downwards covering the whole area without lifting the

swab stick from the surface as indicated in the above figure 1.

Dip the swab stick in the prescribed diluent and squeeze out the swab stick by pressing the swab stick inside the

surface of the sampling test tube / bottle. Flip the swab stick to the opposite direction prior to proceeding for the Step 2.

Repeat the above procedure for each of the patterns indicated in Steps 2, 3 and 4 in figure 1.

Analytical Methods for determination of Residue content

Analytical methods used in residue sampling, especially in the context of cleaning validation, surface contamination, and trace analysis.

1. High-Performance Liquid Chromatography (HPLC)	<ul style="list-style-type: none"> • Most widely used method for detecting active pharmaceutical ingredients (APIs), detergents, and excipients. • Offers high sensitivity and specificity. • Can be coupled with UV, PDA, or MS detectors.
2. Ultra-Performance Liquid Chromatography (UPLC)	<ul style="list-style-type: none"> • Faster and more efficient than HPLC. • Ideal for low-level residue detection with better resolution.
3. Total Organic Carbon (TOC) Analysis	<ul style="list-style-type: none"> • Useful for non-specific residue detection (e.g., cleaning agents, excipients). • Fast and cost-effective, but not compound-specific.
4. UV-Visible Spectroscopy	<ul style="list-style-type: none"> • Used for compounds with chromophores. • Simple and quick, but less sensitive than chromatographic methods. • Often used for detergent or dye residues.
5. Liquid Chromatography– Mass Spectrometry (LC-MS/MS)	<ul style="list-style-type: none"> • Highly sensitive and specific. • Ideal for trace-level detection and complex matrices. • Used in method validation and regulatory submissions.
6. Gas Chromatography (GC)	<ul style="list-style-type: none"> • Suitable for volatile residues (e.g., solvents). • Often coupled with FID or MS detectors. • Requires derivatization for non-volatile compounds.
7. Ion Chromatography	<ul style="list-style-type: none"> • Used for ionic residues like cleaning agents (e.g., phosphates, sulfates). • High sensitivity for inorganic contaminants.
8. Conductivity Measurement	<ul style="list-style-type: none"> • Simple method for detecting ionic cleaning agents. • Used in rinse sampling. • Not compound-specific.
9. Titration Methods	<ul style="list-style-type: none"> • Used for acid/base residues or oxidizing agents. • Less common but still applicable in manual cleaning validation.
10. Surface Enhanced Raman Spectroscopy (SERS)	<ul style="list-style-type: none"> • Emerging technique for non-destructive surface analysis. • Useful for real-time monitoring and low-level detection.

CONCLUSION

Cleaning validation remains a cornerstone of contamination control in regulated industries. As equipment, surfaces vary in composition and texture, understanding the influence of surface type on residue recovery is essential for accurate validation. The integration of appropriate sampling techniques and sensitive analytical methods ensures compliance with regulatory standards and product safety. This review highlights the need for surface-specific validation strategies, emphasizing the importance of recovery studies and method robustness. Future advancements may include real-time monitoring technologies and enhanced material compatibility assessments, further strengthening the reliability of cleaning validation programs.

ACKNOWLEDGEMENT

The authors would like to thank the management of Aurigene Pharmaceutical Services Limited, Hyderabad for providing the necessary facilities to carry out this review work and for their encouragement toward its publication. Dr. Rajesh vooturi extends his sincere gratitude to all co-authors for their valuable

contributions, which were instrumental in successfully completing this publication. APSL Clearance No: APSL_P95_18/12/2025.

REFERENCES

1. D. Narayana Murthy and k. Chitra A review article on cleaning validation, International journal of pharmaceutical Sciences and research (IJPSR), 2013; 4(9): 3317-3327.
2. B. Sahare, A review on cleaning validation: Cleaning method development, EPRA International journal of Multidisciplinary Research (IJMR), 2024; 10(11): Journal of DOI: 10.36713/epra2013, Impact factor 2024: 8402.
3. Saurabh Dahiya, Cleaning validation: A crucial step in Assuring quality during pharmaceutical manufacturing, IJPQA, 2022; 13(4).
4. Saurabh Dahiya, Diwan Chand, Yachika Goyal, Chanchal Sharma; Cleaning Validation: A Crucial Step in Assuring Quality During Pharmaceutical Manufacturing IJPQA, October - December 2022; 13(4).
5. Yukti Narendra Patel, Khushi Chauhan, Shuchi Desai, Review article on cleaning validation-An

- important concept for quality management in pharmaceutical industry, IJSDR, May- 2023; 8(5).
6. <https://www.bing.com/search?q=rinse+sample+advantages&form=ANNH01&refid=693656e40a524b048b9b65814e05cdfc&pc=U531>
 7. Patel Payal K, Patel NM and Patel PM. An Overview on Cleaning Validation. *Int J Pharm Biol Arch*, 2011; 2(5): 1332-36.
 8. Gawai A, Lokhande S, Magar S, Biyani K. A Review On Cleaning Validation In Pharmaceutical Industry. *International Journal of Pharmacy and Engineering*, 2013; 1(2): 133144.
 9. http://apic.cefic.org/pub/4cleaning_val9909.pdf. URL
 10. Active pharmaceutical ingredient committee. Guidelines to Cleaning validation in active pharmaceutical ingredient manufacturing plan. 1999. Available from:
 11. Puchakayala Purnachandra Rao et, al. Stability indicating HPLC method for simultaneous estimation of emtricitabine, tenofovir disoproxil fumarate, cobicistat and elvitegravir in pharmaceutical dosage form, *WJPS*; Print ISSN: 2321-3310; Online ISSN: 2321-3086.
 12. FDA, Guide to inspections of validation of cleaning process division of investigations, Office of regional operations & Office regulatory affairs, July 1993.
 13. Health product and food branch inspectorate: Cleaning validation guidelines, 2008; 1-16.
 14. Lakshmana P: Cleaning validation and its importance in Pharmaceutical Industry. *Pharma Times*, 2010; 42(07): 21-25.