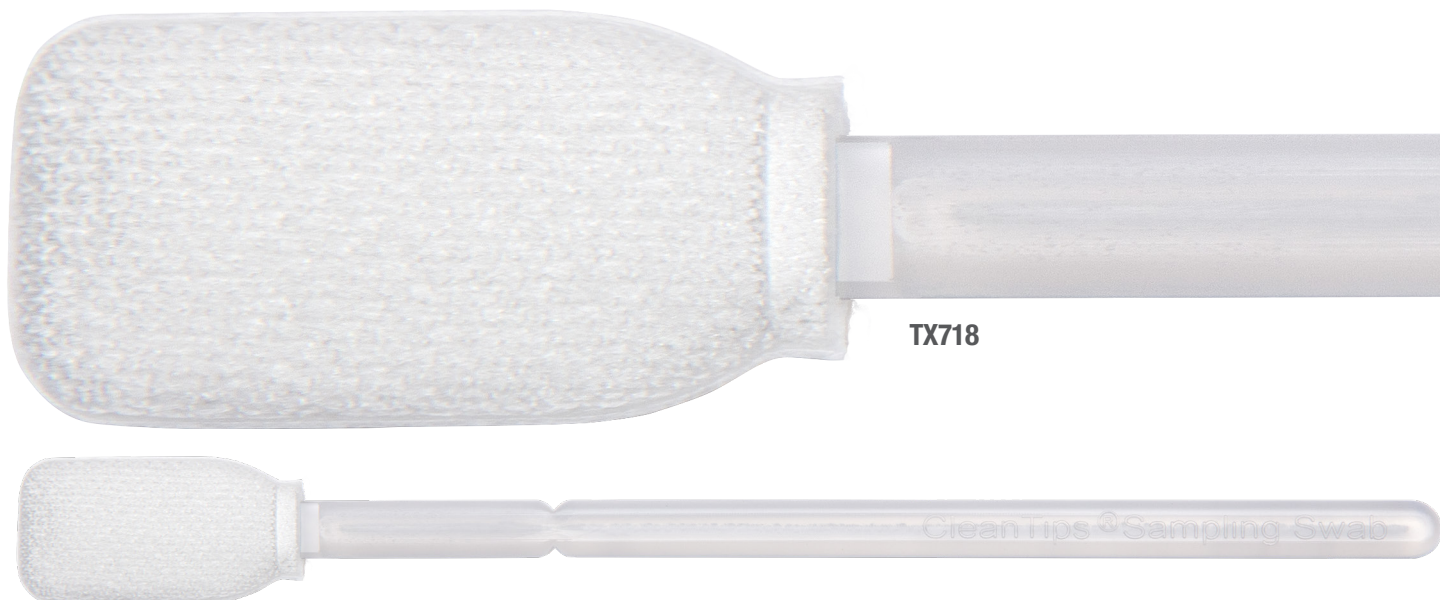


TECHNOTES

NO. 06 | July 2026

Texwipe's New
**Cleaning and Cleaning
Validation Swab**
for Solvent-Based
Analytical
Systems

TX718



Cleaning and Cleaning Validation are an important part of critical manufacturing. Before the next product or production batch starts, the equipment must be clean and validated so that the equipment is known and proven to be clean.

What if something that is undiscovered is wrong with the previous product. This unwanted material could be considered a cross-contamination in the next batch. For the pharmaceutical markets, the FDA Code of Federal Regulations (CFR) directs cleaning validation as part of its many prescriptions for current manufacturing practice (cGMP) for finished pharmaceuticals (Refs. 1, 2). An example that applies directly to cleaning validation is found in 21 CFR 211.67(a), which states, "Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements" (Ref. 3) to prevent adulteration of the final drug product. That prescription is serious.

The FDA's original concern was penicillin products cross-contaminating other products. Later, a batch of the finished drug product, Cholestyramine Resin USP, required a recall because of its contamination with agricultural pesticide residues. Drums that had been used to store recovered solvents from a pesticide production process were later used to store recovered solvents used for the resin manufacturing process. The drums were not cleaned sufficiently and validated to be clean to prevent contamination transfer. Because this product was also used as part of other drug formulations, this contaminated material had a large impact in the pharmaceutical industry. (Ref. 4)

Cleaning Validation

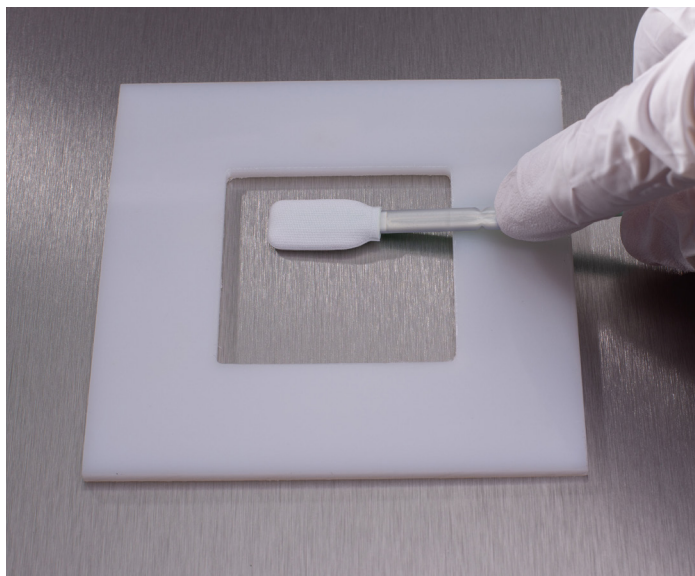
21 CFR 67(a) indicates that the equipment must be clean. How do you prove that it is clean? Through cleaning validation. In 1993, the FDA issued a guideline, Validation of Cleaning Processes (7/93), Guide to Inspections Validation of Cleaning Processes. (Ref 4.) While the document is only a Reference guideline, good practices are described and are a feature and a benefit in this document. Other regulatory agencies have similar requirements for cleaning validation.

These guidance as well as informative documents are found in

- FDA 21 CFR Parts 210/211 (Ref. 1, 2)
- EU GMP Annex 15 (Ref. 5)
- ICH Q7 (Ref. 6)
- USP <1072> Disinfectants and Antiseptics (Ref. 7)
- PDA Technical Reports 29 and 49 (Refs. 8, 9)

Proving that the equipment is clean requires an extensive process. A documented cleaning procedure that considers the formulation being made, e.g., paste versus non-viscous solution, soluble versus insoluble ingredients, toxic versus non-toxic, equipment configurations, and any other feature that may hinder the process of cleaning the equipment to the acceptable limit must be developed, documented, verified and validated. The cleaning process must be successful three sequential times before it can be implemented into manufacturing.

The acceptable limit, the level of contamination that can transfer to the next batch of products without the potential to cause patient harm, is determined though the formulation ingredient toxicities, vessel contact area, and other suitable methods. This value requires complicated calculations that must be defensible, achievable, and measurable. (Refs. 10, 11)



Sampling

The FDA in this Validation of Cleaning Processes (Ref. 4) and EU GMP Annex 15 (Ref. 5) define two types of sampling, rinse and direct surface samples. Both methods have advantages and disadvantages.

- **Rinse sample** – The advantages of a rinse sampling are that larger surfaces can be sampled and inaccessible areas, ones that cannot be accessed through disassembling, can be sampled and evaluated. The disadvantages are for insoluble ingredients and inaccessible areas, e.g., a pit in the vessel wall.
- **Direct surface sampling (swabbing)** – The advantage of direct surface sampling is that the dirtiest spots can be sampled without dilution and insoluble residues can be sampled and removed. The locations for direct sampling are determined by understanding where the risk of cleaning failure is the highest, e.g., pits and holes, heating surfaces for baked on residues, etc.

A disadvantage of earlier swabs was that they might have been manufactured with an adhesive that could interfere with the analytical swab results. Texwipe cleaning validation swabs and swabs made with polypropylene handles are never made with any adhesives. The swab head material is thermally bonded directly to the polypropylene handle. In contrast, cotton and spun polyester swabs do have an adhesive and are not typically used in cleaning validation.

Analytical Method

No matter how the equipment is sampled, an analytical method, which quantifies the amount of the active pharmaceutical ingredient (API) and other contaminants of concern, must be developed. Typically, the ingredients used in cleaning are not included in this requirement because these ingredients are free rinsing.

In 1995, the FDA published in the Federal Register a guideline on the validation of analytical procedures. (Ref. 12) Part of this guideline are definitions of common terms used related to analytical procedures. The guideline lists four

common types of analytical procedures: identification tests, quantitative tests for impurities' content, limit tests for the control of impurities, and quantitative tests of the active moiety in samples of drug substance or drug product or other selected component(s) in the drug product. This TechNote limits the analytical procedure to a method using a separation technique, namely High Pressure Liquid Chromatography (HPLC), and uses a surface sampling swab as the sample collection device. The guideline listed common validation characteristics: Accuracy, Precision: Repeatability and Intermediate precision, Specificity, Detection limit, Quantitation limit, and Linearity. Out of these characteristics, a swab can interfere with the Detection limit, Quantitation limit, and Linearity. Other characteristics can also be affected but are not addressed in this document.

Note: Developing a new HPLC swab does not remove the fact that Texwipe's swabs for TOC, namely TX714K, are still available and are useful for water-based TOC analyses.

The effect to linearity is easiest to understand. Let's set up a thought experiment regarding an interference and two calibration samples. Also, to keep it simple, the height of the peak represents the amount of material. If the interference has a height of two units and the first calibration sample should have a height of four units, the total height is six units. If the next calibration sample should have a height of eight units (double the concentration of the first), the total height is now 10 units, not double the first sample. If the calibration is to be extended to lower values, the impact of the interference increases.

Other guidelines for analytical method development and validation are an FDA Guidance document, Analytical Procedures and Methods Validation for Drugs and Biologics (Ref. 13), ICH Q2 Analytical Validation (Ref. 14), which is supported by ICH Q14 Analytical Procedure Development (Ref. 15).

Lowering the interferences

Swab manufacturing process

The general manufacturing process for polyester-based knit fabrics follows the sequence of polyester beads that are dried, melted and extruded into polyester filaments that are lubricated and spun into a yarn. This yarn is heated (softened), stretched, and cooled to give the yarn a defined set of properties that are necessary for our knit fabrics. The yarn is lubricated again as it is brought into the knitting machine where the yarn is knitted according to a defined design. This design gives the fabric its properties like absorption capacity and abrasion resistance. The knit fabric is processed in what can be thought of as a huge washing machine dedicated to the scouring (a harsh washing process with a strong chemical washing formulation that contains surfactants and other treatment chemicals) of Texwipe's polyester fabric. In the cleaning process, the extrusion and knitting oils and other contaminants including ions, non-volatile residues, particles and fibers are removed. The fabric is framed, which is a drying process that gives the fabric different sets of properties useful for being used as the fabric for a knit polyester swab head.

The general swab forming process combines the swab handle with the swab fabric. The handle is injection-molded from polypropylene beads to which a color package is added, Texwipe's trademarked light green. The swab is made through affixing the swab fabric to the handle through a thermal bonding process (no adhesives are used or needed), joining the fabric to the handle and sealing around the edge to finish the swab head forming process. The swab is processed and packaged in an ISO Class 5 cleanroom, packed, and sent for distribution.

Formation of TX718

Texwipe's Alpha® Polyester Knit TX715 has been around for decades. It was developed for direct equipment surface sampling for cleaning validation when organic solvents are used. This swab is specially processed for use with solvent systems. The handles are made from the trademarked colored polypropylene material. The TX715 swab handle has a notch that allows the handle to be snapped at a specific length such that it can fit into a vial. The fabric in the swab head consists of the same knit polyester material as the other Alpha® swabs like the TX714A swab. However, TX715 undergoes a proprietary cleaning process that TX714A and other Alpha® swabs do not, which differentiates it from the normal swab line into one suitable for cleaning validation. However, the process for manufacturing the TX715 swab is not the same as the TX718 swab. The TX718 swab is different, starting at the beginning.



The rationale for the creation of the Alpha® Polyester Knit TX718 begins with a customer that was able to support the development of a new swab designed for low interference when used for a solvent-based swab sampling for cleaning validation. Working with this customer, Texwipe was able to have all components of the swab, including the fabric, the handle, and all manufacturing inputs analyzed with respect to their interferences. Texwipe appreciates the support of this customer in performing these analyses.

The fabric characterization started with the analysis of the polyester polymer pellets before being extruded into yarn. The next set of ingredients analyzed were extruded yarn and the lubricating oils used in extruding and knitting. Finally, the ingredients in the scour, where the knitting oils and other contaminants are removed, were analyzed. Some of these components showed interferences when analyzed in concentrated form.

The handle components were analyzed similarly. The polypropylene beads before extrusion were analyzed. The colorant package, which gives the handles the trademarked hue, was analyzed by component. Unfortunately, some of the colorant components exhibited interferences.

Putting the Pieces Together

From this data, Texwipe used a minimalist view to create the TX718 swab. For the fabric, the knit pattern was changed to one that is better rinsing. The yarn for the fabric was changed to a low titanium dioxide version, making it suitable for customers that want to analyze for titanium dioxide. We were able to optimize the scour ingredients for this specific application. The scour formula is complicated where each ingredient is used to accomplish certain properties of the final fabric or to remove specific contaminants from the final fabric. For the handle, the complete colorant package was removed, including the titanium dioxide. The handle has a more translucent appearance. The notch, used to break the handle, remains.

To summarize, the TX718 swab has a special, low titanium dioxide fabric head processed specifically for solvent interaction and a notched handle that is colorless and translucent.

Experimental Comparison

Another customer was able to further support the characterization of the TX718 swab. This customer was able to analyze the methanol extracts from the TX715 and TX718 swabs by acquiring the UV spectra for these extract solutions. Texwipe also thanks this customer for their time invested in performing these analyses.

The objective of this study was to evaluate extractables from the polyester swabs TX715 and TX718 with methanol as the solvent using UV spectral analysis.

Method

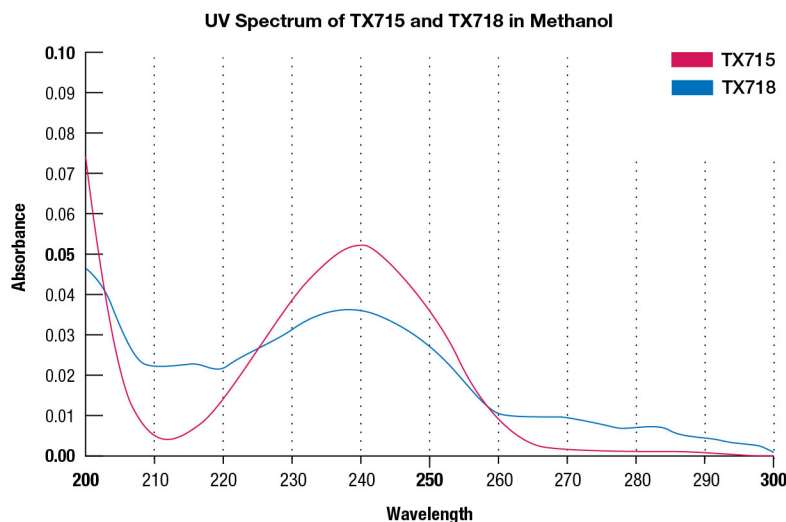
One TX715 swab and one TX718 swab were each placed in a clean 100-ml beaker. Methanol was added to the level of the handle notch and allowed to sit overnight. The methanol extract samples were analyzed by a UV spectrometer and recorded as a UV spectrum.

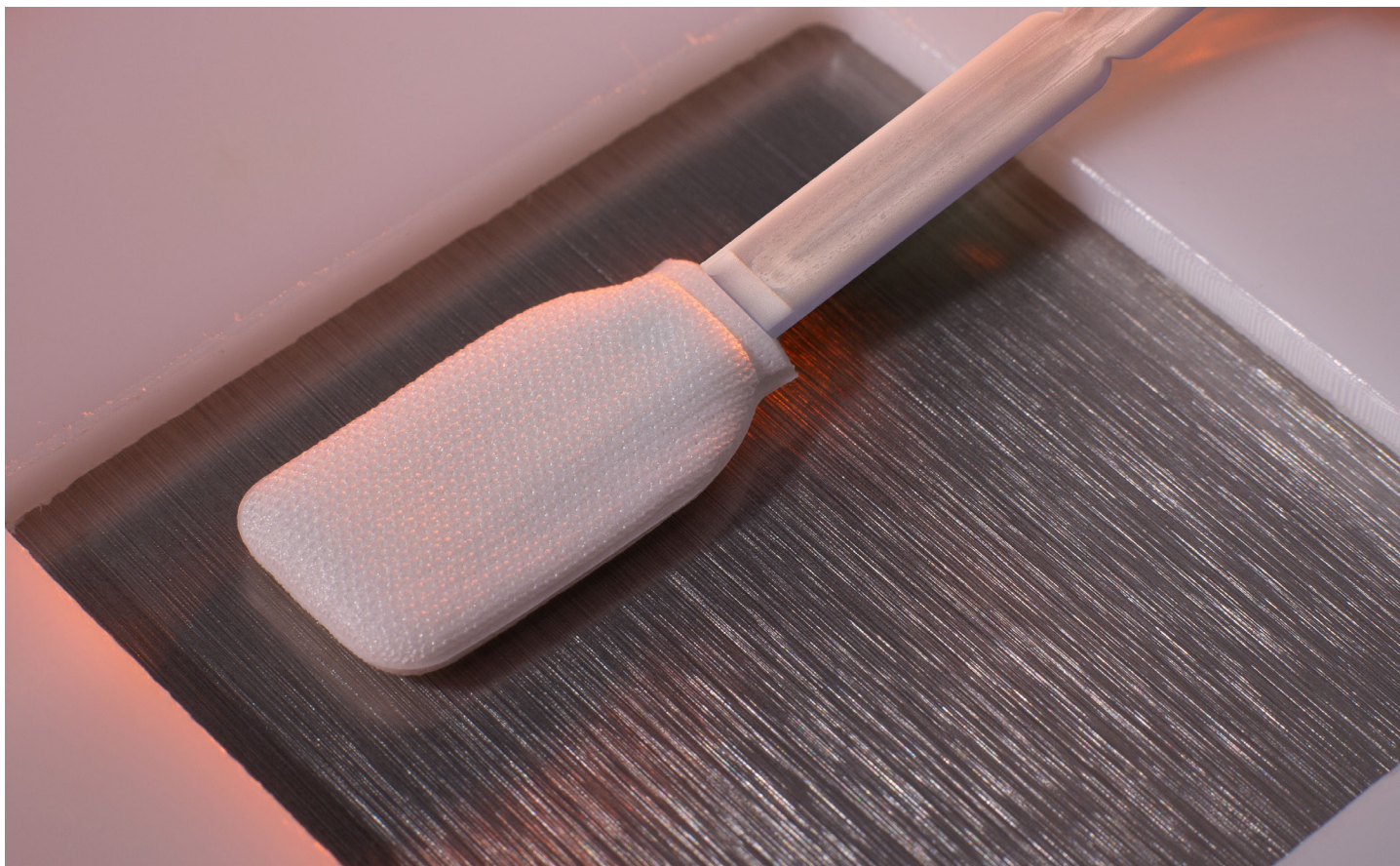
Results

The spectra for these swabs are shown in Figure 1. As can be observed in the absorption curves for TX715 and TX718, TX718 has a lower absorption level overall.

Figure 1

UV spectra of the methanol extracts of TX715 and TX718 swabs showing the lower absorption level for the TX718 swab.





Discussion and Conclusion

The unknown peaks are trace levels of various polymer molecules inherent to the polypropylene handle and polyester fabric head. The lower background shown for the TX718 swab makes it more suitable for applications that require higher analytical sensitivity, such as pharmaceutical quality control or solvent-containing liquid chromatography testing.

Texwipe has worked hard on reducing solvent extractable substances that can interfere with the cleaning validation process. Potential sources of interfering materials would include polypropylene oligomers, polyester oligomers (ethylene glycol, terephthalic acid copolymer units), and polyethylene glycol, which can be made during the polyester polymerization processes. Texwipe has no control over any of these polymerization processes. Our material control starts at the polypropylene beads and polyester yarn steps.

The amounts of contaminants can be improved and mitigated by pre-processing the swabs before use by a solvent wash. Typical pre-processing solvents are methanol and acetonitrile, among other solvents. The pre-processing process can look like this and include any solvents of choice:

1. Soak/swirl in methanol for 10 minutes
2. Soak/swirl in acetonitrile for 10 minutes
3. Soak/swirl in the method eluent or 10 minutes

Dry in a cool area and use as quickly as possible to reduce interference to any contaminants of concern.

During the soaking, the solvent should be agitated or swirled, not sonicated. The sonication can damage the swab materials with pinholes, increasing the area for interfering chemicals to diffuse out, or later, making elution of a chemical of interest difficult (because they are trapped in the pinholes) during the extraction phase of the test method.

Final Thoughts

The TX718 swab is not intended to be a replacement for the TX715 swab. If the TX715 swab is working, continue using the TX715 swab. The TX715 swab has been a work horse for many years in performing sampling for solvent-containing analyses.

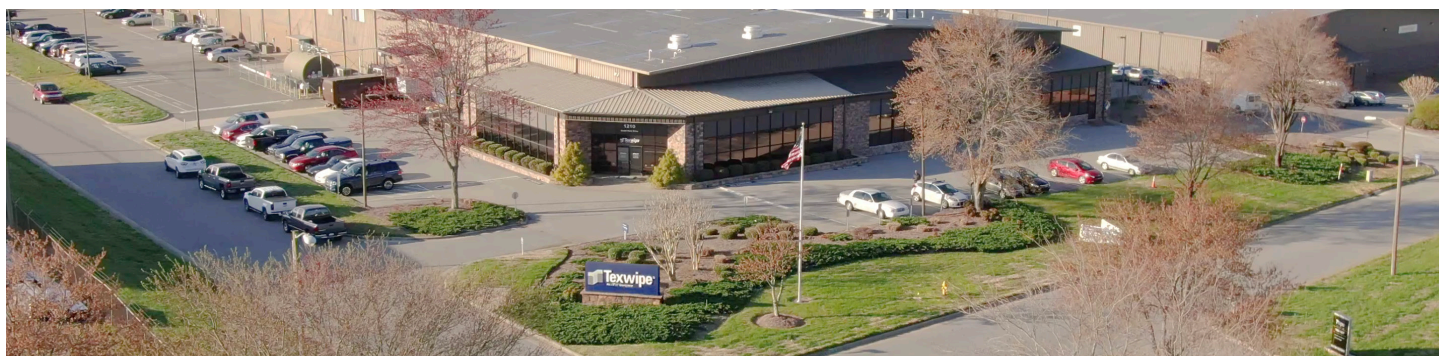
If a new method is being developed or if there is a struggle in using the TX715 swab due to interferences, try the new TX718 swab. There are some peaks that have disappeared due to removal of the colorant package and other processing modifications.

Other analyses where titanium dioxide may be an issue might benefit from a switch to the TX718 swab due to a lower titanium dioxide background. Two features of this swab are that the fabric swab head and the swab handle are made with no intentionally added titanium dioxide.

It is important to note that the TX718 swab continues to have some level of extractable contamination. We can modify the level of contaminants on the surfaces of the swab, but diffusion takes over, bringing contaminants back to the surface. Unfortunately, nothing is contamination free.

The TX718 swab should be considered where the application requires a sampling or cleaning procedure that may use solvents as the material is processed to create hydrophobic characteristics when used with water only.

TECHNOTES



Why Choose Texwipe

Texwipe's commitment and reputation for consistent quality and technology leadership in contamination control make us an ideal partner. Our website offers educational videos, safety and technical datasheets, technotes, published papers, test methods, and other helpful resources, such as our product section guide. You can also contact our sales team or customer service for support in selecting and developing products tailored to your critical environment applications.

Contact Information:

Website:

For the US, Texwipe.com.

For EMEA, Texwipe.eu.

For Asia/Pacific: Asia.Texwipe.com.

Customer Service:

North America: 1-800-TEXWIPE (1-800-839-9473)

Europe/Middle East/Africa: +31 88 1307 410

Asia/Pacific: +65 6468 9433

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