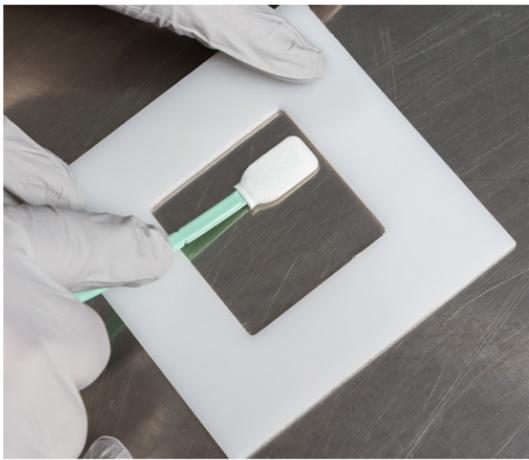


Cleaning Validation Swab Sampling Procedure

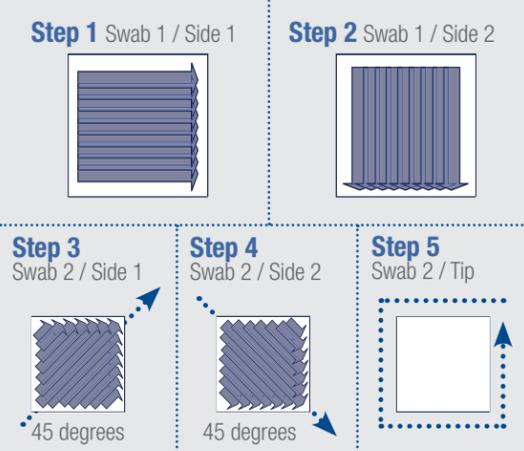


Preparation



1. Select appropriate swab (see below Swab Selection Guide)
2. Define area/region to be tested
3. Do not touch the swab handle below the notch line.
4. Dampen swab with diluent

Sampling



- STEP 1.** Begin sampling by swabbing the surface using horizontal, unidirectional, parallel strokes
- STEP 2.** Flip the swab over and swab in a perpendicular direction using the same technique
- STEPS 3 & 4.** Repeat procedure with second swab at 45° angles. Flip the swab over for Step 4
- STEP 5.** Swab the perimeter with the swab tip

NOTE: Swab using the entire head flat against testing surface.

Transfer



1. Snap swab head at the notch along edge of swab handle
2. Allow swab head to fall into vial
3. Replace the cap, label the sample and transfer for TOC or HPLC analysis

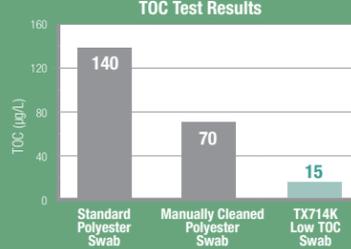
Swab Requirements

- Minimal background interference
- High recovery rate
- Low particle generation

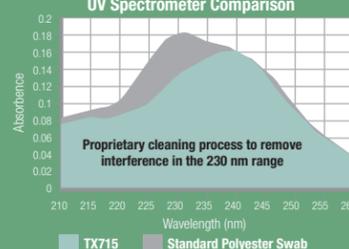
Typical Swab Sampling Locations

- Irregular Surfaces
- Hard-to-reach areas
- Presence of product/cleaning residue
- Heated surfaces
- Porous surfaces

Comparative TOC Analysis

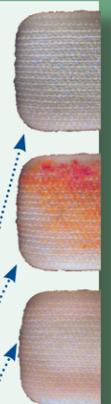


HPLC/UV-Vis Analysis



Example of Contaminant Release from TX714K

- Clean swab (5x magnification)
- Swab after use (5x magnification)
- Swab after contaminant release (5x magnification)



Swab Selection Guide

Cleaning Validation Series Swabs

TX714K
Low TOC Alpha® Swab – cleaned to a level of <50 µg/L TOC. This minute level makes this swab the ideal tool for use in Cleaning Validation of equipment used in the manufacture of APIs, excipients and drugs.

TX761K
Low TOC Alpha® Swab with long handle

TX715
Alpha® Sampling Swab – Polyester swab for HPLC sampling in cleaning validation

TX716
Large Absorbond® Sampling Swab – Ideal tool for use in Cleaning Validation of equipment used in the manufacture of APIs, excipients, drugs, and biotech products

TOC Cleaning Validation Kits



TX3340
12 vials + 24 TX714K swabs/kit for 12 sampling areas

TX3342
72 vials + 144 TX714K swabs/kit for 72 sampling areas

TX3343
12 vials + 24 TX761K swabs/kit for 12 sampling areas

- Packaged in cleanroom-compatible polypropylene boxes
- Contain all the components necessary to sample different areas
- Provide for efficient transport from production to laboratory with minimal chance of contamination.