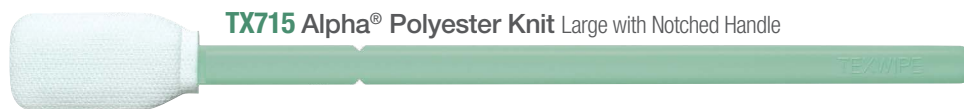


TECHNICAL DATA SHEET

CLEANING VALIDATION SWABS & TOC KITS

TECHNICAL DATA SHEET



Products

| Number | Description | Packaging | Case |
|---------------|--|---|---------|
| TX714K | Low TOC Alpha® Polyester Knit Large Swab | 20 swabs/bag | 50 bags |
| TX761K | Low TOC Alpha® Polyester Knit Swab with Long Handle | 20 swabs/bag | 50 bags |
| TX715 | Alpha® Polyester Knit Large with Notched Handle Swab | 100 swabs/bag; 2 inner bags of 50 swabs | 10 bags |
| TX716 | Absorbond® Polyester Non-Woven Large Swab with Notched Handle Swab | 20 swabs/bag | 50 bags |

TECHNICAL DATA SHEET

Description

Swabbing is a preferred method to determine the effectiveness of cleaning protocols as determined by the US FDA. HPLC/UV-Vis Total Organic Carbon (TOC) analysis are different methods used to validate these cleaning processes.

Texwipe's Alpha® Polyester Knit Series Swabs are made from the cleanest 100% polyester material. These swabs are further cleaned using a proprietary process to make the swab suitable for use in **TOC analysis**:

- TX714K
- TX761K

or in **HPLC analysis** using a UV detector analytical method as part of a cleaning validation protocol:

- TX715

The **Absorbond® Polyester Non-Woven Large Swab** (TX716) is manufactured with 100% polyester nonwoven fabric which contains no contaminating surfactants. Recommended for HPLC analysis.

These swabs are the ideal tools for use in Cleaning Validation of equipment used in the manufacture of APIs, excipients, drugs, and biotech products.

Applications

- Surface sampling for use as part of a cleaning validation protocol
- Pharmaceutical manufacturing cleaning validation with HPLC/UV-Vis or TOC protocol
- Appropriate for applications needing very low levels of contaminants

Industries

| | | |
|------------------------|------------------------|--------------------------|
| Aerospace | Animal Laboratory | Biologics |
| Cleanroom Design/Build | Compounding Pharmacies | Data Storage |
| Facilities Maintenance | Food Industry | Laboratory |
| Medical Device | Microelectronics | Pharmaceutical |
| Printing/Graphics | Semiconductor | USP <797> / USP <800> |

Features & Benefits

- All Cleaning Validation swabs are precision-manufactured and constructed to exacting and consistent tolerances without the use of adhesives for superior performance
- Notched, rigid 100% polypropylene, break-away handle allows the head to be placed into the vial with minimal handling and contamination and provides excellent chemical resistance
- Lot coded for traceability and quality control

Alpha® Polyester Knit Series Swabs

- TX714K, TX761K: Certified Low TOC level (<50 µg/L, <50 ppb) ensures consistency in swab background contribution
- Double layered, double knit polyester head entraps contaminants in the knit structure during sampling, allowing maximum contaminant collection and release into the diluent to provide for excellent recovery rates
- TX715: This swab is additionally processed to reduce the UV background. Proprietary cleaning process reduces interference in the 230 nm range, resulting in an improved limit of detection

Absorbond® Polyester Non-Woven Series Swabs

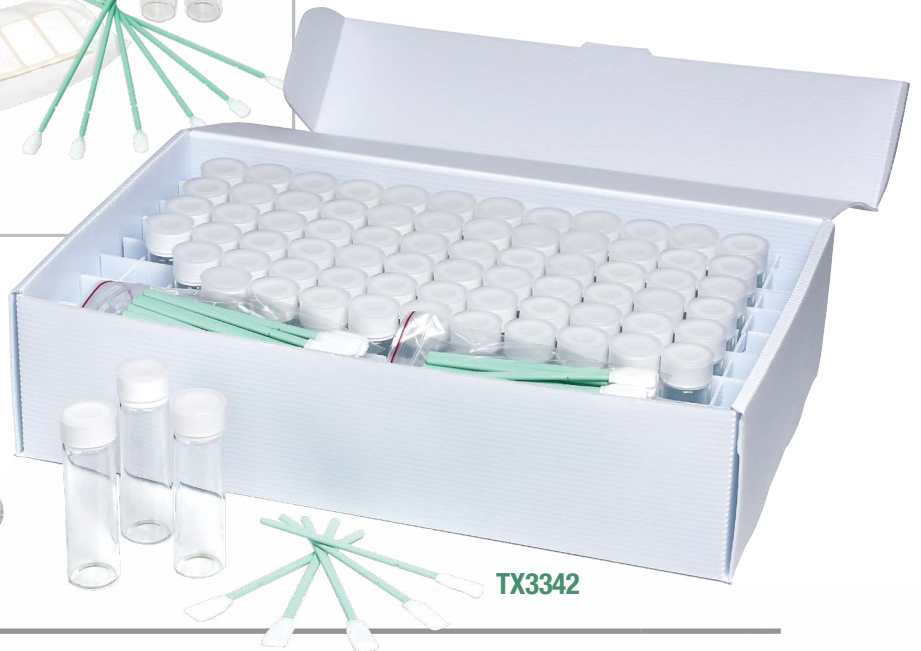
- The nonwoven polyester head provides excellent recovery rates by entrapping contaminants in the swab structure without adhering to the swab head, allowing complete release into the diluent

Shelf Life

- 5 years from date of manufacture

[Click here to find Cleaning Validation swabs on www.texwipe.com](http://www.texwipe.com)

TECHNICAL DATA SHEET



TX714K Swabs are included in **TX3340** & **TX3342** TOC Cleaning Validation Kits

TX761K Swabs are included in **TX3343** TOC Cleaning Validation Kit

Products

| Number | Description | Case |
|---------------|--|---------|
| TX3340 | Cleaning Validation Kit Components <ul style="list-style-type: none"> • 12 40 mL clear vials with bonded septa caps, certified <10 µg/L TOC • 24 TX714K Low TOC Alpha® Sampling Swabs, certified <50 µg/L TOC • 12 blank vial labels | 18 kits |
| TX3342 | Cleaning Validation Kit Components <ul style="list-style-type: none"> • 72 40 mL clear vials with bonded septa caps, certified <10 µg/L TOC • 144 TX714K Low TOC Alpha® Sampling Swabs, certified <50 µg/L TOC • 72 blank vial labels | 1 kit |
| TX3343 | Cleaning Validation Kit Components <ul style="list-style-type: none"> • 12 40 mL clear vials with bonded septa caps, certified <10 µg/L TOC • 24 TX761K Low TOC Alpha® Swab with Long Handle, certified <50 µg/L TOC • 12 blank vial labels | 18 kits |

TECHNICAL DATA SHEET

Description

Texwipe's TOC Cleaning Validation Kits were designed to simplify sampling as part of a cleaning validation protocol. The swabs and vials are further cleaned using a proprietary process to make these kits excellent for use in Total Organic Carbon (TOC) analysis.

Lot coded for traceability and quality control.

Applications

- Surface sampling for use in:
 - TOC analysis as part of a cleaning validation protocol
 - As part of other cleaning validation protocols
- Non-organic liquids sampling for contamination source investigations

Industries

| | | |
|------------------------|------------------------|--------------------------|
| Aerospace | Animal Laboratory | Biologics |
| Cleanroom Design/Build | Compounding Pharmacies | Data Storage |
| Facilities Maintenance | Food Industry | Laboratory |
| Medical Device | Microelectronics | Pharmaceutical |
| Printing/Graphics | Semiconductor | USP <797> / USP <800> |

[Click here to find TOC Cleaning Validation kits on **www.texwipe.com**](#)

[Click here to watch the TOC Cleaning Validation Swab Sampling Guide](#)

Features & Benefits

Kit

- Organized, convenient and secure method for transporting swabs and vials from storage area to sampling sites and laboratory with minimal chance of contamination
- Doubled bagged to reduce the risk of contamination

Vials/Caps

- Certified Low TOC level (<10 µg/L, <10 ppb) ensures consistency in vial background contribution.
- Pre-washed borosilicate glass vials have caps with a one-piece cap-and-septum design for easy extraction of the vial content
- Septum thickness – 1.34 mm (0.053")
- Polyethylene overcap protects septum surface from contamination until time of analysis
- Sloped shoulder design minimizes headspace for reduced background TOC level

Swabs

- Certified Low TOC level (<50 µg/L, <50 ppb) ensures consistency in swab background contribution
- Double layered, double knit polyester head entraps contaminants in knit structure during sampling. This allows maximum contaminant collection and release into the diluent to provide for excellent recovery rates
- Notched, break-away handle allows the head to be placed into the vial with minimal handling and contamination
- 100% polypropylene handle ensures no additional contaminants are introduced and provides excellent chemical resistance

Labels

- Cleanroom compatible for vial sample identification and traceability

Container/Box

- Cleanroom compatible polypropylene box

Shelf Life

- 5 years from date of manufacture

TECHNICAL DATA SHEET

Physical Characteristics

| | TX714K | TX715 | TX761K | TX716 |
|-------------------|---|---|--------------------------------------|---|
| Head material | Alpha [®] Polyester Knit | Alpha [®] Polyester Knit | Alpha [®] Polyester Knit | Non-Woven Polyester |
| Head width | 12.7 mm (0.500") | 12.7 mm (0.500") | 6.8 mm (0.268") | 12.7 mm (0.500") |
| Head thickness | 4.2 mm (0.165") | 4.2 mm (0.165") | 2.8 mm (0.110") | 4.2 mm (0.165") |
| Head length | 25.7 mm (1.012") | 25.7 mm (1.012") | 16.8 mm (0.661") | 25.7 mm (1.012") |
| Handle material | Polypropylene | Polypropylene | Polypropylene | Polypropylene |
| Handle width | 5.2 mm (0.205") | 5.2 mm (0.205") | 3.2 mm (0.126") | 5.2 mm (0.205") |
| Handle thickness | 3.0 mm (0.118") | 3.0 mm (0.118") | 3.2 mm (0.126") | 3.0 mm (0.118") |
| Handle length | 101.8 mm (4.008") | 101.8 mm (4.008") | 145.5 mm (5.728") | 101.8 mm (4.008") |
| Total swab length | 127.5 mm (5.020") | 127.5 mm (5.020") | 162.3 mm (6.390") | 127.5 mm (5.020") |
| Head bond | Thermal | Thermal | Thermal | Thermal |
| Handle color | Light Green | Light Green | Light Green | Light Green |
| Design notes | Flat head paddle; long, easy-grip handle | Flat head paddle; long, easy-grip handle | Flexible head paddle; long handle | Flat head paddle; long, easy-grip handle |

Contamination Characteristics*

| Ions, µg/swab | TX714K | TX715 | TX761K | TX716 |
|---------------|---------------|--------------|---------------|--------------|
| Calcium | 0.06 | 0.06 | 0.03 | < 0.01 |
| Chloride | 0.05 | 0.13 | 0.02 | 0.16 |
| Fluoride | 0.05 | 0.10 | 0.08 | < 0.01 |
| Magnesium | 0.03 | 0.03 | 0.02 | < 0.01 |
| Nitrate | 0.12 | 0.11 | 0.11 | < 0.01 |
| Phosphate | 0.09 | 0.12 | 0.10 | < 0.01 |
| Potassium | 0.04 | 0.05 | 0.08 | 0.05 |
| Sodium | 0.16 | 0.16 | 0.14 | 0.06 |
| Sulfate | 0.12 | 0.10 | 0.13 | 0.41 |

| Non-Volatile Residue, mg/swab | | | | |
|-------------------------------|------|------|------|--------|
| DIW extractant | 0.01 | 0.01 | 0.01 | |
| IPA extractant | 0.03 | 0.03 | 0.03 | < 0.01 |

Note: The data in this table represent typical analyses.

***Test Methods:** Available upon request. Contact Texwipe Customer Service at www.texwipe.com or info@texwipe.com for a copy.

Storage Conditions: Store at ambient conditions, defined as temperatures between 59°F (15°C) and 86°F (30°C).

Texwipe holds an ISO 9001:2015 registration.

All Texwipe products conform to GHS classification for labeling (where applicable).

Shipping classification based on weight of inner package.

Made in The Philippines

