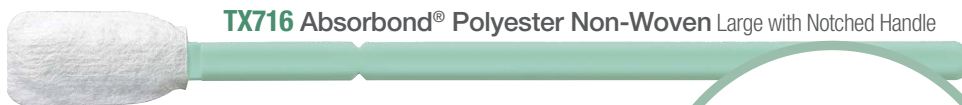
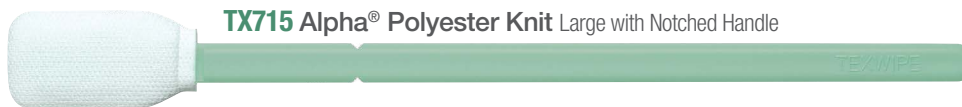


TECHNICAL DATA SHEET

# CLEANING VALIDATION SWABS & TOC KITS

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TECHNICAL DATA SHEET



## Products

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

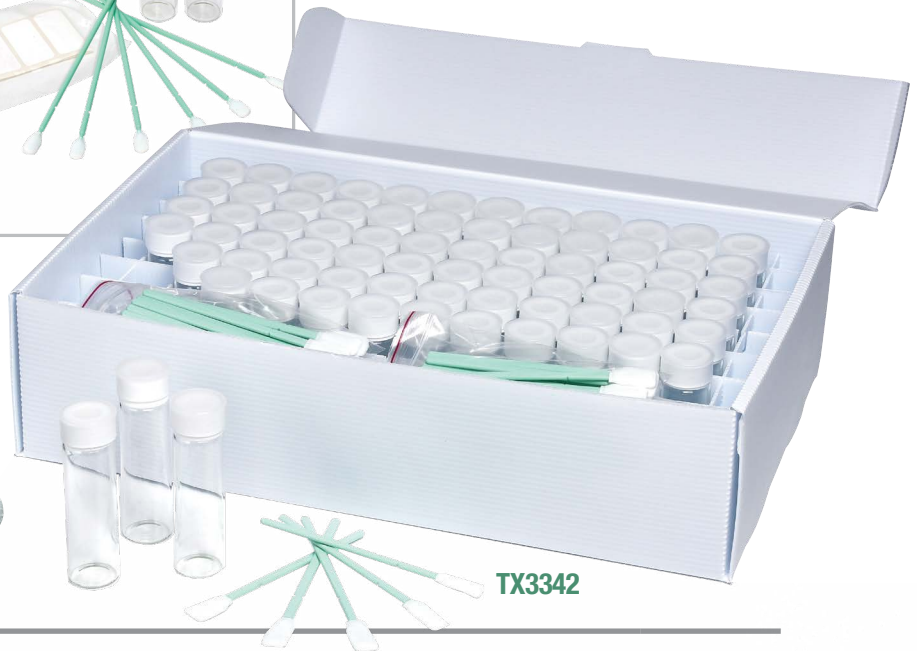
### TECHNICAL DATA SHEET



**TX3340**



**TX3343**



**TX3342**

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

#### 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

	<b>TX714K</b>	<b>TX715</b>	<b>TX761K</b>	<b>TX716</b>
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	<b>TX714K</b>	<b>TX715</b>	<b>TX761K</b>	<b>TX716</b>
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 Customer Service 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*

