Water Technologies & Solutions
application note

selecting the best TOC sample vial for your application

Through its Sievers product line, SUEZ provides complete solutions for your TOC analysis needs, including low-level TOC standards and a range of sample vials suitable for various applications. All scrupulously cleaned for low-level, the vials range from regular TOC certified vials to specialty coated or pre-acidified vials that can give superior TOC recovery on challenging protein applications.

TOC vial applications
USP, EP, JP, KP, and IP Purified Water and Water for Injection Testing
Cleaning validation, including swab recoveries
Method validation and development
Calibration and verification standards
Basic storage

Other vial companies offer only basic low TOC vials for TOC sampling use. SUEZ understands the importance of traceable, certified low TOC vials, but also realizes that these vials may not be best for all your specific application needs. For example, proteins and peptides are known to adhere to many glass and plastic surfaces, including typical borosilicate TOC sample vial containers that SUEZ and other companies provide as standard low TOC vials. This adherence can cause initial sample concentrations to be slightly lower and impact the accuracy and relative standard deviation of TOC measurements.

Sievers specialty TOC vials

Sievers developed two specialty vial types that fit the application needs of many customers: Pre-Acidified TOC vials and DUCT (Dual Use Conductivity & TOC) vials. Both vial types are certified and lot traceable, just like Sievers' heritage Certified TOC vials, but have been found to perform better on specific product families.

Sievers Pre-Acidified vials

- Case of 72 vials
- Automated, calibrated process for dispensing 20 µL of reagent grade phosphoric acid in each vial
- Acidifies sample to approximately pH 2.5, which impedes sample sticking to vial
- Each lot certified to <35 ppb TOC; 6-month shelf life
- Each 40 mL vial includes cap/septum with dust cap
- No Hazmat shipment; available in cardboard packaging or **Certified Blue** (cardboard free packaging)

Sievers DUCT vials

- Case of 30 vials
- Specialty coated glass vials developed for sensitive pharmaceutical formulations
- Specifically developed to avoid leaching and protein adsorption from samples
- Each lot certified to <10 ppb TOC and no ionic leaching
- Each 30 mL vial includes a specialty cap/septum with dust cap
- Available in cardboard packaging or **Certified Blue** (cardboard free packaging)

TOC vial comparison for mAb applications

A global biopharmaceutical company producing a specific monoclonal antibody (mAb) reached out to the SUEZ applications services laboratory to evaluate the most compatible vial for its cleaning validation studies. Samples of the mAb were sent to the applications laboratory for testing and comparison in Sievers Certified TOC vials (<10 ppb), Pre-Acidified TOC vials (<35 ppb), and DUCT vials (<10 ppb and no ionic leaching). The results, as shown in **Figure 1**, demonstrate that the Sievers Pre-Acidified vials were best suited for this customer application.

Recovery of a customer mAb in various vial types			
	Certified TOC vial	**Pre-Acidified TOC vial**	**DUCT vial**
100 ppb	74%	119%	59%
500 ppb	63%	95%	54%
1000 ppb	68%	93%	65%
1500 ppb	78%	97%	79%
3000 ppb	85%	93%	85%
5000 ppb	**90%**	**95%**	**91%**

Figure 1: Vial selection results for a global biopharmaceutical company

vial suitability with common cleaning validation compounds

The SUEZ applications services laboratory tested many common compounds used in pharmaceutical and biopharmaceutical cleaning validation applications to compare recoveries in different vial types. The results from this testing are shown in **Figure 2**. Note that the suitability of the DUCT and Pre-Acidified vials varied across compounds. In some cases, the recoveries were equivalent and with other compounds the recovery was better in one vial type.

	Pre-Acidified TOC vial	**DUCT vial**
mAb	✓	
DNA		✓
Insulin	✓	
Terrific Broth	✓	✓
Urease	✓	✓
Hemoglobin	✓	

Figure 2: Suitability of Sievers specialty TOC vials for recovery of common cleaning validation compounds.

In response to these results, SUEZ developed the Vial Selection Guide[1] to help customers set up similar studies to determine the best vial for their applications.

The SUEZ applications services laboratory is also available as a resource for customers with vial selection needs. The applications laboratory can compare Sievers Pre-Acidified TOC vials, DUCT vials, and conventional Certified TOC vials using customers' specific compounds. Contact your local sales representative for more information.

summary

Sievers Certified TOC, Pre-Acidified, and DUCT vials are:

- Cleaned using validated and automated equipment in an ISO 7 Cleanroom environment; vials are scrupulously cleaned of organic residues using low TOC reagent water
- Tested for minimal TOC background, and certified to <10 ppb (<35 ppb for Pre-Acidified vials) for use in critical applications including USP, EP water testing, and cleaning validation
- Available in the Sievers **Certified Blue** option, which eliminates paper and cardboard products as potential sources of microbial contamination in manufacturing and lab spaces

Through its Sievers product line, SUEZ is the only vial company in the industry offering both Pre-Acidified vials and DUCT vials in addition to traditional low TOC vials to provide solutions for your application needs.

References:

1. Vial Selection Guide, *300 00332*, 2016. Retrieved May 16, 2018, from https://www.geinstruments.com/sites/default/files/pdf_test/br_3_332_A_Vial_Selection_Guide.pdf

Water Technologies & Solutions
application note

selecting the best TOC sample vial for your application

Through its Sievers product line, SUEZ provides complete solutions for your TOC analysis needs, including low-level TOC standards and a range of sample vials suitable for various applications. All scrupulously cleaned for low-level, the vials range from regular TOC certified vials to specialty coated or pre-acidified vials that can give superior TOC recovery on challenging protein applications.

TOC vial applications
USP, EP, JP, KP, and IP Purified Water and Water for Injection Testing
Cleaning validation, including swab recoveries
Method validation and development
Calibration and verification standards
Basic storage

Other vial companies offer only basic low TOC vials for TOC sampling use. SUEZ understands the importance of traceable, certified low TOC vials, but also realizes that these vials may not be best for all your specific application needs. For example, proteins and peptides are known to adhere to many glass and plastic surfaces, including typical borosilicate TOC sample vial containers that SUEZ and other companies provide as standard low TOC vials. This adherence can cause initial sample concentrations to be slightly lower and impact the accuracy and relative standard deviation of TOC measurements.

Sievers specialty TOC vials

Sievers developed two specialty vial types that fit the application needs of many customers: Pre-Acidified TOC vials and DUCT (Dual Use Conductivity & TOC) vials. Both vial types are certified and lot traceable, just like Sievers' heritage Certified TOC vials, but have been found to perform better on specific product families.

Sievers Pre-Acidified vials

- Case of 72 vials
- Automated, calibrated process for dispensing 20 µL of reagent grade phosphoric acid in each vial
- Acidifies sample to approximately pH 2.5, which impedes sample sticking to vial
- Each lot certified to <35 ppb TOC; 6-month shelf life
- Each 40 mL vial includes cap/septum with dust cap
- No Hazmat shipment; available in cardboard packaging or **Certified Blue** (cardboard free packaging)

Sievers DUCT vials

- Case of 30 vials
- Specialty coated glass vials developed for sensitive pharmaceutical formulations
- Specifically developed to avoid leaching and protein adsorption from samples
- Each lot certified to <10 ppb TOC and no ionic leaching
- Each 30 mL vial includes a specialty cap/septum with dust cap
- Available in cardboard packaging or **Certified Blue** (cardboard free packaging)

TOC vial comparison for mAb applications

A global biopharmaceutical company producing a specific monoclonal antibody (mAb) reached out to the SUEZ applications services laboratory to evaluate the most compatible vial for its cleaning validation studies. Samples of the mAb were sent to the applications laboratory for testing and comparison in Sievers Certified TOC vials (<10 ppb), Pre-Acidified TOC vials (<35 ppb), and DUCT vials (<10 ppb and no ionic leaching). The results, as shown in **Figure 1**, demonstrate that the Sievers Pre-Acidified vials were best suited for this customer application.

Recovery of a customer mAb in various vial types			
	Certified TOC vial	**Pre-Acidified TOC vial**	**DUCT vial**
100 ppb	74%	119%	59%
500 ppb	63%	95%	54%
1000 ppb	68%	93%	65%
1500 ppb	78%	97%	79%
3000 ppb	85%	93%	85%
5000 ppb	**90%**	**95%**	**91%**

Figure 1: Vial selection results for a global biopharmaceutical company

vial suitability with common cleaning validation compounds

The SUEZ applications services laboratory tested many common compounds used in pharmaceutical and biopharmaceutical cleaning validation applications to compare recoveries in different vial types. The results from this testing are shown in **Figure 2**. Note that the suitability of the DUCT and Pre-Acidified vials varied across compounds. In some cases, the recoveries were equivalent and with other compounds the recovery was better in one vial type.

	Pre-Acidified TOC vial	**DUCT vial**
mAb	✓	
DNA		✓
Insulin	✓	
Terrific Broth	✓	✓
Urease	✓	✓
Hemoglobin	✓	

Figure 2: Suitability of Sievers specialty TOC vials for recovery of common cleaning validation compounds.

In response to these results, SUEZ developed the Vial Selection Guide[1] to help customers set up similar studies to determine the best vial for their applications.

The SUEZ applications services laboratory is also available as a resource for customers with vial selection needs. The applications laboratory can compare Sievers Pre-Acidified TOC vials, DUCT vials, and conventional Certified TOC vials using customers' specific compounds. Contact your local sales representative for more information.

summary

Sievers Certified TOC, Pre-Acidified, and DUCT vials are:

- Cleaned using validated and automated equipment in an ISO 7 Cleanroom environment; vials are scrupulously cleaned of organic residues using low TOC reagent water
- Tested for minimal TOC background, and certified to <10 ppb (<35 ppb for Pre-Acidified vials) for use in critical applications including USP, EP water testing, and cleaning validation
- Available in the Sievers **Certified Blue** option, which eliminates paper and cardboard products as potential sources of microbial contamination in manufacturing and lab spaces

Through its Sievers product line, SUEZ is the only vial company in the industry offering both Pre-Acidified vials and DUCT vials in addition to traditional low TOC vials to provide solutions for your application needs.

References:

1. Vial Selection Guide, *300 00332*, 2016. Retrieved May 16, 2018, from https://www.geinstruments.com/sites/default/files/pdf_test/br_3_332_A_Vial_Selection_Guide.pdf