Cleaning Validation ¯ Swab Test
(Ref. VAL-020)

Project number:

Protocol Number:

Product/Active:

Process Line:

SWABBING RECOVERY STUDIES

1. Test Description

This test is to be conducted to document the validation of a TOC analysis method for use in measuring samples for cleaning validation. A parallel analysis of swab samples will be carried out and compared using TOC and HPLC analysis. Standard solutions will be applied to stainless steel plates, dried and the residue removed by swabbing using the Texwipe TX761 swab. Assessment of Linearity, Accuracy (recovery), LOQ, LOD and precision of the swabbing method will be determined.

2. Test Objective

1. Determine the linearity and precision of a series of standards swabbed from a stainless steel plate and measured by TOC and HPLC over a known concentration range.
2. Determine the accuracy (recovery) of a series of standards swabbed from a stainless steel plate and measured by TOC and HPLC over a known concentration range.
3. Determine the Limit of quantitation and limit of detection of a series of standards measured by TOC and HPLC over a known concentration range.
4. Determine correlation between HPLC and TOC analysis.
5. Determine the visually clean limit.
6. Determine the final HPLC and TOC swabbing limits based on recovery studies.

3. Acceptance Criteria

Test Objective	Measured Response	Acceptance Criteria
3.1. Linearity	The correlation coefficient (r^2) for the linear concentration range.	**3.1.1. HPLC**: equal to or greater than 0.997 **3.1.2. TOC**: equal to or greater than 0.980

(400%)	

- Plot Actual TOC Concentration (ppm) vs Measured TOC Response (ppm)
- Coefficient of Determination (R^2) =

3.2 Accuracy - Swabbing active residue / Precision

For each measured response over the concentration range examined in the Linearity test calculate **% recovery** and **% RSD** for each of the triplicate samples.

- where % recovery = $\frac{\text{result found}}{\text{result expected}} \times 100$

3.2.1. HPLC Analysis

Actual Active Concentration	Measured responses				Average result	Mean % recovery	% RSD
	1	2	3	4			
(50%)							
(100%)							
(400%)							

- Compare and summarise results according to acceptance criteria

3.2.2. TOC Analysis

Actual Total Organic Carbon Concentration (ppm)	Measured TOC (ppm)				Average TOC (ppm)	Mean % recovery	% RSD
	1	2	3	4			
(50%)							
(100%)							
(400%)							

- Compare and summarise results according to acceptance criteria

3.3. Limit of Quantitation

- Determine Limit of Quantitation by assessing results of Accuracy test in accordance with the acceptance criteria for HPLC and TOC analysis and summarise the results.

3.3.1. Limit of Quantitation for HPLC

- Document the LOQ concentration for HPLC analysis and how this was established.

3.3.2. Limit of Quantitation for TOC

- Document the LOQ concentration for TOC analysis and how this was established.

3.4. Limit of Detection

- Determine Limit of Detection by assessing results of Accuracy test in accordance with the acceptance criteria for HPLC and TOC analysis and summarise the results.

3.4.1. Limit of Detection for HPLC

If each swab is extracted using 25.0 mL of water, the limit becomes:

→0.02898mg/25mL x 1000 μg/mL = 1.16 μg/mL or 1.16ppm per swab.

5.4. TOC Swabbing Limits

Determine the lowest and most conservative active recovery value obtained during the method validation study for TOC analysis.

Lowest TOC swab recovery value = _____

Calculate the final TOC swabbing limit for the surface tested:

Active MAC / cm^2 total surface area X carbon factor** X swabbing area X lowest swab recovery average recovery from swabbing material

= X mg per swab

** Carbon Factor = Product Total Carbon contribution divided by the active concentration in the formula.

- Divide by extraction volume and multiply by 1000 to give ppm limit per swab.

TOC Swabbing Limit =_____=_____mg per swab

TOC Swabbing Limit (ppm) =_____=_____ppm per swab

Example Calculation:

$\frac{0.000417 \text{ mg/cm}^2 \times 1.502 \times 100 \text{ cm}^2 \times 0.8307}{0.9693}$ = 0.05368 mg per swab

If each swab is extracted using 25.0 mL of water, the limit becomes:

0.05368 mg/25mL x 1000 ug/mL = 2.15 ug/mL or 2.15 ppm per swab.

6. Comments

7. Conclusion

8. Attachments

Validation Discrepancy Forms - nil

Completed Operational Qualification Test protocol:

	Position	Signature	Date
Documented by:			
Checked by:			
Approved by :			