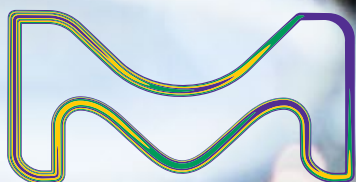


MERCK

BEYOND CLEAN

Tracing the Extran® residue-free path
in Cleaning Validation



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Supelco®
Analytical Products

RELIABLE TRACE DETECTION



K123456789

1.07553.2500

Extran®

Extran® MA 02

liquid, neutral, concentrate

Supelco

2.5 l



Made in Germany

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What is Cleaning Validation?

Cleaning validation is a crucial procedure of establishing documentation to ensure an approved cleaning method will reproducibly remove residues of the active, inactive, and ingredients of a cleaning detergent to below a pre-determined level.

Why is it Needed?

Cleaning validation is essential to maintain analytical experiment integrity, prevent cross-contamination, ensure product quality, and comply with regulations. Inadequate validation can result in downtime, batch failures, costly issue tracking, and false rejections from inaccurate results. Prioritizing thorough cleaning validation helps mitigate these risks.

Role of Cleaning Detergents

To minimize the risk of potential issues, it is essential to use a reliable cleaning detergent, such as Extran[®] detergent, renowned for its excellent solubility. Extran[®] detergents are biodegradable, non-toxic, and designed specifically for laboratory cleaning. They can be used for manual cleaning or in lab washers, ensuring thorough and residue-free cleaning. These properties are crucial for meeting global and local cleaning validation guidelines and regulations.

In Europe, cleaning processes are legally based on regulations such as the European Regulations (EC) on detergents (No. 648/2004) or REACH (No. 1907/2006). Additional guidelines from Pharmacopeias and specific regulations must also be considered, particularly in the pharmaceutical industry where FDA guidelines for cleaning validation are important.

Sampling Methods

When it comes to cleaning validation, sampling residues stands out as a critical phase. There are two general types of sampling that have been found acceptable—Swabbing and Rinsing.

Swabbing is the preferable sampling method. This technique uses swabs to collect samples from planar surfaces and provides two distinct benefits: direct sampling from the surface and the capability to swab poorly soluble substances. Swabs are soaked in a specified solvent (such as water for Extran[®] products), and thoroughly wiped over the target surface with both sides of the swab. For a thorough coverage of the samples, the wiping direction is changed at least once to a direction perpendicular to the previous one. The swabs are extracted with solvent after swabbing, and the resultant solution is analyzed using an appropriate method.

Rinsing, on the other hand, takes an indirect approach to sampling. It involves rinsing glassware with a predefined amount of solvent (water, in the case of Extran[®] products), which is then tested for analytes. Rinsing is especially useful for larger surface areas and inaccessible systems or ones that cannot be routinely disassembled for sampling and evaluation. If rinsing is the chosen, it's critical to confirm the solubility of the residue in the chosen solvent.

Whether swabbing or rinsing, it is critical to validate your chosen sampling technique ahead of time in order to obtain trustworthy results.

Residue-Analysis of Extran® Detergents

One of the common problems encountered with the use of detergents is its composition. As detergent suppliers generally do not disclose the complete composition of their products for reasons due to proprietary formulations, protection of intellectual property, the complexity of formulations, and compliance with regulations. This makes it difficult for the users in cleaning validation to choose an analytical method and establish residue limits.

The table below summarizes the main components and the corresponding analysis methods for the various Extran® products. Although the test methods

are customized for the Spectroquant® series, other methods suitable for the analyte can be used as well. It is critical to note that all Spectroquant® tests require the use of an appropriate Spectroquant® photometer.

All Extran® residues can also be verified through conductivity assessment. Depending on the required detection limit, it might be necessary to use alternative instrumental methods beyond those specified in the table below, such as HPLC or LC-MS. The bold parameters in the table indicate the most sensitive detection for corresponding Extran® residues.

Extran® type	Parameter	Test method	Measuring range	Item no.
107555 Extran® MA 01	Anionic surfactants	Surfactants (anionic) Cell Test	0.05 – 2.00 mg/L (MBAS)	1.02552
	Nonionic surfactants	Surfactants (nonionic) Cell Test	0.10 – 7.50 mg/L (Triton™ X-100)	1.01787
	Phosphate	Phosphate Test	0.0025-5.00 mg/L PO ₄ -P	1.14848
		Phosphate Cell Test	0.05-5.00 mg/L PO ₄ -P	1.14543
107553 Extran® MA 02	Anionic surfactants	Surfactants (anionic) Cell Test	0.05 – 2.00 mg/L (MBAS)	1.02552
	Nonionic surfactants	Surfactants (nonionic) Cell Test	0.10 – 7.50 mg/L (Triton™ X-100)	1.01787
	Phosphorus	Phosphate Test + CrackSet	0.0025-5.00 mg/L PO ₄ -P	1.14848 + 1.14687/1.14688
		Phosphate Cell Test	0.05-5.00 mg/L PO ₄ -P	1.14543
140000 Extran® MA 05	Anionic surfactants	Surfactants (anionic) Cell Test	0.05 – 2.00 mg/L (MBAS)	1.02552
	Nonionic surfactants	Surfactants (nonionic) Cell Test	0.10 – 7.50 mg/L (Triton™ X-100)	1.01787
107558 Extran® AP 11	Phosphorus	Phosphate Test + CrackSet	0.0025-5.00 mg/L PO ₄ -P	1.14848 + 1.14687/1.14688
		Phosphate Cell Test	0.05-5.00 mg/L PO ₄ -P	1.14543
107563 Extran® AP 12	Phosphate	Phosphate Test	0.0025-5.00 mg/L PO ₄ -P	1.14848
		Phosphate Cell Test	0.05-5.00 mg/L PO ₄ -P	1.14543
	Phosphorus	Phosphate Test + CrackSet	0.0025-5.00 mg/L PO ₄ -P	1.14848 + 1.14687/1.14688
		Phosphate Cell Test	0.05-5.00 mg/L PO ₄ -P	1.14543
140006 Extran® AP 17	Chemical Oxygen Demand	COD Cell Test	4.0-40.0 mg/L COD*	1.14560
140118 Extran® AP 18	Chemical Oxygen Demand	COD Cell Test	4.0-40.0 mg/L COD*	1.14560
107559 Extran® AP 21	Phosphate	Phosphate Test	0.0025-5.00 mg/L PO ₄ -P	1.14848
		Phosphate Cell Test	0.05-5.00 mg/L PO ₄ -P	1.14543
107561 Extran® AP 22	Chemical Oxygen Demand	COD Cell Test	4.0-40.0 mg/L COD*	1.14560
107570 Extran® AP 41	Phosphate	Phosphate Test	0.0025-5.00 mg/L PO ₄ -P	1.14848
		Phosphate Cell Test	0.05-5.00 mg/L PO ₄ -P	1.14543
	Phosphorus	Phosphate Test + CrackSet	0.0025-5.00 mg/L PO ₄ -P	1.14848 + 1.14687/1.14688
		Phosphate Cell Test	0.05-5.00 mg/L PO ₄ -P	1.14543

*Low Sensitivity: Please verify if the sensitivity level meets your requirements. If not, consider selecting an alternative method such as conductivity measurement.



The Spectroquant® Photometric System

Explore our comprehensive range of all-in-one solutions for a secure and precise photometric analysis. We offer high-quality test kits, reliable instruments, customized applications, and end-to-end Analytical Quality Assurance (AQA) for all your photometric analysis requirements.

Our carefully designed test kits ensure a simplified photometric analysis. These test kits facilitate a chemical reaction between your analyte and special pre-defined reagents. A thermoreactor becomes necessary, in cases where thermal treatment of the sample is essential — such as when measuring Chemical Oxygen Demand (COD) or using the CrackSet for Phosphorus analysis.

Our Spectroquant® system photometers have pre-programmed and pre-calibrated test methods that facilitate an ease of measurement with prompt display of results. In addition, we also offer guided AQA and ready-to-use reference materials to ensure seamless performance of your analytical system.



Instruments	Order No
Spectroquant® Photometers	
VIS Spectrophotometer Prove 100 plus	1.73026
UV/VIS Spectrophotometer Prove 300 plus	1.73027
UV/VIS Spectrophotometer Prove 600 plus	1.73028
Colorimeter Move 100	1.73632
Spectroquant® Thermoreactors	
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Thermoreactor TR 420	1.71201
Thermoreactor TR 620	1.71202



Supelco®

Analytical Products

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Frankfurter Strasse 250
64293 Darmstadt, Germany

SigmaAldrich.com



For further information on Extran® detergents please visit us at SigmaAldrich.com/cleaning

For specialized application notes on testing of Extran® detergent residues using the Spectroquant® system and outlining all necessary equipment and tests, please visit SigmaAldrich.com or contact your local supplier for further support.



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12/2023