

Extractable and leachables (USP <665>)

Plainsboro, NJ 08536
 P: (609) 799-2299
 F: (609) 784-7889
 www.pendotech.com

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Pendotech has validated and conducted Extractables and Leachables (E&L) studies on Polysulfone and Polycarbonate single-use sensors, including pressure sensors, conductivity/temperature sensors, UV/Turbidity flow cells, and pH sensors, subjected to different irradiation methods (gamma and X-ray). Each study follows the BioPhorum Operations Group (BPOG) Extractables and Leachables guidance as well as USP <665> frameworks. The test studies were conducted following a risk assessment, which included physical (sensor integrity) and functional testing of all sensor types.

Summary ~ (USP<665>)

USP <665> Risk Level Testing Guidelines			Pendotech E&L studies
Risk Level	Extraction Solutions for Chemical Testing	Chemical Testing of Extractions	
Low	Solution C1 (organic extraction, v/v ethanol/water)	Non-volatile residue UV absorbance	
Moderate	Solution C1 (organic extraction, v/v ethanol/water)	Organic extractables profiling	
High	Solution C1 (organic extraction, v/v ethanol/water) Solution C2 (acidic extraction, pH 3) Solution C3 (basic extraction, pH 10)	Organic extractables profiling Extracted elements (as necessary and appropriate)	Pendotech_E&L_24Hour_Full_Study_Report_15-3086.9729
		Extracted elements (as necessary and appropriate)	Pendotech_E&L_24Hour_SU_Pressure_Post Gamma_Irradiation_Report_22-3837-11867

Results

- Reports use solvent extraction of irradiated sensors under controlled conditions.
- Analysis is performed using UPLC-DAD/MS and GC/MS (including headspace GC/MS).
- The analysis identifies organic and volatile extractables.

- Testing meets USP <665> requirements for Extractables and Leachables (E&L).
- Extractable compounds identified include antioxidants and other polymer additives.
- Detected levels are within acceptable limits defined by BPOG.
- Leachables evaluation provides comprehensive data, chromatograms, and system suitability information.
- The extraction duration aligns with the 24-hour recommendation but may be extended or varied depending on product use.
- Full details of the study are available upon request.

Sincerely,
Pendotech