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Ethylene Oxide Residual Extraction Specifics Form

Date:

Sponsor:

Contact:

Email:

Test Article Name:

Part Number:

Lot Number:

Please complete the following information per test article.

Residuals for Analysis:	☐ Ethylene Oxide ☐ Ethylene Chlorohydrin ☐ Ethylene Glycol	Category:	☐ Limited Exposure (<24hrs exposure) ☐ Prolonged Exposure (24hr - 30days exposure) ☐ Permanent Contact (>30days exposure)
Extraction Type:	☐ Simulated ☐ Exhaustive* ☐ Direct Inject (no extraction)	Extraction Temp.:	☐ 25 ± 2° C ☐ 37 ± 2° C
Extraction Duration:	Extraction Time (min. 1hr) Repetitive: ☐ Yes ☐ No Example: For an exhaustive extraction- Extraction time: 24hrs Repetitive: Yes	Testing Standard:	☐ ANSI/AAMI/ISO 10993-7 2008/AMD 1:2019 ☐ Device is intended for neonates/infants/children (Please enter desired spec limits in Notes section) ☐ Other:
Extraction Method:	☐ Water ☐ Immersion ☐ Fluid Path Fill	Portion of the Test Article to be Extracted:	☐ Entire Article ☐ Portion of Article Define Portion (Drawings may be submitted with form):
Tolerable Contact Limit:	☐ Not Required (no patient contact) ☐ Required Patient Contacting Surface Area(cm ²) Total Surface Area(cm ²)		
Storage Conditions:	Ambient Freezer (recommended for ANSI/AAMI/ISO 10993-7 compliance)		

Notes:

*Canyon Labs defines Exhaustive Extraction as extracting until the amount of residual in a subsequent extract is less than 10% of that detected in the first extract, the amount of residue is less than the limit of quantitation for the GC method or there is no analytically significant increase in the cumulative residue levels detected. Canyon Labs defines analytically insignificant as the amount of residue less than the maximum Average Daily Dose as outlined in ANSI/AAMI/ISO 10993-7 with at least three extractions to establish a downward trend.

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