

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.

<p>Residuals for Analysis:</p> <p><input type="checkbox"/> Ethylene Oxide</p> <p><input type="checkbox"/> Ethylene Chlorohydrin</p> <p><input type="checkbox"/> Ethylene Glycol</p>	<p>Category:</p> <p><input type="checkbox"/> Limited Exposure (<24hrs exposure)</p> <p><input type="checkbox"/> Prolonged Exposure (24hr - 30days exposure)</p> <p><input type="checkbox"/> Permanent Contact (>30days exposure)</p>
<p>Extraction Type:</p> <p><input type="checkbox"/> Simulated</p> <p><input type="checkbox"/> Exhaustive*</p> <p><input type="checkbox"/> Direct Inject (no extraction)</p>	<p>Extraction Temp.:</p> <p><input type="checkbox"/> 25 ± 2°C</p> <p><input type="checkbox"/> 37 ± 2°C</p>
<p>Extraction Duration:</p> <p>Extraction Time (min. 1hr) <input style="width: 80px; height: 20px;" type="text"/></p> <p>Repetitive: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Example: For an exhaustive extraction- Extraction time: 24hrs Repetitive: Yes</p>	<p>Testing Standard:</p> <p><input type="checkbox"/> ANSI/AAMI/ISO 1993-7 2008/AMD 1:2019</p> <p><input type="checkbox"/> Device is intended for neonates/infants/children (Please enter desired spec limits in Notes section)</p> <p><input type="checkbox"/> Other: <input style="width: 150px; height: 20px;" type="text"/></p>
<p>Extraction Method:</p> <p><input type="checkbox"/> Water</p> <p style="padding-left: 20px;"><input type="checkbox"/> Immersion</p> <p style="padding-left: 20px;"><input type="checkbox"/> Fluid Path Fill</p>	<p>Portion of the Test Article to be Extracted:</p> <p><input type="checkbox"/> Entire Article</p> <p><input type="checkbox"/> Portion of Article</p> <p>Define Portion (Drawings may be submitted with form):</p> <div style="border: 1px solid black; height: 150px; width: 100%;"></div>
<p>Tolerable Contact Limit:</p> <p><input type="checkbox"/> Not Required (no patient contact)</p> <p><input type="checkbox"/> Required</p> <p>Surface Area(cm²): <input style="width: 100px; height: 20px;" type="text"/></p>	
<p>Storage Conditions:</p> <p><input type="checkbox"/> Ambient</p> <p><input type="checkbox"/> Freezer (recommended for ANSI/AAMI/ISO 10993-7 compliance)</p>	

Notes:

*iuvo BioScience 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. iuvo BioScience 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.