



TOXICOLOGY SUPPLEMENTAL SAMPLE SUBMISSION FORM

Reference SRP-13 (ROC)

Section A: Toxicology and/or Biocompatibility Specific Test Requirements (to be completed where applicable):

Note: if testing requires a formal protocol (as requested by sponsor), the approved protocol will supersede information selected on this form.

Have samples been submitted sterile? * <i>*Note: Samples that are sold and used sterile should be submitted sterile or be processed by the intended sterilization method prior to testing.</i>
<input type="checkbox"/> Yes, customer sterilized per following method: <input type="checkbox"/> Ethylene Oxide <input type="checkbox"/> Steam <input type="checkbox"/> Gamma Irradiation <input type="checkbox"/> Other: _____
<input type="checkbox"/> No, Canyon Labs to process per following method prior to testing: <input type="checkbox"/> Ethylene Oxide <input type="checkbox"/> Steam <input type="checkbox"/> Other: _____
<input type="checkbox"/> No, samples not intended to be sold or used sterile.
<input type="checkbox"/> N/A (Testing to be performed on sample as submitted)

Submitted Material Type:
<input type="checkbox"/> Plastic/polymer
<input type="checkbox"/> Elastomer
<input type="checkbox"/> Coated material, composite, laminate
<input type="checkbox"/> Metal
<input type="checkbox"/> Pharmaceuticals
<input type="checkbox"/> Other

Safety Precautions:
<input type="checkbox"/> None/unknown (standard precautions will be used)
<input type="checkbox"/> SDS enclosed
<input type="checkbox"/> Flammable
<input type="checkbox"/> Biohazard level
<input type="checkbox"/> Other

<input type="checkbox"/> Test entire sample, sample may be subdivided/cut into appropriate sizes for testing.
<input type="checkbox"/> Test entire sample, DO NOT sub-divide (cut) test sample for testing
<input type="checkbox"/> Do NOT test entire sample (Identify specific components or materials to be <input type="checkbox"/> excluded or <input type="checkbox"/> included below):

If Samples are submitted for testing requiring USP/ISO biocompatibility-based extractions, complete section B, where applicable below.
If Samples are submitted for USP/ISO biocompatibility-based testing requiring direct application, complete section C, where applicable on Page 2.
Canyon Labs Biocompatibility Questionnaire (for ISO 10993 GLP studies) and/or Canyon Labs Chemical Characterization Test (10993-18) Questionnaire may be required for protocol preparation.

Section B: Extraction Method Selections: ☐ N/A OR ☐ as selected below

Extraction Methods for GPMT, Irritation Test, Systemic Injection Test, Material Mediated Pyrogen, Hemolysis Tests
• Extraction Condition Options:
<input type="checkbox"/> 121°C – 1 hour <input type="checkbox"/> 70°C – 24 hour <input type="checkbox"/> 50°C – 72 hour <input type="checkbox"/> 37°C – 72 hour (requires justification) <input type="checkbox"/> Other: _____
• Extraction Media Options (unless otherwise requested by Sponsor):
<input type="checkbox"/> Saline & Vegetable Oil (GPMT, Irritation, and Systemic Toxicity tests, unless indicated in "Other" below)
<input type="checkbox"/> Saline (Material Mediated Pyrogen test)
<input type="checkbox"/> Saline, Vegetable Oil, 1:20 Alcohol: Saline, & Polyethylene Glycol (USP <88> Class VI plastics testing)
<input type="checkbox"/> Phosphate Buffered Saline (PBS) (ASTM Hemolysis Test)
<input type="checkbox"/> Other: _____
Extraction Methods for Elution Cytotoxicity Test (USP <87> or ISO 10993-5):
• Extraction Condition/Media Options:



TOXICOLOGY SUPPLEMENTAL SAMPLE SUBMISSION FORM

Reference SRP-13 (ROC)

<input type="checkbox"/> 37°C – 24 hour in Serum Supplemented MEM (for devices with contact < 24 hours)
<input type="checkbox"/> 37°C – 72 hour in Serum Supplemented MEM (for devices with contact ≥ 24 hours)
<input type="checkbox"/> 121°C – 1 hour <input type="checkbox"/> 70°C – 24 hour <input type="checkbox"/> 50°C – 72 hour in Saline with justification
Extraction Methods for BET/Rabbit Pyrogen test (Lot Release):
• Extraction Condition/Media Options
<input type="checkbox"/> As per Test System Suitability (Method Validation): Reference Validation Study #:
<input type="checkbox"/> As per Canyon Labs internal work instruction, PYT-8

Toxicology and/or Biocompatibility Specific Test Requirements (Continued from page 2; to be completed where applicable):

Section C: Direct Contact Method Selections: ☐ N/A OR ☐ as selected below

<input type="checkbox"/> Cytotoxicity (Direct Contact Test)
<input type="checkbox"/> Sensitization (Closed Patch Test)
<input type="checkbox"/> Skin Irritation Test
<input type="checkbox"/> ASTM Hemolysis
<input type="checkbox"/> Implantation Evaluation:** <input type="checkbox"/> Histopathology (required per ISO 10993-6) <input type="checkbox"/> Macroscopic (USP <88>)
**Samples for histology and post mortem clinical evaluation will be submitted to an approved vendor. Samples submitted for implantation testing must be submitted sterile or be sterilized before testing (make appropriate selection above).