

## **SAMPLE SUBMISSION FORM**

(Reference SRP-13)

7500 West Henrietta Road | Rush, NY 14543 | 585.533.1672 | fax 585.533.1796

Quotation #		PO#	FedEx/UPS # for return					
Send Final Report To:				Billing Information:				
Company:				Company:				
Contact:				Contact:				
Address:				Address:				
Email:				Email:				
Phone:				Phone:				
Sample Inform	nation: ne / Guideline	Number of						
	O, USP, etc.)	Samples		Product Name		Part #	Lot #	
Replacement Value:								
Comments or Special Handling Instructions:								
Select most a	pplicable require	ment for testi	ng:					
GLP	☐ GMP (e.g. Lo			h/investigational)	Other:			
Submitted Ma	terial Type:							
☐ Medical De	vice	☐ Pharmace	utical	Other:				
Storage Cond	itions:							
☐ Room temp	erature	Refrigerat	e (2-8°C)	☐ Freeze (-10 to -2	25°C)	Other:		
Sample Dispo	sition: *							
Discard		Return un	used sample	☐ Return used and	d unused samp	le		
*Product v	/ill be discarded/d	destroyed unl	ess otherwise indi	cated.				
Applicable De	partments: (pleas	se mark all tha	t apply)					
Applicable Departments: (please mark all that apply)  Toxicology: For Toxicology/Biocompatibility Specific Test Requirements, complete Section A, Section B, Section C, and Section D.								
☐ Microbiology / BI / Reusables: Complete Section D								
☐ Analytical	Chemistry: Comple	te Section D						

## 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.

Note: Samples that are sold and used sterile should be submitted sterile or be processed by the intended sterilization method prior to testing.    Yes, customer sterilized per following method:   Ethylene Oxide   Steam   Gamma Irradiation   Other:     No, Canyon Labs to process per following method prior to testing:   Ethylene Oxide   Steam     Other:     No, Samples not intended to be sold or used sterile.     No, Samples not intended to be sold or used sterile.     No, Samples not intended to be submitted)    Submitted Material Type:   Safety Precautions:   None/unknown (standard precautions will be used)     Elastomer   SDS enclosed   Flammable     Pharmaceuticals   Biohazard level     Other     Test entire sample, sample may be subdivided/cut into appropriate sizes for testing.     Test entire sample, DO NOT sub-divide (cut) test sample for testing     Do NOT test entire sample (Identify specific components or materials to be   excluded or   included below):    If Samples are submitted for USP/ISO biocompatibility-based testing requiring direct application, complete section B, where applicable on Page 3.   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.	testing.  Yes, customer sterilized per following method: Ethylen No, Canyon Labs to process per following method prior to Other: No, samples not intended to be sold or used sterile. N/A (Testing to be performed on sample as submitted)  Submitted Material Type:	te Oxide							
No, Canyon Labs to process per following method prior to testing:   Ethylene Oxide   Steam   Other:   No, samples not intended to be sold or used sterile.   N/A (Testing to be performed on sample as submitted)    Submitted Material Type:   None/unknown (standard precautions will be used)   Safety Precautions:   None/unknown (standard precautions will be used)   SDS enclosed	□ No, Canyon Labs to process per following method prior to Other: □ No, samples not intended to be sold or used sterile. □ N/A (Testing to be performed on sample as submitted)  Submitted Material Type:	testing: Ethylene Oxide Steam							
Other:  No, samples not intended to be sold or used sterile.  N/A (Testing to be performed on sample as submitted)  Submitted Material Type:  Plastic/polymer  Elastomer  Coated material, composite, laminate, metal  Pharmaceuticals  Other  Test entire sample, sample may be subdivided/cut into appropriate sizes for testing.  Test entire sample, DO NOT sub-divide (cut) test sample for testing  Do NOT test entire sample (Identify specific components or materials to be excluded or 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 3.  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.	Other:  No, samples not intended to be sold or used sterile.  N/A (Testing to be performed on sample as submitted)  Submitted Material Type:								
Submitted Material Type:  Plastic/polymer Elastomer Coated material, composite, laminate, metal Pharmaceuticals Other  Test entire sample, sample may be subdivided/cut into appropriate sizes for testing Do NOT test entire sample (Identify specific components or materials to be excluded or 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 3.  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.	N/A (Testing to be performed on sample as submitted)  Submitted Material Type:	Safety Precautions:							
Submitted Material Type:    Plastic/polymer	Submitted Material Type:	Safety Precautions:							
□ Plastic/polymer □ Elastomer □ Coated material, composite, laminate, metal □ Pharmaceuticals □ Other □ Test entire sample, sample may be subdivided/cut into appropriate sizes for testing □ Do NOT test entire sample (Identify specific components or materials to be □ excluded or □ 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 3.  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.	_	Safety Precautions:							
□ Coated material, composite, laminate, metal □ Pharmaceuticals □ Other □ Oth	☐ Plastic/polymer								
Coated material, composite, laminate, metal  □ Pharmaceuticals □ Other □ Test entire sample, sample may be subdivided/cut into appropriate sizes for testing. □ Test entire sample, DO NOT sub-divide (cut) test sample for testing □ Do NOT test entire sample (Identify specific components or materials to be □ excluded or □ 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 3.  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.		☐ None/unknown (standard precautions will be used)							
Pharmaceuticals  □ Other  □ Other  □ Test entire sample, sample may be subdivided/cut into appropriate sizes for testing. □ Test entire sample, DO NOT sub-divide (cut) test sample for testing □ Do NOT test entire sample (Identify specific components or materials to be □ excluded or □ 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 3.  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.	☐ Elastomer	☐ SDS enclosed							
□ Other □ Test entire sample, sample may be subdivided/cut into appropriate sizes for testing. □ Test entire sample, DO NOT sub-divide (cut) test sample for testing □ Do NOT test entire sample (Identify specific components or materials to be □ excluded or □ 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 3.  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.	Coated material, composite, laminate, metal	☐ Flammable							
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Test (10993-18) Questionnaire may be required for protocol preparation.									
ection B: Extraction Method Selections:  N/A OR as selected below									
	ection 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:									
☐ 121°C – 1 hour ☐ 70°C – 24 hour ☐ 50°C – 72 hour ☐ 37°C – 72 hour (requires justification) ☐ Other:	☐ 121°C – 1 hour ☐ 70°C – 24 hour ☐ 50°C – 72 h	our 37°C – 72 hour (requires justification) Other:							
Extraction Media Options (unless otherwise requested by Sponsor):	Extraction Media Options (unless otherwise requester	d by Sponsor):							
☐ Saline & Vegetable Oil (GPMT, Irritation, and Systemic Toxicity tests, unless indicated in "Other" below)									
☐ Saline (Material Mediated Pyrogen test)	☐ Saline (Material Mediated Pyrogen test)								
☐ Saline, Vegetable Oil, 1:20 Alcohol:Saline, & Polyethylene Glycol (USP <88> Class VI plastics testing)									
☐ Phosphate Buffered Saline (PBS) (ASTM Hemolysis Test)	Other:								
	☐ Other:								
	∐ Other:								
		i7> or ISO 10993-5):							
Other:	Extraction Methods for Elution Cytotoxicity Test (USP <8	37> or ISO 10993-5):							
Other:  Extraction Methods for Elution Cytotoxicity Test (USP <87> or ISO 10993-5):	Extraction Methods for Elution Cytotoxicity Test (USP <8 • Extraction Condition/Media Options:	·							
□ Other:  Extraction Methods for Elution Cytotoxicity Test (USP <87> or ISO 10993-5):  • Extraction Condition/Media Options:	Extraction Methods for Elution Cytotoxicity Test (USP <8  Extraction Condition/Media Options:  37°C – 24 hour in Serum Supplemented MEM (for dev	rices with contact < 24 hours)							
□ Other:  Extraction Methods for Elution Cytotoxicity Test (USP <87> or ISO 10993-5):  Extraction Condition/Media Options:  □ 37°C – 24 hour in Serum Supplemented MEM (for devices with contact < 24 hours)	Extraction Methods for Elution Cytotoxicity Test (USP <8  Extraction Condition/Media Options:  37°C – 24 hour in Serum Supplemented MEM (for dev	rices with contact < 24 hours) rices with contact ≥ 24 hours)							
<ul> <li>Other:</li> <li>Extraction Methods for Elution Cytotoxicity Test (USP &lt;87&gt; or ISO 10993-5):</li> <li>Extraction Condition/Media Options:</li> <li>37°C - 24 hour in Serum Supplemented MEM (for devices with contact &lt; 24 hours)</li> <li>37°C - 72 hour in Serum Supplemented MEM (for devices with contact ≥ 24 hours)</li> </ul>	Extraction Methods for Elution Cytotoxicity Test (USP <8  Extraction Condition/Media Options:  37°C – 24 hour in Serum Supplemented MEM (for dev	rices with contact < 24 hours) rices with contact ≥ 24 hours)							
<ul> <li>Other:</li> <li>Extraction Methods for Elution Cytotoxicity Test (USP &lt;87&gt; or ISO 10993-5):</li> <li>Extraction Condition/Media Options:</li> <li>37°C - 24 hour in Serum Supplemented MEM (for devices with contact &lt; 24 hours)</li> <li>37°C - 72 hour in Serum Supplemented MEM (for devices with contact ≥ 24 hours)</li> </ul>	Extraction Methods for Elution Cytotoxicity Test (USP <8  Extraction Condition/Media Options:  37°C - 24 hour in Serum Supplemented MEM (for dev 37°C - 72 hour in Serum Supplemented MEM (for dev 121°C - 1 hour 70°C - 24 hour 50°C - 72 hour	rices with contact < 24 hours) rices with contact ≥ 24 hours) our in Saline with justification							
<ul> <li>Other:</li> <li>Extraction Methods for Elution Cytotoxicity Test (USP &lt;87&gt; or ISO 10993-5):</li> <li>Extraction Condition/Media Options:         <ul> <li>37°C - 24 hour in Serum Supplemented MEM (for devices with contact &lt; 24 hours)</li> <li>37°C - 72 hour in Serum Supplemented MEM (for devices with contact ≥ 24 hours)</li> <li>121°C - 1 hour</li></ul></li></ul>	Extraction Methods for Elution Cytotoxicity Test (USP <8  Extraction Condition/Media Options:  37°C – 24 hour in Serum Supplemented MEM (for dev 37°C – 72 hour in Serum Supplemented MEM (for dev 121°C – 1 hour 70°C – 24 hour 50°C – 72 hour	rices with contact < 24 hours) rices with contact ≥ 24 hours) our in Saline with justification							
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<u>Toxicology and/or Biocompatibility Specific Test Requirements</u> (Continued from page 2; to be completed where applicable):								
Section C: Direct Contact Method Selections: N/A OR as selected below								
Cytotoxicity (Direct Contact Test)								
☐ Sensitization (Closed Patch Test)								
☐ Skin Irritation Test								
☐ ASTM Hemolysis								
☐ Implantation Evaluation:** ☐ Histopathology (required per ISO 10993-6) ☐ 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).								
Section D: Sponsor Authorization for testing, sign/date below:								
Reports will be released by email unless otherwise requested.								
		Internal Use Only						
Sponsor Authorization	Date	Received By	Date					
Unless other arrangements have been made, p		Approved By	Date					
are net 30, prices are FOB Canyon Labs Roche								
valid for 6 months after acceptance of the quote	the quote.	Test Number(s):						
		Test numbers verified by:						
		Initial/date						
		GLP Study No(s):						
		(if applicable)						