



A Pharmaceutical Development Company.

EXTRACTABLES/LEACHABLES PROJECT INITIATION FORM

CLIENT INFORMATION:

Contact Name:		Salutation (Mr., Ms., Dr.):	
Title:		Company Name:	
Mailing Address:		City, State, Zip Code:	
Phone #:		Fax #:	
Email address:		Company website:	

NATURE OF WORK:

<input type="checkbox"/> cGMP	<input type="checkbox"/> non cGMP
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<input type="checkbox"/> Method Development	<input type="checkbox"/> Feasibility	<input type="checkbox"/> Compendial <381>
<input type="checkbox"/> Method Validation	<input type="checkbox"/> Stability	<input type="checkbox"/> Other: _____
<input type="checkbox"/> Method Optimization	<input type="checkbox"/> Analytical Chemistry	_____
<input type="checkbox"/> Method Transfer	<input type="checkbox"/> Compendial <661>	

PRODUCT INFORMATION:

Name of Product: Product Description: (# of strengths / # of lots) Placebo included? <input type="checkbox"/> Y <input type="checkbox"/> N	Product Matrix <input type="checkbox"/> Tablet <input type="checkbox"/> Capsule <input type="checkbox"/> Powder <input type="checkbox"/> Solution <input type="checkbox"/> Suspension <input type="checkbox"/> MDI <input type="checkbox"/> Nasal <input type="checkbox"/> Inhalation Solution <input type="checkbox"/> Other (please describe) _____ _____	Development Phase <input type="checkbox"/> Pre-IND <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> FDA Approved <input type="checkbox"/> Other (please describe) _____
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TECHNICAL BACKGROUND:

<input type="checkbox"/> Container Closure DMF
<input type="checkbox"/> Previous Work at Irvine
<input type="checkbox"/> Special Equipment Needs? Identify _____

TIME FRAME:

Requested Start Date:		End Date:	
Standard Time Frame:	Method Development 4 – 6 Weeks	Method Validation 6 – 8 Weeks	

PROJECT DETAILS:

Critical compounds to determine:	_____
Components of container closure:	_____
Extraction Conditions:	_____
Methods include:	<input type="checkbox"/> USP <381> <input type="checkbox"/> USP <661> <input type="checkbox"/> Other: _____



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Limits include:

Compound	LOD	LOQ
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

SAFETY INFORMATION:

Hazardous Yes No Unknown DEA Controlled No X I II III IV V
 If yes, list type(s): _____
 Mass/volume to be sent: _____ Please attach MSDS (required).
 Special Handling Requirements: _____

REFERENCES, PROTOCOLS, AND MATERIALS:

•Compendial Method Reference: _____
 •Client Method Reference: _____
 •Method Development Protocol: Author: Client Irvine SOP: Client Irvine
 •Method Validation Protocol: Author: Client Irvine SOP: Client Irvine
 •Degradation Products: _____
 •Impurities: _____
 •Formulation Ingredients: _____
 •Placebo: _____

STANDARDS, COLUMNS, AND RAW DATA:

Reference Standards provided by: Client Irvine * Notes: _____
 Reference Standards characterized by: Client Irvine * _____
 Columns provided by: Client Irvine * _____

* Project specific materials, purchased through Irvine Pharmaceutical Services, will be charged to Client at Irvine invoiced price

QUALITY ASSURANCE:

Full QA Review Peer Review Other: _____

FINAL REPORT:

Irvine Template Client Template Other: _____

TECH TRANSFER:

Back to client To Irvine AC Other: _____

DISPOSAL OF SAMPLES:

Standard (30 days post report):
 Special Handling (return to client):
 Attention: _____ Client Shipping Account Number: _____
 Address: _____

ADDITIONAL NOTES (attach other pages as needed):

Empty rectangular box for additional notes.