

LC/MS & GC/MS 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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PROJECT TYPE:

<input type="checkbox"/> LC/MS	<input type="checkbox"/> GC/MS
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<input type="checkbox"/> Method Development	<input type="checkbox"/> Feasibility	<input type="checkbox"/> Compendial
<input type="checkbox"/> Method Validation	<input type="checkbox"/> Stability	<input type="checkbox"/> Other: _____
<input type="checkbox"/> Method Optimization	<input type="checkbox"/> AC	_____
<input type="checkbox"/> Method Transfer	<input type="checkbox"/> Release	

PRODUCT INFORMATION:

Name of Product:	Product Matrix	Development Phase
Product Description: (# of strengths / # of lots)	<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) _____ _____ _____	<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) _____ _____
Placebo included? <input type="checkbox"/> Y <input type="checkbox"/> N		

TECHNICAL BACKGROUND:

<input type="checkbox"/> Physical and Chemical Properties
<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:

Available method or literature reference:	_____ _____ _____
Preferred detector (EI or CI):	_____ _____ _____
Preferred LOD or LOQ:	_____ _____ _____

Other Information:

Analytical Parameters to be evaluated:

- | | |
|--|--|
| <input type="checkbox"/> Linearity | <input type="checkbox"/> Intermediate Precision |
| <input type="checkbox"/> Accuracy | <input type="checkbox"/> System Suitability |
| <input type="checkbox"/> Precision | <input type="checkbox"/> Limit of Detection |
| <input type="checkbox"/> Range | <input type="checkbox"/> Limit of Quantification |
| <input type="checkbox"/> Repeatability | <input type="checkbox"/> Solution Stability |
| <input type="checkbox"/> Specificity | <input type="checkbox"/> Selectivity |
| <input type="checkbox"/> Robustness (please describe parameters):
_____ | <input type="checkbox"/> Other (please describe):
_____ |
| _____ | _____ |
| _____ | _____ |

Other Information:

Approximate Concentration: _____

Approximate pKa: _____

Functional Groups / Related Structures : _____

Chromatographic conditions: _____

MS settings, mode and m/z: _____

SAFETY INFORMATION:

Hazardous Yes No Unknown DEA Controlled No I II III IV V

If yes, list type(s): _____

Mass/volume to be sent: _____ Please attach MSDS (required).

Special Handling Requirements: _____

REFERENCES, PROTOCOLS, MATERIALS, ETC.:

•Compendial Method Reference:		
•Client Method Reference:		
•Method Development Protocol:	Author: Client <input type="checkbox"/> Irvine <input type="checkbox"/>	SOP: Client <input type="checkbox"/> Irvine <input type="checkbox"/>
•Method Validation Protocol:	Author: Client <input type="checkbox"/> Irvine <input type="checkbox"/>	SOP: Client <input type="checkbox"/> Irvine <input type="checkbox"/>
•Degradation Products:		
•Impurities:		
•Formulation Ingredients:		
•Placebo:		

STANDARDS, COLUMNS, AND RAW DATA:

Reference Standards provided by:	<input type="checkbox"/> Client	<input type="checkbox"/> Irvine *	Notes: _____
Reference Standards characterized by:	<input type="checkbox"/> Client	<input type="checkbox"/> Irvine *	_____
Columns provided by:	<input type="checkbox"/> Client	<input type="checkbox"/> Irvine *	_____

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



A Pharmaceutical Development Company.

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):

Large empty rectangular box for additional notes.