

REFERENCE STANDARD CHARACTERIZATION 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"/> Extend to Stability
<input type="checkbox"/> Method Feasibility	<input type="checkbox"/> Extend to AC
<input type="checkbox"/> Method Validation	<input type="checkbox"/> Other (please describe)
<input type="checkbox"/> Method Optimization	

PRODUCT INFORMATION:

Name of Product:	Product Matrix	Development Phase
Product Description: (# of strengths / # of lots)	<input type="checkbox"/> DPI	<input type="checkbox"/> Pre-IND
	<input type="checkbox"/> Nasal	<input type="checkbox"/> I
	<input type="checkbox"/> Powder	<input type="checkbox"/> II
	<input type="checkbox"/> Solution	<input type="checkbox"/> III
	<input type="checkbox"/> Suspension	<input type="checkbox"/> FDA Approved
	<input type="checkbox"/> Other (please describe)	<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	

R&D DETAILS:

Method Development Characteristics: <input type="checkbox"/> Method will be provided by client Type of Method: <input type="checkbox"/> Assay <input type="checkbox"/> Gel <input type="checkbox"/> Related Substances <input type="checkbox"/> Identification <input type="checkbox"/> Stability-Indicating <input type="checkbox"/> CE <input type="checkbox"/> Preservative <input type="checkbox"/> Inorganic Residues <input type="checkbox"/> CE <input type="checkbox"/> Other:	Method Validation Characteristics: <input type="checkbox"/> Linearity <input type="checkbox"/> System Suitability <input type="checkbox"/> Accuracy <input type="checkbox"/> Intermediate Precision <input type="checkbox"/> Precision <input type="checkbox"/> Limit of Detection <input type="checkbox"/> Range <input type="checkbox"/> Limit of Quantification <input type="checkbox"/> Specificity <input type="checkbox"/> Standard (Sample) solution stability <input type="checkbox"/> Robustness <input type="checkbox"/> Other (please describe):
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A Pharmaceutical Development Company.

SAFETY INFORMATION:

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

REFERENES, PROTOCOLS, MATERIALS:

•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

QUALITY ASSURANCE:

<input type="checkbox"/> Full QA Review <input type="checkbox"/> Peer Review <input type="checkbox"/> Other: _____

FINAL REPORT:

<input type="checkbox"/> Irvine Template <input type="checkbox"/> Client Template <input type="checkbox"/> Other: _____

TECH TRANSFER:

<input type="checkbox"/> Back to client <input type="checkbox"/> To Irvine AC <input type="checkbox"/> Other: _____

DISPOSAL OF SAMPLES:

Standard (30 days post report): <input type="checkbox"/>	
Special Handling (return to client): <input type="checkbox"/>	
Attention: _____	Client Shipping Account Number: _____
Address: _____	

ADDITIONAL NOTES (attach other pages as needed):