

INHALATION/NASAL 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
<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 Description: (# of strengths / # of lots) Placebo included? <input type="checkbox"/> Y <input type="checkbox"/> N	Product Matrix <input type="checkbox"/> DPI <input type="checkbox"/> MDI <input type="checkbox"/> Inhalation Solution <input type="checkbox"/> Nasal <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"/> 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

STUDIES TO BE PERFORMED:

<input type="checkbox"/> Dose Delivery	<input type="checkbox"/> Moisture Determination	<input type="checkbox"/> Aerodynamic Particle Size Distribution
<input type="checkbox"/> Guidance Testing	<input type="checkbox"/> Dehydrated Alcohol Content	<input type="checkbox"/> Andersen Cascade Impactor
<input type="checkbox"/> Droplet Size Determination	<input type="checkbox"/> Leak Rate	<input type="checkbox"/> Marple Miller Impactor
<input type="checkbox"/> Net Content (Fill) Weight	<input type="checkbox"/> Spray Pattern	<input type="checkbox"/> Multi-staged Liquid Impinger
<input type="checkbox"/> Drug Content Assay	<input type="checkbox"/> Plume Geometry	<input type="checkbox"/> Next Generation Impactor
<input type="checkbox"/> Spray Content Uniformity	<input type="checkbox"/> Impurities and Degradation Products	<input type="checkbox"/> Others: _____

SAFETY INFORMATION:

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

REFERENCES, PROTOCOLS, AND 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: _____
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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):