



A Pharmaceutical Development Company.

PREFORMULATION/FORMULATION 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"/> AAA	<input type="checkbox"/> Extend to Stability
<input type="checkbox"/> GC/MS	<input type="checkbox"/> Extractables/Leachables	<input type="checkbox"/> Preformulation
<input type="checkbox"/> LC/MS	<input type="checkbox"/> Method Validation	<input type="checkbox"/> Formulation
<input type="checkbox"/> ELISA	<input type="checkbox"/> Cleaning Validation	<input type="checkbox"/> API Characterization
<input type="checkbox"/> CE	<input type="checkbox"/> Method Optimization	<input type="checkbox"/> Other (please describe)
<input type="checkbox"/> Gel Electrophoresis	<input type="checkbox"/> Method Feasibility	

PRODUCT INFORMATION:

Name of Product: Product Description: (# of strengths / # of lots) Placebo included? <input type="checkbox"/> Y <input type="checkbox"/> N	<table style="width: 100%;"> <tr> <td style="width: 33%;">Product Matrix</td> <td style="width: 33%;">Development Phase</td> </tr> <tr> <td><input type="checkbox"/> DPI <input type="checkbox"/> Nebulized <input type="checkbox"/> MDI</td> <td><input type="checkbox"/> Pre-IND</td> </tr> <tr> <td><input type="checkbox"/> Nasal</td> <td><input type="checkbox"/> I</td> </tr> <tr> <td><input type="checkbox"/> Lyophile</td> <td><input type="checkbox"/> II</td> </tr> <tr> <td><input type="checkbox"/> Solution</td> <td><input type="checkbox"/> III</td> </tr> <tr> <td><input type="checkbox"/> Suspension</td> <td><input type="checkbox"/> FDA Approved</td> </tr> <tr> <td><input type="checkbox"/> Capsule/ Tablet</td> <td><input type="checkbox"/> Other (please describe)</td> </tr> <tr> <td><input type="checkbox"/> Other (please describe) _____</td> <td></td> </tr> </table>	Product Matrix	Development Phase	<input type="checkbox"/> DPI <input type="checkbox"/> Nebulized <input type="checkbox"/> MDI	<input type="checkbox"/> Pre-IND	<input type="checkbox"/> Nasal	<input type="checkbox"/> I	<input type="checkbox"/> Lyophile	<input type="checkbox"/> II	<input type="checkbox"/> Solution	<input type="checkbox"/> III	<input type="checkbox"/> Suspension	<input type="checkbox"/> FDA Approved	<input type="checkbox"/> Capsule/ Tablet	<input type="checkbox"/> Other (please describe)	<input type="checkbox"/> Other (please describe) _____	
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API: Crystalline: <input type="checkbox"/> Y <input type="checkbox"/> N Aqueous Solubility: <input type="checkbox"/> Y <input type="checkbox"/> N Value: _____ Hydroscopic: <input type="checkbox"/> Y <input type="checkbox"/> N Stable: <input type="checkbox"/> Y <input type="checkbox"/> N Sensitive to Light: <input type="checkbox"/> Y <input type="checkbox"/> N PKa Value: _____ Salt Form: _____ Finished Dosage Form: _____	Finished Dosage Form: Packaging Configuration: _____ Dosage Form Strength: _____ Excipients: _____																

TECHNICAL BACKGROUND:

<input type="checkbox"/> Physical and Chemical Properties
<input type="checkbox"/> Previous Work at Irvine
<input type="checkbox"/> Special Equipment Needs? Identify _____

ANALYTICAL DEVELOPMENT DETAILS:

<p>Method Development Characteristics:</p> <p><input type="checkbox"/> Method will be provided by client</p> <p>Type of Method:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Assay</td> <td style="width: 50%;"><input type="checkbox"/> Gel</td> </tr> <tr> <td><input type="checkbox"/> Related Substances</td> <td><input type="checkbox"/> Identification</td> </tr> <tr> <td><input type="checkbox"/> Stability-Indicating</td> <td><input type="checkbox"/> SEC</td> </tr> <tr> <td><input type="checkbox"/> Preservative</td> <td><input type="checkbox"/> Inorganic Residues</td> </tr> <tr> <td><input type="checkbox"/> CE</td> <td><input type="checkbox"/> Other:</td> </tr> </table>	<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"/> SEC	<input type="checkbox"/> Preservative	<input type="checkbox"/> Inorganic Residues	<input type="checkbox"/> CE	<input type="checkbox"/> Other:	<p>Method Validation Characteristics:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Linearity</td> <td style="width: 50%;"><input type="checkbox"/> System Suitability</td> </tr> <tr> <td><input type="checkbox"/> Accuracy</td> <td><input type="checkbox"/> Intermediate Precision</td> </tr> <tr> <td><input type="checkbox"/> Precision</td> <td><input type="checkbox"/> Limit of Detection</td> </tr> <tr> <td><input type="checkbox"/> Range</td> <td><input type="checkbox"/> Limit of Quantification</td> </tr> <tr> <td><input type="checkbox"/> Specificity</td> <td><input type="checkbox"/> Standard (Sample) solution stability</td> </tr> <tr> <td><input type="checkbox"/> Robustness</td> <td><input type="checkbox"/> Other (please describe):</td> </tr> </table>	<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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SAFETY INFORMATION:

<p>Hazardous <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/></p> <p>If yes, list type(s): _____</p> <p>Mass/volume to be sent: _____</p> <p>Special Handling Requirements: _____</p>	<p>DEA Controlled No X <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V</p> <p>Please attach MSDS (required).</p>
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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: _____ Address: _____ _____	Client Shipping Account Number: _____
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ADDITIONAL NOTES (attach other pages as needed):