

## STABILITY STUDY INITIATION FORM

### CLIENT INFORMATION:

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

### PURPOSE OF WORK:

<input type="checkbox"/> Stability Protocol Generation	<input type="checkbox"/> Stability Testing	<input type="checkbox"/> Stability Storage
<input type="checkbox"/> Other (please describe):		

### PRODUCT INFORMATION:

<b>Product Name:</b>	<b>Product Lot#:</b>	<b>Product Strength:</b>
<b>Packaging Lot #:</b>	<b>Packaging Type</b>	<b>Purpose of Stability Study</b>
<b>Product Type:</b> <input type="checkbox"/> Tablet <input type="checkbox"/> Suspension <input type="checkbox"/> Capsule <input type="checkbox"/> Solution <input type="checkbox"/> Powder <input type="checkbox"/> Other (please describe):	<input type="checkbox"/> Bottles            # and size: <input type="checkbox"/> Blistered Packs    # and size: <input type="checkbox"/> Boxes                # and size: <input type="checkbox"/> Vials                 # and size: <input type="checkbox"/> Bags                  # and size: <input type="checkbox"/> Other (please describe):	<input type="checkbox"/> R&D <input type="checkbox"/> Pre-IND <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> FDA Approved
<b>Sample Type:</b> <input type="checkbox"/> Drug Substance <input type="checkbox"/> Drug Product <input type="checkbox"/> Placebo	<b>Secondary Package?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <b>Secondary Package Instruction:</b>	<b>Temporary Storage Condition (Before and After the Study)</b> <input type="checkbox"/> Ambient <input type="checkbox"/> Refrigerated(2° to 8°C) <input type="checkbox"/> Frozen (-20°C) <input type="checkbox"/> Protect from light
<b>Storage Orientation:</b> <input type="checkbox"/> Upright <input type="checkbox"/> Inverted <input type="checkbox"/> Tilted <input type="checkbox"/> Other (please describe):		

<b>Initial (Zero) Time Point Data:</b> <input type="checkbox"/> Release Testing <input type="checkbox"/> Assay before stability study	<b>Stability Launch within 30 days of Characterization assay?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No
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### STABILITY TIME POINT:

Weeks	0	1	2	3	6	9	Reserve
# of Samples per Pull							

Months	0	1	2	3	6	9	12	18	24	36	48	60	Reserve
# of Samples per Pull													

Special Scheduled Date e.g. (07/15/2006)													Reserve
# of Samples per Pull													

**STABILITY TESTING DETAILS:**

Analytical Testing:		Microbiology:
<input type="checkbox"/> Appearance <input type="checkbox"/> Disintegration <input type="checkbox"/> Purity <input type="checkbox"/> Potency <input type="checkbox"/> Assay <input type="checkbox"/> Reconstitution Time <input type="checkbox"/> Related Substances <input type="checkbox"/> Loss on Drying <input type="checkbox"/> Melting Point <input type="checkbox"/> Water Content (KF) <input type="checkbox"/> Moisture	<input type="checkbox"/> Dissolution <input type="checkbox"/> Description <input type="checkbox"/> LOD/LOQ <input type="checkbox"/> TGA <input type="checkbox"/> pH <input type="checkbox"/> Particulate matter <input type="checkbox"/> Related Substances/Impurities <input type="checkbox"/> % Label Strength <input type="checkbox"/> Impurity Content <input type="checkbox"/> Optical Rotation <input type="checkbox"/> Other (please describe):	<input type="checkbox"/> Microbial Limits <input type="checkbox"/> Bacterial Endotoxins <input type="checkbox"/> Sterility

**STABILITY STORAGE DETAILS:**

<b>Sample Description:</b>	
<b>Dimension or Size of each sample:</b>	
<b>Number of Samples per batch or Lot:</b>	
<b>Number of Batch or Lot per study:</b>	
<b>Tentative Date of Study Initiation:</b>	
<b>Duration of Study per storage condition:</b>	
<input type="checkbox"/> ICH Storage condition: <b>25°C/60%RH</b> <input type="checkbox"/> ICH Storage condition: <b>30°C/65%RH</b> <input type="checkbox"/> ICH Storage condition: <b>40°C/75%RH</b> <input type="checkbox"/> Storage condition: <b>25°C</b> <input type="checkbox"/> Storage condition: <b>60°C</b> <input type="checkbox"/> Storage condition: <b>5°C</b> <input type="checkbox"/> Storage condition: <b>-20°C</b> <input type="checkbox"/> Storage condition: <b>-30°C</b> <input type="checkbox"/> Storage condition: <b>-70°C</b> <input type="checkbox"/> ICH Special Storage condition: <b>25°C/40%RH</b> <input type="checkbox"/> ICH Special Storage condition: <b>40°C/25%RH</b>	<input type="checkbox"/> Photostability Option II Storage (Detailed Description)  <input type="checkbox"/> Special Storage Condition Request (Detailed Description)

**OOS:**

<b>Type of communication preferred (email, phone etc.):</b>	<b>Who to contact for OOS:</b>	<b>Phone number/e-mail for OOS:</b>
SOP for OOS <input type="checkbox"/> Irvine <input type="checkbox"/> Client		

**SAFETY INFORMATION:**

Hazardous <input type="checkbox"/> Yes 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):	
Quantity and type of containers to be sent:	Please attach MSDS (required).
Special Handling Requirements:	



A Pharmaceutical Development Company.

**REQUIRED REFERENCES AND DOCUMENTS:**

Stability Protocol: Author: Client <input type="checkbox"/> IAL <input type="checkbox"/>	Raw Data Package Required: Yes <input type="checkbox"/> No <input type="checkbox"/>
Testing Methods Reference: Author: Client <input type="checkbox"/> IAL <input type="checkbox"/> USP <input type="checkbox"/>	Issue Report for Storage Condition: Yes <input type="checkbox"/> No <input type="checkbox"/>

**DISPOSAL OF SAMPLES:**

Standard (30 days post report): <input type="checkbox"/> Specific Date <input type="checkbox"/> : Special Handling & Attention: Address to be shipped to:	Return Samples to client require : Yes <input type="checkbox"/> No <input type="checkbox"/> Client shipping account number:
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**ADDITIONAL NOTES (attach other pages as needed):**