

STABILITY STUDY REQUEST FORM



Stability Protocol Number: _____

Step 1: Client Information

Date: _____ Requested by: _____

Company: _____ Avatar Client Code: _____

Contact: _____ Email: _____

Phone: _____ Fax: _____

Step 2: Complete and Check applicable Product Information

Product <input type="checkbox"/> Intermediate <input type="checkbox"/> DS <input type="checkbox"/> DP <input type="checkbox"/>	Lot #	Desired Start Date:
Type of Stability Study		
<input type="checkbox"/> Reconstitution <input type="checkbox"/> Photo <input type="checkbox"/> Real time: Temp.: _____ <input type="checkbox"/> Accelerated: Temp.: _____ <input type="checkbox"/> Other (describe): _____		
Amounts: <input type="checkbox"/> DP (____ vials) <input type="checkbox"/> DS (____) <input type="checkbox"/> Intermediate: _____ <input type="checkbox"/> Other: _____		

Step 3: Fill out the Storage and Test Schedule, Page 3.

Identify special instructions, such as reconstitution, dilution schemes, method; attach additional sheets, if necessary.

Step 4: Check Protocol Tests required for Stability Study. Attach additional sheets, if necessary.

(X)	Chemical Test	Method Reference	(X)	Micro Test	Method Reference
	Appearance			General Safety	
	Assay			LAL	
	Completeness and Clarity of Solution			Pyrogen	
	Dissolution			Sterility	
	% Moisture			Total Plate Count (TPC)	
	Osmolality			Yeast/Molds (Y/M)	
	pH			Other:	
	Purity				
	Related Substances				
	Tm				
	USP Particulates				
	UV				
	Viscosity				
	Other:				
			(X)	Immunogenicity Test	Method Reference
				ELISA	

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Step 5: Stability Protocol

Stability Protocol Creation and Stability Study Approvals	
Protocol Initiated by: _____	Date: _____
Documentation Change Request form or Client Document Transfer Form completed. Fill in Stability Protocol Number in headers of request form. Date: _____ Initials: _____	
Protocol Approved: Date: _____	Initials: _____
Stability Study: <input type="checkbox"/> Approved Study Scheduled: _____ (Quarter/Year) <input type="checkbox"/> Not Scheduled. Reason: _____	
Final Approval for Stability Study: _____ Laboratory Manager	Date: _____

Step 6: Sample Distribution Verification

Samples placed in chambers on (date/time): _____ By: _____

Chambers used (Record temperature and humidity at time of placement):			
Chamber Equipment I.D.	Temperature (°C)	Relative Humidity (%)	Number of Samples

Reviewed By: _____ Date: _____

QA Review: _____ Date: _____

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Step 7: Storage and Test Schedule

Station	Position	Initial	1	2	3	6	9	12	18	24	36	Reserve(s)	Total vials/cond./orient.
PULL DATE =>													
-20°C	Upright												
	Inverted												
4°C	Upright												
	Inverted												
25°C/60%RH	Upright												
	Inverted												
30°C/60%RH	Upright												
	Inverted												
30°C/65%RH	Upright												
	Inverted												
40°C/75%RH	Upright												
	Inverted												
Photo Stability													
Total Vials/study													

Active Ingredient: _____ Container - closure system: _____ Claim: _____

Store at _____°C upon pulling prior to testing Requested final disposition of material: _____