

AMERICAN TESTING LAB	American Testing Lab. (ATL) Stability Study Requisition	PRO-011-5 Version 1 Effective date : 2018-01-09
--------------------------------	---	--

Client Information
 (Notice: Please fill all the boxes)

Company Name :	Address :
Contact Name	City/ State :
Email :	Country :
Phone :	Fax:

Section I: Product Information
 (Notice: Please fill all the boxes)

Product Name :				
Req#	Lot#	Code#		
Product Type :	Drug <input type="checkbox"/>	NHP <input type="checkbox"/>	Other (Specify) <input type="checkbox"/>	

Test Name	Method	Specification

AMERICAN TESTING LAB	American Testing Lab. (ATL) Stability Study Requisition	PRO-011-5 Version 1 Effective date : 2018-01-09
--------------------------------	--	--

Section II: STABILITY TESTING

(Notice: This testing shall to be carried out on a single batch of a drug substance)

Batch / LOT	
Strength	
Container	
Number of Containers	
I have Provided ATL with enough containers to perform the stability Study. ATL is not responsible for shortage of containers during the study.	
Yes <input type="checkbox"/> No <input type="checkbox"/>	

Analytical test procedures		
Includes Analytical test procedures validation	Yes <input type="checkbox"/>	Quote No:
	Not required for this study. <input type="checkbox"/>	
Includes Analytical test procedures stability-indicating verification	Yes <input type="checkbox"/>	Quote No:
	Not required for this study. <input type="checkbox"/>	

Type of Stability Study				
	Conditions	Minimum storage period	Total time period	Requested
Long-term Study	25°C ± 2°C 60% RH ± 5%	12 Months		Yes <input type="checkbox"/> No <input type="checkbox"/>
Accelerated Study	40°C ± 2°C 75% RH ± 5%	6 Months		Yes <input type="checkbox"/> No <input type="checkbox"/>
Intermediate condition	30°C ± 2°C 60% RH ± 5%	12 Months		Yes <input type="checkbox"/> No <input type="checkbox"/>

AMERICAN TESTING LAB	American Testing Lab. (ATL) Stability Study Requisition	PRO-011-5 Version 1 Effective date : 2018-01-09
--------------------------------	--	--

	5%			
Custom Study				Yes <input type="checkbox"/> No <input type="checkbox"/>
Comment				
Perform additional testing at an intermediate condition when a significant change occurs during accelerated testing point in one of the following cases:				
				Perform additional testing
5 percent potency loss from the initial assay value of a batch.				Yes <input type="checkbox"/> No <input type="checkbox"/>
Any specified degrading exceeding its specification limit.				Yes <input type="checkbox"/> No <input type="checkbox"/>
The product exceeding its pH limits.				Yes <input type="checkbox"/> No <input type="checkbox"/>
Dissolution exceeding the specification limits for 12 capsules or tablets (USP Stage 2).				Yes <input type="checkbox"/> No <input type="checkbox"/>
Failure to meet specifications for appearance and physical properties (e.g., color, phase separation, resuspendability, delivery per actuation, caking, hardness)				Yes <input type="checkbox"/> No <input type="checkbox"/>

Study															
Test															

AMERICAN TESTING LAB	American Testing Lab. (ATL) Stability Study Requisition	PRO-011-5 Version 1 Effective date : 2018-01-09
--------------------------------	--	--

Study															
Test															

Client Signature

Date :

<div>ATL Section</div> <div>Received by :</div> <div>Date :</div>	
---	--