ANNEXURE – I : STABILITY STUDY PROTOCOL

Company Logo Here **XX PHARMACEUTICALS LIMITED** **117 Adams Street, Brooklyn, NY 11201, USA**

ANNEXURE – I : STABILITY STUDY PROTOCOL	
Product Name :	Protocol Number :
Generic Name & Strength:	Version Number : Page Number :

Issue Date :	Effective Date :	Supersedes: None

Protocol Review and Approval

	Name	Designation	Sign & Date
Prepared By			
Checked By			
Agreed By			
Approved By			

Revision Details

Sl No	Version Number	Effective Date	Change History

Distribution List

1. **Purpose of the study :**
2. **Scope of the Study :**
3. **Definition**
4. **Responsibility**

Role	Responsibility

5. **Study Design**
6. **Batch size determination**
7. **Number of batches under design**

Batch Number	Batch Size	Mfg Date	API Source	Primary Packing Material

8. **Composition of the product**

Name Of the Material	Spec	Unit Qty	Source
Active Pharmaceutical Ingredient			
Excipients			
Coating Material			

9. **Packing materials**

Batch Number	Primary Packing Material	Source

10. Stability Storage Conditions

Stability Storage Conditions for this product will be as below

Name	Storage Condition	Test Frequency	Batches Number
Accelerated	40°C±2°C & 75%RH±5%RH		
Long Term	30°C±2°C & 65%RH±5%RH		

11. Specification and acceptance criteria

Sl No	Test Parameters	Specification	Acceptance Criteria

12. Test methods of the relevant test

13. Matrixing & Bracketing

Batch Number	Time Points (Month)		
	Initial	03 Month	06 Month

Batch Number	Time Points (Month)						
	Initial	03	06	09	12	18	24

14. Test Frequency and Number of sample

Batch Number	Time Points (Month) Storage Condition: 40°C±2°C & 75%RH±5%RH		
	Initial	03 Month	06 Month

Batch Number	Time Points (Month) Storage Condition: 30°C±2°C & 65%RH±5%RH						
	Initial	03	06	09	12	18	24

15. Number of Sample to be stored at specific condition

Batch Number	Storage Condition		
	40°C±2°C & 75%RH±5%RH	30°C±2°C & 65%RH±5%RH	Total sample

16. Sample withdrawal plan

Frequency of Testing (in Month)	**Withdrawal Dates**		**Batch Number**	
	Accelerated	**Long Term**	**Accelerated**	**Long Term**
Storage Date				

17. Significant change criteria

18. Data evaluation procedure

19. Stability study report

20. Labeling