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

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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

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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

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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

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