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XX PHARMACEUTICALS LIMITED

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ANNEXURE – VII : STABILITY STUDY REPORT

Product Name :	Protocol Number :
Generic Name & Strength:	Version Number :
	Page Number :

Issue Date :	Effective Date :	Supersedes:

Report 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

Prepared by :	**Checked by** :

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1. **Purpose of the study :**
2. **Scope of the Study :**
3. **Number of batches under design**

   Number of batches and their details are as follows

Batch Number	Batch Size	Mfg Date	API Source	Primary Packing Material

4. **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		

5. **Specification and acceptance criteria**

Sl No	Test Parameters	Specification	Acceptance Criteria

2. **Test methods of the relevant test**

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3. Data Presentation

Batch Number	Storage Condition	Specifications	Results		
			Initial Result	03 Month Result	06 Month Result
	Accelerated				
	Accelerated				
	Accelerated				
Batch Number	**Storage Condition**	**Specifications**	**Results**		
			03 Month Result	**06 Month Result**	**09 Month Result**
	Long Term				
	Long Term				
	Long Term				
Batch Number	**Storage Condition**	**Specifications**	**Results**		
			12 Month Result	**18 Month Result**	**24 Month Result**
	Long Term				
	Long Term				
	Long Term				

4. Significant change criteria

5. Data evaluation procedure

6. Labeling

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