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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

SI No	Version Number	Effective Date	Change History

Distribution List

Prepared
by :

Checked
by :

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

SI No	Test Parameters	Specification	Acceptance Criteria

2. Test methods of the relevant test

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