

ANNEXURE – XII : PHOTOSTABILITY STUDY REPORT OF DEVELOPMENT BATCH

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Product Name :		Protocol Number :	
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Protocol 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 :
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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	Fluorescent Lamp	UV energy	Batches Number

5. Specification and acceptance criteria

Specifications of this product are as follows. This specification and acceptance criteria are the shelf life acceptance criteria which may differ from release specification and acceptance criteria.

SI No	Test Parameters	Specification	Acceptance Criteria

6. Test methods of the relevant test

7. Data Presentation

Batch Number	Storage Condition	Specifications
	NLT 1.2 million lux hour & NLT 200 watt hours/square meter	
	NLT 1.2 million lux hour & NLT 200 watt hours/square meter	
	NLT 1.2 million lux hour & NLT 200 watt hours/square meter	
	NLT 1.2 million lux hour & NLT 200 watt hours/square meter	

8. Tests done**9. Stability study report****10. Labeling**