FORCED DEGRADATION STUDY PROTOCOL

1.0 DOCUMENT PREPARATION AND APPROVAL:

Preparation and Approval of this Forced Degradation Study protocol will be joint responsibility of the following functional area. Any modification in this document shall be documented and approved.

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY CONTROL)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY CONTROL)			
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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Protocol No.:	**Product Name :**	**Date of Issue:**
Revision No.:	**Method/STP No.:**	**Effective Date:**

- PURPOSE :----------

- SCOPE :----------
- SITE OF THE STUDY :----------
- RESPONSIBILITY :
- PARAMETERS TO BE COVERED:
- **Degradation Conditions:**

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- EXPERIMENTAL DESIGN :----------

- ACCEPTANCE CRITERIA:----------

- OBSERVATIONS:----------

- CONCLUSION :

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Chromatographic Conditions

Name of the Instrument:	
HPLC ID:	
Instrument/Equipment ID:	
Flow rate: **Injection Volume:**	
Wavelength:	
Mobile Phase Detail:	
Column Detail/ID:	

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Test Solution Preparations Details

System Suitability Preparation	
Standard Preparation	
Test Preparation	
Placebo Preparation	

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Experimental Design

a) FOR AS SUCH SAMPLE DEGRADATION STUDY:

1. **Photolysis :**

2. **Exposure to elevated temperature (80°C) :**

b) DEGRADATION OF SAMPLE IN SOLUTION FORM

1. **Acid hydrolysis**:

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Experimental Design

2. Base hydrolysis :

3. Oxidation:

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Experimental Design

Details of Chemicals/Solvents /Working Standard Used

S.No.	Name of the chemical/Solvent	Batch No.

SR.No	Name of WS/Reference Standard	Batch No/A.R no.

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Experimental Design

Chromatographic conditions :

Preparation of buffer solution :

Mobile Phase Preparation :

Preparation of Blank solution :

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Preparation of 0.1 M NaOH/1.0 M NaOH/0.1 M HCL/1.0 M HCL/H_2O_2: