PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Preparation of Stability Protocol	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for preparation of stability protocols for stability study of Drug Products.

2.0 SCOPE:

This SOP is applicable for preparation of stability protocols for Stability Study of Drug Products manufactured.

3.0 RESPONSIBILITY :

3.1 Preparation - Executive QC.

3.2 Checking - Assistant Manager QC.

3.3 Approval - Manager QC / QA

4.0 PROCEDURE:

4.1 After the receipt of the specification & Standard Test Procedure PRC/CQA/QA , QC Executive shall prepare the stability protocol as per Annexure – I.

4.2 Stability protocol shall be prepared as per following guidelines.

4.2.1 All the protocols shall be written in clear, unambiguous language, easy to understand and easy to follow.

4.2.2 Required test of the protocol shall be described in details.

4.2.3 Each protocol shall have a unique number. Once a number is allotted to any protocol the same number shall not be repeated to other protocol.

4.2.4 Protocol number shall be alphanumeric and having ten characters which are as follows.

NUMBERING SYSTEM			
CHARACTER	**SYMBOL**	**CHARACTER**	**SYMBOL**
1st Character	S	7th Character	/
2nd Character	S	8th Character	N
3rd Character	P	9th Character	N
4th Character	/	10th Character	N
5th Character	Y		
6th Character	Y		

Where:-

First three characters “SSP” indicates Stability Study Protocols

4th and 7th characters are separators

5th and 6th characters indicate current year in two digits

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8^{th}, 9^{th} & 10^{th} characters are serial No. start from 001

For example: First stability protocol prepared in 2023 shall be numbered as SSP/23/001. Only year will change and serial number will continue for the stability protocol prepare in next years.

4.3 Stability protocol shall be prepared by executive, checked by Assistant Manager and approved by Manager QC and Manager QA.

4.4 After initiation, approval and authorization of protocol, the master copy shall be submitted to QA documentation cell.

4.5 QA department shall issue the photocopy of the master copy by stamping on the back side of each page as "OPERATIONAL COPY FOR PHOTOCOPYING"

4.6 Take a photocopy of operational copy for usage purpose.

4.7 Maintain the issuance record of stability protocols as per Annexure-II.

4.8 Stability protocols shall be reviewed whenever any change in specification or in testing procedure amended by the pharmacopoeia or any other relevant source.

4.9 Any change in protocols shall be done as per change control procedure.

4.10 After revision master copy of data sheet shall be submitted to QA documentation cell for control and issuance.

5.0 SAFETY AND PRECAUTION:

Not Applicable.

6.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

7.0 REFERENCES:

Not Applicable.

8.0 ABBREVIATIONS:

SOP : Standard Operating Procedure

CQA : Corporate Quality Assurance

QA : Quality Assurance

Dept. : Department

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No. : Number

QC : Quality Control

A.R. No.: Analytical report number

RM : Raw Material

Sr. No.: Serial number

9.0 ANNEXURE:

Annexure –I	:	Data sheet Format for Stability Protocol
Annexure – II	:	Issuance Record of Stability Protocol

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Annexure- I

DATA SHEET FORMAT FOR STABILITY PROTOCOL

	PROTOCOL FOR STABILITY STUDY	Page no. 1 of Y
NAME OF PRODUCT :		
STRENGTH :		

PRODUCT DETAILS	
Generic Name:	Batch No:
Shelf Life :	Batch Size:
Storage Condition:	Sample Quantity:
Stability Type:	Date of Stability study started:
Stability Interval :	Test Request Slip No:

SPECIFICATION DETAILS	**STANDARD TEST PROCEDURE DETAILS**
Specification No : Effective date : Revision No :	STP as per : STP No :
PROTOCOL DETAILS	
Protocol No. : Effective date : Revision No. :	Issued by : Issued date :

	PREPARED BY	**CHECKED BY**	**APPROVED BY**	
Signature / Date				
Name				
Department	**QUALITY CONTROL**	**QUALITY CONTROL**	**QUALITY CONTROL**	**QUALITY ASSURANCE**

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	PROTOCOL FOR STABILITY STUDY	Page no. 2 of Y
NAME OF PRODUCT :		
STRENGTH :		

Test Name :

Instrument ID. No. :

Analysed by **Checked by**

	PROTOCOL FOR STABILITY STUDY	Page no. Y of Y
NAME OF PRODUCT :		
STRENGTH :		

STABILITY DATA:

S.No.	TESTS	SPECIFICATION	RESULTS

Analysed by & Date

Checked by & Date

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Annexure-II

ISSUANCE RECORD OF STABILITY PROTOCOL

S.No.	Name of Product	Batch No.	Stability Station	Issued By/Date	Remarks