PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Procedure for the Storage and Destruction of Control Samples of Raw Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 Objective:

To lay down a procedure for the storage and destruction of control samples of raw materials.

2.0 Scope:

This procedure is applicable at Quality Control department.

3.0 Responsibility:

Officer / Executive -QC	: Shall be responsible for storage and destruction of the control samples of Raw materials
Head-QC / Designee	: Shall be responsible for compliance of this SOP.

4.0 Abbreviations and Definitions:

SOP	: Standard Operating Procedure
QC	: Quality Control
QA	: Quality Assurance
HDPE	: High Density Polyethylene

5.0 Procedure:

5.1 The control sample for solid raw materials (i.e. excipients and active ingredients) shall be drawn at the time of sampling and enter the material details in the control sample inward register as per the Annexure-1.

5.2 The control sample of solid raw material is shall be stored in a HDPE bottles with label as per the Annexure-2.

5.3 All the liquid raw material shall be kept for the purpose of controlled sample except, solvents, volatile substances and gases.

5.4 The Control sample room should be away from fumes, chemicals and direct sunlight. The room should be secured and provided with a Hygrometer for the recording of temperature on daily basis as shown in the Annexure-3.

5.5 The control samples of raw materials are to be stored at the temperature not more than 27°C.

5.6 Control sample shall be destroyed if the material does not comply to the specification.

5.7 Control sample quantity shall be twice the quantity necessary to perform all the tests (one time) as per specifications.

5.8 The control samples of raw materials (i.e. excipients and active pharmaceutical ingredients) are to be examined visually every year for the evidence of deterioration or any change in the appearance.

5.9 Any evidence of deterioration is to be brought to the notice and investigated. The results of visual examination of Raw materials are to be recorded in the format shown in Annexure-1. Any abnormality found in the control sample should be informed to Head-QC and Head-QA.

5.10 The control samples of raw materials are to be retained for five years after the expiration date.

5.11 For control samples destruction, prepare list of products to be destroyed and get approval from Head-QC before destruction.

5.12 All control samples shall be destroyed as per the respective SOP.

5.13 If the control sample is to be taken for checking as part of investigation or any market complaint or as per some regularity requirement, the details of the same are to be entered as per the Annexure-4.

6.0 Forms and Records

6.1	Control sample inward record	:	Annexure-1
6.2	Control sample label	:	Annexure-2
6.3	Temperature record	:	Annexure-3
6.3	Record of sample taken	:	Annexure-4

7.0 Distribution

7.1	Master Copy	:	Documentation cell (Quality Assurance)
7.2	Controlled Copies	:	Quality Control, Quality Assurance

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Procedure for the Storage and Destruction of Control Samples of Raw Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

8.0 History:

Date	Revision Number	Reason for Revision

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Procedure for the Storage and Destruction of Control Samples of Raw Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Annexure I

CONTROL SAMPLE INWARD RECORD

S. No	Material Name	Batch No.	A.R. No	Mfg Date	Exp Date	Release Date	Sample Qty	Sample Received by	VISUAL OBSERVATION AFTER												Destroyed By/ Date	Checked By/Date
									1st YEAR		2nd YEAR		3rd YEAR		4th YEAR		5th YEAR		6th YEAR			
									Observation	Checked by & Date	Observation	Checked by & Date	Observation	Checked by & Date	Observation	Checked by & Date	Observation	Checked by & Date	Observation	Checked by & Date		

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Procedure for the Storage and Destruction of Control Samples of Raw Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Annexure II

CONTROL SAMPLE LABEL

Quality Control Department	
Control Sample	
Material Name	
Batch Number	
A.R Number	
Mfg. Name	
Supplier Name	
Mfg. Date	
Exp Date	
Sample Qty.	
Sampled By & Date	
Form No: ……	

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Procedure for the Storage and Destruction of Control Samples of Raw Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE III
TEMPERATURE RECORD

Location:
Month and Year:

DATE	Morning (9.30 am to 10.30 am)		Evening (4.00 pm to 5.00 pm)	
	Temperature Limit: NMT 27°C	**Sign**	**Temperature Limit:** NMT 27°C	**Sign**
01				
02				
03				
04				
05				
06				
07				
08				
09				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				

Reviewed By:
Date:

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Procedure for the Storage and Destruction of Control Samples of Raw Materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE IV
RECORD OF SAMPLE TAKEN

S.No.	Material Name	A.R. No	Mfg Date	Exp Date	Release Date	Qty. Taken	Checked By	Remarks