



**Title:** Shutdown Policy

<b>SOP No.:</b>		<b>Revision No.:</b>	00
<b>Effective Date:</b>		<b>Supersedes No.</b>	Nil
<b>Review Date:</b>		<b>Page No.</b>	1 of 4

**1.0 OBJECTIVE:**

To lay down a procedure for shutdown of area or system or equipment.

**2.0 SCOPE:**

This SOP is applicable for shut down work to be carried out.

**3.0 RESPONSIBILITY:**

**Concern User Department** : Department Manager –Intimation to all sections

**QA** : Review and approval for execution

**4.0 ACCOUNTABILITY:**

Head QA

**5.0 ABBREVIATIONS:**

Ltd. Limited  
Pvt. Private  
ER Engineering  
SOP Standard Operation Procedure

**6.0 PROCEDURE:**

- 6.1** Establish a system of prior approval for shutdown activity to be performed in an area or on any equipment / Utility.
- 6.2** Concern area / equipment in charge will initiate the intimation of the shutdown activity.
- 6.3** Establish a system for evaluation of pre and post shutdown necessary activities are to be performed before production start and to be documented.
- 6.4** The respective area manager is responsible for evaluation of shutdown activity and nature of work to be performed in his area along with risk assessment procedure as per SOP.
- 6.5** Initiator shall raise the planned deviation for same along with risk assessment, pre evaluation & post evaluation action plan and should be marked to all committee members.
- 6.6** The pre information shall be acknowledged as per Annexure-I. All committee members (cross functional department) shall review the details and shall be approved by Head - QA.



# PHARMA DEVILS

ENGINEERING DEPARTMENT

**Title:** Shutdown Policy

<b>SOP No.:</b>		<b>Revision No.:</b>	00
<b>Effective Date:</b>		<b>Supersedes No.</b>	Nil
<b>Review Date:</b>		<b>Page No.</b>	2 of 4

**6.7** Training shall be provided to all concerns person for risk assessment, pre evaluation & post evaluation with protocol based study as per SOP.

**6.8** After resuming of shutdown of pre-post area / equipment / utilities, QA shall verify the all recommended post activities. If all recommended post activities found satisfactory than routine activities shall be carried out as per respective procedures.

**6.9** The post information shall be acknowledged as per Annexure-I. All committee members (cross functional department) shall review the details and shall be approved by Head - QA.

## **7.0 ANNEXURES:**

<b>ANNEXURE No.</b>	<b>TITLE OF ANNEXURE</b>	<b>FORMAT No.</b>
Annexure – I	Information / Acknowledgement Record For Facility Shut Down	

**ENCLOSURES:** SOP Training Record.

## **8.0 DISTRIBUTION:**

- Controlled Copy No. 01      Quality Assurance
- Controlled Copy No. 02      Quality Control
- Controlled Copy No. 03      Engineering
- Master Copy                      Quality Assurance

## **9.0 REFERENCE:**

Not Applicable.

## **10.0 REVISION HISTORY:**

### **CHANGE HISTORY LOG**

<b>Revision No.</b>	<b>Change Control No.</b>	<b>Details of Changes</b>	<b>Reason for Change</b>	<b>Effective Date</b>	<b>Updated By</b>



# PHARMA DEVILS

ENGINEERING DEPARTMENT

**Title:** Shutdown Policy

<b>SOP No.:</b>		<b>Revision No.:</b>	00
<b>Effective Date:</b>		<b>Supersedes No.</b>	Nil
<b>Review Date:</b>		<b>Page No.</b>	3 of 4

## ANNEXURE – I INFORMATION / ACKNOWLEDGEMENT RECORD FOR FACILITY SHUTDOWN

<b>Block</b>		<b>Section</b>	
<b>Reference Document No.</b>		<b>Proposed Closing TCD</b>	

**Details of Shutdown:**

---

---

---

---

---

**Pre Information/Acknowledgement:-**

S.No.	Name	Designation	Department	Signature & Date

**Approved By**  
**Head – QA**  
**(Sign. / Date)**



# PHARMA DEVILS

ENGINEERING DEPARTMENT

**Title:** Shutdown Policy

**SOP No.:**

**Revision No.:**

00

**Effective Date:**

**Supersedes No.**

Nil

**Review Date:**

**Page No.**

4 of 4

**Post Information/Acknowledgement:-**

S.No.	Name	Designation	Department	Signature & Date

**Approved By**  
**Head – QA**  
**(Sign. / Date)**