



PHARMA DEVILS

ENVIRONMENT HEALTH SAFETY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Compliance Obligations

SOP No.:		Department:	EHS
		Effective Date:	
Revision No.:		Revision Date:	
Supersede Revision No.:		Page No.:	1 of 6

1.0 OBJECTIVE:

To lay down a procedure for fulfillment of Compliance Obligations.

2.0 SCOPE:

This SOP is applicable for the all Environmental Legislative Laws, Regulations and Policies relevant to products, activities and services.

3.0 RESPONSIBILITY:

Officer / Executive - EHS

4.0 ACCOUNTABILITY:

Head – EHS

5.0 ABBREVIATIONS:

EMS	Environmental Management System
EMR	Environmental Management Review
EMP	Environment Management Plan
HR	Human Resource
IER	Initial Environmental Review
Ltd	Limited
LOR	Legal & Other Requirements
MOEF	Ministry of Environment and Forest
No.	Number
OCP	Operation Control Plan
PCB	Pollution Control Board
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 IDENTIFICATION:

6.1.1 EMS core team shall obtain copies of Acts/Rules/Notification from all related agencies, internet or any other source.

6.1.1.1 Regulatory websites.

6.1.1.2 Corporate Legal Cell.

6.1.1.3 Any other source.



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6.1.2 Review the regulatory & legislative requirements, identify those relevant and applicable to our operations and include in **Annexure-I**, Titled “**List of Applicable Legislations**”.

6.1.3 Disseminate and communicate the information to relevant agencies including justification for its applicability; and sharing the changes in review meetings.

6.1.4 If applicable to our operations then interact with concerned personnel, and review existing data. Action plans (EMP/OCP) to ensure compliance in given time frame if not doing so and act to Revise Aspect / hazard register if required as per new /revised requirements.

6.1.5 Make a new legal register in case of new regulation or Update the existing register whenever there is any change/updation of relevant Acts/Rules /Regulations/terms of permits/consent and applicable company targets/threshold limits.

6.1.6 Observations of any legal authority during plant inspection/visits shall be communicated to all concerned including unit Head EHS and Plant/Functional heads will ensure that all observations are complied. The legal authorities may include:

6.1.6.1 Factory Inspectorate.

6.1.6.2 Electrical Inspectorate.

6.1.6.3 Inspection by Explosives Department.

6.1.6.4 MOEF/PCB Authorities.

6.1.6.5 Ground water Authorities.

6.1.6.6 Any other consultant etc.

6.2 ACCESS:

6.2.1 Original copy of LOR shall be maintained by HR Department.

6.2.2 Reference copy will be disseminated through e-mail or electronic file by EMS LOR coordinator to reduce papers, energy and other printing materials.

6.2.3 Any controlled copies shall be requested from QA department.



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6.3 EVALUATION OF COMPLIANCE:

- 6.3.1** EHS Departments will check compliance with LOR and the level of such compliance will be indicated in the LOR Matrix.
- 6.3.2** Use external agencies for testing of conditions with known Legal standard as appropriate.
- 6.3.3** LOR shall be periodically checked for compliance, as a minimum, shall do it yearly.
- 6.3.4** Lists of LOR with due dates may be used to check if all requirements are met based on the set deadlines and regulations.

6.4 NON-COMPLIANCE:

- 6.4.1** Re-test shall be done and Corrective Action will be taken for Minor Non-Compliance.
- 6.4.2** For Major and continuous Non-conformance, it shall be considered in setting the Objectives and Targets.

6.5 PERIODIC CHECK FOR NEW, REVISED LEGAL AND OTHER REQUIREMENTS:

- 6.5.1** To update LOR Matrix, EHS or any designated persons by the EMR shall regularly check for new revisions of existing LOR. EHS shall do it once a year.
- 6.5.2** In the event of major changes in the interim, LOR shall be updated.
- 6.5.3** EHS may approach any of the following for access to new/revised regulations:
 - 6.5.3.1** Directly to the agency
 - 6.5.3.2** Newspapers
 - 6.5.3.3** Consultants
 - 6.5.3.4** Websites
- 6.5.4** EHS will review and check if the new or revised LOR are applicable. If applicable, requirements will be reviewed and cascaded by EHS for implementation and compliance.



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6.6 INFORMATION DISSEMINATION:

6.6.1 Information regarding LOR shall be disseminated to all affected Departments through Electronic files.

7.0 REFERENCES:

7.1 ISO 14001:2015 Environmental Management System (EMS)–Requirements with guidance for use.

7.2 Environmental Protection Act 1986 & Uttar Pradesh Factory Act.

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	List of Applicable Legislations	
Annexure-II	Compliance Obligations Matrix	

ENCLOSURES: SOP Training Record

9.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Environment, Health & Safety
- Master Copy Quality Assurance

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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ANNEXURE – I LIST OF APPLICABLE LEGISLATIONS

S.No.	Legislation	Remarks
1.	The Factories Act, 1948	
2.	The Indian Electricity Rules ,1956	
3.	The Environmental (Protection) Act, 1986, Rules 1986	
4.	The Water (Prevention & Control of Pollution) Act 1981	
5.	The Air (Prevention & Control of Pollution) Act 1981	
6.	Noise Pollution (Regulation and Controls) Rules 2000	
7.	Ozone Depleting Substances Rules,2000	
8.	Indian Explosives Act 1884, Petroleum Act 1934 and Rule 1970	
9.	The Static Mobile Pressure Vessels(Unfired) Rules,1981	
10.	Central Motor Vehicle Rules,1989	
11.	Gas Cylinder Rules.1981	
12.	The Batteries(Management & Handling) Rules 2001	
13.	The Public Liability Insurance Act 1990 and Rules 1991	
14.	The MSI of Hazardous Chemical Rules, 1989	
15.	The Hazardous Wastes (Management & Handling) Rules, 1989	

