STANDARD OPERATING PROCEDURE				
TITLE: Non Conformity, Corrective & Preventive Action				
SOP No.:		**Department:**	EHS	
		Effective Date:		
Revision No.:		**Revision Date:**		
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1.0 OBJECTIVE:

To ensure that corrective and preventive actions are implemented by concerned authorities and there is a systematic follow-up to ensure their effectiveness.

2.0 SCOPE:

This SOP is applicable to describe the procedure to the responsibility and authority for handling and investigating actual and potential non-conformance and for taking action to mitigate any negative impact it causes and for initiating and completing corrective and preventive actions at ……

3.0 RESPONSIBILITY:

The responsibility for assuring that this procedure is implemented lies with all division and department heads. The responsibility to follow-up the effectiveness of the corrective and preventive actions taken shall be with the, EMS Audit Team and the concerned division and department heads.

4.0 ACCOUNTABILITY:

Head-EHS

5.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
Ltd.	Limited
SH	Environment Health & Safety
No.	Number
QA	Quality Assurance
IT	Information Technology
QC	Quality Control
EMS	Environmental Management System
EMR	Environmental Management Review
NCR	Non Conformity Report
TCD	Tentative Completion Date

6.0 PROCEDURE:

Identification of Problems:

6.1.1 The first step is to identify the problems to eliminate the root of actual and potential non-conformities which can originate from sources such as:

6.1.1.1 Monitoring and measurement of environmental activities which where identified to have had significant aspects and impacts;

6.1.1.2 Periodic auditing of the environmental management system;

6.1.1.3 Market feedback;
6.1.1.4 Feedback from government agencies and concerned parties;

6.1.1.5 Result of the review of company's compliance to legislative and regulatory requirements; and

6.1.1.6 Other methods of review.

6.1.2 Identified problems shall be communicated to concerned personnel in order to start the investigation and the formulation of corrective and preventive actions. Described below are some of the problems that may arise and the people who are responsible in dealing with each:

6.1.2.1 Problems related to manufacturing activities - Concerned Production Department head, Production Engineering depending on the extent of the problem observe.

6.1.2.2 Non-conformities arising from non-compliance to legal and regulatory requirements – Pollution Control Officer and concerned Department Head/s.

6.1.2.3 Non-conformities observed in the environmental management system – Management Representative and all concerned department heads.

6.1.2.4 Problems related to building and facilities administration (e.g. waste disposal, power generation, etc.) – Pollution Control Officer and the General Administration department head/s.

6.1.2.5 Problem arising from vendors – Purchasing Department.

6.1.2.6 Market Feedback – The problem shall be forwarded to the department who is responsible for the implementation of action. The procedure on handling external communication shall apply.

6.1.2.7 Potential non-conformities – concerned personnel must provide samples or analysis describing the source and details of the possible non-conformities.

6.2 Method of Correction And Prevention:

6.2.1 The corrective and preventive actions to be taken shall depend on the magnitude of the non-conformance shall be evaluated and treated based on the actual or potential impact it will cause to the environment.

6.2.2 Remedial or temporary corrective actions can be implemented if the situation calls for it in order to minimize the effect of the problem. However, study should be made to come up with permanent solution to the problem.

6.2.3 All changes made in the documented procedures due to the corrective and preventive actions shall be recorded and implemented. Procedure on document control shall be followed

6.2.4 Procedures, specifications, instructions, etc., that were affected by the implementation of the action plan shall be revised to reflect the changes made (if any) in these documents and distributed to all concerned. Document control.

6.3 Recording and Transmittal:

6.3.1 Corrective and Preventive actions to be taken shall be recorded and disseminated to all concerned. There may be other areas where similar problems may occur. The Department head concerned shall be responsible to ensure that the action plan has been implemented and monitored and is effective

6.4 Follow-Up:

6.4.1 Follow-up action is conducted to ensure that the correction has been completed and is effective. Follow-ups can be done in several ways.

6.4.1 Through continuous monitoring of the activity or process;

6.4.2 Through system audits;

6.4.3 Through checking of documents and records; and

6.4.4 Through feedback reports.

6.4.5 Non-Occurrence of the problem will indicate that the actions taken were effective. However, recurrence means that further investigation is required to come up with a better solution.

6.5 Reporting:

6.5.1 Major Non-Conformance shall be discussed during the EMS Committees Management Review.

7.0 REFERENCES:

- ISO 14001:2004 Environmental Management System (EMS) – Requirements with guidance for use

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Non-Conformance Report	
Annexure-II	Non-Conformance and Corrective Action Register	

9.0 DISTRIBUTION:

- Controlled Copy No.1 — Head Personnel & Administration
- Controlled Copy No.2 — Head Production
- Controlled Copy No.3 — Head Quality Control
- Controlled Copy No.4 — Head Information Technology
- Controlled Copy No.5 — Head Warehouse
- Master Copy — Quality Assurance Department

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By
00	New SOP	Introduction of New SOP		

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ANNEXURE–I

PHARMA DEVILS
ENVIRONMENT HEALTH SAFETY DEPARTMENT

NON CONFORMANCE REPORT

Department		**Date**	
NCR No.			
Category			
Copies To:	**1.**	**2.**	**3.**
Detail of NCR:			
QA Executive / Officer		**Head QA**	
Cause of NCR:			
Corrective Action Proposed:			
QA Officer / Executive:		**Date:**	
Corrective Action Taken:			
Concerned Executive / Officer Signature		**Date:**	
Progress Review:			
Concerned Department Head:		**QA Officer / Executive**	
Date:		**Date:**	
Remarks:			
		QA Head	
NCR Closed / TCD Revised **QA Head**			

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PHARMA DEVILS
ENVIRONMENT HEALTH SAFETY DEPARTMENT

NONCONFORMANCE AND CORRECTIVE ACTION REGISTER

NCR No.	Date Reported	Location	Responsible Person	Problem Encountered	Date Action Completed	Corrective Action Date Completed	NCR Closure Date