

ENVIRONMENT HEALTH SAFETY DEPARTMENT

#### STANDARD OPERATING PROCEDURE

**TITLE:** Environmental Aspect & Impact

SOP No.:	Department:	EHS
	<b>Effective Date:</b>	
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#### 1.0 OBJECTIVE:

To lay down a procedure for Environmental Aspect & Impact.

#### 2.0 SCOPE:

This SOP is applicable for the Environmental Aspect and Impact that are relevance to all of the products, activities, and services.

#### 3.0 RESPONSIBILITY:

Officer / Executive - EHS

#### 4.0 ACCOUNTABILITY:

Head – EHS

### **5.0 ABBREVIATIONS:**

SOP Standard Operating Procedure

Ltd Limited No. Number

EMS Environmental Management System
EMR Environmental Management Review

IER Initial Environmental Review

CER Continuous Environmental Representative ISO International Organization for Standardization

RPN Risk Priority Number

#### **6.0 PROCEDURE:**

#### **6.1 ENVIRONMENTAL ASPECT IDENTIFICATION:**

The Organization shall identify its environmental aspects by undertaking two approaches:

#### 6.1.1 BY MEANS OF AN INITIAL ENVIRONMENTAL REVIEW (IER):

The purpose is to consider all environmental aspects of the organization as a basis for setting up objectives and targets for selected significant aspects. This is also done to establish the organization's current position regarding the EMS. Prior to the IER, the EMR shall select key personnel who will constitute the EMS Core Team. The EMS Core Team shall be given appropriate guidelines to properly identify environmental aspects and its impacts through the help of consultants. Once equipped with the appropriate knowledge, the EMS Core Team together with the EMR shall conduct the initial Environmental review using the Aspect / Impact Matrix Form.

#### 6.1.2 BY MEANS OF CONTINUOUS ENVIRONMENTAL REVIEW (CER):

As opposed with IER, which is a one-time event, CER is multi-event, which means it can be conducted anytime. Identification of environmental aspects by means of CER is done when any of the following exists:



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### **6.1.2.1** Expansion projects.

- **6.1.2.2** Planned and new product developments and new or modification of the following:
  - Products
  - Processes
  - Equipment
  - Raw Materials
- **6.1.2.3** Revision of ISO 14001 standard.
- **6.1.2.4** New or revised legal and other requirements.

Members of the EMS Core Team shall conduct CER. Results coming from these two approaches shall be recorded using the Environmental Aspect Impact Matrix and to be forwarded to the EMS Core Team for evaluation.

Suitable methods to conduct IER may include checklist, interviews, direct inspection and measurement. The process to identify environmental aspects and associated with the activities within the organization should, where relevant, consider:

- Emissions to air
- Releases to water (leakage or spillage)
- Waste and by-products
- Contamination of land
- Use of raw materials and natural resources.
- Past accidents and incidents
- Health hazards
- Other local Environmental and community issues.
- Subcontractor activities

The above considerations shall also be used when grouping the environmental aspects according to their nature. (E.g. Aspect = smoke coming from generator; Nature = emissions to air or Air Emissions).

#### **6.2 ENVIRONMENTAL ASPECT EVALUATION:**

After the environmental aspects have been identified and recorded to the Aspect / Impact Matrices these shall be forwarded to the EMS Core Team which in turn shall evaluate environmental aspects that have or can have significant impacts.



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The EMS Core Team shall, when evaluating the significant aspects, do the following:

**6.2.1** Group the environmental aspects according to their nature form.

#### **6.2.2** Assessment:

**6.2.2.1 Severity of the Impact**: In rating the severity, the planning committee shall consider Environmental Consequences based on the aspects identified. Using the Environmental Aspect Matrix, the EMS Core Team will tally Environmental Consequences considered and rank them for their severity.

	SEVERITY				
1	Positive impact on environment thus positive impact on business.				
2	Limited and/or localized impact on the environment and/or business				
3	Reversible impacts, wider implications to environment and/or business				
4	Serious long term implications for environment and/or business				
5	Serious permanent damage to the environment and/or business				

#### 6.2.2.2 PROBABILITY:

Rate the Occurrence of the aspect in terms of its frequency of generation, incident / accident, consumption, exposure, usage, amount, etc. When rating the occurrence the Core team should consider normal operating conditions, abnormal conditions (i.e. shut down & startup), as well as the realistic potential significant impacts associated with reasonably foreseeable or emergency situations.

Probability				
1	Maybe as a result of extraordinary events leading to an environmental incident			
2	Maybe as a result of a chain of unusual events leading to an environmental incident			
3	Maybe as a result of a little used operated process, activity or occurrence.			
4	Maybe as a result of a frequently used operated process, activity or occurrence.			
5	Maybe as a result of a continuously operated process, activity or occurrence.			

#### **6.2.2.3 ESTABLISH THE LEVEL OF SIGNIFICANCE:**

Level of significance can be determined using the Risk Priority Number (RPN).

 $RPN = (Severity \times Probability)$ 

- High Risk ~ if RPN is greater than the set limit based on the aspects rated.15-25
- Medium Risk ~ if RPN is within the range of the set limit based on the aspects rated. 10-15



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■ Low Risk ~ if RPN is below the range of the set limit based on the aspects rated 1-10 Consider all high risks in setting the objectives and targets and in establishing management programs.

Any aspects or hazards that are covered by any regulatory requirements shall be considered as High Risk.

EMS Core Team shall review and make the corresponding changes on the environmental aspect and impact on a regular basis or at least twice a year to determine other aspects that can still be considered in setting objectives, targets and programs and operational controls and previously identified significant aspects new rating.

#### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Work sheet for identification of environmental aspects	
Annexure-II	Aspect and Impact Matrix	
Annexure-III	Environmental Aspect and their Impacts	

#### 8.0 DISTRIBUTION:

• Controlled Copy No.01 Head EHS

Master Copy
 Quality Assurance Department

#### 9.0 REFERENCES:

➤ ISO 14001:2004 Environmental Management Systems (EMS) – Requirements with guidance for use.

#### 10.0 REVISION HISTORY:

#### **CHANGE HISTORY LOG**

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



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### ANNEXURE – I



## PHARMA DEVILS

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## WORKSHEET FOR IDENTIFICATION OF ENVIRONMENTAL ASPECTS

	ENVIRONMENTAL ASPECTS								
Activity	Consumption of Goods	Consumption of Energy	Consumption of Water	Storage, use and release of chemicals / dangerous goods	n of Waste	Generation of Traffic	Generation of Noise	Emissions to Air	Release to Water/Soil



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### ANNEXURE – II



## PHARMA DEVILS

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### ASPECT AND IMPACT MATRIX

Activity	Aspect	Impact	Severity	Probability	Risk/ Significance



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### ANNEXURE – III



## PHARMA DEVILS

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## ENVIRONMENTAL ASPECT AND THEIR IMPACTS

Activity Impact	Admin	Warehouse	Production	Use of Amenities	QC Lab	DG Set Operation	Boiler Operation	Maintenance Equipments
Air Pollution								
Storm water Consumption								
Ground water contamination								
Soil Contaminatio								
Waste Disposal								
Consumption of natural resources								
Accoustic inspection staff and community								
Public Annoyance /Nuisance								