CHAPTER 7.0: RISK ASSESSMENT AND DISASTER MANAGEMENT

7.0 Introduction

M/s. Aurobindo Pharma Limited, Unit I proposed to expand the production capacity of existing Bulk Drugs and Bulk Drug Intermediates manufacturing plant at Sy. No. 379, 385, 386, 388 to 396 & 269, Borapatla(V), Hathnoora Mandal of Medak District in Telangana. The site is situated Between $17^0$40'01.1" N Latitude and $17^0$40'21.1" N Latitude and $78^0$10'21.4" East Longitude and $78^0$10'41.0" East Longitude. The total land area of the plant is 71.0 acres.

7.1 Objectives and Scope

The production of Bulk Drugs and Drug Intermediates involves usage of many chemicals which are both hazardous and non-hazardous in nature. Risk analysis has been carried out to identify the hazardous materials and quantify the hazards to arrive at safe disaster management plan and emergency preparedness plan for storage and handling of the potentiality hazardous material also. The purpose of carrying out risk assessment study for **M/S. Aurobindo Pharma limited, Unit I.** Industries is to obtain clearance from the Ministry of Environment and forests (MOEF) which calls for a study on nature of hazards due to proposed location of process and storage units and also to study whether any accident, if occurs, leads to any off-site disaster. In this endeavour, the study objectives are outlined here under.

1. **Hazard identification and Visualization of Maximum Credible Accident Scenarios.**

To identify major hazards relating to fire, explosion and toxicity due to chemicals, processes and storages of the proposed units.

2. **Hazard Analysis and Risk Assessment**

Hazard analysis is the process of determining the release probabilities and quantities, emission or release rates, the routes/pathways by which the released substances could reach the receptors, the fate of the substances in

environmental media through which they are transported or moved and the characteristics of the receptors at risk.

3. Disaster Management

To provide guidelines for Disaster Management Plan(DMP) for on-site emergencies and Emergency Preparedness Plan(EPP) for off-site emergency, based on above 1& 2 studies of proposed plant.

7.2 Hazard Analysis and Risk Assessment

7.2.1 Introduction

Hazard analysis is the process of determining the release probabilities and quantities, emission or release rates, the routes/pathways by which the released substances could reach the receptors, the fate of the substances in environmental media through which they are transported or moved and characteristics of the receptors at risk. The basis of risk estimation is to determine the dose-effect relationship between an indicator chemical and receptor. Estimation of risk follows only when the hazard analysis shows a frequency or occurrence, which is significant.

Risk evaluation is the process of identifying, whether the estimated level of risk is tolerable. Tolerable risk is not equated with acceptability; it refers to a willingness to live with a risk so as to secure certain risk benefits, and in the confidence that the risk is being properly controlled.

Hazard analysis involves the identification and quantification of the various hazards (unsafe conditions) that exist in the plant. On the other hand, risk analysis deals with the identification and quantification of risks, the plant equipment and personnel are exposed to, due to accidents resulting from the hazards present in the plant.

Hazard and risk analysis involves very extensive studies, and requires a very detailed design and engineering information. The various hazard analysis techniques that may be applied are hazard and operability studies, fault-tree analysis, event-tree analysis and failure and effects mode analysis.

Risk analysis follows as extensive hazard analysis. It involves the identification and assessment of risks; the neighbouring populations are

exposed to as a result of hazards present. This requires a thorough knowledge of failure probability, credible accident scenario, vulnerability of population's etc. Much of this information is difficult to get or generate. Consequently, the risk analysis is often confined to maximum credible accident studies.

The common terms used in risk Assessment and Disaster Management are elaborated below:

"Risk" is defined as a likelihood of an undesired event (accident, injury or death) occurring within a specified period or under specified circumstances. This may be either a probability depending on the circumstances.

The term **"Hazard"** is defined as a physical situation, which may cause human injury, damage to property or the environment or some combination of these criteria.

"Hazardous substance" means any substance or preparation, which by reason of its chemical or physic chemical properties or handling is liable to cause harm to human beings, other living creatures, plants, micro-organisms, property or the environment.

"Hazardous process" is defined as any process or activity in relation to an industry which may cause impairment to the health of the persons engaged or connected therewith or which may result in pollution of their general environment.

"Disaster" is defined as a catastrophic situation that causes damage, economic disruptions, loss of human life and deterioration of health and health services on a scale sufficient to warrant an extraordinary response from outside the affected area are community. Disasters occasioned by man are factory fire explosions and release of toxic gases or chemical substances etc.

"Accident" is an unplanned event, which has a probability of causing personal injury or property damage or both.

"Emergency" is defined as a situation where the resources out pass the demand. This highlights the typical nature of emergency; it will be after

experiences that enough is not enough in emergency situations. Situations of these kinds are avoidable but it is not possible to avoid them always.

In the sections below, the identification of various hazards, probable risks in a process industry manufacturing optical brighteners, maximum credible accident analysis, consequence analysis are addressed which gives a broad identification of risks involved in the plant.

7.2.2 Hazard Identification

Identification of hazards in the synthetic chemicals organic plant is of primary significance in the analysis, quantification and cost effective control of accidents involving flammable compounds. A classical definition of hazard states that hazard is not in fact the characteristic of system/plant/storage that presents potential for an accident. Hence, all the components of a system/plant/process need to be thoroughly examined to assess their potential for initiating or propagating an unplanned event/sequence of events which can be termed as an accident.

Typical schemes of predictive hazard evaluation and quantitative risk analysis suggest that hazard identification step plays a key role. Estimation of probability of an unexpected event and its consequences from the basis of quantification of risk in terms of damage to property, environment or personal. Therefore, the type quantity, location and conditions of release of a toxic or flammable substance have to be identified in order to estimate its damaging effects, the area involved, and the possible precautionary measures required to be taken.

Some of the hazard identification procedures are as follows:

1. Fire Explosion and Toxicity Index(FETI) Approach;
2. HAZOP studies
3. Maximum Credible Accident and Consequence Analysis(MCACA);

7.2.3 Hazards Related to Materials

The manufacturing capacities of the proposed products are presented in **Table 7.1** and Raw Material inventory is presented in **Table 7.2**

Table 7.1

Manufacturing Capacity of Proposed Products

S. No.	Name of the Product	Quantity in TPM
1	Amisulpride	0.50
2	Aripiprazole	0.50
3	Atorvastatin	4.00
4	BisprololFumarate	0.50
5	Bupropion HCl	0.50
6	Candesartan Cilexetil	1.00
7	Cefaclor Monohydrate	1.00
8	Cefadroxil	3.00
9	Cefalothin Acid	2.00
10	Cefazolin Sodium	3.00
11	Cefdinir	2.50
12	CefditorenPivoxil	0.50
13	CefepimeHCl	2.00
14	CefiximeTrihydrate	1.50
15	Cefotaxime	3.00
16	Cefoxitin Sodium	0.50
17	CefpiromeDihydroiodide	0.20
18	CefpodoximeProxetil	3.00
19	Cefprozil	3.00
20	Cefradin	2.00
21	Cefsulodin Sodium	0.50
22	CeftazidimeDiHydrochloride	2.00
23	CeftibutenDihydrate	2.00
24	CeftiofurHCl	3.00
25	Ceftizoxime Acid	0.50
26	Ceftriaxone Disodium Hemiheptahydrate	3.00
27	Cefuroxime Axetil	23.50
28	Cephalexin Monohydrate	15.00
29	CephapirinBenzathine	0.50
30	Ciprofloxacin HCl	7.00
31	Citalopram Hydrobromide	2.50
32	Donepezil Hydrochloride	0.50
33	DoxazosinMesylate	0.50
34	Entacapone	3.00
35	Escitalopram Oxalate	2.00
36	Famciclovir	2.00
37	Florfenicol	5.00
38	Fluvastatin	0.50
39	Gabapentin	40.00
40	Gemfrozil	10
41	Glyburide	2.50

42	Irbesartan	5.00
43	Lamivudine	1.00
44	Lisinopril	1.00
45	Losartan Potassium	5.00
46	Metformin HCl	200.00
47	Metoprolol Succinate	2.00
48	Metoprolol Tartrate	10.00
49	Mirtazapine	2.00
50	Modafinil	1.00
51	Nevirapine	5.00
52	Ondansetron	0.20
53	Pantoprazole Sodium Sesquihydrate	3.00
54	Paroxetine HCl	3.00
55	Perindopril tert-Butylamine	0.50
56	Rabeprazole Sodium	0.50
57	Ritonavir	2.00
58	Ribavirin	0.50
59	Risperidone	0.50
60	SevelamerHCl/Carbonate	1.00
61	Simvastatin	7.00
62	Stavudine	1.00
63	Telmisartan	2.00
64	Terazosin HClDihydrate	0.30
65	TerbinafineHCl	3.00
66	Topiramate	5.00
	Total	**421.20**

Table 7.2

Inventory and hazard characteristics of key raw material

S.No	Raw material	Inventory-MT	Physical form	Type of hazard	Storage method
1	Absolute Alcohol	66.46	Liquid	flammable	Drums
2	Acetic Acid	33.46	Liquid	flammable	Drums
3	Acetic Anhydride	1.08	Liquid	flammable	Drums
4	Acetonitrile	64.20	Liquid	flammable	Drums
5	Acetone	452.46	Liquid	flammable	Tank form
6	Ammonia	42.96	Gas	flammable	Cylinder
7	Boron Trifluoride	2.69	Gas	Non- flammable	Cylinder
8	Bromine	0.25	Liquid	Non- flammable	Drums
9	potassium Hydroxide flakes	0.89	Solid	Non- flammable	Drums
10	Caustic Soda Flakes (Sodium Hydroxide flakes)	1.48	Solid	Non- flammable	Drums
11	Chloro Hexane	51.65	Liquid	flammable	Drums
12	Chloroform	19.30	Liquid	Non-flammable	Tank form
13	Cyclo hexane	181.4	Liquid	flammable	Tank form
14	Di isopropyl Ether	38.68	Liquid	flammable	Drums

15	Diethyl Amine	0.308	Liquid	flammable	Drums
16	Dimethyl Formamide	78.59	Liquid	flammable	Tank form
17	Epichlorohydrine	0.87	Liquid	flammable	Drums
18	Ethyl Acetate	471.86	Liquid	flammable	Tank form
19	HBr	1.08	Liquid	Non- flammable	Glass Bottles
20	Hydrogen Chloride	0.105	Gas	Non- flammable	Cylinder
21	Hexane	29.42	Liquid	flammable	Tank form
22	Hydrochloric Acid	168.67	Liquid	Corrosive	Tank Form
23	Hydrogen	3.16	Gas	Flammable	Cylinders
24	Hydroquinone	0.0007	Solid	Non- flammable	drums
25	Isopropyl Alcohol	275.56	Liquid	flammable	Tank form
26	Methanol	555.53	Liquid	flammable	Tank form
27	Methyl Isobutyl Ketone	5.67	Liquid	flammable	Drums
28	Methylene Chloride	797.57	Liquid	Toxic	Tank form
29	Mono Isopropyl Amine	0.282	Liquid	flammable	drums
30	N-Butanol	28.608	Liquid	flammable	Tank form
31	N-Butylamine	3.31	Liquid	flammable	Drums
32	N-Heptane	29.61	Liquid	flammable	Drums
33	N,N-Di isopropylethylamine	0.15	Liquid	flammable	Drums
34	N,N-Dimethyl Acetamide	66.11	Liquid	Combustible	Drums
35	N,N Dimethyl Formamide	172.66	Liquid	flammable	Drums
36	O-Xylene	127.55	Liquid	flammable	Tank form
37	Paraformaldehyde	0.077	Solid	flammable	Drums
38	Phenol	6.25	Solid	Non-flammable	Drums
39	Phosphoric acid	7.94	liquid	Non-flammable	Drums
41	Phosphorus Pentachloride	0.59	Solid	Non-flammable	Drums
42	Phosphorus Oxychloride	0.64	liquid	Non-flammable	Drums
43	Tributylamine	1.30	Liquid	Combustible	Drums
44	Triethylamine	9.82	Liquid	Flammable	Drums
45	Trimethylamine	0.33	Gas	Flammable	Drums
46	Toluene	279.67	Liquid	flammable	Tank form

7.2.3.1 Hazardous Characteristics of Raw Materials

Out of the total 303 raw materials, 35 chemicals were listed in Part II of Schedule I of MSHIS Rules, 1989. None of the chemical inventories are exceeding threshold quantities listed in schedule III of MSHIS Rules. Out of the 35 chemicals listed bulk storages proposed is only for 14chemicals. List of Hazardous chemicals and Hazardous characteristics of key raw materials are given in **Table 7.3**. List and quantities of bulk Storages proposed at the site are given in **Table 7.4**

Table 7.3

List of Hazardous Chemicals (Listed in Part II of Schedule I)

S.No.	Hazardous Chemicals	Physical Form	Maximum Inventory Kgs/day
1	Acetic Acid	Liquid	1637
2	Acetic Anhydride	Liquid	72
3	Acetone	Liquid	30164
4	Acetonitrile	Liquid	4280
5	Ammonia	Liquid	2864
6	Boron Trifluoride	Liquid	179
7	Chloroform	Liquid	1287
8	Cyclohexane	Liquid	26914
9	DMS	liquid	9
10	Di Methyl Amine Hydrochloride	Liquid	4394
11	Diethylamine	Liquid	20
12	Ethanol	Liquid	44661
13	Ethyl Acetate	Liquid	31457
14	Ethyl Bromide	Liquid	14
15	Hydrogen Gas	Gas	3168
16	Hydrochloric Acid	Liquid	11245
17	Hydroquinone	Solid	0.1
18	Hexane	Liquid	1961
19	Iodine	Liquid	7
20	IPA	Liquid	18371
21	Methanol	Liquid	37035
22	Methylene Chloride	Liquid	53171
23	Methyl Iso butyl Ketone	Liquid	378
24	N-Butanol	Solid	1907
25	Para Formaldehyde	Liquid	5
26	Phenol	Liquid	416
27	Phosphoric acid	Liquid	529
28	Phosphorous Pentachloride	Liquid	39
29	Phosphorus oxychloride	Solid	42
30	Potassium Hydroxide	Solid	194
31	Pyridine	Solid	80
32	Sodium Hydroxide	Liquid	1151
33	Sulphric Acid	Liquid	835
34	TEA	Solid	655
35	Toulene	Liquid	18644

Physical properties& Hazard characteristics of Key Raw materials

S.No	Name of the Material	Boiling point	Flash Point in °C	Explosive Limits volume % in air	NFPA Rating		
					Health	Fire	Reactivity
1	Toluene	110.6	4.4	1.2-6.7	2	3	0
2	Methanol	65.5	16	6.7-36	1	3	0
3	Ethyl acetate	77	7.2	2.2-9.0	1	3	0
4	Ethanol	78	16.6	3.3-19.0	0	3	0
5	Methylene chloride	39.75	-	16-66	2	1	0
6	Isopropyl alcohol	82.5	12.77	2-12.7	1	3	0
7	Caustic soda lye	145	-	-	3	0	1
8	Acetone	55.6	-17.8	2.5-12.8	1	3	0
9	Cyclo Hexane	80.7	-18	1.3-8.4	1	3	0
11	DMS	37	-38	2.2-9.7	2	4	0
13	N-Butanol	117	34	4-11	1	3	0
14	Hexane	68	-23	1.2-7.7	1	3	0

Table 7.4

List of Bulk storages & Quantities proposed

S.No.	Name of the Solvent	Capacity KL	MOC
1	Acetone	170.76	MS
2	Chloroform	30.87	MS
2	Cyclohexane	150.86	MS
3	DMF	90.79	MS
4	Ethanol	91.08	MS
5	Ethyl Acetate	180.84	MS
6	Hexane	31.21	MS
7	Isopropyl Alocohol	77.39	MS
8	Methanol	171.79	MS
9	Methylene Chloride	211.09	MS
10	N-Butanol	52.05	MS
11	O-Xylene	30.87	MS
12	THF	90.79	MS
13	Toluene	62.41	MS
14	Butyl Acetate	14.97	MS

7.3 Fire& Explosion Index (F&EI)

7.3.1 Methodology

Dow Chemical Company issued a guideline for hazard determination and protection. By this method a chemical process unit is rated numerically for hazards. The numerical value used is the Fire and Explosion Index (F&EI) which is most widely used for hazard evaluation in chemical process industries.

The guide applies to process unit only and not to auxiliary units such as power generating stations, plant water systems, control rooms, fired heaters, structural requirements, corrosive nature of material handled and personal safety equipment. These are regarded as basic features that do not vary according to the magnitude of the fire and explosion hazard involved. The guide also does not cover the processing and handling of explosives such as dynamite, TNT etc.

7.3.2 Computation of F&EI

The computation of fire and explosion index of each unit is based on the material factor. This is a measure of the intrinsic rate of potential energy release from fire explosion of most hazardous material or mixture of materials present in significant quantity, whether it is raw material, intermediate, product, solvent etc., by combustion or chemical reaction. "In significant quantity" here means such quantity that the hazard represented by the material actually exists. The Nationality Fire Protection Agency of USA (NFPA) have specified standard values for material factor which should be used for F&EI calculations and are available in DOW's hazard classification guide.in case it is not readily available, it can be calculated using the heat of combustion, flammability indices etc.

General process hazard are factors that play a primary role in determining the magnitude of loss of incident. It takes into account the nature of the reaction, ventilation of the unit, accessibility of the unit, drainage facilities etc., special process hazards are factors that contribute primarily to the probability of a loss incident. They consist of specific process conditions that have shown themselves to be major causes of fire and explosion incidents.

It takes into account toxicity of the material, operatingpressure, operation near flammable range, quantity of material, joints and packing, use of hot oil exchange system etc., The F&EI calculated as a product of material factor, general process hazard factor, and special process hazard factor.

7.3.3 Hazard Ranking

The hazard ranking based on F&EI value is as follows

Table 7.5

Degree of Hazard for F&EI

F&EI Index Range	Degrees of Hazard
1-60	Light
61-96	Moderate
97-127	Intermediate
128-158	Heavy
159 & above	Severe

The estimated values of F&EI reflect light hazard in view of the low volume of chemicals.

The fire and explosion index evaluation can be very useful in developing plant layouts or adding equipment and buildings to existing plants. Evaluation of the F&EI calculations and layout considerations will result a safe operable, maintainable and cost effective arrangement of equipment and buildings.

Table 7.6

Fire & Explosion Index for Tank farm

S. No.	Name of the Solvent	Fire & Explosion Index (F1*F2*MF)	Degree of Hazard
1	Acetone	75.12	Moderate
2	Cyclohexane	85.76	Moderate
3	DMF	27.30	Light
4	Ethanol	62.40	Moderate
5	Ethyl Acetate	66.00	Moderate

6	Hexane	84.48	Moderate
7	Isopropyl Alocohol	65.76	Moderate
8	Methanol	64.80	Moderate
9	Methylene Chloride	27.30	Light
10	N-Butanol	60.00	Light
11	O-Xylene	63.12	Moderate
12	THF	79.60	Moderate
13	Toluene	65.76	Moderate
14	Butyl Acetate	60.00	Light

Table 7.7

Heat Radiation Damage Distances – Tank Farm

S.No	Name of Raw material	Storage Tank Details				Scenario Details				
		Tank Capacity (KL)	No.s	Diameter (m)	Height (m)	Hole Dia (mm)	Release Rate (Kg/sec)	Heat radiation damage distances in m for KW/m2		
								37.5	12.5	4.0
1	Acetone	170.76	6	3.14	5.10	50	8.90	<1	10	18
2	Cyclohexane	150.86	3	3.30	5.60	50	10.35	<1	11	21
3	DMF	90.79	2	3.22	5.28	50	11.15	…	10	16
4	Ethanol	91.08	2	3.22	5.30	50	9.42	<1	10	17
5	Ethyl Acetate	180.84	5	3.22	5.26	50	10.63	<1	12	17
6	Hexane	31.21	1	3.00	4.39	50	5.05	<1	12	21
7	Isopropyl Alocohol	77.39	3	2.78	4.18	50	5.66	…	11	18
8	Methanol	171.79	5	3.02	4.55	50	7.19	<1	11	15
9	Methylene Chloride	211.09	5	3.18	5.06	50	14.52	…	...	11
10	N-Butanol	52.05	2	3.00	4.36	50	6.92	…	12	18
11	O-Xylene	30.87	1	3.00	4.34	50	7.50	…	12	21
12	THF	90.79	2	3.22	5.28	50	10.57	<1	12	20
13	Toluene	62.41	3	2.66	3.96	50	5.31	<1	12	21
14	Butyl Acetate	14.97	1	2.35	3.77	50	4.00	…	11	19

The storage is a small capacity facility and accordingly the F& E index value is found to be moderate reflecting the threshold limits as prescribed in MSHC rules. Both MSHC rules and F & E index indicate that the present facility does not require a detailed risk assessment.

7.4 Hazard and Operability Study (HAZOP)

Safety and reliability of modern processing plant can be improved by using procedures that recognize and eliminate potential problems in the design stage. This is especially important because of the increasing need to operate the different units, for economic reasons, more closely to known risk situations. Hence, it requires refined methods like HAZOP study technique for identifying hazardous situations and problems and eliminating them at the design stage.

Based on process reactions, a list of process reactions were identified for taking additional care precautions and presented in **Table 7.9**

7.4.1 Hazard and Operability Study (HAZOP)

Safety and reliability of modern processing plant can be improved by using procedures that recognize and eliminate potential problems in the design stage. This is especially important because of the increasing need to operate the different units, for economic reasons, more closely to known risk situations. Hence, it requires refined methods like HAZOP study technique for identifying hazardous situations and problems and eliminating them at the design stage.

The HAZOP study technique normally based on a word model. The procedure of conducting the study involves examining the flow sheet or line diagram of the process unit section by section or line by line(depending on the level of detail required)looking for inadequacies in design.

A checklist of guide words is applied to each stage of the process in turn thereby generating deviations opposite of all conceivable eventualities.

Table 7.8

Checklist of guide words in HAZOP

NO,NOT,NONE The activity is not carried out of ceases	No activity or operation takes place. There is no forward flow when should be. A task may not be done, something may not be done, something may not be delivered or be there. There may be no action in response to activating signal. A check is omitted.no catalyst present.
MORE OFF A quantitative increase in an activity	There is more of something. More of any physical quantity than there should be. For example, of Temperature, pressure quantity of flow. More of a task can be carried out.An activity is done for a longer time
LESS OFF A quantity decrease in an activity	There is loss of something present. Less of an activity is carried out. Less time is taken
PART OF Incomplete Performance of an activity	Only part of an action is carried out. There might be a transfer of part of a load or batch. More components or an extra phase or impurities might be present.
REVERSE Inversion of an activity	Something happens backwards. A back siphon occurs. Heating rather than cooling occur. This keyword can also be used to generate ideas as to how to recover from a situation
OTHER(THAN)	A gas X can be sent down the line instead of gas Y.An operator might press the wrong bottom or open the wrong valve. This key word is also used to identify what needs to happen other than normal operation—for example, start-up, shutdown, regeneration, maintenance.
AS WELL AS Another activity occurs as the original activity	Can button A and B pressed only A was meant be pressed? Can both gas X and gas Y be sent down the line? What happens if the operator eats his lunch at the same time as packing cyanide?
SOONER/LATER THAN An activity occurring at the wrong time/relative to others	Every system has its running clock. What happens if task G is done before task K? what if batch reaction is not completed in the normal time

For a major new project the study team should include representatives from production/operation department i.e. production/operations Manager (or designate); from the technical department i.e. project engineer together

with an instrument engineer to advise on the instrumentation and to deal with any control problems and all aspects of plant operation are considered and also force consideration of the unexpected or obscure.

Potential problems as represented by the consequences of the deviation should be evaluated as they arise and a decision reached on whether they merit further consideration or action. Except for major risk areas where a fully quantitative assessment is required this decision is made semi-quantitatively on the consequence (usually scaled as trivial, important or very probable)

There are no temperature and pressure conditions in this process. Hence only flow is considered for the HAZOP. The sheets of HAZOP study are presented below;

7.4.2 HAZOP Work Sheets

Process Parameter: Raw material flow

Table 7.9

HAZOP Work Sheet – Raw Material Flow

S. No	Deviation	Causes	Consequences	Safety Features/Measures	Remarks
1	No Flow	No supply Malfunctioning of pump Power failure	No Reaction	Operation control devices and emergency plant shut down procedure, alarm system etc. Alternative Automatic power source	Inspect Operations Frequently
2	Less Flow	Malfunctioning of pump Malfunctioning of Shut off valve Valve on charging line not opened	Operational trouble in reactors	Operation control devices and emergency plant shutdown procedure, alarm systems etc.	Check the shut off valve. Ensure the feed valve is opened
3	More Flow	Malfunction of control valve	Operational trouble in reactor	Flow regulators, Excess flow diversion devices to Alternative storage or Flare etc.	Flow control devices inspection and examination and maintenance will be continuous

II) Process Parameter: *Pressure*

Table 7.10

HAZOP Work Sheet - Pressure

S.No	Deviation	Causes	Consequences	Safety Features/Measures	Remarks
1	No Pressure	--	--	--	Not Envisaged during operation
2	Low Pressure	Malfunctioning of pump Malfunctioning of Shut off valve Valve on charging line not opened Leakages in pipe line	Operational trouble in reactors	Periodic inspection &Examination, Maintenance Leak detect system Shut off valve Low pressure alarm/indicators shall be provided	Pipe line and flow control devices examined frequently
3	High Pressure	High Temperature Excess supply Malfunction of control valve	Operational trouble in reactor Rupture of pipe line Fire or Explosion	Periodic inspection &Examination, Maintenance Pressure relief system Automatic flow diverter Alternative storage system	Pipe line and flow control devices examined frequently

(III) Process Parameter: *Temperature*

Table 7.11

HAZOP Work Sheet: Temperature

S.No	Deviation	Causes	Consequences	Safety Features/Measures	Remarks
1	No Temperature	--	--	--	Not envisaged during operation
2	Low Temperature	Malfunctioning of Temp. Indicator External cooling	--	Calibration of Temperature indicators, periodic Inspection Examination	Examine the pipe line and control devices working conditions frequently
3	High Temperature	Malfunctioning of Temp.Indicator External fire/Heating	Rupture/ failure in pipe line	Calibration of Temp.Indicator, periodic Inspection Examination Thermal Insulation Around the pipe Radiation Detectors/Sensors will be provided	Examine the pipe line and control devices working conditions frequently

7.4.3 Hazardous Processes identified in the unit

Following process steps are identified as potential process hazards based on temperature, pressure, run away reactions. Below table gives process hazardous identified, mitigative measures suggested and Emergency equipment required at the place of work

Table 7.12

Hazardous Process reactions

S.No	Product	Process stage	Brief process reaction	Potential hazard	Mitigative measures	Emergency equipment installed any
1	Amisulpride	1	4-Amino-5-(ethylsulfonyl)-2-Methoxy benzoic acid is reacted with ethyl chloroformate to yield a mixed anhydride, which is reacted with 2-(Aminomethyl)-1-Ethyl pyrrolidine to obtain Amulsulpride crude. Crude Amlsulpride is purified by recrystallization from acetone to yield pure amusulpride.	Skin burns and fire	Usage of PPE, Nitrogen blanketing, and interlocks for centrifuges	
3	Atorvastatin	1	t-butyl [(4R,6R)-6-cyanomethyl-2,2-dimethyl-1,3dioxan-4-yl] acetate is subjected hydrogenation in rany nickel catalyst and methanolic ammonia	Fire	Adequately designed hydrogenator with safety features	Dump tank as secondary containment. Flame arrestors
4	BisprololFumarate	1	Bisoprolol phenol is treated with epichlorohydrin in presence of sodium hydroxide to produce bisoprolol epoxide	Hazardous decomposition	Steam pressure control to operate in safe limits	Fire hydrant system
5	Citalopram Hydrobromide	1	1-Bromo 4-Flurobenzene is reacted with megesium, to obtain Grignard-1 and similarly n,n-dimethyl 3-chloropropylamine is reacted with magnesium to obtain Grignard-2. 5-Cyanothalide is reacted with Grignard-1 and then Grignard-2 to obtain Citalopram diol	Run away reaction	Controlled addition of reagents, high temperature alarm, high reliable utilities	
6	Donepezil Hydrochloride	2	Dehydrodonepezil is hydrogenated over palladium and charcoal in presence of hydrogen in toluene to yield debenzylated Donepezil	Fire	Adequately designed hydrogenator with safety features	Dump tank as secondary containment. Flame arrestors

7	Escitalopram Oxalate	1	1-Bromo 4-Flurobenzene is reacted with magnesium, to obtain Grignard-1 and similarly n,n-dimethyl 3-chloropropylamine is reacted with magnesium to obtain Grignard-2. 5-Cyanothalide is reacted with Grignard-1 and then Grignard-2 to obtain Citalopram diol	Run away reaction	Controlled addition of reagents, high temperature alarm, high reliable utilities	
8	Famciclovir	2	N-(2-amino-4,6-dichloro-5-pyrimidinyl) formamide is reacted with 4-amino-2-hydroxymethylbutan-1-ol HCl in ethanol and the product is subjected to dechlorination using Pd/C and hydrogen	Fire	Adequately designed hydrogenator with safety features	Dump tank as secondary containment. Flame arrestors
9	Fluvastatin	1	t-Butylacetate is reacted with NaH and n-butyl Lithium in THF and Indole-2E-propenal to t-butyl-3-keto-5-hydroxy fluvastatin	Fire	Operational controls to avoid water ingress into the area. Flame arrestors	
10	Gabapentin	1	1-isocyanatomethyl-1-cyclohexane acetate is hydrolysed by refluxing with aqueous hydrochloric acid in presence of methylene dichloride and acetone medium to give 1-aminomethyl-1-cyclohexane acetic acid hydrochloride	Exothermic reaction	Emergency low temperature cooling system	
11	Gemfibrozil	2	2,5-dimethyl phenol is treated with sodium hydroxide in a mixture of o-xylene and DMSO to get sodium-2,5-dimethyl phenoxide which is reacted with methyl-5-chloro-2,2-dimethyl pentanoate to get gemfibrozil methyl ester which is subjected to alkaline hydrolysis to get gemfibrozil	Exothermic reaction	Emergency low temperature cooling system	
12	Irbesartan	2	Irbesartan nitrile is treated with sodium azide in presence of tributyl tin chloride in o-xylene to afford irbesartan crude	Harmful to skin, eyes &respiratory tract, water reactive	LEV system and scrubber connection	

13	Lamivudine	1	S-I: Lamivudine coupled ester is reduced using sodium borohydride and salt formation with salicylic acid in buffered methylated spirit medium to get lamivudine salicylate	Hydrogen gas liberation and fire	Flame arrestors and suitable electrical fittings	
14	Lisinopril	4	N6-(trifluoro acetyl)-L-Lysyl-L-proline is condensed with ethyl-2-oxo-4-phenyl butyrate in presence of molecular sieves in methanol and resulting imine is concomitantly hydrogenated with hydrogen in presence of raney nickel	Fire	Adequately designed hydrogenator with safety features	Dump tank as secondary containment. Flame arrestors
15	Losartan Potassium	1	S-I: Trityl losartan base is reacted with sulphuric acid and sodium hydroxide in presence of acetonitrile, methanol and toluene to give losartan stage-I product S-II: Losartan base on salt formation with potassium hydroxide in presence of methanol and acetone media gives losartan potassium	Chemical burns	Defined handing procedure and personal protective equipment	
16	Metformin HCl	1	Dimethylamine hydrochloride is reacted with cyano guanidine in presence of isopropyl alcohol to give metformin hcl crude	Exothermic	Defined operating procedures and safety interlocks	
17	Mirtazapine	3	Mirtazapins stage-II material is cyclized in presence of conc.sulphuric acid and sodium hydroxide in methylene dichloride, diisopropyl ether and methanol solvent media to produce mirtazapine stage III material	Fire and skin burns	Closed handling systems, nitrogen and defined operating procedures	
18	Perindopril tert-Butylamine	2	hydrogenation	Fire	Adequately designed hydrogenator with safety features	

19	Ribavirin	1	1,2,3,5-tetra-O-acetyl-β-D-ribofuranose is reacted with methyl-1H-1,2,4-triazole-3-carboxylate at molten temperature in presence of catalytic amount of trifluoromethane sulfonic acid	Fire and chemical burns	Trained operators and defined operating procedures	
20	Sevelamer HCl/ Carbonate	2	Poly allylaminehcl reacts with epichlorohydrin in presence of sodium hydroxide/ sodium bicarbonate to give sevelamerhcl/ carbonate	Decomposition and run-away reaction	Safe operating limits and process controls	
21	Simvastatin	3	Diprotected lovastatin amide reacts with NBL & methyl iodide in presence of THF &Hcl	Fire and chemical burns	Closed handling system for NBL and adequate PPE	
22	Telmisartan		Biphenyl acid is treated with sulphuric acid in presence of methanol followed by aqueous sodium bicarbonate to obtain biphenyl esterwhich is diluted with methylene chloride and directly taken for bromination reaction with n-bromosuccinimide followed by AIBN to obtain bromobiphenyl methyl ester	Chemical burns	Closed handling system and PPE	
23	Topiramate	1	2,3,4,5, bis-O(1-methylethyledene)-β-D-fructopyranose is reacted with sulfuryl chloride in presence of tri-n-butyl amine to form S-I material	Chemical burns	Defined operating procedures and LEV	

7.4.4 Hazard Factors

A study of past accident information provides an understanding of failure modes and mechanisms of process and control equipment and human systems and their likely effects on the overall plant reliability and safety.

Some of the major contributing factors for accidents in chemical industries are:

Table 7.13

Contributing factors for accidents

S.No	Contributing Factor	Per cent Loss
1	Equipment design faults	41
2	Process design faults	10
3	Operator errors	31
4	Maintenance deficiencies	12
5	Material Hazards	6

A study AICHE (1972) indicates that majority of equipment of component failures involve compressors, furnaces and heat exchangers as there are lesser opportunities to take them off for maintenance. The frequency of equipment or component failures is observed as follows:

Table 7.14

Failure frequency statistics of key equipment

S.No	Equipment	Frequency (%)
1	Compressors	30
2	Furnaces	18
3	Heat Exchangers	17
4	Process Vessels	18
5	Others	17

However, failures of storage vessels and those during transportation have been reported more frequently than cases of plant failures. The failure rate of various equipment in a typical power plant is provided in the following table.

7.4.5 Equipment Failure Rates

(Data from reliability Technology by A.E.Green and J.R Bourne, Copyright C,1972,reproduced with permission of John Wiley and Sons,Inc)

Table 7.15

Equipment failure rates

Equipment	Failure Rate(Failures/10^6h)
Electric Motors	10
Transformers(<15 kv)	0.6
Transformers(132-400k V)	0.7
General, (33k V)	2
Circuit breakers	10
Pressure vessels(general)	3
Pressure vessels (High standard)	0.3
Pipes	0.2
Pipe joints	0.5
Ducts	1
Gaskets	0.5
Bellows	5
Diagrams(metal)	5
Diagrams(Rubber)	8
Unions and junctions	0.4
Hoses(heavily stressed)	40
Hoses(Lightly stressed)	4
Ball bearings(heavy duty)	20
Ball bearings(Light duty)	10
Roll bearings	5
Sleeve bearings	5
Shafts(heavily stressed)	0.2
Shafts(Lightly stressed)	0.02
Relief valves leakage	2
Relief valves blockage	0.5
Hand-operated valves	15
Control valves	30

Ball valves	0.5
Solenoid valves	30
Rotating seals	7
Sliding seals	3
'O' ring seals	0.2
Couplings	5
Belt drives	40
Spur gears	10
Helical gears	1
Friction clutches	3
Magnetic clutches	6
Fixed orifices	1
Variable orifices	5
Nozzle and flapper assembles: blockage	6
Nozzle and flapper assembles: breakage	0.2
Filters: blockage	1
Filters: Leakage	1
Rock and pinion assembles	2
Knife edge fulcrum: wear	10
Springs(heavily stressed)	1
Springs(Lightly stressed)	0.2
Hair springs	1
Calibration springs: creep	2
Calibration springs: Breakage	0.2
Vibration mounts	9
Mechanical joints	0.2
Grub Screws	0.5
Pins	15
Pivots	1
Nuts	0.02
Bolts	0.02
Boilers(all types)	1.1
Boilers feed pumps	1012.5
Cranes	7.8

7.4.6 Common Causes of Accidents

Engineering and Instrumental

Based on the analysis of past accident information, common causes of major chemical plant accidents are identified as:

- Poor house keeping
- Improper use of Tools, equipment, facilities
- Unsafe or defective equipment facilities
- Lack of proper procedures
- Improving Unsafe procedures
- Failure to follow prescribed procedures
- Jobs not understood
- Lack of awareness of hazards involved
- Lack of proper tools, equipment, facilities
- Lack of guides and safety devices
- Lack of protective equipment and clothing

7.4.7 Failures of Human Systems

Na assessment of past chemical accidents reveals human factor to the cause for over 60% of the accidents while the rest are due to other plant component failures. This percentage will increase if major accidents alone are considered for analysis. Major causes of human failures reported are due to:

- Stress induced by poor equipment design, unfavourable environmental conditions, fatigue, etc.
- Lack of training in safety and loss prevention
- Indecision in critical situations.
- Inexperienced staff being employed in hazardous situations

Often, human errors are not analysed while accident reporting and accident reports only provide information about equipment or component failures. Hence, a great deal of uncertainty surrounds analysis of failure of human systems and consequent damages.

The number of persons/materials are potentially exposed to a specific hazard zone is a function of the population density and distribution near the

accident location. The failure rate data and ignition sources of major fires are presented in the following **Tables 7.15 & 7.16**

Table 7.16

Ignition Sources of Major Fires

S. No	Ignition source	Percent
1	Electrical (wiring of motors)	23%
2	Smoking	18%
3	Friction	10%
4	Overheated material	8%
5	Burner flames	7%
6	Combustion sparks	5%
7	Spontaneous ignition	4%
8	Cutting & Welding	4%
9	Exposure (fires jumping into new areas)	3%
10	Incendiarism (fires maliciously set)	2%
11	Mechanical sparks	2%
12	Molten substances	1%
13	Chemical actions	1%
14	Static sparks	1%
15	Lightening	1%
16	Miscellaneous	1%

7.4.8 Suggested safety measures for storage of chemicals

Following measures are suggested for safe handling of chemicals in Aurobindo Pharma Limited, Unit-I.

- Containers shall be labelled and level indicators shall be installed.
- Appropriate Safety signs shall be posted.
- Material safety Data sheets shall be made available.
- Chemical safety training shall be provided and an inventory of hazardous chemicals is maintained.
- Proper preventive measures on electrostatic hazards.
- Follow good CGMP and dispensing practices.

- Regular inspection and checking to assure risk control (proper earthling, functioning of safety interlocks, bonding, transferring in closed system and no spillages).
- Dykes shall be provided for all storage tanks as per the statutory norms.

Preventive maintenance of storage vessels shall be followed

7.4.9 Toxic Chemicals & handling

In regards to toxic chemicals, 3 chemicals comes under the definition of toxic chemicals (MSHIS Rules) based on LD 50 values. List and quantities handled are given in the **Table 7.17** below

Table 7.17

List of Toxic Chemicals & handling quantities

S.No	List of Hazardous Chemicals	Form Liquid/solid	TLV	LD 50 (mg/kg)	Quantity used	Maximum quantity stored
1	Chloroform	Liquid	2 PPM	36	1287 Kgs	In drums; 25 drums of 200 L capacity
2	Ammonia	Gas	25 ppm	Not applicable	2864 kgs	In cylinders; 25 Cylinders in cylinder storage shed
3	Formaldehyde	Liquid	0.3 ppm	42	5.16kgs	In drums; 25 drums of 200 L capacity

All chemicals are stored in tank form and all precautions applicable for bulk storage tanker shall be applied.

Following precautions are suggested for handling of these chemicals

- All the chemicals shall be stored in isolated place in stores with proper labelling
- MSDS shall be made available to workers
- All workers in the area of handling and use shall be trained
- Personnel protective equipment shall be made mandatory to handle the chemicals.
- Detailed safety instructions shall be placed at the place of use

- All the reactors where these chemicals are used shall be connected to wet scrubber
- Periodical health check shall be made mandatory for work force involved in handling of these chemicals as per the provisions of the Factory Act
- All containers and container liners shall be de-toxified and certified by production in –charge before sending to disposal area

7.5 Disaster Management Plan

7.5.1 Introduction

A disaster is a catastrophic situation in which suddenly, people are plunged into helplessness and suffering and, as a result, need protection, clothing, shelter, medical and social care and other necessities of life.

Disasters can be divided into two main groups In the first, are disasters resulting from natural phenomena like earthquakes, volcanic eruptions, storm surges cyclones, tropical storms. Floods, avalanches, landslides, and forest fires. The second group includes disastrous events occasioned by man, or by man's impact upon the environment. Examples are armed conflict. Industrial accidents, radiation accidents, factory fires, explosions and escape of toxic gases or chemical substances, river pollution, mining or other structural collapses, air, sea rail and road transport accidents and can reach catastrophic dimensions in terms of human loss.

There can be no set criteria for assessing the gravity of a disaster in the abstract since this depends to a large extent on the physical, economic and social environment in which it occurs. However, all disasters bring in their wake similar consequences that call for immediate action, whether at the local, national or international lever, for the rescue and relief of the victims. This includes the search for the dead and injured, medical and social care, removal of the debris, the provision of temporary shelter for the homeless, food, clothing and medical supplies, and the rapid re-establishment of essential services

An emergency may be said to begin when operator at the plant or in charge of storage of hazardous chemicals cannot cope up with a potentially hazardous incident, which may turn into an emergency. The emergencies

could be a major fire or explosion or release of toxic gas or a combination of them

The proposed plant will store fuels, which are flammable in nature, and the storage will be as per the Controller and the project is still in the initial stages of designing. Hence a tentative disaster management plan is prepared to be suitably modified before commissioning of the plant.

7.5.2 Objectives of Emergency Management Plan (On-Site)

A quick and effective response during emergency can have tremendous significance on whether the situation is controlled with little loss or it turns into a major emergency therefore, the objectives of this onsite emergency plan (ONSEP)

During Emergency: is to provide basic guidance to the personnel for effectively combating such situations to minimize loss of life, damage to property and loss of property.

- To localize the emergency and if possible eliminate it;
- To minimize the consequences of an emergency;
- To prevent spreading of the damage in other areas
- To give necessary warning to plant personnel and neighbourhood;
- To maximize resource utilization and combined efforts towards the emergency operations;
- To mobilize internal resources and utilize them in the most effective way;
- To arrange rescue of persons, transport and treatment of causalities;
- To seek necessary help from industries in neighbourhood or local authorities;
- To provide information to government agencies and to provide information to public

During Normal Time

- To keep the required emergency equipment in stock at right places and ensure their working condition;
- To keep the concerned personnel fully trained in the use of emergency equipment;

- Preserving records, evidence of situation for subsequent emergency etc.

7.5.3 Scope of ONSEP

This ONSEP is prepared for industrial emergencies like fired, explosions, toxic releases, asphyxia and does not cover natural calamities and societal disturbances related emergencies (like strikes, bomb threats, civil Commissions etc.). Also, the scope this ONSEP is limited to onsite emergencies and does not include measures for offsite Emergency Management.

Necessary information with regards to Off Site Emergency Management will be furnished to district authorities.

7.5.4 Methodology of Development ONSEP

The consideration in preparing this Emergency Plan includes the following steps:

- Identification and assessment of hazards and risks;
- Identifying, appointment of personnel & Assignment of Responsibilities;
- Identification and equipping Emergency Control Centre;
- Identification of Assembly, Rescue points, Medical facilities;
- Training, Rehearsal & Evaluation;
- Action on site.

Earlier, a detailed Hazards Analysis and Risk Assessment were carried out for the plant facilities and the hazards are quantified. The likely location of hazards and consequences are evaluated, duly following the standard procedure.

7.5.5 Elements of onsite Emergency Plan

Important elements considered in this plan are:

- Identification of emergencies
- Emergency organization
- Emergency facilities
- Emergency procedure
- Communications during emergency

- Rescue, Transport and Rehabilitation
- Roles and responsibilities of key personnel and essential employees
- Mutual aid

7.5.6 Emergencies Identified

Following are the typical emergencies anticipated from this type of industries

- Fire accidents at Bulk solvent storage &HSD areas
- Fire accidents at Boiler area, DG area
- Fire in reactors area
- Food /Water Contamination..
- Fire accidents in QC Laboratory.
- Major Spillage of solvents & HSD.
- Fire accident in scrap yard.
- Electric shocks.
- Reaction hazards in Hydrogenation area
- Hydrogen Cylinder explosion
- Catalyst fire

The other emergencies are asphyxiation of persons, apart from risks due to cyclonic conditions, earth quake, lightning, floods (natural calamities), sabotage, bombing (social and other reasons) etc. which are not under the management control.

Priority of protection in the event of an emergency is; Life and Safety of personnel, preservation of property, restoration of normalcy.

7.5.7 Emergency Organization

The project employs people in 3 shifts. The general shift will be for the administrative employees, while the three shifts of 8 hours each are for technical employee's Key personnel and essential employees are identified and are assigned emergency responsibilities. The organogram of the essential organization are presented below:

Security personnel, all operators, filters, electricians etc. in the shifts are designated essential employees. During emergencies, their services are drafted for essential operations.

7.5.8 Emergency Facilities

The design criteria for this facility encompasses the latest concepts and technology in-terms of layouts, flow of materials, Production and personnel, Heating Ventilation and Air Conditioning (HVAC) systems, Water treatment system and other utilities. National Quality Assurance Limited has accredited the manufacturing facility for ISO 9001:2008 & ISO 14001:2004 and Central Drugs Standards Organization has accredited with World Health Organization's GMP Certification.

The immediate environment around the locations is free of any population. Nearest village to the location is about seven hundred meters. There is no other Pharmaceutical, chemical or heavy industrial production units within the immediate locality.

a) Emergency Control Centre (ECC)

Security office is designated as emergency control centre. The emergency control centre is provided with intercom-100 and land line facility also.

Security people are available round the clock to take control over the emergency and they will act as communication team to inform all concern.

The other infrastructures provided in the Emergency Control Centre are:

a. Onsite emergency plan.
b. MSDS of chemicals and Products.
c. List of Important telephone Number.
d. List of both ERT, Fire squad and trained first aiders.
e. Plant Layout showing emergency assembling point, wind socks and Escaping route.
f. Fire alarm panel.
g. Hand speaker.
h. Emergency lamp.

b) Assembly Points

Around Six safe locations are identified and display boards are arranged for assembling people during emergency. The following are the different locations identified:

1. Main Security
2. F & G Security
3. K. Block Security Gate
4. D & E road
5. I Block Road
6. L&M Block road

c) Emergency control systems present

The following emergency control systems are in place in M/s. Aurobindo Pharma Limited, Unit I

1. Lightening protection for all buildings and high raised chimneys.
2. Earthing & Bonding for electrostatic hazards.
3. Closed arrangement for solvent transferring.
4. Safety interlocks for equipments
5. Pressure Relief system & Rupture Discs etc.
6. Earth Rite system for road tanker loading and unloading.
7. Nitrogen blanketing system with breather valve arrangement for all the bulk storage tanks.
8. Dust collection system with proper measures from electrostatic hazards.
9. Closed circuit Powder Transferring System for Granulation/blending/milling equipments.
10. Laminar air flow booths for raw materials dispensing and weighing operations.
11. FLP fittings at Flammable materials handling areas.
12. Product containment booth at raw material sifting.
    - ❖ Addressable fire detection system.
    - ❖ Fire detectors
    - ❖ Beam detectors
    - ❖ Smoke detectors
13. PLC operating system for critical equipment/operations.
14. Fire protection systems :
    - ❖ Portable Fire Extinguishers

- ❖ Fire Hydrant System

15. Occupational Health Centre.
16. Ambulance (Round the clock)
17. Safe handling procedures.
18. Spill Control kits.

d) Location of First Aid Boxes

First aid centre is functioning round the clock. Trained male nurse are available to take care of the victim. Intercom number for Occupational Health centre is 3104.

e) Fire protection system

A well equipped fire hydrant system is available with two separate water tank of capacity 400 KL. Water tank is interconnected with two separate pump houses having Jockey pump (10.5 m3/hr, electrical driven pump (171 m3/hr, and diesel pump (171 m3/hr). The mode of operation of the pump house is auto. All the process buildings are provided with ring mains with single hydrant points and Monitors. Escape hydrants are provided based on the requirements. Pump house will be provided with DG supply during emergency.

f) Emergency Siren

Emergency siren will be provided with 1.0km range of audibility and the location will be time office. The siren will operate on regular supply and also on emergency electrical supply.

g) Emergency Escapes

Emergency escapes in the plant area and floor wise emergency are conspicuously marked.

h) Wind Sock

Wind socks are provided in different location to identify wind direction during emergency.

Sl. No.	Location	Wind Sock number.
1	On D & E block	1
2	On Ceph SRP	2

3	Opp G block M - III	3
4	On I - block	4
5	Near Hazard Material storage	5
6	On C Block	6
7	Old SRP	7
8	L & M SRP junction	8
9	Near 27.5 T Boiler	9
10	Opp ETP RO plant	10
11	MEE	11

7.6 Organisation

Aurobindo Pharma Limited (APL), a center of excellence was inspired by the passionate belief that "Every man, woman and child is entitled to affordable medical care and freedom from pain and suffering", Mr. P.V. Rama Prasad Reddy along with a team of dedicated professionals, established Aurobindo Pharma Ltd in Hyderabad, India in the year 1986.

Aurobindo Pharma Limited, unit-I committed to manufacture Intermediates and Active Pharmaceutical Ingredients (APIs) of the highest quality. The total area consists of 71 acres, out of which 17.5 acres is built-up area. Schematic lay out of the site is enclosed as **Appendix-1**.Address of the site is Survey. No:379, 385, 386, 388 to 396 & 269, Borpatla Village, Hatnoora Mandal, Medak (District), Telangana - 502 296, INDIA.

The Drug Control Administration of Telangana (India) has given the license for the manufacture of the API and intermediate vide the license No. 47/MD/AP/95/B/R dated 06.04.1993 and 31.03.1998.

7.7 Man Power

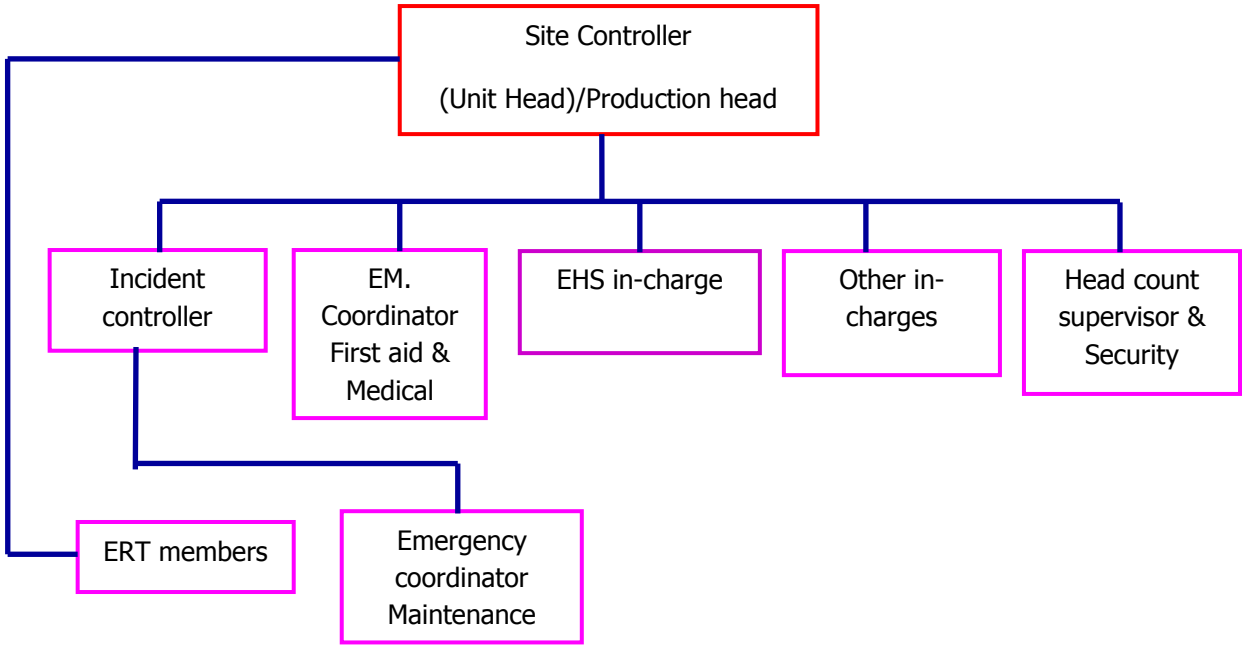
All Chemists/Executives/Assistants/Managers are well qualified and experienced in Chemical Industry. Experience is varying from 2 to 15 years in the similar field.

SHIFT TIMINGS

A Shift	06 Hrs - 14 Hrs
B Shift	14 Hrs – 21:30 Hrs
C Shift	21:30 Hrs - 06 Hrs
General Shift	09.00 Hrs – 17.30Hrs

7.7.1 Emergency Organization

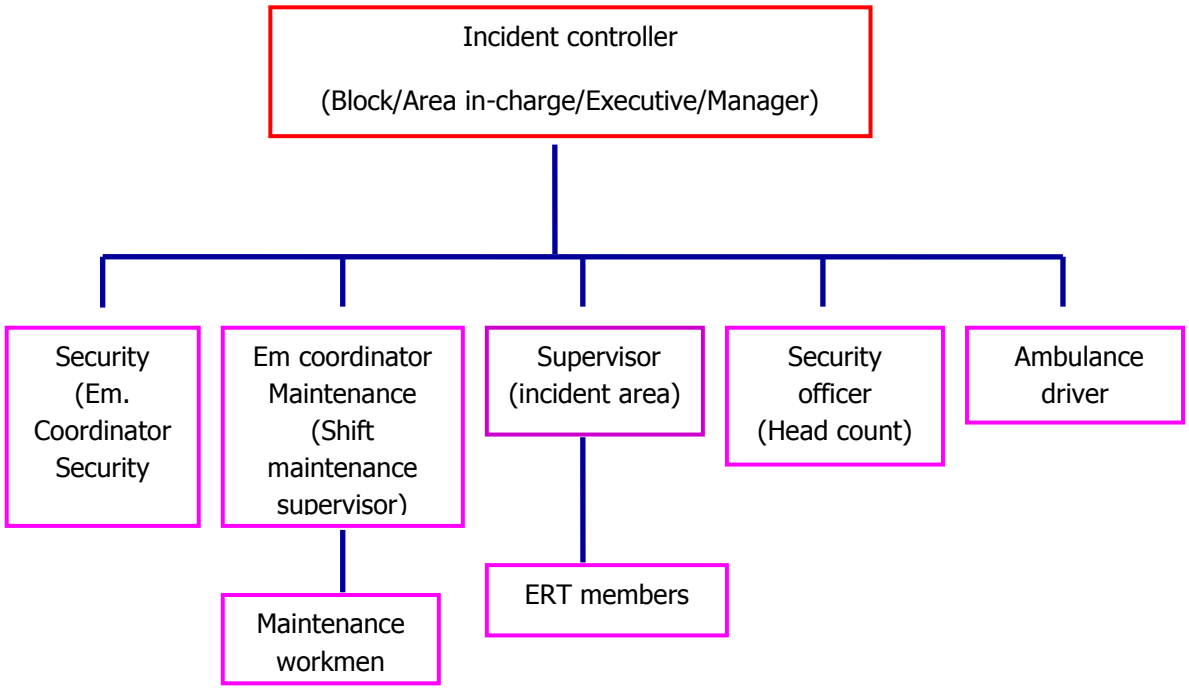
7.7.1.1 GENERAL SHIFT (09.00 to 17.30 hrs)



7.7.1.2 NON GENERAL SHIFT HOURS (17.30 to 09.00 hrs)

EMERGENCY ORGANISATION DURING

17.30 to 21.30, 21.30 to 06.00 & 6.00 to 9.00 HOURS



Incase of emergency during 18.00 to 21.30, 21.30 to 06.00 & 6.00 to 9.00 hours, Emergency coordinator-Security & transport member should communicate regarding on site emergency to minimum one or two of the following:

Site controller (Unit Head/Production Head), Incident controller (Location Head/In-charges) & EHS team.

7.7.2 Emergency Organization-Roles and Responsibilities

7.7.2.1 Functions of Site Controller

Site Controller who will retain overall responsibility for the factory and its personnel. As soon as he is informed of the emergency, shall rush to the emergency control Centre based on the situation and in touch with incident controller accordingly. The duties of the site controller will be

- Site main Controller is who will retain overall responsibility for the factory and its personnel.
- As soon as he is informed of the emergency, he will rush to the control room based on the situation and in touch with incident controller and other team members.
- He will arrange for messengers if any other mode of communication is not available.
- He will assess the magnitude of the emergency and decide the total course of action including the help from outside.
- He will arrange for necessary supply of fire fighting materials, manpower, neutralizing materials, ambulance, first aiders etc. to incident controller.
- He will give instructions for shutting down of other plants and operations after assessing the situation from time to time.
- He ensures effective evacuation of all people and proper attention to the casualties.
- He ensures effective head count of all the people present on the site.
- He continuously reviews and assesses the situation.
- When emergency is over he asks security to give all clear siren.
- He communicates the emergency details to senior management and statutory authorities if necessary.
- He chairs the meeting after the emergency is called off and prepare report on the incident and the details of action initiated.

7.7.2.2 Functions of Incident Controller

The person who identifies incident is called "Incident Identifier". He has to take following actions immediately:

a. Sound "Fire! Fire! or Leak! Leak!

b. Inform area shift in charge. The area shift in charge will assess the situation and inform to emergency control center by dialing 100 to declare emergency. In case of worst scenario the identifier himself is authorized to inform emergency control center to declare emergency then inform to area shift in charge.

c. Information to be given:

i. Name and Emp.Code.

ii. Location and Area.

iii. Nature of incident.

7.7.2.3 Role of Emergency Response Team

Unit Head is the Emergency main controller. After receiving information either by alarm or through phone, he will immediately arrive to the Emergency Control Centre (Main Security Gate) and takes full charge. He directs all the efforts at the site. The main responsibilities during an emergency are:

- Assess the situation, decide and activate the emergency procedure
- Takes actions for controlling the incident, securing the safety of personnel and minimizing damage to environment, plant and material through incident controller.
- Direct the rescue and fire fighting operations at site
- Search for causalities and arrange for proper first aid for them
- Ensure treatment of causalities and accounting of personnel
- Evacuate non essential persons from site to safe location
- Direct shutting down of plants and evacuation of personnel
- Ensure good communication with emergency control center
- Ensure proper communication to inside and outside emergency services
- Take direct operational control of works area not affected by the incident
- Preserve evidence for enquiry.

To perform the entire above responsibilities emergency main controller is assisted by Dy. Emergency controller.

7.7.2.4 Team Functions

7.7.2.5 Shut – down Team

Leader : Production Officer

Member : Chemist, Maintenance Charge man

To shut down the unit/section of the plant as directed by the site controller or as situation demands, as per emergency shutdown procedure.

* If approach is difficult take help of ERT members.
* Co-ordinates all actions of the control room to control emergency

7.7.2.6 Control Team – MAINTENANCE

Leader : Executive – Maintenance

Members : Fitters and Electricians.

- To identify source of leak and arrest it.
- To neutralize spillages/leaks.
- Attend to all repair jobs, which are needed for emergency control operations eg. Changing gaskets, replacing pipe sections, repairing of motors, pumps, valves, etc.
- To install additional pumps, blowers or other equipment for decanting, evacuating and draining as needed.
- To give temporary electrical connections as needed.
- To minimize damage to plant & environment and loss of material by segregation, covering, salvaging, diverting/stoppage of fire water by canal gate closing etc.,
- To retrieve and protect plant records (log books, indicator charts, drawings, manuals, inventory documents etc.) form destruction / damage during emergency control operation.
- Inform the message to in-charge (Safety Dept./Security in-charge) of fire hydrant pumps and operation.
- Arrange for shut down of non-essential utilities as per instruction of incident controller
- In consultation with incident controller, arrange power supply cut-off to the affected area. Ensure that emergency power and water

supply is on.

- Consult incident controller and with the help of maintenance supervisor and emergency squad, execute leakage control operations

7.7.2.7 Fire Fighting & Rescue Team

Leader : EHS Head/Safety officer

Member : Emergency Response Team Members

- To rush to the incident spot and start fire-fighting operations by wearing appropriate PPE.
- To attend fire pumps and maintain adequate water pressure in the hydrant system.
- To maintain supply of fire extinguishing media and equipment as necessary.
- To guide outside firefighting agencies.
- To rescue the injured personnel.
- To transport injured personnel to first-aid post or safe places.
- To guide employees to reach Assembly point.
- To search for missing personnel.

7.7.2.8 Male Nurse/Ambulance Driver/First aid members

- To render first aid.
- To administer O2 in case of toxic gas inhalation.
- To arrange stretchers to the FF & Rescue team.
- To arrange for sending the injured person to Hospital. On the advice of these Hospitals, arrange for, if necessary, transportation of patients to any of the specialty hospitals as needed.
- Arrange for anti-dotes to all effected people

7.7.7.2.9 Team – Admin

- Contacting other industries for help.
- Notifying the emergency to civil/local authorities as per the advice of the emergency controller/site controller.
- Giving necessary details to statutory bodies regarding emergency and keeping them abreast of the development.
- Informing kith and kin of injured

- Arranging alternate transportation in case of breakdown of transport vehicles, ambulance, etc.
- Arranging for relievers and catering facilities.
- Arranging transportation of injured to hospitals.
- Contacting medical centers/ hospitals identified for mutual aid.
- Arranging transportation (I) for persons connected with emergency functions including relieving staff if emergency prolongs (ii) transportation of materials / equipment needed from outside.

7.7.2.10 Security Officer

- On receiving the information blow the main siren after getting approval from site controller.
- Communicate location of the incident, Safe Escape Routes, wind direction & assemble location by mega phone with the help of incident controller.
- Depute required number of security guards to close the main gate to bar the entry of unauthorized persons.
- Ensure transport of injured and ensure transport for additional injuries in absence of Admin personnel.
- Keeps security guards at the gate and move to the emergency area.
- Ensure all the security guards (near main gate, other designated places) are reporting to Incident controller/site controller.
- Permit minimum delay in the entry of authorized personnel and outside agencies, vehicles, etc., who have come to help.
- If needed on the advice of incident controller, he rushes to emergency control center and reports to site controller, with the attendance record of employees, list of contract workmen and visitors.
- To direct all drivers of vehicles / tankers which are waiting outside the main gate for entry into the plant to remove the vehicles away from the factory.
- After arrival of all statutory bodies, co-ordinate with them for permitting entry/exit of vehicles related to emergency. Collect work

permits issued on the day from Safety Dept. to identify possible locations of deployment of contract laborers for the purpose of reconciling any missing employees.

- After the mitigating emergency situation on the advice of site controller/incident controller all clear siren will be blown for two minutes on which the normalcy will be restored.

7.7.3 Duties of Employees

Duties of Employees other than KEY Personnel

- On hearing the emergency siren, contact the shift supervisor for necessary action.
- Alert other employees in concern section.
- If he/she is not an employee of affected area, close down operations safely before leaving to assembly point.
- If he/she is not an employee of the adjacent location of the mishap area, should close down operations/ plant / equipment.
- Be ready to go to nearby assembly point. Those who are not involved directly in the plant operations should assemble at assembly point.
- If he/she is present in an area, which is not your regular work place, inform the shift supervisor of that area about your presence and follow his advice.
- Pending advice from shift supervisor, if you hear announcement over megaphone, act according to such announcement especially in respect of evacuation and escape route.
- If you do not get any directions from shift supervisor or by megaphone and if you happen to get affected at any stage by the spreading toxic vapor or fire, act as indicated. Position yourself upwind side of source of leakage and if you don't get any directions over the megaphone, leave the place in cross wind direction and proceed to the assembly point located in that direction.
- Warn nearby employees, if possible by shouting.

7.7.4 Duties of Section in charges/Engineers/supervisors General approach:

- As soon as the emergency siren is heard, alert the visitors in your area of jurisdiction and ask them to stand by for further instructions from you. Do not permit them to move out of your area.
- Await directions over megaphone with the help of security regarding emergency shut-down of your unit/section or regarding evacuation.
- Meantime, select two of your plant operators and instruct them to be ready for shutdown if necessary.
- If evacuation is announced over megaphone or otherwise, or pending announcement of evacuation if you observe spread of toxic vapor or fire so as to affect persons in your unit, direct and guide them to the assembly point.
- If escape routes are not announced, guide the persons to follow the routes not involved in the wind direction.
- Permit members of Control Team, FF & Rescue Team to report to the respective team leaders.
- If the emergency occurs in your area or jurisdiction
- Immediately direct your trained employees to put out fire and arrange to report to Site Controller /EC.
- Note: If toxic materials are involved in fire, do not allow employees to fight fire without use of SCBA.

7.7.5 EHS Head/Safety In Charge

- As soon as he hears about the emergency, he rushes to the incident site.
- He advises incident controller and site controller for managing on site emergency
- Fire extinguishers, hoses, nozzles, mechanical foam compound located in various points shall be provided to ERT members.
- Be drawn and arranged for firefighting.
- Coordinate with fire brigade group and help them.

7.7.6 Driver- Ambulance

- Upon hearing the warning signal, he should observe wind direction proceed to the vicinity of spot and reverse the vehicle.
- Keep engine in running condition
- Open the back door of ambulance
- Go back to the seat
- Take the injured to first aid center / Prime Hospital, Road No:1, KPHB, Hyderabad.
- (as directed by emergency coordinator- first aid & medical)

7.7.7 Emergency Coordinator (First Aid & Medical) /Male Nurse:

- Available at / Rush to first aid center.
- Stay on alert for first aid and medical treatment for chemical poisoning and other injuries.
- Receive the injured, examine and quickly assess the condition and treat.
- Report to the hospitals and make arrangements for likely more cases of injuries.
- Shift the injured to Prime Hospital, Road No:1, KPHB, Hyderabad
- Stay put in first aid center for subsequent injury cases if any.
- Gather feedback from hospital and communicate to site controller.

7.7.8 Head Count Supervisor

- At assembly point, take the head count and compare with the attendance
- Records of the day/ shift. In case of missing people, informs site controller.
- Hold on till all clear signal is received or act as per instructions of site controller

7.7.9 The task summary includes

- Assessment of potential impact based on systematic risk identification program for both fire & exposure hazardous substances.
- Assessment of potential impact on harm to the environment by spill or release of harmful vapor/material.

- Essential need for evacuation
- Areas to be evacuated
- Information sharing
- Alert communication mode
- Transportation/Medicare/Safe Sheltering and Security aspects with concerned authorities.

Post Emergency Procedures should include:

- Incident review.
- Identification of remedial measures and implementation.
- Information dissemination within the Site to prevent recurrence.
- Reporting to Statutory authorities as applicable.

7.8 Risk Control Procedures

7.8.1 Hazard Communication Program

The department head or his/her designee is responsible for compliance with the provisions of the hazard communication program, systematic risk identification and control measures with the help from EHS department. Training program for all operators/executives on operational/equipment risk control measures includes preventing flammable atmospheres by engineering controls. Specific responsibilities include the periodic review of department operations that use or store and handle hazardous chemicals to ensure that

- Containers are properly labelled
- Appropriate signs have been posted
- Material safety Data sheets are available
- Chemical safety training has been provided and an inventory of hazardous chemicals is maintained.
- Proper preventive measures on electrostatic hazards
- Follow good CGMP and dispensing practices.
- Regular inspection and checking to assure risk control (proper earthling, functioning of safety interlocks, bonding, transferring in closed system and no spillages) The EHS Department will coordinate the implementation of the hazard communication program.

Chemical manufacturers, importers, or distributors are required to ensure that each container for hazardous chemicals is labeled with hazardous warning signs, and the name and address of the chemical manufacturer, importer or other responsible party. The individual Departments will ensure that chemicals they receive are labeled with the identity of the hazardous chemical(s) and appropriate hazardous warning signs, and the name and address of the chemical manufacturer, importer or other responsible party. The user shall ensure that the indented chemicals are received along with the MSDS from the supplier with the help of Supply Chain Management (SCM) /Purchase.

- All employees who work in areas where there are hazardous chemicals will receive chemical safety training at the time of initial employment and documented
- chemical safety training includes the following essential information:
- Location of hazardous materials in the work place
- Location and availability of material safety data sheets
- Acute and Chronic effects of chemicals
- Safe handling procedures
- Personal protective equipment's (PPE)
- Emergency procedures and how to obtain First Aid.
- Spill clean – up and Waste disposal

7.8.2 Detailed Action Plan to mitigate in case of Emergency:

- When the emergency observed the operator/supervisor to operate manual call point in case of emergency.
- Operator will move to safe distance and also ask nearby personnel to move to safe place (Assembly point).
- Security will inform to site controller, incident controller & EHS head.
- Incident controller (concern area head) will rush to the site and ask ERT members to approach the site with SCBA and inform to site controller to declare emergency.
- Site controller will inform to security to declare emergency by

hooting emergency siren based on the report received from incident controller.

- Security will declare emergency based on site controller instruction and request to evacuate by using a megaphone. Wind direction also to be informed.
- Meanwhile incident controller will initiate the control procedure with the help of ERT members (Spill control procedure/operating fire hydrant system etc.).
- Help from maintenance dept. will be sought if necessary to cut off power supply/ close the valves to receivers and any temporary power connections to emergency appliances.
- Site controller will assess the situation from Emergency control centre and will send ambulance, spill content/firefighting equipment's and required PPE.
- Care shall be taken that no vehicle shall be allowed in the close vicinity of the spill/fire (about 50 meters) and movements shall be from upwind directions only.
- Incident controller will ask explosive meter to monitor the area with the help of ERT member/Safety in-charge.
- Incident controller will inform site controller of requirement of outside help, if any.
- When the situation is under control incident controller will inform to site controller.
- Incident controller will ensure that,
- The spilled material, spill control materials and other wastes are disposed off properly.
- Area washed with water thoroughly
- PPE are washed and kept at their respective locations.
- Spill control materials, fire extinguishers are replenished.
- Evidence recorded and maintained for further investigations.
- Site controller will ask security to give "all clear" siren and employees will be allowed to go to their respective work places, if head count is complete.

- A meeting will be called in conference room with all block in-charges, maintenance engineers, ERT members, security officer, incident controller and site controller.
- The incident will be discussed in detailed and minutes will be maintained for future improvements.
- A detail report will be prepared by site controller and incident controller and submitted for management review.

7.8.3 Control Measures

- A current inventory of all chemicals and hazardous chemicals present in the workplace is maintained, the inventory of flammable materials are maintained in less quantities.
- Lightening protection provided at diesel storage tanks area.
- Flammable solvents are handling at FLP areas.
- Flammable solvents are transferring by using metallic hand operated pumps into metal containers. Proper earthing and bonding provided for solvent handling equipments.
- Equipment's only wiping with lint free cloth instead of cleaning with flammable solvents.
- Dispensing carried out at FLP zone.
- Spill control kits are provided at flammable solvents handling areas. Spill control procedures are also displayed to control risk.
- Explosion flaps provided for Air tray dryers to prevent explosion.
- Addressable fire detection system provided.
- Fire hydrant system provided with diesel driven backup.

7.8.4 Handling Spills

The risk assessment includes the following factors:

- The nature of the spilled chemical (high/low hazard material)
- The quantity spilled (large/small amounts)
- The location of the spill (difficult access, public site / bonded area)

When evaluating risks associated with chemical spills, the following points need to be considered:

Is special training required to handle the situation?

Is special equipment required to clean up the spill? (i.e. Self-Contained

Breathing Apparatus (SCBA), Personal Protective Equipment (PPE etc.)

Are special procedures required to clean up the spill? e.g. pumps, hoses etc.

Where the response is HIGH to any of the above factors then the spill must be considered as HIGH RISK.

7.8.4.1 Spill Controls (Risk Controls)

Engineering – Handling in closed system. Bund provided for storage area. Includes redesigning the work area, fixing rollover bund guard(s) or maintenance.

Administrative – standard operating procedure, supervision, training and signage.

Personal protective equipment – Includes PAPR/3M half face masks, safety shoes, goggles, safety glasses and gloves.

- Spill kits available for use where assessed as required. The contents of the spill kit should be relevant to the area and the potential spill, this may include such things as;
- Soda Ash available for spills of corrosive liquids.
- Sand to absorb spilt liquids
- Absorbent pillows or booms to contain larger liquid spills and prevent spills entering drains
- Heavy duty HDPE containers (with a lid) to contain hazardous material prior to disposal.
- Appropriate personal protective clothing (such as chemical resistant gloves, safety glasses)
- Spill kits are clearly labelled and located in an easily accessible position for all staff.

7.8.4.2 Spills Handling Procedure

- If spill involves personal injury, remove clothing, flush with water for 15 minutes.
- Alert people in the immediate area of spill.
- Wear protective equipment, including safety goggles, gloves while going near the spillage.

- Avoid breathing vapors from spills.
- If spilled material is flammable, turn off ignitions and heat sources.
- Confine spill to small area by creating a bund with soda ash and sand.
- Absorb with soda ash, dry sand or adsorbent. Collect the residue, place it in the empty container for disposal. Dispose as chemical waste.
- Mop the spill area with water.

7.9 Health Hazards from exposure to hazardous substances and control measures.

Existing hazards considered from operational/equipment manuals. Detailed Hazard identification and health based risk assessment of various operations and processes will be carried out. Risk assessment based on

Which substances are involved? In what way are they harmful? You can find out by:

Checking information that came with the product, eg a safety data sheet;

Asking the supplier, sales representative and your trade association;

Once exposed some substances can attack the nose, throat or lungs while others get into the body through the lungs and harm other parts of the body, eg the liver. Some dusts are irritating to eyes and skin.

When the task involves very small amounts of material, even if these are harmful, when there is little chance of it escaping, the risk is low. But the risk in a different task – such as cleaning up and disposal – will be higher because the harmful substance may be breathed in or get onto the skin.

When the task involves larger amounts of material, with obvious leaks, exposure is higher and so is the risk. Whether the substance is harmful or not, your need to control it is obvious.

7.9.1 Control Measures (Risk Control procedures) :

- Management process available for selecting suitable safe equipment.
- Engineering controls consideration on risk controls for preventing

or controlling exposure during procurement.

- Closed circuit Powder Transferring system where ever dust generation areas to prevent exposure and dust explosion.
- Laminar flow booths are provided at weighing and dispensing areas.
- Product containment booth provided at raw material sifting area.
- Dust collectors provided with proper prevention from electrostatic hazards.

- Wet mass charging into bowl by gravity by using PAPR/3M nose mask.
- Spill control kits and procedures are established.
- Good Manufacturing practices and housekeeping practices are established.
- Provide personal protective equipment (PPE) such as gloves, goggles and respirators.
- Operators trained on control measures by on job training/induction training.
- Carry out practice drills for cleaning up spills safely – do this before any spillages happen.
- Annual health checks are being carried out for all employees.

7.10 Drum Explosion

Reasons:-

Pressure build up due to heat or incompatible chemicals

Safeguards:(Existing)

- Weather protected.
- Run down gradient.
- No incompatible or decomposing contents in drums.
- Drum storage at designated places under shade.

Potential Impact Area:-

- Manufacturing area
- Stores
- On transporting area

Potential Impact:-

- Possible personnel harm
- Drum flying/leaking
- Leak of content with water
- Spread of hazardous contamination liquid of low flash point.
- Possible escalating fire

Onsite Measures:-

- Reports to assembly area.
- Take head count.
- Keep vigilance on unusual symptoms
- Keep in touch with Emergency Response team
- Proceed to safe shelter and confirm head count.
- Stay with people until all clear
- Do not wander or move about
- Await all clear and instruction from Emergency controller/Site controller.

7.11 Evacuation Of Personnel

On hearing the emergency siren all employees of the factory shall proceed to assembly point as directed by their department heads. Head count supervisor will take the head count at assembly point and report the same to Site controller. During emergencies the knowledge of exact direction of wind helps the plant personnel to decide on the escape route to be taken for safe evacuation of personnel and also the safe assembly points and emergency operations center. It is therefore necessary that the personnel get an idea of the direction of the wind by seeing the windsocks provided at the following.

Sl. No.	Location	Wind Sock number.
1	On D & E block	1
2	On Ceph SRP	2
3	Opp G block M - III	3
4	On I - block	4
5	Near Hazard Material storage	5

6	On C Block	6
7	Old SRP	7
8	L & M SRP junction	8
9	Near 27.5 T Boiler	9
10	Opp ETP RO plant	10
11	MEE	11

7.12 Information To Relatives Of Injured

The relatives of injured will be informed by emergency coordinator (security/transport). The employees residential address file is available at emergency control Centre and also in the residence of emergency coordinator (security/transport). The communication to the relatives of injured will be passed on through telecom or by a messenger with car. The clear address of the injured person (Local residential address/address of hospital if hospitalized) will be communicated to The Relatives.

7.13 Information to Local Authorities

In case of onsite emergency, the Dy. Chief inspector of factories and inspector of factories will be informed immediately. The information will be passed on over telecom, telegram or through a messenger deputed by Emergency Controller.

After consulting Dy. Chief Inspector of factories and inspector of factories, the information will be sent to Chief inspector of factories also. The company will implement the advice of local authorities in improving the safety in dealing with the event.

State Pollution Control Board authorities will be informed in case of accidents like toxic gas release, spillage of hazardous chemicals.

7.14 Information to District Authorities

The Emergency controller/site controller/Head HR on advise of Emergency controller is authorized to inform the police. The inspector of Police Bollaram will be informed for the control of law and order situation at the Plant or in vicinity or at hospital where injured are under treatment.

Police department will be requested for protecting the lives of employees

and property of the company, evacuation of personnel outside the Plant. District Collector, Dist. Medical Officer and Superintendent of Police, Medak district will be informed by Site controller if required.

7.15 Mock Drill

In spite of detailed training, it may be necessary to try out whether, the OSEP works out and will there be any difficulties in execution of such plan. In order to evaluate the plan and its effectives of meeting the objective of the OSEP, occasional mock drills are contemplated. After a few pre-informed mock drills, few un-informed mock drills would be taken. All this is to familiarize the employees with the concept and procedures and to see their response. These scheduled and unscheduled mock drills would be conducted during shift change, public holidays, in night shift etc. to improve preparedness.

Emergency Coordinator (EHS) is responsible for organizing planned and unplanned mock drills.

Two types of mock drills are in practice. They are

1. Announced - Once in 3 months
2. Unannounced - Once in 6 months

Announced mock drill

Unit Head decides the date and time with the concurrence of safety in charge. A hypothetical incident identified is communicated to all concerned in the organization for action on onsite emergency and emergency is declared by plant manager.

Unannounced mock drill

Unit Head and Safety in-charge decides on the time and date. A hypothetical incident decided and it is not disclosed until the drill is announced. In this Plant manager and Safety in-charge enters the production block and hand over a written hypothetical incident to the shift in charge concerned for that area. Block in charge initiates action for onsite emergency.

Mock drill observation:

Mock drill observation team (ERT members) is constituted and they note

down the action of various coordinators in chronological order. The time of arrival of each coordinator and their duties are detailed in a note. Immediately after mock drill, the advisory team and emergency coordinators meet and review the mock drill records in chronological order and take note of corrective action. The record of this meeting note is circulated for compliance of concerned.

Role of Mock drill observers

- Note readings of plant instruments
- Meteorological conditions
- Time of emergency declaration and time when the personnel responded/reported
- Ambulance reported and time when additional vehicles reported
- Collect information description of the event, estimated quantity of the gas release, fire, contamination and effected levels at various locations, injuries and equipment damage.

7.16 Review Of OSEP

The plan is to be reviewed once in a year or if any major changes happens in the process or building

OSEP would be reviewed periodically about the effectiveness, any changes to be made, based on actual need or whenever, there is a change in propositions made in the OSEP or change of key personal or essential employees etc. Whenever, changes are made, due notification of the changes to all concerned would be made, The OSEP will be discussed in plant meetings and employee participation in emergency planning would be ensured. Emergency Coordinator (Safety) is responsible for review of Onsite Emergency Plan and making it up to date.