Hazards Management in Pharmaceutical Industry
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Hazards Management in Pharmaceutical Industry

Prelude
Indian pharma industry has been making tremendous progress not only in creation of excellent infrastructure but also attending to the global needs of the supply of APIs as well as quality medicines in addition to entering into growing fields of contract research and manufacturing and clinical trials. Like most chemical industries, the Pharma industry also has various environmental issues especially in manufacture of APIs. To provide technical support for dealing with national hazards in the pharmaceutical sector, the Department of Pharmaceuticals (DoP) in the Ministry of Chemicals and Fertilisers, Government of India has constituted an Environmental Cell to bring awareness about hazards, avoidance of hazards, be in preparedness mode to suitably respond to the effects and impacts of national hazards including Disaster Management in the pharmaceutical industry.

Emergency Management of Hazards involves preparing for disaster before it occurs, disaster response as well as supporting, and rebuilding society after natural or human-made disasters have occurred. It is a continuous process by which all individuals, groups, and communities manage hazards in an effort to avoid or ameliorate the impact of disasters resulting from the hazards. Actions taken depend in part on perceptions of those exposed. Effective emergency management relies on thorough integration of emergency plans at all levels of government and non-government involvement. The mandate of the Environment Cell in Department of Pharmaceuticals(DoP) broadly include the following:

Considering the usage of a large number of basic chemicals particularly organic chemicals in the production of bulk drugs and drug intermediates, remedial measures to prevent incidents similar to what happened in Bhopal in 1984.
To identify the potential causes of emergencies in bulk drugs, drug intermediates and Pharma formulations manufacturing units and advise their management to take remedial measures in advance so as to avoid such emergencies from taking place.

To devise advance planning to ensure adequate & timely supply of life saving medicines needed for epidemics etc, to avoid large scale mortality & morbidity of human & animals.

Take adequate precautionary measures to effectively prevent accidents involving chemicals, processed or handled in bulk drugs, drug intermediates and Pharma formulations manufacturing units.

Take adequate precautionary measures to effectively prevent accidents involving handling of chemicals in bulk drugs, drug intermediates and Pharma formulations manufacturing units.

2. **Awareness of Hazardous Waste**

The process of bulk drug manufacturing activities is quite complex and has inherent risks of on-site and off-site environmental overheads.
A typical of bulk drug manufacturing process is depicted in the following flow diagram:
2.1 Hazardous Waste Generating States - Leading Contributors

The high concentration of particulates in the atmosphere over large urban and industrial areas can produce a number of general effects. Smoke and fumes can increase the atmospheric turbidity and reduce the amount of solar radiation reaching the ground. According to Ministry of Environment & Forests, leading hazardous waste generating states are Rajasthan, Maharshtra, Gujarat, Andhra Pradesh, West Bengal, Tamil Nadu and Jharkhand as depicted in the Chart given below:

![Hazardous Waste Generating States-Major Contributors](image)

<table>
<thead>
<tr>
<th>State</th>
<th>HW (Lakh Tonnes)</th>
<th>HW (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rajasthan</td>
<td>35.57</td>
<td>43.06</td>
</tr>
<tr>
<td>Maharashtra</td>
<td>14.07</td>
<td>17.04</td>
</tr>
<tr>
<td>Gujarat</td>
<td>12.76</td>
<td>15.45</td>
</tr>
<tr>
<td>Andhra Pradesh</td>
<td>4.96</td>
<td>6.00</td>
</tr>
<tr>
<td>West Bengal</td>
<td>2.36</td>
<td>2.86</td>
</tr>
<tr>
<td>Tamil Nadu</td>
<td>1.91</td>
<td>2.31</td>
</tr>
<tr>
<td>Jharkhand</td>
<td>1.81</td>
<td>2.19</td>
</tr>
</tbody>
</table>

2.2 Hazardous Waste Generating Units

Air borne emissions emitted from various industries are a cause of major concern. These emissions are of two forms, viz. solid particles (SPM) and gaseous emissions (SO2, NOx, CO, etc.). Liquid effluents, generated from certain industries, containing organic and toxic pollutants are also a cause of concern. Heavily polluting industries were identified which are included under the 17 categories of highly polluting industries for the purpose of monitoring and regulating pollution from them. The Ministry of Environment and Forests has developed standards for regulating emissions from various industries and emission standards for all the polluting industries including thermal power stations, iron and steel plants, cement plants, fertilizer plants, oil refineries, pulp and paper, petrochemicals, sugar, distilleries and
tanneries. The industrial units in India are largely located in the States of Gujarat, Maharashtra, Uttar Pradesh, Bihar, West Bengal and Madhya Pradesh. The highest concentration of sulphur dioxide and oxides of nitrogen is, therefore, often found in cities located in these states.

3. Avoidance of Chemical Disasters

Avoidance and mitigation of chemical disasters will now not only be limited to strict regulation and safety audits of industries handling hazardous chemicals but will also cover transportation emergency management to deal with spills and leaks on highways as well as in pipelines. According to the National Chemical Disaster Management Guidelines drawn up by the National Disaster Management Authority (NDMA):

i. The industrial units using hazardous chemicals as raw materials in processes, products and wastes with inflammable, explosive, corrosive, toxic
and noxious properties will be required to have onsite and offsite emergency plans in place and put them to test by organising regular mock drills.

ii. The units will also have to undergo mandatory safety audits and have dedicated manpower and infrastructure to prevent and mitigate chemical disasters at all levels.

iii. In June 2006, the World Bank established the Global Facility for Disaster Reduction and Recovery (GFDRR), a longer term partnership with other aid donors to reduce disaster losses by mainstreaming disaster risk reduction in development, in support of the Hyogo Framework of Action. The facility helps developing countries fund development projects and programs that enhance local capacities for disaster prevention and emergency preparedness.

iv. Industrial disasters on the scale of Seveso and Bhopal prompted chemical firms to rethink their response to accidents, and more generally, how they do business. According to Ms Mara Caboara\(^1\), the global chemical industry launched a voluntary initiative ‘Responsible Care’ in 1987, committing chemical companies to achieve continuous improvements in environmental, health and safety performance beyond levels required by local and international regulations. A fundamental element of ‘Responsible Care’ is open communication with governments and international and local organizations including disaster avoidance and emergency response.

v. Chemical companies are working to prevent chemical accidents and reduce their impact. Global and regional networks are a crucial part of this strategy. In Europe the International Chemical Environment (ICE) network of emergency professionals provides information, practical help and equipment to the competent emergency authorities to cope with chemical incidents.

vi. In the United States the Chemical Transportation Emergency Centre (CHEMTREC) operates a public service hotline for fire fighters, law enforcement, and other emergency agencies, providing data and assistance for incidents involving chemicals and hazardous materials.

vii. The chemical industry, in countries such as Japan, Mexico, Canada, China and Thailand, has also set up emergency networks. Every major region and

\(^1\) Manager of the International Council of Chemical Associations,
country has developed and adapted its own system, following ICE and CHEMTREC guidelines.

viii. Chemical companies are complementing emergency networks with their own schemes and systems. Most chemical companies provide their deliveries with safety data sheets, emergency procedures and emergency labels, under the supervision of technical agencies.

i. Companies may also offer direct assistance and support to disaster victims, by funding recovery activities, helping implement conservation and emergency preparedness plans, and offering medical care to victims and their families.

ii. We must create a portfolio of disaster reduction actions, compiling best practice and lessons learned from previous disasters, and a catalogue of technologies for disaster reduction. The chemical industry should share well-developed codes, translated into several languages and adapted to the different environments in which we operate.

iii. Lastly we must develop and enhance early-warning systems, still the most critical aspect of risk reduction. We need to create suitable technical instruments, constantly monitored and improved by networks of professionals. The lack of suitable early-warning systems is the key obstacle to prevention, allowing accidents to develop into full-fledged disasters.

4. Response

i. The response phase includes the mobilization of the necessary emergency services and first responders in the disaster area. This is likely to include a first wave of core emergency services such as firefighters, police and ambulance crews. They may be supported by a number of secondary emergency services such as specialist rescue teams.

ii. In mass emergency situations, people are generally overwhelmed initially and therefore it makes sense to mobilize organized emergency volunteers such as community emergency response teams, and NGOs such as the local Red Cross branch or St. John Ambulance. These may
provide immediate practical assistance from first aid provision to professionally-organized mass emergency shelters.

iii. A well rehearsed emergency plan developed as part of the preparedness phase enables efficient coordination of rescue efforts. Emergency plan rehearsal is essential to achieve optimal output with limited resources. In the response phase, medical facilities may be used in accordance with the appropriate triage of the affected victims.

iv. Search and rescue efforts commence at an early stage, depending upon gravity of injuries sustained by the victims.

4.2 Organizational Response to Disaster

Normally response to any natural or terrorist-borne disaster is based on existing emergency management organizational systems and processes: the Federal Response Plan (FRP) and the Incident Command System (ICS). These systems are solidified through the principals of Unified Command (UC) and Mutual Aid (MA).

Individuals often volunteer directly after a disaster. Unorganized, untrained volunteers can be both a help and a hindrance to emergency management and other relief agencies. Pre-organized, pre-trained volunteers, who understand and support the official incident command system, lend valuable extra manpower support.

5. Management of Hazard:

The process of Hazard management involves following four phases:

- Mitigation,
- Preparedness,
- Response, and
- Recovery.
5.1 Mitigation
Mitigation efforts attempt to prevent hazards from developing into disasters, or to reduce the adverse impact of disasters when they occur. The mitigation phase differs from the other phases because it focuses on long-term measures for reducing or eliminating risk. The implementation of mitigation strategies can also be considered a part of the recovery process if applied after a disaster occurs. However, even if applied as part of recovery efforts, actions that reduce or eliminate risk over time are considered mitigation efforts.

A precursor activity to the mitigation is the identification of risks. Physical risk assessment refers to the process of identifying and evaluating hazards. In risk assessment, various hazards within a given area are identified. Mitigation measures can be structural or non-structural. Structural measures use technological solutions while non-structural measures include legislation, land-use planning and insurance. Mitigation is the most cost-efficient method for reducing the impact of hazards. However, mitigation is not always suitable and structural mitigation in particular may have adverse effects on the ecosystem.
5.2 Preparedness

An efficient preparedness measure is to create an Emergency Operations Center (EOC) combined with a practiced region-wide doctrine (such as the incident command system) for managing emergencies. Common preparedness measures include the following:

i. communication plans with easily understandable terminology and methods.

ii. development and practice of multi-agency coordination and incident command.

iii. proper maintenance and training of emergency services, including mass human resources such as community emergency response teams.

iv. development and exercise of emergency population warning methods combined with emergency shelters and evacuation plans.

v. stockpiling, inventory, and maintenance of supplies and equipment.

vi. developing organizations of trained volunteers from amongst civilian populations. Professional emergency workers are immediately overwhelmed in mass emergencies, trained, organized and responsible volunteers can be extremely valuable. Another is the Red Cross. If volunteers are organized, trained in the incident command system, and agree to mobilize, it may go a long way in mitigating hazards as has been demonstrated by experience of Emergency Response Teams such as in the Red Cross etc.

vii. casualty prediction to forecast casualties and injuries arising out of a given kind of event. This gives planners and administrators an idea of size and package of resources needed to be made available to respond to a particular kind of event.

5.3 Response & Recovery

In the recovery phase, an attempt is made to restore the affected area to its original state. It differs from the response phase in its focus; recovery efforts are concerned with issues and decisions that must be made after immediate needs are addressed. Recovery efforts are primarily concerned with actions that involve rebuilding destroyed property, re-employment, and the repair of other essential infrastructure. An important
aspect of effective recovery efforts is taking advantage of a ‘window of opportunity’ to take measures that might be otherwise unpopular. Citizens of the affected area are more likely to accept more mitigate changes when a recent disaster is in fresh memory. In the United States, the National Response Plan stipulates how the resources provided by the Homeland Security Act of 2002 are to be used in recovery efforts. Government often provides most of technical and financial assistance for recovery efforts in United States.

5.3.1 International Association of Emergency Managers

The International Association of Emergency Managers (IAEM) is a non-profit educational body dedicated to promoting the goals of saving lives and protecting property during emergencies and disasters. The mission of IAEM is to serve its members by providing information, networking and professional opportunities, and to advance the emergency management profession.

5.3.2 Red Cross/Red Crescent

National Red Cross/Red Crescent societies often have pivotal roles in responding to emergencies. Besides, the International Federation of Red Cross and Red Crescent Societies (IFRC, or "The Federation") may deploy assessment teams to the affected country. They specialize in the recovery aspects of the emergency management framework.

5.3.3 United Nations

Within the United Nations system responsibility for emergency response rests with the Resident Coordinator within the affected country. However, in practice international response will be coordinated, if requested by the affected country’s government, by the UN (UN-OCHA), by deploying a UN Disaster Assessment and Coordination (UNDAC) team.
5.3.4 World Bank

The World Bank has approved more than 500 operations related to disaster management since 1980. These include post-disaster reconstruction projects, as well as projects with components aimed at preventing and mitigating disaster impacts.

5.3.5 National Organizations

In India, the role of Emergency Management is entrusted with National Disaster Management Authority of India (NDMA) under the Ministry of Home affairs. In recent years, there has been a shift in emphasis, from response and recovery to strategic risk management and reduction and from a government-centered approach to decentralized community participation. Survey of India, an agency within the Ministry of Science and Technology is also playing a role in this field by bringing the academic knowledge and research expertise of earth scientists to the Disaster Management process.

5.3.6 EMRI

The Emergency Management Research Institute (EMRI) has been established at Hyderabad as a group representing a Public Private Partnership and can be considered as Pioneer of Emergency Management in India. It aims at improving the general response of communities in emergencies, in addition to those incidents which might be described as disasters. Some of the groups early efforts include:

i. The provision of emergency management training for first responders,
ii. Creation of a single emergency telephone number, and
iii. Establishment of standards for EMS staff, equipment and training.

At present, EMRI operates in the states of Andhra Pradesh, Assam, Goa, Gujarat, Karnataka, Rajasthan, Tamil Nadu and Uttarakhand, using a single 3-digit toll-free number 1-0-8. This service, launched in August 2005, is accessible from both landline and mobile phones without a prefix or suffix. Apart from handling day to day
emergencies, EMRI is also involved in research activities in the areas of medicine (prevention, diagnosis and treatment), crime, traffic disorders, fire, chemicals, pharmacology and biotech. EMRI also provides Emergency Management Training programs.

The intent to operate all these programs is to focus on providing quality Emergency Response with an emphasis on “The more we care…the more we value…the more we respect human life…the more we will develop as a nation…with humanity, humility and commitment to service”. This initiative contributes towards developing the future with state-of-the-art technology in Emergency Management.

5.4 Guidelines on Management of Chemical Disasters

Guidelines on Management of Chemical disasters, the second series, have been issued by Union Ministry of Environment & Forest. The guidelines, to be incorporated in the national and state-level chemical and industrial disaster management plans, focus on industrial installations, transportation, pipelines, cryogenics and storage of hazardous chemical compounds. A key feature of the guidelines prepared in consultation with over 270 experts drawn from the government, industry, federations of industrial bodies, besides scientists and technocrats, is that they not only deal with possible chemical spills, gas leaks and man-made accidents in industrial plants but also cover disasters that can occur during transportation of hazardous chemicals on highways or through pipelines. For transportation disasters, the NDMA recommends the promotion of transportation emergency management by development of highway disaster management plans and a pipeline management system.

5.4.1 NIDM

NIDM (National Institute of Disaster Management), a premier national organization, work for human resource development at national level in the area of disaster mitigation and management. The Vision of NIDM is to be a Center of Excellence in the field of disaster risk mitigation and management in India and the region. Its Mission is to work as a think tank for the Government by providing policy advice and facilitating capacity building services including strategic learning, research, training, system development and expertise promotion for effective disaster preparedness and mitigation. In order to realize
its Vision & Mission the NIDM has devised a **Strategy** to build a National Hub to share, learn & create a critical mass of institutions, trainers and trained professionals.

NIDM will be gearing up the national, state and district level administration to tackle natural calamities and will also be coordinating research projects, training programme and will build a database on natural disasters with case studies.

6. **Framework for Disaster Management: State Specific Cases**

6.1 **Delhi**

The State of Delhi has been prone to disasters. Over the years these disasters have caused extensive damage to life and property and have adversely impacted economic development. The Government of NCT of Delhi recognized the need to have an proactive, comprehensive and sustained approach to disaster management to reduce the detrimental effects of disasters on overall socio-economic development of the State. NCR of Delhi had held a workshop on **Chemical Disaster Management** in New Delhi in August, 2006. The highlights of the Workshop include:

i. The Chief Minister called upon the disaster management agencies to develop appropriate strategies to counter the fallout of possible chemical attacks by terrorists and put in place a mechanism for effective community response to such emergencies.

ii. creating a monitoring mechanism to mitigate disasters in small industrial and chemical units was stressed. This could only be done through sharing of knowledge and information and close partnership amongst industry bodies, specialized academic institutions and organizations such as the National Disaster Management Authority. The CM advised business and manufacturing units to make preventive management of disasters an integral part of the overall management practices,

iii. Member(NDMA, Lt-Gen J. R. Bhardwaj) observed that medical facilities were “substandard” across the country and hence incapable of properly dealing with any disaster situation. He observed that “Not even two per cent of the budgetary allocation of the state governments is going towards medical
preparedness. Uttar Pradesh and Bihar are spending even less than 0.2 per cent of their budget on medical preparedness," he added.

iv. The Executive Director of NDMA (Prof P. G. Dhar) observed that as '..the manufacturing sector is growing, the number of hazardous units will increase. The enforcement of safety norms needs to be strengthened in all these units', he said.

6.2 Maharashtra
The Government of Maharashtra has meticulously planned and implemented a Special Disaster Management Scheme for dangerous chemical industries functioning in the State. The scheme, would promote the vital chemical industry in Maharashtra and at the same time, would ensure safety of industrial workers as well as citizens residing in areas surrounding any major chemical plant.

The State Government has implemented the disaster management scheme for all 335 hazardous chemical plants operational in different parts of Maharashtra. The Government is committed to maintain a fine control over pollution, care for the environment and avoid serious disasters. The State strives for safe growth of the important chemical industry. At the same time, industrialists are called upon to adhere to various safety norms.

7. Conclusions /Recommendations
Chemical and industrial disasters are capable of causing massive loss to human lives apart from damaging the environment and ecology. Seveso Disaster of Italy of 1976 and Bhopal gas tragedy of 1984 are perhaps the rudest reminders of the scourge of chemical disasters. There is, therefore, an urgent need to create awareness about disasters, create situations to avoid possibility of occurrence of such disasters, prepare full-fledged response to tackle hazards just in case such an eventuality arises and put in place all that is required for management of hazards. Further, the following measures would go a long way in effectively tackling hazards:

- Put in place comprehensive ‘SHE’ policy (Safety, Health & Environment) including Onsite & Offsite Emergency Plan.
- Ensure zero level of APIs in the treated effluents.
Move beyond mere compliance. Just meeting stipulated standard parameters may be necessary but not sufficient.
Commission state-of-art ETPs (Effluent Treatment Plants).
Better to ‘Avoid’ than to repent later. It makes an economic and commercial sense to invest in hazards control measures and adhere to international norms.

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Hazards Management in Pharmaceutical Industry
By-NIPER-SAS NAGAR

A Department of Pharmaceuticals has come into being vide Cabinet Secretariat’s Order from 1st July, 2008. This Department has one of the subjects as - technical support for dealing with national hazards.

Indian Pharmaceutical Industry as is known has been making tremendous progress not only in the creation of excellent infrastructure but also attending to the global needs of the supply of API’s. They are also involved in introducing quality medicines in addition to entering into growing fields of contract research and manufacturing as well as clinical trials. Like many chemical industries, the pharma industry has also environment & hazard management issues, especially in the manufacturing of active pharmaceuticals ingredients (API’s or Bulk Drugs).

After discussions with various stakeholders it has been decided to hold a Seminar at New Delhi by the Department in association with NIPER, Mohali to discuss on following important issues.

**Functions of the newly created Hazard Management Cell in DOP are:**

1 - Developments and interaction with pharma industries.

2 - Interaction with pharma industry: To clearly understand the present hazard issues, problem areas, how the industry is adopting good practices for protection of health of people.

3 - Technological changes taking place and modern practice needed to prevent, mitigate and respond in case of emergency arises.
4-Creating awareness on technical advancement in R&D taking place in pharma manufacturing industry with emphasis on the need for use of green processes, reduction in the use of organic solvents in the manufacturing process.

5- Devise strategies to assist MSME’s to synergies efforts in preventing, mitigation and training in Hazards Management as MSME’s constitute a big segment..

**NEED FOR HAZARD MANAGEMENT**

- Major Accidents do happen in many ways and places
- Damage caused to plant, environment and people
- Exposure can/does go beyond the plant area
- Prevention is not an absolute guarantee
- Awareness must therefore be raised
- Response capability must be before an accident
- Emergency plans must be devised and tested
**Very probable**
More than once a year

Once in 1 - 10 years

**Quite probable**
Once per 10 to 100 years

Once per 100 to 1000 years

**Improbable**
Less than once per 1000 years

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**Probability**
A          B          C          D          E

Unimportant  Limited  Serious  Very serious  Catastrophic

**Consequences**

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**Results of hazard/risk analysis**

**Legal & other requirements**

**Accident/injury history**

**Results from previous investigations**

**Internal organizational requirements**

**Planning**

**Measurable objectives (with indicators)**

**Management programs**
Hazard identification

Accident scenario development

Fault tree for the envisaged scenario

Consequences analysis

Risk estimation

Whether risk is in acceptance?

No

Suggest maintenance measures to control risk

Yes

End

Start

What may go wrong?

How it may go wrong?

How likely its occurrence?

What maintenance schedule would reduce its likelihood of occurrence?

Quantitative hazard assessment

Probabilistic hazard assessment

Fault tree analysis

Risk estimation
Paradigm Shift from response oriented to:
- prevention, mitigation,
- preparedness, capacity development, response, relief & rehabilitation

What would be the impacts?
- Hazard identification
- Quantitative hazard assessment
- Accident scenario development
- Consequences analysis

What may go wrong?
- Fault tree for the envisaged scenario
- Probabilistic hazard assessment
- Fault tree development
- Fault tree analysis

How it may go wrong?
- How likely its occurrence?
- Whether risk is in acceptance?

What maintenance schedule would reduce its likelihood of occurrence?
- Risk estimation
- Whether risk is in acceptance?
- Apply maintenance measures and re-evaluate risk
- Suggest maintenance measures to control risk
- Yes
- End
- No
  - No
  - Yes
Preventing chemical disasters

Ms Mara Caboara, Manager of the International Council of Chemical Associations, in an article, highlighted the current state of affairs on the issue of Chemical Disasters. According to her the chemical industry has been at the forefront of disaster prevention. Industrial disasters on the scale of Seveso and Bhopal prompted chemical firms to rethink their response to accidents, and, more generally, how they do business. A part of her article is reproduced below:

“In 1987 the global chemical industry launched a voluntary initiative, Responsible Care, committing chemical companies to achieve continuous improvements in environmental, health and safety performance beyond levels required by local and international regulations.

The chemical industry, in countries such as Japan, Mexico, Canada, China and Thailand, has also set up emergency networks. Every major region and country has developed and adapted its own system, following ICE and CHEMTREC guidelines. Chemical companies are complementing emergency networks with their own schemes and systems. Most chemical companies provide their deliveries with safety data sheets, emergency procedures and emergency labels, under the supervision of technical agencies.

Companies may also offer direct assistance and support to disaster victims, by funding recovery activities, helping implement conservation and emergency preparedness plans, and offering medical care to victims and their families.

These are only a few examples of disaster prevention and management practices in the chemical sector, over and above concerted action by chemical industry networks. Experience at association and company-level has led us to formulate our own
recommendations on how best to use international resources in disaster prevention and remediation, and how public-private partnerships may reduce impacts.

We must create a portfolio of disaster reduction actions, compiling best practice and lessons learned from previous disasters, and a catalogue of technologies for disaster reduction. The chemical industry should share well-developed codes, translated into several languages and adapted to the different environments in which we operate.

We should also do more to integrate environmental emergency preparedness and response activities into strategies and sustainable development programmes. In particular we must identify specific activities, to implement relevant provisions of the 2002 Johannesburg Plan of Implementation, and conform more closely with the Millennium declaration and its goals.

Discussion of emergency prevention, preparedness and response issues involving the competent authorities, private sector and general public must develop. We should assess the effectiveness of existing public-private partnerships.

Would the World Conference on Disaster Reduction, for instance, be an appropriate venue to create new partnerships, and if so, how should partnerships differ from existing ones?

Lastly we must develop and enhance early-warning systems, still the most critical aspect of risk reduction. We need to create suitable technical instruments, constantly monitored and improved by networks of professionals. The lack of suitable early-warning systems is the key obstacle to prevention, allowing accidents to develop into fully-fledged disasters.”

**National organizations**

IN India the role of Emergency Management falls to National Disaster Management Authority of India; It is a Government agency subordinate to the Ministry of Home affairs. In recent years there has been a shift in emphasis, from response and recovery to
strategic risk management and reduction and from a government-centered approach to
decentralized community participation. Survey of India, an agency within the Ministry of
Science and Technology is also playing a role in this field, through bringing the
academic knowledge and research expertise of earth scientists to the Disaster
Management process.

The Emergency Management Research Institute (EMRI) has been established at
Hyderabad as a group representing a Public Private Partnership and can be considered
as Pioneer of Emergency Management in India. It is funded by a large Indian Computer
company; “Sat yam Computer Services” and is aimed at improving the general response
of communities in emergencies, in addition to those incidents which might be described
as disasters.

Phone number 108 is accessible from fixed and mobile phones without a suffix or a
prefix.

EMRI also provides Emergency Management Training programs for medical
professionals, policy makers, public, volunteers and students.

Its goal is to be the best in the world in Emergency Response. EMRI has developed
processes and state-of-the-art infrastructure and is operating successfully in the states
of Pradesh, Gujarat, Uttarakhand, Goa, Rajasthan, T N, Karnataka and Assam

New norms to avert chemical disasters:

Prevention and mitigation of chemical disasters will now not only be limited to strict
regulation and safety audits of industries handling hazardous chemicals but will also
cover transportation emergency management to deal with spills and leaks on highways
as well as in pipelines. According to the National Chemical Disaster Management
Guidelines drawn up by the National Disaster Management Authority (NDMA):

1) The industrial units using hazardous chemicals as raw materials in processes,
products and wastes with inflammable, explosive, corrosive, toxic and noxious properties
will be required to have onsite and offsite emergency plans in place and put them to test
by organizing regular mock drills.
The units will also have to undergo mandatory safety audits and have dedicated manpower and infrastructure to prevent and mitigate chemical disasters at all levels.

The NDMA’s guidelines on management of chemical disasters — the second in the series of disaster management guidelines, have been issued by Union Ministry of Environment & Forest. The guidelines incorporated in the national and state-level chemical and industrial disaster management plans, focus on industrial installations, transportation, pipelines, cryogenics and storage of hazardous chemical compounds. A key feature of the guidelines — prepared in consultation with over 270 experts drawn from the government, industry, federations of industrial bodies, besides scientists and technocrats, is that they not only deal with possible chemical spills, gas leaks and man-made accidents in industrial plants but also cover disasters that can occur during transportation of hazardous chemicals on highways or through pipelines. For transportation disasters, the NDMA recommends the promotion of transportation emergency management by development of highway disaster management plans and a pipeline management system.

National Institute of Disaster Management: The National Institute of Disaster Management (NIDM) is a premier national organization working for human resource development at national level in the area of disaster mitigation and management. The NIDM came into existence since October 16, 2003 by a Government of India order upgrading the National Centre for Disaster Management (NCDM), which was located at Indian Institute of Public Administration, New Delhi. The NCDM was established by the Ministry of Agriculture, Department of Agriculture and Cooperation, Government of India, in March 1995. The NCDM had been functioning as a nodal Centre for the human resource development in the area of disaster management. NIDM will be gearing up the national, state and district level administration to tackle natural calamities and will also be coordinating research projects, training programmes and will build a database on natural disasters with case studies.

Philosophy, essential features & Process of Disaster Management:
In order to understand the philosophy of Disaster Management in general, following basic approaches are considered:

The process of Disaster management involves four phases:

![Disaster Management Process Diagram]

**Mitigation**

Mitigation efforts attempt to prevent hazards from developing into disasters altogether, or to reduce the effects of disasters when they occur. The mitigation phase differs from the other phases because it focuses on long-term measures for reducing or eliminating risk. The implementation of mitigation strategies can also be considered a part of the recovery process if applied after a disaster occurs. However, even if applied as part of recovery efforts, actions that reduce or eliminate risk over time are still considered mitigation efforts.

Mitigative measures can be structural or non-structural. Structural measures use technological solutions. Non-structural measures include legislation, land-use planning and insurance. Mitigation is the most cost-efficient method for reducing the impact of hazards. However, mitigation is not always suitable and structural mitigation in particular may have adverse effects on the ecosystem.

A precursor activity to the mitigation is the identification of risks. Physical risk assessment refers to the process of identifying and evaluating hazards. In risk assessment, various hazards within a certain area are identified.
Each hazard poses a risk to the population within an area.

**Preparedness:**
In the preparedness phase, disaster managers develop plans of action when the disaster strikes. Common preparedness measures include the:

- Communication plans with easily understandable terminology and methods.
- Development and practice of multi-agency coordination and incident command.
- Proper maintenance and training of emergency services, including mass human resources.
- Development and exercise of emergency population warning methods combined with emergency shelters and evacuation plans, stockpiling, inventory, and maintenance of supplies and equipment.
- An efficient preparedness measure is to create an Emergency Operations Center (EOC) combined with a practiced region-wide doctrine (such as the incident command system) for managing emergencies.
- Preparedness measure is to develop organizations of trained volunteers from civilian populations. Professional emergency workers are immediately overwhelmed in mass emergencies, so trained, organized; responsible volunteers can be extremely valuable.
- One notable system is the Community Emergency Response Team. Another is the Red Cross. If volunteers are organized, trained in the incident command system, and agree to mobilize, experience in the Red Cross etc. has shown that they can be utilized in responsible positions, including as staff in EOCs.
- Preparedness is casualty prediction, the study of how many deaths or injuries to expect for a given kind of event. This gives planners an idea of what resources need to be in place to respond to a particular kind of event.
- Response: The response phase includes the mobilization of the necessary emergency services and first responders in the disaster area.

**Prevention techniques**

Through planning
By response plans
Through mitigation
Education and awareness
Best practices Risk Based Maintenance Planning
Risk estimation
Hazard identification
Quantitative Hazard Assessment
Probabilistic Hazard Assessment
Risk Quantification
Risk evaluation
Setting up risk acceptance criteria
Risk comparison
Maintenance planning

“The more we care
…the more we value
…the more we respect human life
…the more we will develop as a nation
…with humanity, humility and commitment to service”.
Hazard Management in Pharmaceuticals Sector: Some First Ideas
Discussion Paper

1. Introduction

India has 10,563² (2007) pharmaceuticals units with 77.4% in formulation sector and 22.6% in manufacturing sector. Five states, names Maharashtra, Gujarat, West Bengal, Andhra Pradesh and Tamil Nadu combinedly account for 63.6% of the pharmaceuticals industry in India. Ref. Table below.

Table: Number of Pharmaceuticals Industries - State-wise¹

<table>
<thead>
<tr>
<th>S.No.</th>
<th>State</th>
<th>Number of Manufacturing Units</th>
<th>% Share</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Formulation</td>
<td>Bulk Drugs</td>
</tr>
<tr>
<td>1</td>
<td>Maharashtra</td>
<td>1,928</td>
<td>1,211</td>
</tr>
<tr>
<td>2</td>
<td>Gujarat</td>
<td>1,129</td>
<td>397</td>
</tr>
<tr>
<td>3</td>
<td>West Bengal</td>
<td>694</td>
<td>62</td>
</tr>
<tr>
<td>4</td>
<td>Adhra Pradesh</td>
<td>528</td>
<td>199</td>
</tr>
<tr>
<td>5</td>
<td>Tamil Nadu</td>
<td>472</td>
<td>98</td>
</tr>
<tr>
<td>6</td>
<td>Others</td>
<td>3,423</td>
<td>422</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>8,174</td>
<td>2,389</td>
</tr>
</tbody>
</table>

The Pharmaceuticals Industry consists of establishments primarily engaged in one or more of the following:

1. Manufacturing medical and biological products;

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² Ref: Directory of Pharmaceutical Manufacturing Units in India 2007, National Pharmaceutical Pricing Authority, Government of India, New Delhi
2. Processing botanical drugs and herbs;
3. Isolating active medical principles;
4. Manufacturing pharmaceutical products intended for internal and external consumption in such forms as tablets, capsules, ointments, powders and solutions

There a number of hazards associated with the Pharmaceuticals Industry. Brief details are presented in this paper.

### 2. Hazards in Pharmaceuticals Industry

The hazards from the pharmaceuticals could be categorised as:

- **Ecotoxic** - damage is caused to the environment.
- **Carcinogenic** - contribute to the causation of cancer.
- **Persistent** - remain dangerous for a long time.
- **Bio-accumulative** – accumulates as it makes its way up the food chain.
- **Disastrous** due to a catastrophe, mishap, calamity or grave occurrence in any area.

The risks of hazards depend on the severity and likelihood of the event. The hazards pose risks to the people in the neighbourhood, to the living organisms and to the environment and to the environmental resources. There are also hazard to the workers in the plants that are exposed to toxic chemicals and emissions.

The hazards could turn out to be disasters. As defined in the Disaster Management Act, 2005, “Disaster” means a catastrophe, mishap, calamity or grave occurrence in any area, arising from natural or manmade causes, or by accident or negligence which results in substantial loss of life or human suffering or damage to, and destruction of, property, or damage to, or degradation of, environment, and is of such a nature or magnitude as to be beyond the coping capacity of the community of the affected area.
Disasters result due to fire, explosion, toxic release, poisoning and combination of these. "Disaster Management" means a continuous and integrated process of planning, organising, coordinating and implementing measures which are necessary or expedient for:

- Prevention of danger or threat of any disaster.
- Mitigation or reduction of risk of any disaster or its severity or consequences.
- Capacity-building.
- Preparedness to deal with any disaster.
- Prompt response to any threatening disaster situation or disaster.
- Assessing the severity or magnitude of effects of any disaster.
- Evacuation, rescue and relief.
- Rehabilitation and reconstruction.

The impacts of chemical disasters lead to impacts on living organisms, environment and property resulting in death, injury, disease and disability to human, livestock, plants etc. and pollution of soil and water bodies (surface/ground) and atmosphere. The impacts of chemical disasters are depicted in the figure below:

Figure 1: Impact of a Chemical Disaster

3 National Disaster Management Guidelines, Chemical Disasters, National Disaster Management Authority, 2007
3. Sources of Hazards in Pharmaceuticals Industry

There are a number of sources of hazard in the Pharmaceuticals Industry including:

Manufacturing and formulation installations.
Handling and storage of hazardous chemicals including warehouses, godowns, tank forms in ports/fuel depots/docks.
Transportation (road, rail, air, water, pipelines).
Emission of pollutants – the air pollutants include carbon monoxide (CO), nitrogen dioxide (NO₂), particulate matter of 10 microns or less (PM₁₀), total suspended particulate matter (SPM), sulphur dioxide (SO₂), and volatile organic compounds (VOCs). The most common VOCs include methanol, dichloromethane, toluene, ethylene glycol, N,N-Dimethylformamide, and acetonitrile.
Effluents, especially those that are not easily biodegradable and toxic in nature. The effluent releases could go directly to streams, rivers, lakes, oceans, or other bodies of water. The releases due to runoff, including storm water runoff, could also be a potential hazard.
Hazardous wastes – these are in the form of liquids, solids, contained gases or sludges. As a general measure, about 200kg⁴ of waste is generated per metric ton of active ingredient manufactured by the pharmaceutical industry. This waste, containing spent solvents and other toxic organics in significant concentrations, requires treatment before it can be disposed of safely.
The toxic releases from the pharmaceuticals industry includes on-site discharge of a toxic chemical to the environment. This includes emissions to the air, discharges to bodies of water, releases at the facility to land, as well as contained disposal into underground injection wells.
Use of a hazardous technology.
Natural hazard events such as flood, cyclone, earthquake, tsunami.

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4. Some Relevant Acts and Rules

Some Acts and Rules relevant to hazards in Pharmaceuticals Industry are briefed below.


   Applicable for the chemicals handled, used and stored or imported are covered in the Schedule 1 and/or 3 of the Rules, Schedule 2 for isolated storages.

   Industry (occupier) to submit a safety audit update report once a year and forward a copy within 30 days.

   Industry to prepare up-to-date on-site emergency plan before commencing a new industrial activity involving specified chemicals.

   Industry shall conduct a mock drill of emergency plan every six months and submit a report.

2.  **The Public Liability Insurance Act, 1991**

   Owner to provide relief in case of death or injury or damage to property from an accident on the principle of no fault.

   Owner to draw insurance policies more than the paid-up capital but less than Rs. 50 crores.


   As per these Rules, the Crisis Groups are constituted as below:

   a) **Central Crisis Group** shall be the apex body to deal with major chemical accidents and to provide expert guidance for handling major chemical accidents. They meet once in six months.
b) **State Crisis Group** shall be the apex body in the State to deal with major chemical accidents and to provide expert guidance for handling major chemical accidents. They meet once in 3 months.

c) **District Crisis Group** shall be the apex body in the district to deal with major chemical accidents and to provide expert guidance for handling chemical accidents. They meet once in 45 days.

d) **Local Crisis Group** shall be the body in the industrial pocket to deal with chemical accidents and coordinate efforts in planning, preparedness and mitigation of a chemical accident. They meet every month. The members of the Local Crisis Group include:

- Sub-divisional magistrate
- Inspector of Factories
- Industries in the industrial area
- Transporters of hazardous chemicals
- Fire officer
- SHO (police)
- BDO
- Rep of Civil Defence
- Primary Health Officer
- Editor of local News Paper
- Community leader/Sarpanch/Village Pradhan
- Rep. of NGO
- Two eminent doctors
- Two social workers

The functions of the Local Crisis Group are:

- To prepare local emergency plan for the industrial pocket;
» To ensure dovetailing of the local emergency plan with the district off-site emergency plan.
» To train personnel involved in chemical accident management.
» To educate the population likely to be affected in a chemical accident about the remedies and existing preparedness in the area.
» To conduct at least one full scale mock-drill of a chemical accident at a site every six months forward a report to the District Crisis Group.
» To respond to all public inquiries on the subject.

4. **The Disaster Management Act, 2005**

As per this Act, the functional groups are named as Disaster Management Authorities at various levels as blow:

» **National Disaster Management Authority** has the responsibility for laying down the policies, plans and guidelines for disaster management for ensuring timely and effective response to disaster.

» **State Disaster Management Authority** has the responsibility for laying down policies and plans for disaster management in the State.

» **District Disaster Management Authority** acts as the district planning, coordinating and implementing body for disaster management and take all measures for the purposes of disaster management in the district in accordance with the guidelines laid down by the National Authority and the State Authority.

The **Local Authority** includes panchayati raj institutions, municipalities, a district board, cantonment board, town planning authority or Zila Parishad or any other body or authority, by whatever name called, for the time being invested by law, for rendering essential services or, with the control and management of civic services, within a specified local area.
As per the Disaster Management Act, 2005, the Ministry of Chemicals & Fertilisers of the GoI is one of the stakeholders within the stated institutional framework\(^5\) (Ref. figure below).

The identified Ministries or Departments of the Government of India are required to prepare Disaster Management Plans, which include:

- Measures to be taken for prevention and mitigation of disasters in accordance with the National Plan.
- Specifications regarding integration of mitigation measures in its development plans in accordance with the guidelines of the National Authority and the National Executive Committee.
- Roles and responsibilities in relation to preparedness and capacity-building to deal with any threatening disaster situation or disaster.
- Roles and responsibilities in regard to promptly and effectively responding to any threatening disaster situation or disaster.

\(^5\) National Disaster Management Guidelines, Chemical Disasters, National Disaster Management Authority, 2007
Present status of its preparedness to perform the roles and responsibilities on above. Measures required to be taken in order to enable it to perform its responsibilities specified above. Update annually the plan referred above and forward a copy of the plan to the Central Government, which Government shall forward a copy thereof to the National Disaster Management Authority for its approval.

5. First Ideas for Pharmaceuticals Sector

The site of the industry and the Chemical Park or the Industry Park where the industry is located play an import role in hazard management. The clarification on the industry, chemical park and the industrial park is given below:

**Industry site:** A site owned and operated by a single company. All the activities on the site are conducted directly by this company or are carried out by third parties exclusively for the company.

**Chemical park:** A site accommodating several chemical companies which are legally separate entities. The infrastructure and a variable range of services are provided by the largest chemical company on the site (the major user) or by one (or more) independent infrastructure companies.

**Industrial park:** Similar to the chemical park, but is (also or more heavily) used by companies from other sectors.

There is a need for hazard/disaster preparedness/management systems *on-site* at the industry level, at the industry park level as well as *off-site* around the industry/industrial park covering the neighbourhood in the estimated areas of disaster. While the large scale industries may afford their own hazard/disaster management systems, especially the SMEs may beneficially integrate their own
disaster/hazard management systems with the Industry Park level hazard/disaster management systems. While the industry level disaster management, emergency preparedness has to continue, synergies could be worked out between Park level and Industry level disaster preparedness/management for sharing of equipment, facilities, personnel etc. Smaller or less hazardous chemical parks may possibly rely partially/completely on the emergency services of a nearby municipality or a nearby chemical park. The advantages of Industry Park level disaster management includes:

- Improved emergency response due to far shorter response times and emergency services which know the disaster premises perfectly.
- Reduced cost of fire protection equipment and insurance premiums.
- Public emergency services may have to be called only for major incidents, thereby drawing less public attention to smaller incidents.

Some first ideas on the approach to hazard management in Pharmaceuticals Industry are given below.

- **Managing hazards due to effluents, emission and hazardous wastes:** The hazards due to effluents, emission and hazardous wastes to be handled through the environmental management initiatives proposed to be taken up by the Department of Pharmaceuticals.

- **Understanding the hazard/disaster management** – The Department of Pharmaceuticals may hold consultations by the Environment Cell of the Department of Pharmaceuticals with the National Disaster Management Authority and the Central Crisis Group of the Ministry of Environment & Forests to understand the hazard/disaster management in Pharmaceuticals Industry and the role of the

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6 Project Management Tool of German Technical Cooperation (GTZ)
Department of Pharmaceuticals, the pharmaceuticals industry and other relevant stakeholders and accordingly develop an overall strategy for disaster management in the pharmaceuticals sector. The strategy should include the objectives, results, processes, cooperation networks, steering structures and learning & knowledge management.

- **Preparation of Disaster Management Plan** - Undertake preparation of national/state/regional level Disaster Management Plan for Pharmaceuticals Sector in India. The disaster potentials should be documented and assessed, and accordingly disaster management plans prepared including the proposed Organizational Structure for Disaster Management in Pharmaceuticals Sector at National Level, State/Regional Level, Local Level covering the aspects of planning, coordination and implementation (preparedness/management).

- **Demonstration of pilot efforts** – The demonstration of pilot efforts could be taken up in selected Industrial Parks having pharmaceuticals industries. These parks may be selected from one of the States/region where the pharmaceuticals industry has major presence. The pilot efforts should include setting up of disaster management teams at industry level and industry park level and putting in place the necessary disaster management infrastructure.

- **Capacity building** - Guidelines should be developed for Chemical Disaster Management (CDM) in Pharmaceuticals Sector (Chemical Park level, industry level). Teams should be developed at all relevant levels (national/state/region, industry park level, industry level). Training/capacity development needs assessment to be taken up and accordingly the training/capacity building programmes implemented.

The possible disaster management structure for catering to the Pharmaceuticals Industry is shown in the figure below.
As shown above, while developing its own system for the Pharmaceuticals Industry, there is a need for bringing in synergies with the existing structures under the Disaster Management Act and under the Chemical Accidents (Emergency Planning, Preparedness, and Response) Rules, 1996 of the Environment Protection Act, 1986.

6. Concluding Note

There is obvious need for hazard/disaster management in Pharmaceuticals Industry in India. For effectiveness and optimal solution, there is a need to synergise the efforts of the Department of Pharmaceuticals with the disaster management structures existing under the Disaster Management Act and the Environment Protection Act.

The paper is intended to generate discussions in the workshop on “Technical Support for hazard Management in Pharmaceuticals Industry” so as to workout the Next Steps for initiating hazard management in Pharmaceuticals Industry.
ECOLOGY AND RISK MANAGEMENT OF HAZARDS IN PHARMACEUTICAL INDUSTRY

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Abstract: The objective of risk management is to prevent incidents due to the operation of facilities which handle hazardous materials. While most releases are minor, there is always a high potential for a significant release which could have direct effect on public health and environment. There is a wide range of available models for risk analysis which help to understand the risk of a hazardous facility.

The paper compares the predicted hazard zones as function of wind speed following the accidental release scenario. The ALOHA atmospheric dispersion model was run for direct release of acetone under different weather conditions. The movement of pollutants is governed by the motions of the atmosphere. Some of the transport phenomena determine the path that the airborne contamination will follow. By defining the width of vulnerable and dangerous zones, potentially vulnerable objects can be identified and the response procedure to accidental situation can be defined. An effective hazard and risk assessment allows to develop an incident action plan and implement strategies and tactics.
Keywords: ecology, risk management, ALOHA, accident, hazard zone

1 INTRODUCTION

Over the past few decades, there has been an increasing concern that human actions and natural catastrophes have been adversely impacting the environment, and posing serious ecological and health hazards [1]. Environmental risk management aims at studying the nature of hazards (emission of a pollutant, natural hazard events, use of a hazardous technology, or any possible combination of these), estimating the associated probability of occurrence of such events and characterizing the adverse effects of environmental hazards resulting from human and ecological exposures.

There is no such thing as zero risk because no matter what precautionary steps are taken, there is always some chance of an accidental release of a hazardous substance and a chance that someone will be adversely affected. The objective of risk and environmental management is to prevent or reduce the illness, injury or loss of life due to the operation of facilities which handle hazardous materials [2].

Risk includes a consideration of both the likelihood and severity of an event. Parameters that influence the level risk include the hazards of the material, the quantity of the material involved, the containment system, the type of stress applied to the container, the proximity of exposures, and the level of available response resources, including the level of training and the experience of the responders [3].

There are hazardous materials in every community. While most releases are minor, there is always a high potential for a significant release which could have direct effect on public health and environment. The risks associated with a chemical release in a community are not confined to city or country boundaries. A "worst case" release could affect an area across any border [4]. Major chemical accidents cannot be predicted solely through regulatory requirements. Rather, understanding the fundamental root causes, widely disseminating the lessons learned, integrating these lessons into safe operations and good practice in environmental management is also required [5].
2 UNDERSTANDING THE HAZARD

The first step in managing chemical reactivity hazards is identifying those facility operations and chemicals that represent a potential chemical hazard. Facilities that handle chemicals are actively engaged in managing risks to ensure the safety of their workers and the community. Most of the efforts focus on ensuring that the facility is designed and operated safely on a day-to-day basis, using well-designed equipment, preventive maintenance, up-to-date operating procedures, and well-trained staff [6].

Before risk can be managed, it must be understood. Risk analysis helps to understand the risk of a hazardous facility and the reductions in risk achievable by certain risk control measures. Whether we judge a risk to be small or large, acceptable or unacceptable depends on many factors. A hazardous facility is often seen as posing an involuntary risk to someone living nearby, but it might be seen as a voluntary risk if someone chooses to live near an existing facility provided that the person is aware of the risks before moving there [2].

Risk can be reduced by decreasing the likelihood and/or consequences of hazardous events. Risk control measures can be broadly classified into:

- safety management of the hazardous facility,
- incident management, and
- land-use restrictions.

Hazard identification is the first of several elements in the process of risk analysis. When selecting the hazardous events for quantifying risks, it is important to include a range of scenarios, from a worst possible case to more realistic scenarios. In order to identify hazardous events it is necessary to:

- establish the undesirable consequences of interest, and
- identify the material, system, process and facility characteristics that can produce these undesirable consequences.

Risk analysis results are always derived from the processing of large quantities of information obtained from numerous scientific fields. Some of these can be highly subjective, incorporating numerous assumptions. In addition, they are based on limited and imperfect data. There are many uncertainties in the process which can be described as:
- uncertainties due to inherent variability in the physical systems that we study,
- modeling uncertainties, and
- input data uncertainties.

Once the undesirable consequences of interest are established, the next stage is to identify the hazard, system, process and facility characteristics that can produce these undesirable consequences. A process recommended for this purpose includes identifying the hazardous substances, gathering hazardous substances information and identifying specific events that can lead to hazardous substance release. The next step in the risk analysis is to analyze the consequences and to estimate the magnitude of damage to the receptors of interest should those hazardous events occur. The inputs to the analysis include the physical, chemical and toxicological characteristics of the hazardous substance and the characteristics of the system in which it is contained.

Numerous studies have attempted to develop comprehensive consequence models for the hazards of interest; however due to the wide range of variables that may affect the behaviour of hazardous releases, there is no single model that will satisfy all situations. There is a wide range of available models that may be based on simple or complex equations, state-of-the-art research and actual field test results.

Under normal circumstances, the theory of atmospheric dispersion, diffusion and transport is a tool in studying the disposition of hazards in the atmosphere and it is applicable to a variety of release conditions, including unintentional releases of hazards which are potentially harmful for humans, biota and environment in general. Pollutants released in the atmosphere consist of particles and gases. Atmospheric residence times for these materials span from a few minutes to several years. The movement of pollutants is governed by the motions of the atmosphere. Some of these determine the path that the airborne contamination will follow [7].

This paper compares the predicted hazard zones as function of wind speed following the accidental release scenario on the example of the chosen plant on the territory of Serbia that has been operating for many years.
3 EXPERIMENTAL WORK

The ALOHA atmospheric dispersion model was run for direct release of acetone under different weather conditions. Experimental weather conditions were selected such that they would cover most scenarios that can conceivable occur under normal circumstances. The model ALOHA is used for simulation of acetone emission in order to show the possibility of accidental risk for both the industry and its surrounding. At low wind speed the model used heavy gas dispersion algorithm, while at high wind speed employed a Gaussian model. Acetone is commonly used in the chosen pharmaceutical industry as a solvent for paints. By defining the width of vulnerable and dangerous zones, potentially vulnerable objects can be identified and the response procedure to accidental situation can be defined. Table 1 summarizes the relevant release parameters:

Table 1. Release scenarios used in the dispersion estimates

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage temperature</td>
<td>ambient, 12°C</td>
</tr>
<tr>
<td>Time of release</td>
<td>10, 30 and 60 minutes</td>
</tr>
<tr>
<td>Wind speed</td>
<td>3 m/s and 30 m/s</td>
</tr>
<tr>
<td>Stability class</td>
<td>D</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>32 %</td>
</tr>
<tr>
<td>Ground roughness</td>
<td>Urban, 20 cm</td>
</tr>
<tr>
<td>Accidental simulation</td>
<td>Outdoor and indoor</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pollutant</th>
<th>Daily storage kg</th>
<th>Amount of pollutant for the specified time of release, kg</th>
<th>PEL ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>5600</td>
<td>560</td>
<td>1000</td>
</tr>
</tbody>
</table>

A very important characteristic of the dispersion is the released chemical. The thermo-chemical properties of the released substance determine how it will enter into the atmospheric environment. Acetone quickly evaporates to a gas if released as a liquid and exposure to this hazard can cause some serious symptoms such as headache,
fatigue, liver and lung damage, unconsciousness and death [8]. Chemical characteristics of the analyzed hazard are given in the Table 2.

Table 2. *Chemical characteristics of analyzed hazard*

<table>
<thead>
<tr>
<th></th>
<th>Acetone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular weight, g/mol</td>
<td>58.08</td>
</tr>
<tr>
<td>Ambiental boiling point °C</td>
<td>55.70</td>
</tr>
<tr>
<td>Vapor pressure, atm</td>
<td>0.14</td>
</tr>
<tr>
<td>Ambient saturation concentration, %</td>
<td>14.10</td>
</tr>
<tr>
<td>TEEL-1, ppm</td>
<td>1000</td>
</tr>
<tr>
<td>TEEL-2, ppm</td>
<td>8500</td>
</tr>
<tr>
<td>TEEL-3, ppm</td>
<td>8500</td>
</tr>
</tbody>
</table>

Direct dispersion of acetone in relation to the wind speed and time of release is given in the following figures. Despite important differences in the atmospheric terms, the behaviour of the threat zone as function of wind speed for the chosen hazard is remarkably similar, as shown in figures 1 and 2. Even though the large amount of acetone is released into the atmosphere it is clearly seen that the increasing of vulnerability distance will result in reduction of outdoor concentration of acetone below its permissible level of concern.

At higher wind (30 m/s) the outdoor concentration attains not even the permissible level of concern for acetone which results in lower rates of accident due to better atmospheric dispersion.
Fig. 1. Illustration of the impact of acetone at wind speed of 3 m/s

Fig. 2. Illustration of the impact of acetone at wind speed of 30 m/s
It is obvious that under the worst accident conditions, possible level of accident can spread long-term on the industrial complex and short-term on the parts of the nearby town.

Even though the consequences of the possible accident could be significant, it is recommended to stay indoor after the accident alarming. Frequent changes in wind direction present additional extenuating circumstances, which contribute to better dispersion of pollutants.

Coinciding with the increasing of the distance from the accidental place, the outdoor concentration has its continual decrease which points out the short-term effect on some parts of the town.

4 CONCLUSION

The fact that acetone is stored in the tanks in amount that satisfies monthly and even annual consumption, showed, by using ALOHA mathematical prediction, the constant possibility of appearing of accidental situation in which human’s health and the environment in general could be affected badly.

Obtained results confirm that acetone has relatively low risk assessment for the chosen industrial complex. Furthermore, it should be considered that the chosen pharmaceutical industry works in inadequate conditions of transition and former economic isolation. Knowing and understanding the risk of hazardous facility and hazard release are the most important segments of an optimal environmental management. An effective hazard and risk assessment allows to develop an incident action plan and implement strategies and tactics.
5 REFERENCES


1.0 Background

Just after midnight on December 2/3, 1984, a pesticide plant in Bhopal, accidentally released approximately 40 metric tons of methyl isocynate (MIC) into the atmosphere. The incident was a cataclysm for Bhopal with thousands of casualties, and significant damage to environment. The long-term environment effects from such an incident are difficult to evaluate. The incident started serious debate at home and abroad on the issues of chemical safety to protect the environment from such events by providing regulatory provisions to industries as well as civil administrations.

India enacted Environment (Protection) Act 1986, after Bhopal gas tragedy. Under this Act several rules were also made to control chemical accidents. Manufacture, Storage and Import of Hazardous Chemical (MS&IHC) Rules, 1989 and Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996 were made under the
Environment (Protection) Act 1986, by Union Govt. of India. The MS&IHC Rules 1989 were again amended subsequently numbers of time for the better enforcement of EPA 1986.

Though, India has created these rules and regulations for chemical safety, but proper monitoring and implementation guidelines are still required for the better results. It is our opinion that for effective implementation and monitoring of the chemical safety issues (technical as well legislative) the fresh consultation is required for the total capability development of the regulators and operators for effective Disaster Risk Management when we consider the pharma industries.

Therefore, it is suggested that industry-specific evaluating guideline is today’s need for management of emergency. Such documents will also establish a mutual confidence in between regulators, community and operators.

2.0 Need of the Hazards Identification and Risk Assessment:

Manufacture, Storage and Import of Hazardous Chemicals (MS&IHC) Rules of 1989 applies to a wide variety of facilities that handle, manufacture, store, or use toxic/hazardous substances, including chlorine, ammonia and highly flammable substances such as propane; organic solvents and flammable substances used solely as fuel. Pharmaceutical industries store, process and handle all such hazardous chemicals in various quantities. Under the mandatory provisions pharmaceutical industries may be classified as hazardous and or major accident hazard (MAH) units depending upon the inventory of the hazardous chemicals as listed in MS&IHC Rules 1989. Under the existing regulations, the covered pharmaceutical facilities must prepare and implement the safety reports, safety audits, on-site emergency plans and maintain documentation at the site. Covered facilities are also supposed to identify major accidents and prevent such accidents to limit their consequences to persons and the environment. Hazardous industries are also responsible to implement the risk management programme and update their risk management programme periodically or when process change, as required by the rule. But there are no evaluating procedures or
guidelines to insure that the occupier does have an effective prevention programme in place. The first element in the chemical accident management system is the hazard identification and subsequent the risk calculation (qualitative and quantitative) to the environment human and property. These are the vital inputs of mandatory requirement on Emergency Planning, Preparedness and Response. Proper guidelines are required for these areas to take appropriate action.

Pharmaceutical industries, as hazardous industries, under the existing regulations have to take action for following:-

- Identification of hazardous chemicals, processes and operations.
- Release scenario, consequences in terms of heat radiation, over pressure and toxicities.
- Preparations of plot and site plan incorporating the damage contours.
- Identification of vulnerable zones.
- Classification of units, which have the potential for creating an off-site emergency.
- Identification of important receptors (both environment and physical) in the vulnerable zone.
- Recording, investigation and publication of major cases.

It is our experience that in absence of the various outputs and information on the above pointed issues the civil administration, development authorities and response agencies are not in a position to take appropriate steps in disaster risk reduction strategies. *This is probably due to poor awareness about the regulatory provisions and weaknesses in computation of hazards and risk assessment.* This weakness resulted in wrong consequence analysis and these wrong analyses may lead to wrong planning decisions by civil authorities and even by industries.

State, District and Local Crisis groups have the following cumulative responsibilities under the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules 1996 for major accident hazards units:
a) Review all district off-site emergency plans in the State with a view to examine its adequacy in accordance with the Manufacture, Storage and Import of Hazardous Chemicals Rules, and forward a report to the State / Central Crisis Groups once in three months;

b) Assist the State Government in managing chemical accidents at a site;

c) Assist the State Government in the planning, preparedness and mitigation of major chemical accidents at a site in the State;

d) Continuously monitor the post accident situation arising out of a major chemical accident in the State and forward a report to the Central Crisis Group;

e) The District Crisis Group shall be the apex body in the district to deal with major chemical accidents and to provide expert guidance for handling chemical accidents.

f) Assist in the preparation of the district off-site emergency plan;

g) Review all the on-site emergency plans prepared by the occupier of Major Accident Hazards installation for the preparation of the district off-site emergency plan;

h) Assist the district administration in the management of chemical accidents at a site lying within the district;

i) Continuously monitor every chemical accident;

j) Conduct at least one full-scale mock-drill of a chemical accident at a site each year and forward a report of the strength and the weakness of the plan to the State Crisis Group.
Based on our national experience we may like to conclude that in absence of proper
guidelines and evaluating procedures on hazards identification and risk assessment
(HIRA) for pharmaceutical industries the district and local crisis groups are unable to
justify their duties. Which ultimately affects the evaluating procedures of the for Disaster
Risk Management. In our opinion the threshold values for various types of hazards also
need to be notified in pharmaceutical industries.

In absence of the HIRA and public-private-people participation the present situation is
summarized as below for pharmaceutical companies:

District administration {District Crisis Group constituted as per CA(EPPR)
Rules 1996} has little knowledge of the hazardous chemicals, processes and
operations.

District administration, regulatory agencies and community in the vicinity has
almost no idea of release scenarios, consequences in term of heat radiation,
over pressure and intoxication. Which leads to an ambiguous situation to take
an appropriate action for rescue in case of an emergency.

Regulatory authorities (Chief Inspector of Factories, Controller of Explosives,
State Pollution Control Board) are unable to take appropriate decision for
industrial development.

Right action is not possible for other development activities (i.e. housing,
recreation, education, and social) related to land use planning.

Response agencies (i.e. fire, police and medical) are in dilemma to response
effectively in post disaster scenario.

No guidelines to industries to evaluate their own risk management* programmes.

This is due to a number of barriers to the pharmaceutical industries, which should be
recognised by policy makers in industry and government. Among the major issues
currently evident are:
Lack of capacity of experienced practitioners,
Consensus on modelling of frequency of hazardous events
Estimation of consequences,
Improving the failure rate data bases,
Experience in the use of QRA for decision-taking within companies communication of the meaning of risk assessments within and to company managements, to regulators, and to the public.

The outcome of HIRA will provide guidance to regulatory as well as local civil administration on following issues when we consider the industrial estates with pharmaceutical units and exclusive pharmaceutical industrial estates:

Provide an idea about worst-case and alternate scenarios due to a disaster.
Help key-decision making process simpler, faster, realistic, transparent and reliable.
Provide a basis for incorporating environmental aspects into physical (land use) planning process effective.
Help in finding out the best routes for escape.
Help in finding out the alternatives of infrastructure facilities, such as roads, water supply, electricity, hospital etc.
Provide guidelines to decide the rehabilitation site.
Ensure that an industry with high-risk potential in high-risk area will have to adopt high standards for safety and also caution to regulatory authorities to be more vigilant.
Help in increasing the public awareness of the vicinity
Will provide guidelines for, e.g., setting policy, ranking risks, prioritising action, and weighing options.
3.0 Components for Mandatory Hazards Identification and Risk Assessment (HIRA) in Pharmaceutical industries:

The risk assessment process, regardless of the method or techniques used, includes the following components:

_Hazard:_ an inherent property of a substance, agent, source of energy or situation having the potential to cause undesirable consequences (e.g., properties that can cause adverse effects or damage to health, the environment or property)

_Hazard identification:_ systematic investigation of the possible hazards associated with an installation, particularly identification of the hazards of the chemical(s) that can cause injury or death to people or damage to property by the release of the chemical or by the release of energy in the event of an accident

_Events identification:_ determination of the different situations that can occur and lead to harm, including estimation of the probable quantity, concentrations, transport, and fate of the hazardous substance(s) or energy released in each specified situation, as determined in part by the environmental conditions at the time of the event

_Events frequency:_ an estimate of the number of times a specified phenomenon (event) occurs within a specified interval

_Consequence assessment:_ a calculation or estimate of the nature and extent of the damage caused by all specified hazardous events, including the influence of environmental factors and the probability of exposure of individuals, populations or ecosystems

_Risk characterization:_ integrates the previous components into an estimation of the combination of the event frequencies and consequences probabilities of the hazardous events specified (for each event and the sum of all events)
Determining significance: evaluation of the significance of the risk estimation and each of the components of the risk assessment process, including elements of risk perception and cost/benefit considerations

a value judgement that combines the results of risk characterization and the estimate of the significance of the risk.

There is another way of looking at the estimation and evaluative steps of risk assessment. Estimation is the technical aspect of what happens when a hazard is present and how often it manifests itself. Evaluation is the part that predicts the effects on people either as individuals or as groups.

3.1 The Adequacy of Data

The quality and robustness of a risk assessment is crucially dependent on the adequacy of the data on which it is based. The lack of data or doubts about its accuracy and validity are major obstacles to improving risk assessment. Inadequacies and gaps exist in the following areas, *inter alia*:

- Equipment failure modes, failure rates and event frequencies;
- Human error;
- The fate/effects of chemicals released into the environment;
- The long-term or delayed health effects of acute exposures, as well as the short-term effects;
- Environmental effects and health consequences related to environmental degradation; and
- Variations in an individual's susceptibility to toxics, heat and explosion forces.

A particular benefit of improved data on environmental and health effects will be to enable more use to be made of the concept of "dangerous dose", rather than the crude measure of death as a risk assessment parameter.
It was also recognized that data limitations can be managed, in part, through the use of less detailed, more generic approaches/methodologies or the use of comparative assessments when choosing among alternatives. The use of comparative assessments normally involves similar assumptions, limitations and uncertainties and therefore their effect on the assessment results is dissipated.

3.2 The Availability of Expertise and Resources

There are gaps in knowledge, and a limited number of knowledgeable experts in risk assessment techniques and especially in the use of more sophisticated quantitative risk assessment techniques. This has two major implications. First, it indicates a need for a transfer of knowledge and experience between countries, states and between experts/organisations. Second, it indicates that it would be a mistake to recommend the use of specific approaches/methodologies which require the use of expertise which is not widely available except in special circumstances.

It is recommended that countries and organisations improve the exchange of information so that competence in the use of risk assessment approaches/methodologies is enhanced. Such information exchange can also be used to facilitate training in order to increase the expertise available. In general, a conscious effort should be made to train assessors in order to ensure continuing competence.

The fact that risk assessment can be a resource-intensive activity influences the use of particular methodologies. In some situations resources might be an overriding constraint. But in most cases there will be a link between the resources for risk assessment and the significance of the assessment for a decision or process. Having clear objectives for the uses of the risk assessment will help ensure that the allocation of resources to the process is properly considered.

3.3 The Socio-Political Context

It has been recognised that the approach to risk assessment and the use to which it is put will be strongly influenced by the socio-political context. This can be characterised by a spectrum from systems that favour a deterministic approach, based on standards,
through to those, which adopt a probabilistic approach. But such an analysis might be too simplistic. Even within a single national system detailed approaches might be more, or less, deterministic or probabilistic depending on the specific application. Thus, risk assessment might be used for novel processes but there might, in the same system, be a heavy reliance on standards for very well established processes which have had many years’ operating experience. It was concluded that the socio-political context is an overriding influence on risk assessment approaches, and it is recommended that this fact be kept in the forefront during any future work on the specific subject of pharma industries in Indian context.

3.4 Risk communication

Risk communication is a very complex process with strong psychological undertones, which hinges on the purpose for which it is being undertaken, the setting in which it will take place, the cultural and technical environments surrounding it, and the key stakeholders who may be involved. Examples of different situations that could affect the risk communications strategy include:

- Is it in support of a new situation or an existing one familiar to the community?
- Is it to provide information following a serious Disaster?
- Is the setting urban or rural?
- Is it part of a continuous improvement programme or a new situation?

Risk communication forms an important, perhaps a vital, element in the risk management process. However, at this time the considerable experience that has been gained has not been collected and organised in a comprehensive form to provide guidance and assistance to users. Some areas where help would be particularly welcome including:
How are key stakeholders identified?

What are the common pitfalls and how can they be avoided? and

What are some of the techniques of successfully communicating about risks in different situations?

Important elements in any risk communications process include, for example:

The identification of key stakeholders (this may include plant employees, representatives of the local news media, community leaders, members of the health community, academics, schoolchildren, representatives of religious groups, persons with special interests, and others);

Ways to take account of the needs and interests of the various stakeholders from multi-faceted communities concerned with economic as well health and environmental consequences;

The identification of the objectives of the process and the needs of the various stakeholders;

Fostering an interactive flow of information among stakeholders;

Approaches to facilitate the development of trust and credibility; and

The use of techniques to help people reach a common understanding of risk, recognising that the public often perceives risk differently than do experts.

An effective risk communication programme requires an understanding of the real issues and concerns of stakeholders and a demonstrated willingness to address them. The issues and concerns need to be identified through research directly involving stakeholders.

4. Business Continuity Plan

Whether pharma industry operates from an isolated site or in an industrial
complex; whether it is a large or small company; the concepts of HIRA will apply for overall emergency management planning so that company have the business continuity plan for all types of Disaster Risk management.

To begin, we need to have in-depth knowledge of emergency management based on HIRA. What you need is the authority to create a plan and a commitment from the Chief Executive officer to make emergency management part of corporate culture. Simultaneously we have to initiate the making the procedures of evaluation of total business continuity plans in the sector of Pharma.

Obviously, numerous events can be “emergencies,” including:

- Fire
- Hazardous materials incident
- Flood or flash flood
- Hurricane
- Tornado
- Winter storm
- Earthquake
- Communications failure
- Radiological accident
- Civil disturbance
- Loss of key supplier or customer
- Explosion

In fact, each event must be addressed within the context of the impact it has on the company and the community. What might constitute a nuisance to a large industrial facility could be a “disaster” to a small business.

We propose the following steps for an effective plans considering the hazards in a pharmaceutical industry:-
Section 1: 4 Steps in the Planning Process — how to form a planning team; how to conduct a vulnerability analysis; how to develop a plan; and how to implement the plan. The information can be applied to virtually any type of business or industry.

Section 2: Emergency Management Considerations — how to build such emergency management capabilities as life safety, property protection, communications and community outreach.

Section 3: Hazard-Specific Information — technical information about specific hazards your facility may face.

Section 4: Information Sources — where to turn for additional information.

5.0 Proposed Model of Business Continuity Plan based on Risk Assessment

With above background the following methodology is proposed in Indian context:
Spatial information

- Land use of the area;
- Geo-physical/climatic characteristics;
- Natural resources’ information;
- Release scenario, consequences in terms of heat radiation, over pressure and toxicities;
- Preparations of plot and site plan incorporating the damage contours;
- Identification of vulnerable zones;
- Identification of important receptors (both environment and physical) in the vulnerable zone;
- etc.,

Non-Spatial information

- Identification of type disasters;
- Classification of events, which have the potential for creating an emergency;
- Recording investigation and publication of major disasters;
- Requirement of various departments for coping with emergency situations;
- etc.;

Experiences of past disasters in the pharma units

- Review of available resources for risk reduction
- Public-Private-People

Analysis through computer modeling, GIS,

Risk estimation/quantification

Disaster Risk reduction strategies & Business continuity plan
1. About APIIC

The Andhra Pradesh Industrial Infrastructure Corporation Ltd. (APIIC), Hyderabad is a company owned by the Government of Andhra Pradesh and is envisioned as a facilitator for industrial investment and development of industrial estates in Andhra Pradesh in India. APIIC has so far developed over 290 Industrial Parks spreading over an extent of about 85,000 acres. A large number of leading industrial houses have their presence in these Industrial Parks.

Besides the multi-product Industrial Parks, the Corporation is also developing sector focussed parks viz. Apparel Park, Food Processing Park, Leather Park etc. With the advent of economic liberalization, APIIC has reoriented itself to the changing needs of economy and assumed the role of facilitator and some of the signature projects are the Hi-Tech City with L&T, Pharma City with Ramky Infra, Mindspace IT Park with Rahejas.. The APIIC is the principle facilitator of mega projects viz. Special Economic Zone, Visakha Industrial Water Supply, Gangavaram Port, Convention Centre, Mega Industrial Parks at Parawada and Pashamylaram, Financial District, Hardware Park near Hyderabad etc.

APIIC is also the Nodal Agency for the Government Sponsored schemes such as Growth Centres, Export Promotion Industrial Parks, Integrated Infrastructure Development Centres and executed successfully many of the Mega Infrastructure Projects. The project conceptualisation and development till financial closure of the individual projects is carried out through Project Development and Promotion
Partnerships (PDPPs) with expert business houses or through directly appointed consultants or through in house expertise, as may be most appropriate.

A large number of pharmaceuticals industries have presence in the Industrial Parks of APIIC such as those at Jeedimetla, Patancheru Pashamylaram Pydibhimavaram, APIIC has an exclusive Pharma City developed at Visakhapatnam in an area of 2,000 acres together with Ramky Group with an Integrated Waste Management facilities providing for disposal for Solid and Liquid effluents with designated Landfills and Marine Outfall

In line with the international trends, APIIC has planned to transform all its existing Industrial Parks into Eco Industrial Parks in a phased manner. GTZ is providing technical support to APIIC since 2004, under the Advisory Services in Environment Management Programme (ASEM) within the framework of the Indo-German Development Cooperation, for developing Eco Industrial Parks in Andhra Pradesh. ASEM is a joint programme of GTZ and the Ministry of Environment and Forests (MoEF), Government of India and addresses various challenges in the areas of environmental policy, sustainable industrial development and sustainable urban environment.

In the pilot phase of GTZ-APIIC cooperation, a number of efforts were taken up on preparation of Status Reports, development of infrastructure viz. storm water drainage, sewerage, CETP, plantation etc., setting up of Environment Management Cells in various industrial parks and training of relevant stakeholders.

2. APIIC’s Vision for Environment and Disaster Management

APIIC’s vision to transform the Existing Industrial Parks into Eco Industrial Parks includes interventions related to environment, disaster management and the needed capacity building. The interventions include:

- Strengthening of environmental infrastructure – storm water drainage, sewerage network and Common Effluent Treatment Plants, waste management facilities, plantation.
Disaster management – infrastructure development and organisational
development (Disaster Management Teams).
Capacity building – training programmes, strengthening of environmental
management capacities through creation of Environment Management Cells,
strengthening of disaster management capacities through creation of Disaster
Management Teams, facilitation of EcoClub Forums etc.

The pilot phase during 2004 to 2007 covered Industrial Park Nacharam and Industrial
Park Mallapur. In these Industrial Parks, the measures taken up include implementation
of sewerage system, storm water drainage system, plantation and a Common Effluent
Treatment Plant (CETP). Also, to strengthen the environment management capacities in
these two Industrial Parks, an Environment Management Cell has been made
operational. A number of training programmes were conducted for the managers from
APIIC. Also, awareness programmes were conducted intensively for the industries in the
two Industrial Parks.
Based on the experience from the pilot efforts in Industrial Park Nacharam and Industrial Park Mallapur, APIIC has now expanded the efforts to cover all the exiting industrial Parks in phased manner. The Environment Management Cells have already been set up catering to 32 Industrial Parks converging 8 zones of APIIC in various parts of Andhra Pradesh. not APIIC is keen to step up interventions in the Disaster Management.

3. Disasters/Hazards in Industries/Industrial Parks

The Industrial Parks of APIIC have a number of disaster/hazard risk sources in the form of manufacturing and formulation installations, and material handling and storage, isolated storages, warehouses, godowns and tank forms. Also, the transportation of hazardous chemicals/materials is also a source of disaster/hazard risk. The disasters/hazards could result in fire, explosion, toxic release, poisoning and combination of these.

The examples of two industrial disasters that took place recently are briefed below.

**Case 1 - Disaster in a Pharmaceuticals Industry:** On 9th February 2009 a major disaster took place in a pharmaceuticals industry located in APIIC developed Industrial Park at Moulali when a huge blast occurred in the storage tank of a petrochemical-based solvent used in manufacturing medicines. The industry manufactures intermediary drugs used in manufacturing 5-cyanophthalide. The high intensity explosion caused critical injuries to two workers and ripped apart the compound wall and damaged the reactors, dryers, vats and a centrifuge in the company. Nine industries surrounding the pharmaceuticals industry were also damaged. The sound from the explosion was heard upto 2 k.m. radius, smoke engulfed the area posing breathlessness to residents, window panes of many buildings developed cracks and some buildings in the vicinity shook. Five fire engines and three water tenders battled the blaze for three hours to bring the fire under control. Eight ambulances were rushed to the site. Thousands of locals thronged the spot and police had to cordon off the area. It is reported that the locals had alerted the factory management about an “unbearable, pungent, chemical odour” days before the disaster.
The likely causes for the disaster include:

- Hazard from highly toxic and flammable gas was ignored and leakage was not arrested.
- Improper maintenance of safety/warning equipment.
- Lack of safety training to the personnel.
- Lack of preparedness to handle the hazards.
- Factory buildings not complying to fire safety norms.
- Cheaper and non-standard hazard/disaster management equipment.
- Lack of periodic inspection of pressure vessels and preventive maintenance.

**Case 2 - Disaster in a Pharmaceuticals Industry:** On April 28th, 2008 at 1:43 am major fire broke out in Sodium Methoxide Plant of a Pharmaceuticals Industry located in L.B. Nagar, Hyderabad severely injuring seven workers and damaging the factory buildings and machinery. The accident took place when a sodium methoxide cylinder exploded and flames leaped to a height of 20 feet. The effect of the fire accident has generated huge smoke causing breathing problems to the workers and residents of the surrounding locality. Panic gripped the citizens living in the surrounding L.B Nagar area and utter chaos prevailed as drums filled with sodium methoxide started exploding. The impact of the explosion echoed in a radius of three km surrounding the factory. The likely causes for the disaster include:

» Improper storage of chemicals.
» Improper maintenance of safety/warning equipment.
» Lack of safety training to the personnel.
» Shortage of fire fighting equipment

The above cases indicate lack of “Awareness”, “Avoidance” and “Response” on disaster/hazard thereby inflicting damage to the personnel working and property of the
chemical units. Some for the issues related to disaster/hazard management in the industries and industrial parks are briefed below:

As of now, the Industrial Parks of APIIC do not have disaster/hazard management systems at industrial park level.
Many of the Industrial Parks do not have basic security systems.  
Latest information on the industries located in the Industrial Parks is not readily available due to which it is difficult to assess which industries and how many of them have disaster/hazard risk potential.
The Industrial Parks mainly have SMEs and are of multiproduct type. Many of the SMEs may not be adequately equipped with required infrastructure as well as qualified personnel to deal with disasters/hazards.  
Inadequate awareness on disaster/hazard/risk management.

Hazardous wastes including toxic chemicals are haphazardly disposed or wildly dumped and often these wastes are put to fire accidently or even purposely to get rid of the waste. These wastes pose serious disaster/hazard risks.
Many of the Industrial Parks are located in close proximity of urban areas and are surrounded by dense residential areas.

APIIC, the leading Industrial Park developer in Andhra Pradesh, has initiated steps towards disaster/risk management.

4. Disaster/Hazard Management – APIIC Way Forward

APIIC has set up Environment Management Cells (EMCs) catering to 32 of its Industrial Parks. The EMC’s are presently involved in generating Industrial Park Information System. The information on plot-wise details, industry-wise data on raw materials and products etc. which enable to make a preliminary assessment of disaster/risk potential and accordingly prioritise the setting up of disaster/hazard risk management system.  
APIIC is also developing state level Industrial Park Information System on location of Industrial parks, contact details, environmental quality data, infrastructure details etc.
With the technical support of GTZ, APIIC is planning to set up Disaster Management Teams, as a pilot effort, in one of the Industrial Parks in Andhra Pradesh, preferably in the pharmaceuticals clusters. The process would include:

- Inventorisation of industries and information compilation of layouts, land use in the surrounding areas etc.
- Providing the necessary skills for colour code and maintenance of ambient temperatures for storage
- Preparation of disaster management plan including personnel/equipment requirements for setting up of Disaster Management Teams at the Industrial Park level.
- Setting up of Disaster Management Teams in the identified Industrial Park,
- Training to the Disaster Management Teams.
- Awareness programmes to the stakeholders (industries, neighbourhood etc.).
- Conducting of mock drills.

Based on the results of the pilot efforts, disaster/hazard management will be taken up in larger scale in a phased manner to cater to all the existing industrial parks.

5. Conclusion

There is a need for disaster/hazard management at industry level as well as at industrial park level. APIIC, as a part of its commitment, is going ahead with disaster/hazard management and environment protection in a phased manner. APIIC is willing to cooperate with the Department of Pharmaceuticals and other like organisations in dealing with ‘Awareness’, ‘Avoidance’ and ‘Response’ to disaster/hazard management.