CHAPTER I

INTRODUCTION

1.0 An Overview of Indian Pharmaceutical Industries

India’s pharmaceutical industry is the 3rd largest in the world in terms of volume and its rank is 14th in terms of value. The total turnover of India’s pharmaceutical industry is US$ 21.04 billion with a domestic market of US$ 12.26 billion (Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers). As per IMS Health India, the Indian pharmaceutical market reached US$ 10.04 billion in size in July 2010. The Indian Pharmaceuticals market is expected to reach US$ 55 billion in 2020 from US$ 12.6 billion in 2009 (1).

India tops the world in exporting generic medicines worth US$ 11 billion with a growth rate of 17%. The drugs and pharmaceuticals sector has attracted FDI worth US$ 1707.52 million between April 2000 and April 2010. Due to increase in the population of high income group, there is every possibility that they will open a potential US$ 8 billion market for multinational companies selling costly drugs by 2015. Indian domestic pharma market is estimated to touch US$ 20 billion by 2015, making India a lucrative destination for clinical trials for global giants (2).

The Indian Pharmaceutical Industries meet 95% of country’s pharmaceutical needs. The Indian Pharmaceutical Industry today is in the front rank of India’s science-based industries with wide ranging capabilities in the complex field of drug manufacturing technology. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously.

The Indian Pharmaceutical sector is highly fragmented with more than 20,000 registered units. It has expanded drastically in the last two decades. The leading 250 Pharmaceutical Companies control 70% of the market with market leader holding nearly 7% of the market share. The Indian Pharmaceutical industry in India meets around 70% of the country’s demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, oral liquids and injectables. There are about 250 large units and about 8000 small scale units, which form the
core of the pharmaceutical industry in India including 5 Central Public Sector Units. These units produce the complete range of pharmaceutical formulations and about 350 bulk drugs (3).

1.1 Waste Generation

Only 23% of world’s population live in developed countries, consume 78% of the resources and produce 82% of the waste products. At present out of five million known registered substances 70,000 are widely used worldwide, and about 1,000 new chemical substances are added to this list each year (4).

Pharmaceutical manufacturers use water for process operations, as well as for other non-process purposes. However, the use and discharge practices and the characteristics of the wastewater vary depending on the operations conducted at the facility. Process water includes any water that, during manufacturing and processing, come into direct contact with or results from the use of any raw material or production of any intermediate, finished product, byproduct or waste. Water is used to clean process equipments and floors. Non-process water is cooling water, water used in heat exchanger, boiler blow down, bottle washing, and sanitary water. Following tables show the huge consumption of water resources and fast increase of water requirement in pharmaceutical industries.

**Water Resource of India**

<table>
<thead>
<tr>
<th>Surface runoff – utilization</th>
<th>6840 km³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ground water – utilization</td>
<td>4200 km³</td>
</tr>
</tbody>
</table>

**Water Requirement (km³/yr)**

<table>
<thead>
<tr>
<th></th>
<th>1985</th>
<th>2000</th>
<th>2025</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surface water</td>
<td>360</td>
<td>500</td>
<td>700</td>
</tr>
<tr>
<td>Ground water</td>
<td>180</td>
<td>250</td>
<td>350</td>
</tr>
</tbody>
</table>

Until recently neither the industries nor the Government is bothered about the enormous and unaccounted use of water and least concern is felt regarding vast amount of wastewater generated and disposed of indiscriminately into the environment. Natural assimilation capacity of the environment to bear the load and maintain wholesomeness of water has been the only hope towards the sustainability of the ongoing chaotic use of water, wastewater generation and disposal system.
Wholesomeness of water means an aquatic ecosystem acting as a dynamic biological machine that sustains physicochemical characteristics of water to cater diverse aquatic flora and fauna and various uses for human beings. This biological machine assimilates pollutants to a great extent.

\[
\text{Re-aeration constant} \\
\text{Assimilative capacity} = \frac{\text{De-oxygenation rate}}{\text{Re-aeration constant}}
\]

With the continuous awareness campaign launched by different government and non-government agencies, the industries at least know that they have to take some measures to reduce water use, minimize wastewater generation and treat the wastewater properly before disposal to the environment. Simultaneously, due to enactment of laws and attempts by the governmental agencies to implement the laws in all the sectors, the major pharmaceutical industries have taken up some programmes in tune with the requirement in this regard.

At present, most of the big plants have their own established waste management system, but small and medium sized (SME) companies do not have such services. The Central Government has announced some subsidy in case of small-scale industries to install Common Effluent Treatment Plant (CETP) to treat the combined effluents generated from these industries. In India, CETP for pharmaceutical industries exists in few cases where they are situated as clusters in a common place. The places where the CETPs are prevalent are Maharashtra, Gujarat, and Hyderabad and rest of the country is lacking in such facilities. Annual burden for pollution treatment expense to annual turnover ratio has been presented in Table1.1 (5).

Table 1.1 Annual Burdens for Pollution Treatment Expense to Annual Turnover Ratio

<table>
<thead>
<tr>
<th>Serial no.</th>
<th>Name of the industry</th>
<th>Best practicable means</th>
<th>AB/AT Ratio (in percentage)</th>
</tr>
</thead>
</table>
| 1          | Caustic soda industry (mercury cell) | a) Ion exchange  
b) Sodium sulfide  
c) Amalgamation with iron fillings | 0.10  
0.27-0.49  
0.28 |
| 2          | Pharmaceutical Industry  
a) Bulk Drug  
b) Fermentation  
c) Formulation | Secondary Biological Treatment | 0.28 – 0.44  
0.8  
0.08 |
From government level for pharmaceutical sector waste minimization programme is started recently after forming a new department as ‘Department of Pharmaceuticals’ under the Ministry of Chemicals and Fertilizers.

The priority lists of Indian corporate are now slowly paying due importance in environmental strategy formation and implementation. Environment management is even more necessary in pharmaceutical industry as this is regarded as waste intensive industry; the ratio of waste to product is often 10:1, while it is true that newer technologies are coming up and ‘cleaner’ technologies are geared towards pollution prevention rather than treatment (6).

1.2 Status of Waste Minimization

Formulation industries are equipped with stringent infrastructure, machineries, utilities, resource, and manpower but completely dependent on input materials or raw materials for their formulation, generally used either as active or as inactive ingredients. Judicious reduction in input supplies and change in input materials and processes will invariably lead to saving of materials on one hand and minimization of waste on the other. Hence extensive study is required to see whether there is any scope of saving of some input materials to accomplish this objective. Many leading pharmaceutical industries are attempting to change their manufacturing processes or input materials to find out ways of saving and waste minimization.

1.3 Status of Pollution Control

Environmental pollution control in bulk drug manufacturing industry requires high skilled manpower due to its nature of pollutants. In general, it has been observed that the final product’s purity is of major concern to the industry. Thus the rejects (unreacted/converted portion of raw materials) contribute to the major pollution load from the industry. The industry involves several batch reactors to get required product and each reaction yields different kind of pollutants depending upon particular reaction and process. There are number of streams with different characteristics which emanate from the various sections of the industry, requiring segregation and corresponding treatment instead of the conventional end-of-pipe treatment system for combined effluent (7).

These companies’ water consumptions and discharges are of a huge volume. But in the arena of minimization of waste and proper effluent treatment in India, efforts are still to be improved. Few industries have adequate effluent treatment system but many industries have not adopted the adequate measures to prevent pollution of natural resources. The wastewaters of bulk drug industries contain huge organic and inorganic matter with a high BOD and COD level. The wastewater of pharmaceutical formulation industries are also containing organic and inorganic matter but in a lesser level than bulk drug industries. There are many small scale sector pharmaceutical industries in India those have not adopted any effluent treatment plant till now.
The big companies have installed and running ETP plant but recycling of final treated effluent water are not cared of. In major cases final treated effluent water are simply drained.

### 1.4 Objective and Scope of Work

The objectives of the present thesis may be delineated as follows:

1. To carry out an extensive literature survey on different approaches (change of materials and processes) made by leading pharmaceutical industries to save materials.

2. To appraise the current scenario of waste minimization and effluent treatment system in Indian Pharmaceutical Industries and prospective measures to be undertaken to meet the need of proper environmental management.

3. To study in-depth three Indian Pharmaceutical Industries and evaluate possibilities of materials saving, waste minimization and effluent treatment in those three industries under study.

4. To study on waste minimization in a basic drug plant producing sodium hydroxide and prospective measures to be undertaken to meet the need of proper environmental management and to suggest corrective actions to be taken to reduce wastage, to improve characteristics of wastewater by process modification.

5. To study the possible outcome of implementation of ISO14000 norms in pharma plants.

6. To identify an organism from activated sludge process of a biological wastewater treatment plant of a basic drug industry and to study on the utilization characteristics of this microorganism Pseudomonas aerugensosa with different active pharmaceutical ingredients in order to assess whether this organism may be used to degrade these drugs present in wastewater.

7. To study the potentiality of a low cost waste treatment plant to treat the effluent from a pharmaceutical industry manufacturing medicated ointments.