ISSN 2348-1218 (print)
International Journal of Interdisciplinary Research and Innovations ISSN 2348-1226 (online)
Vol. 6, Issue 3, pp: (34-38), Month: July - September 2018, Available at: www.researchpublish.com

Environmental Audit on Pharmaceutical Industry: A Case Study of IPCA laboratories Indore

[1]Priyanka Jagwani, [2]Devendra Dohare, [3]Rahul Tyagi

[1]M.tech (Environmental Engineer) Civil Engineering and Applied Mechanics Department S.G.S.I.T.S. Indore, (M.P.)
[2]Assistant Professor, Civil Engineering and Applied Mechanics Department S.G.S.I.T.S. Indore (M.P.)
[3]Manager- EHS, Ipca Laboratories Indore (M.P.)

Abstract: **In order to restrict the deterioration of the environment by industries, it is now mandatory to perform environmental audit as per Environmental Protection Act (II Amendment) Rules, 1992. The Environmental Audit is the key for sustainable development as it leads to waste minimization, pollution prevention and environmental management. This paper reviews fundamental aspects of environmental audit which is the need of today. High speed industrialization has focused mainly on the production and quality control with a minor concern on sustainable development with respect to the environment. Thus a potent Environmental audit will provide a true path to the industries to restrict the environmental damage. Proper implementation of the environmental management policies are the reflection of an effective performance of the industries. This paper gives a brief study of the manufacturing, waste production and waste treatment of pharmaceutical industries. "Indian pharmaceutical combine association (Ipca) Laboratories Ltd; Indore" was reviewed for its environmental policies and management.**

Keywords: **Environmental Audit, Environmental Statement, Sustainable development, Pharmaceutical industry, Ipca, Waste, Environmental management, Limits, Drug regulatory authorities.**

1. INTRODUCTION

As the environmental surveillance are being tough and tight all over the world, thus for the survival, industries have to improve their environmental performances. For this Environmental Audit is the efficacious management tool which evaluates the proficiency of any industry. Environmental Audit is known as "Environmental Statement" in India. The main aim of environmental audit is to increase the positive aspects of the environment by eliminating the negative aspects of the industries and hence to establish an environmentally sound system. This is deeply concerned with the Sustainable development. A sound environment management programme should involve constant monitoring and needs corrective measures for better environmental performances. Thus environmental audit is an aid to check the potency of the environmental endeavours locally.

2. COMPANY PROFILE

Ipca Laboratories Indore: The Indian Pharmaceutical Combine Association, known as Ipca is fully integrated, rapidly growing Indian pharmaceutical company. APIs and formulations of Ipca are endorse by leading drug regulatory authorities including US-FDA, South Africa- Medicines Control Council, UK-Medicines and Healthcare products Regulatory Agency, Australia- Therapeutic Goods Administration and Brazil- Brazilian National Health Vigilance Agency. In Indore, IPCA has been successfully operating since 1994. The plant is located in Pologround Industrial Estate, Indore, Madhya Pradesh. Ipca Indore received following certifications:

ISO 9001: 2008

ISO 14001: 2004

OHSAS 18001

WHO-GM

3. ENVIRONMENTAL AUDIT

Environmental audit (EA) as an organized and documented verification process of objectively obtaining and evaluating evidence to determine whether an organization's environmental management system obeys the audit criteria set by the industrial agency or not, and for communicating the results of this process to management. An Environmental Audit encompasses pollution audit, waste minimization audit and environmental management system audit. Environmental Protection (II Amendment) Rules, 1992 made it mandatory for the industries to submit Environmental Audit Report in prescribed format. Audit is very much important for the sustainability of the environment. It provides a bridge between realistic problems and environmental management plans.

3.1 Types of Environmental Audits:

The Environmental Audit may be of different types but the two main types are; Objective-based audit and Client-driven audit. Both types are explained as under.

3.1.1 Objective-based Audit:

As the environmental audit investigates any action that affects the environment in any way thus the results are more likely to be based on the objective of the audit. Liabilities audit, management audit and activities audit are categorised under objective based audit.

Liabilities audit checks the compliance, operational risks, acquisition and health & safety aspects. The most common type is compliance audit which observes the emission limits, environmental legislations, regulations etc. Operational risk focuses on outcomes of environmentally damaging activities in feedstock and product storage, handling and manufacturing process. Liabilities due to contaminated land and building remediation cost are assessed in acquisition audits. Health and safety audit assess the personal protection in case of emergencies and focuses on disaster management plans. This ensures the proper use of personal protective equipments such as goggles, safety shoes, helmets etc.

Management audit is for effective and efficient running of the industries. This includes corporate audit, policy audit, system audit and issues audit. The corporate audit ensures that the main board is hyper efficient to reassure its aims and objectives. The policy audit reviews the legal, financial and technical aspects. The system audit checks the management system against the legal standards such as ISO 14001 etc. Issues audit is carried out to set up environmental management plans and targets.

Activities audit is an audit of technical and management issues. This audit includes product audit, waste audit and cross boundary audit. Product audit is concerned with the design, manufacturing, utilization and destruction/disposal of the products but with due consideration of 'Green labelling'. Waste audit covers waste minimization practises and waste management programmes. The audit which assess those activities which cut across the departments and business sectors are cross boundary audits (e.g. supply chain audits, transport etc).

3.1.2. Client-driven Audit:

These audits are those which are based on the client, who has been appointed or ordered to continue the audit procedures. This includes regulatory external audit, independent external audit, internal environmental audit and third party audit.

The regulatory external audit is the inspection carried out by any or for any regulatory agency to ensure that the concerning industry is following legislations and regulations or not.

Independent external audit is supervised by external auditors such as investment funds, banks, insurance companies, local government, environmental firms and environmentally aware citizens etc to appraise the attitude of the industries towards environmental issues.

Internal environmental audit involves the study appointed by the management authority of the concerning firm. In this type of audit the results remains within the firm only and is generally executed to check their liability to pay fines, damages or clean-up cost by the cause of breaking the laws such as liberating more emissions than permitted.

ISSN 2348-1218 (print)
International Journal of Interdisciplinary Research and Innovations ISSN 2348-1226 (online)
Vol. 6, Issue 3, pp: (34-38), Month: July - September 2018, Available at: www.researchpublish.com

The third party audit is ordered by certifying organization's top management or members of board to verify whether the internal or external audits calibrates with the guidelines or not.

3.2 Environmental Audit in India:

In India EA is named as 'Environmental Statement' (ES) which aims at the inspection and supervision of the industries. ES empowers the units to take a comprehensive look at their industrial performances and provisions, understanding the material flow, practising waste reduction and ultimately saving the input costs, if possible. In India it has become mandatory to fill up ES Form V (Rule 14).

3.2.1 Objectives of ES: the main objectives of environmental statement are-

1. To prevent the waste generation by identifying its origin and production practises.
2. Maximise the raw material conversion and boost up in-plant operations.
3. To analyse whether recycle, reduction, recovery or reuse is possible or not.
4. Minimise the adverse effects of unavoidable wastes by treating it in any way.
5. To assess the alternatives for raw material substitution and check whether if any process changes are effective for environmental sustainability.

4. OVERVIEW OF PHARMACEUTICAL INDUSTRIES

The pharmaceutical manufacturing industries are concerned with the manufacturing, extraction, processing, purification and packaging of the medication in solid or liquid form. Pharmaceutical industries can be Active pharmaceutical ingredients (API), intermediates and formulation manufacturer. API's are the bulk drugs with desired medicinal properties. Most of the chemical reactions take more than one elementary step to be processed. An API is an outcome of complex chemical chain reactions in various steps whereas intermediates are in stable forms. Formulation is that form of drug which is ingested by the consumer. Ipca Indore is API based plant which was established in 1994. The major activities of this laboratory include chemical researches, analytical researches, new drug recovery, intellectual property management and biotech researches.

4.1 Pharmaceutical manufacturing processes:

The pharmaceutical laboratories includes following manufacturing processes-

i. Chemical synthesis
ii. Fermentation
iii. Natural or biological extraction
iv. Formulation

The process flow diagrams of manufacturing processes and waste water ejection are explained in the figures below:

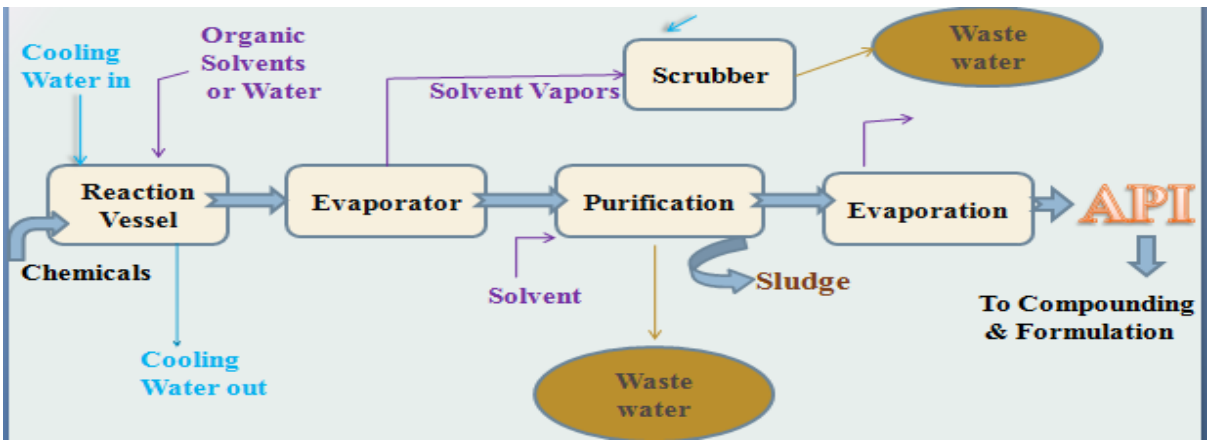

Figure 1: Process flow sheet diagram for the chemical synthesis process

ISSN 2348-1218 (print)
International Journal of Interdisciplinary Research and Innovations ISSN 2348-1226 (online)
Vol. 6, Issue 3, pp: (34-38), Month: July - September 2018, Available at: www.researchpublish.com

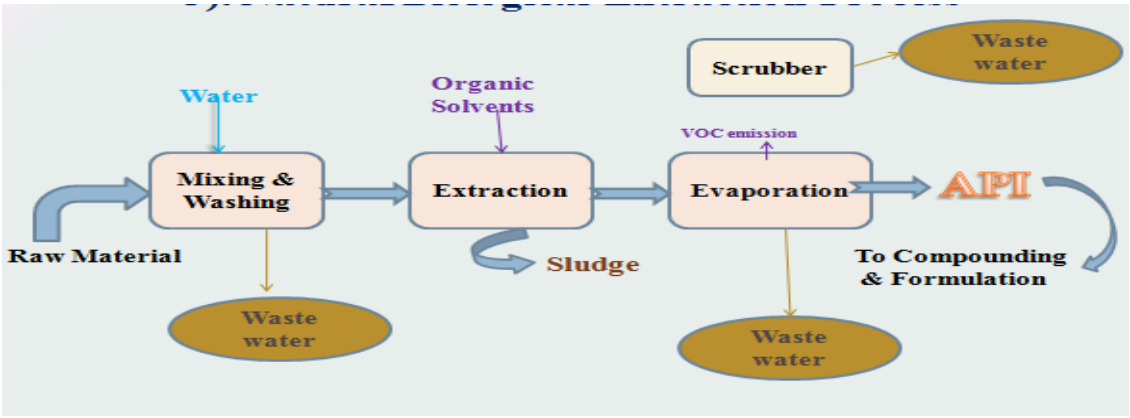

Figure 2: Process flow sheet diagram for natural/biological extraction process

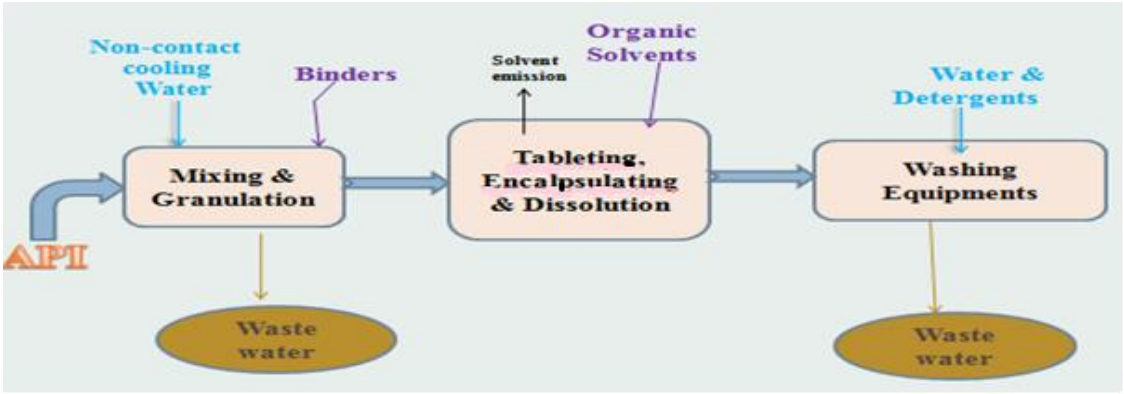

Figure 3: Process flow sheet diagram for the compounding/ formulation process

[Source: Chandrakanth et.al; Pharmaceutical Industry Wastewater: Review of the Technologies for Water Treatment and Reuse]

4.2 Types of wastes and their respective treatment practices in pharmaceutical industries:

A number of sub-processes occur in a pharmaceutical industry thus it is laborious to distinguish every single kind of waste product. Solid cake and extraction requires a multiple washing with ultrapure water in pharmaceutical industries. But this should not be reused as per drug master file. So high value pharmaceutical drug and API can be recovered from dilute streams rather than treating them. Water is a crucial raw material in the manufacturing processes of pharmaceutical industries which needs to be effectively managed or treated in after its use. The following units/processes ejects waste water which needs to be treated- potable water, process water, water from by-product treatment, water from desalination unit, water recycling, feedwater for utilities etc. The waste coming out from these industries differ in concentration and quantity thus it is laborious to provide a single treatment. The following treatments can be provided to the pharmaceutical waste water-

i. Recovery of APIs or drugs present in solvents and wash water.
ii. Inactivation of active substances by UV oxidation.
iii. Biological treatments (aerobic and anaerobic treatment)
iv. Advanced treatments (activated carbon, membrane technology)
v. Advanced oxidation processes.
vi. Sterilization of infectious substances using biotechnology
vii. Other hybrid technologies.

It is suggested that the effluent should be treated under prescribed standards. The treated effluent can be reused in the process, for cooling and for green belt development within the premises. Hence zero discharge conditions could be practiced.

As per Water (Prevention and control of pollution) Cess Act 1977, electromagnetic/ultrasonic water meter should be installed for category wise consumption of water for industrial cooling/boiler feed, mine spray, process and domestic purpose etc. Oil or other hazardous substances should not be discharged into natural water course.

According to the conditions pertaining to Water (Prevention & control of pollution) Act 1974 the industries shall provide comprehensive effluent treatment system as per the proposal submitted to the board and maintain the same properly to achieve following standards-

Table 1: Trade effluent Treatment

Parameters	Limits
pH	between 5.5-9.0
Suspended solids	not exceed 100 mg/L
BOD (3 days at 270˚C)	not exceed 30 mg/L
COD	not exceed 250 mg/L
Oil and grease	not exceed 10 mg/L
TDS	not exceed 2100 mg/L
Chlorides	not exceed 1000 mg/L

Table 2: Sewage Treatment

Parameters	Limits
pH	between 6.5-9.0
Suspended solids	not exceed 10 mg/L
BOD (3 days at 270˚C)	not exceed 10 mg/L
COD	not exceed 50 mg/L
Oil and grease	not exceed 10 mg/L
NH_4-N	not exceed 5 mg/L
N-Total	not exceed 10 mg/L
Fecal coliform	<230 (MPN/100 ml)
PO_4-P	not exceed 2 mg/L

5. CONCLUSION

The pharmaceutical manufacturing industries should be regulated under strict supervision of food and drug agencies. Acceptable water quality standards should be carefully followed. The manufacturing, purification, cleaning, washing and maintenance activities generate a large amount of waste

REFERENCES

[1] Badrinath. S.D., and Raman, N.S. (1995). “Environmental Audit: Indian Scenario”, Journal of Environmental Engineering, 121 (6).

[2] Gadipelly, C., Gonzalez, A.P., Yadav, G.D., Ortiz, I., Ibanez, R., Rathod, V.K., and Marathe, K.V. (2014). “Pharmaceutical Industry Wastewater: Review of the Technologies for Water Treatment and Reuse”. Industrial & Engineering Chemistry Research, 53, 11571-11592.

[3] Igole, S.P. (2012). “Environmental Auditing: Its benefits and Counterance”. International Journal of Science Innovations and Discoveries, 2(5), 152-156.

[4] Ipca Laboratories Ltd. Indore. Online at https://www.google.co.in/search?q=ipca+laboratories+ltd+indore&rlz=1C1NHXL_enIN736IN736&oq=ipca+laboratories+ltd+indore&aqs=chrome..69i57j69i61.1656j0j7&sourceid=chrome&ie=UTF-8(Accessed on December, 2017)

[5] Kimtee, S., and Nighojkar, A. (2017). “Environmental Audit on Tyre Industry: A Case Study of Bridgestone Pvt. Ltd Pithampur, Indore”.International journal of scientific & engineering Research, 8, 1427-1430.

[6] Mehta R.M and Sharma V.K., “Environmental Audit - An Overview”. Int. Journal of Env.Protection. Vol 17 (1),pp 212-214,2002.

[7] Ramachandra, T.V., and Bachamanda, S. (2007). “Environmental Audit of Municipal Solid Waste Management”.International Journal Technology and Management”, 7, 369-391.

[8] Rao, T.B., Chode S.G., Bhosale P.R., Jadhav A.S., and Raut P.D. (2011). “Environmental Audit of Sugar Factory, Kuditre, Kolhapur”.Universal journal of Environmental Research and Technology”, 1, 51-57.

[9] R.K . Trivedy .,"Handbook of Environmental Laws Acts , Rules, Guidelines , Compliances and Standards".Vol 2,1996.

[10] Tripathi,N., Shrivastava, A.,Sairn, R.(1991). “Role of Environment Audit in Environment Management by industries”. International Association of Emergency Managers (IAEM), 18, 242-244.