Report on

Performance Evaluation of ETPs & Hazardous Waste Management in Pharmaceutical Industries

MULTIPLE EFFECT EVAPORATOR

Zonal Office (Central)
Central Pollution Control Board
Bhopal

PROJECT TEAM

Principal Coordinator	:	Sh. R.S. Kori, Zonal Officer
Project Coordinator	:	Sh. P. Jagan, Scientist 'C'
Report Compilation	:	Sh. P. Jagan, Scientist 'C'
		Dr. Yogendra Kumar Saxena, SSA
Monitoring Team	:	Dr. Yogendra Kumar Saxena, SSA
		Sh. Sunil Kolhatkar, JLA
		Sh. S. K. Bhatia, Lab Attendant.
Type Set By	:	Smt. Farzana Khan, DEO
		Sh. Prahlad Baghel, Attendant.

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ABBREVIATIONS

PM	**Particulate Mater**
MEE	Multi Effective Evaporator
DTRO	Disc Tube Reverse Osmosis
SRO	Spiral Reverse Osmosis
ATFD	Agitated Thin Film Dryer
COD	Chemical Oxygen Demand
BOD	Biochemical Oxygen Demand
TSS	Total Suspended Solid
TS	Total Solid
ETP	Effluent Treatment Plant
CTSDF	Common Treatment, Storage and Disposal Facility
HW	Hazardous Waste
pH	Potential of Hydrogen
SO_2	Sulfur Dioxide
NO_X	Nitrogen Oxides
CREP	Corporate Responsibility for Environmental Protection
BDL	Below Detection Limit

(1) Executive Summary

Pharmaceutical industry is one of the category of highly polluting industries and generates strong wastewater of high COD along with hazardous waste which require effective treatment and disposal/reuse of effluents. Generally the pharmaceutical industries provides conventional ETPs based on activated sludge process consisting primary treatment (neutralization, flocculation & primary settling), secondary treatment (biological treatment comprising of surface aeration, secondary settling) and tertiary treatment (dual media filtration i.e. pressure sand & activated carbon filter, MEE, RO).

There are 20 large and medium scale pharmaceutical industries in Central Zone out of that 16 are in Madhya Pradesh and 04 are in Rajasthan States. There was no bulk drug manufacturing unit exist in Chhattisgarh state. To know the status of effluent treatment and hazardous waste management, Zonal office, Bhopal has taken a project on performance evaluation of ETPs & Hazardous waste management in pharmaceutical industries.

As a part of the project 15 industries in the central zone have been visited which have adopted various treatment options i.e. Anaerobic Digesters, Activated Sludge Process (ASP), Electro-coagulation followed by ASP, and tertiary treatment i.e. MEE and RO. At the time of inspection composite samples were collected from the inlet & outlets of ETPs and analyzed for performance evaluation. The range of inlet COD was 3782 mg/l to 114307mg/l and BOD was found to be 964 mg/l to 35100mg/l. The range of COD and BOD in treated effluent was 43 mg/l to 5327 mg/l and 11mg/l to 1205 mg/l respectively against the prescribed limits for BOD-30 mg/l and COD- 250 mg/l.

During the visit the hazardous waste management practices adopted by the industries have been studied especially for spent mother liquor, spent solvent, spent catalyst, Distillation Residues, Spent carbon, Date expired, discarded & off specification drugs, Discarded containers, ETP sludge, Incinerated ash and Used oil & waste oil for better management of Hazardous Waste as per the provisions of Hazardous Waste (M, H & TM)

Rules, 2008. The status of wastes being sent for resource recovery and co-processing / co-incineration by the industries has also reviewed and resolved the issues related to final disposal of hazardous wastes through sharing of experience and technical discussions. All the twenty units have taken membership from TSDFs for final disposal of their hazardous wastes.

Out of 20 only 7 large scale industries have installed MEE followed spray dryer for treatment of high COD wastes & RO rejects. Whereas small and medium scale bulk drug industries did not have the facilities like MEE for treatment of high COD & TDS effluents. Only 02 industries have waste incineration facilities within their premises for disposal of hazardous waste. The remaining industries are disposing the hazardous waste through Treatment Storage & Disposal Facility (TSDF).

All the large scale industries are having solvent recovery plants whereas small scale industries are not much aware about solvent recovery and spent solvent is being discharged along with low COD wastewater and reaching to ETPs for conventional treatment.

It is revealed from the performance study report that major pharmaceutical industries are complying most of the statutory conditions whereas serious efforts are required in small scale industries for compliance up to the satisfaction w.r.t. effluent treatment, hazardous waste disposal and solvent recovery.

कार्यकारी सारांश

फार्मास्यूटिकल' उद्योग अत्यधिक प्रदूषणकारी उद्योगों की श्रेणी में सम्मिलित हैं जिनमें अत्यधिक सान्द्र सी.ओ.डी. अपशिष्ट जल तथा खतरनाक अपशिष्ट निकलते हैं, जिनके निपटान/पुनःउपयोग हेतु प्रभावी उपचार आवश्यक होता है । सामान्यतः फार्मास्यूटिकल उद्योग अपशिष्ट जल के उपचार हेतु परम्परागत 'दूषित जल उपचार संयंत्र' (ई.टी.पी.) जो कि 'एक्टिवेटेड स्लज प्रक्रिया' पर आधारित होते हैं, स्थापित किए जाते हैं । इस प्रक्रिया के मुख्य अवयव निम्नानुसार हैं :–

प्राथमिक उपचार :– न्यूट्रलाइजेशन, फ्लोक्यूलेशन तथा प्रारंभिक सैटलिंग ।

द्वितीय उपचार :– स्तरीय एरेशन के साथ जैविक उपचार, द्वितीयक जमाव।

तृतीय उपचार :– ड्यूअल मीडिया फिल्ट्रेशन जैसे – प्रेशर सेण्ड तथा कार्बन फिल्टर, मल्टी इफेक्ट इवेपोरेटर और रिवर्स ऑस्मोसिस ।

आंचलिक कार्यालय (मध्य) के कार्यक्षेत्र (मध्यप्रदेश, छत्तीसगढ़, राजस्थान) में कुल 20 वृहद एवं मध्यम फार्मास्यूटिकल उद्योग स्थापित हैं जिसमें से 16 मध्यप्रदेश तथा 04 राजस्थान में स्थापित हैं । छत्तीसगढ़ राज्य में कोई वृहद फार्मा उद्योग नहीं हैं । इन उद्योगों के अपशिष्ट उपचार संयंत्र तथा खतरनाक अपशिष्ट प्रबंधन की वास्तविक स्थिति तथा कार्यक्षमता मूल्यांकन हेतु आंचलिक कार्यालय, भोपाल द्वारा परियोजना संचालित की गई थी।

परियोजना के अंतर्गत 15 उद्योगों का निरीक्षण किया गया । इन उद्योगों में एनारोबिक डाइजेस्टर, एक्टिवेटेड स्लज प्रोसेस, इलेक्ट्रो–कोग्यूलेशन, तृतीय उपचार के लिए मल्टी इफेक्ट इवेपोरेटर (एम.ई.ई.) व रिवर्स ऑस्मोसिस जैसे उपचार व्यवस्थाएं स्थापित हैं। निरीक्षण के दौरान ई.टी.पी. के इनलेट तथा आउटलेट के मिश्रित नमूने (कम्पोसिट सेंपल) लिए गए तथा कार्यक्षमता मूल्यांकन हेतु प्रयोगशाला में जांचा गया । विश्लेषण परिणाम अनुसार इनलेट पर सी.ओ.डी. 3782 मिलीग्राम/लीटर से 114307 मिलीग्राम/लीटर तथा बी.ओ.डी. 964 मिलीग्राम/लीटर से 35100 मिलीग्राम/लीटर तथा आउटलेट पर सी.ओ.डी. 43 मिलीग्राम/लीटर से 5327 मिलीग्राम/लीटर व बी.ओ.डी. 11 मिलीग्राम/लीटर से

1205 मिलीग्राम/लीटर की सीमा में पाई गई हैं जबकि निर्धारित सीमा सी.ओ.डी. हेतु 250 मिलीग्राम/लीटर तथा बी.ओ.डी. हेतु 30 मिलीग्राम/लीटर है ।

परिसंकटमय अपशिष्ट (प्रबंधन, हथालन और सीमापार संचलन) नियम, 2008 के अनुसार स्पेंट मदर लिकर, स्पेंट सॉल्वेंट, स्पेंट कैटालिस्ट, डिस्टीलेशन रेसि़ड्यू, स्पेंट कार्बन, ई.टी.पी. स्लज, यूज्ड व वेस्ट ऑयल के प्रबंध की व्यवस्था का भी निरीक्षण किया गया तथा तकनीकी चर्चा उपरांत प्रबंधन निस्तारण में आने वाली समस्याओं को दूर किया गया।

अत्यधिक सी.ओ.डी. वाले अपशिष्ट तथा रिवर्स ऑस्मोसिस रिजेक्ट के उपचार हेतु 20 उद्योगों में से 07 ने मल्टी इफैक्ट इवेपोरेटर तथा स्प्रे ड्रायर स्थापित किए हैं। केवल 02 उद्योगों ने अपशिष्ट जलाने (इंसीनरेटर) की व्यवस्था स्थापित की है । मध्यम एवं लघु उद्योगों में अपशिष्ट उपचार की इस प्रकार की व्यवस्था स्थापित नहीं की गई है। शेष उद्योग अपशिष्ट को टी.एस.डी.एफ. भेज रहे हैं ।

सभी बड़े उद्योगों में सॉल्वेंट रिकवरी प्लांट लगाए गए हैं मगर छोटे उद्योगों द्वारा इस प्लांट संबंधी अनभिज्ञता व्यक्त गई । इन उद्योगों द्वारा स्पेंट सॉल्वेंट को निम्न सी.ओ.डी. अपशिष्ट के साथ ही दूषित उपचार संयंत्र में उपचार किया जा रहा है ।

कार्यक्षमता मूल्यांकन से यह स्पष्ट होता है कि बड़े उद्योग निर्धारित वैधानिक प्रावधानों का पालन कर रहे हैं परन्तु मध्यम व लघु उद्योगों को दूषित जल उपचार, खतरनाक अपशिष्ट के प्रबंधन के वैधानिक प्रावधानों के अनुपालन हेतु गंभीर प्रयासों की आवश्यकता है ।

(02) General

India is a developing country having a large & growing population. Increasing health care, medical treatment & health consciousness have demonstrated a fairly rising growth in the consumption of pharmaceutical products in India. As India is yet to achieve self-sufficiency in the pharmaceutical sectors, any projects which help to meet this need are a valuable asset to the nation. Poverty eradication & providing sanitary & hygienic living conditions to the majority living below the poverty line is still a far cry. As a results, there is a wide spread occurrence of contagious diseases & other carrier borne maladies. Providing healthcare products not only helps to check the disease but also improve the health of the people and thus the productivity & wealth of the nation. Pharmaceutical Industries in India not only saves valuable for foreign exchange because of its import substitute products but also earns valuable foreign exchange from its exports.

There are about 596 numbers bulk drug industries in India with a production capacity of 18902 TPA which are mostly located in Maharashtra, Gujarat, Andhra Pradesh and West Bengal. Share of Indian companies has increased steadily. The country now ranks 3rd in terms of volume of production (10% of global share) and 14th largest by value. The annual turnover of the Indian Pharmaceutical Industry is estimated to be about 1lakh crores. Outside USA India is the only country having the highest number of USFDA approved plants for generic drugs manufacture outside USA.

The pharmaceutical industry in India meets around 70% of the country demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectable. There are about 250 large units (including 5 Central Public Sector Units) and about many Small Scale Units engaged in direct & indirect manufacturing which form the core of the pharmaceutical industry in India. These units produce the complete range of pharmaceutical formulations, i.e. medicines ready for consumption by patients and about 350 bulk drugs

i.e. chemicals having therapeutic value and used for production of pharmaceutical formulations.

The leading 250 pharmaceutical companies control 70% of the market with market leader holding nearly 7% of the market share. It is an extremely fragmented market with severe price competition and government price control. It has expanded drastically in the last two decades because the manufacturing costs are typically less than those in Europe or the US, More than 20 Indian manufacturers have been accredited by the USFDA, India has become an attractive location for contract R&D as well as for contract manufacturing of pharmaceuticals. It offers several advantages like lower costs combined with an abundance of trained scientific personnel, the common use of the English language in business and a robust legal system. India has around 7 lakhs postgraduates. It is estimated that 10% of researchers in pharma/biotech sectors in the US are of Indian origin. It is not just in old drugs and formulations that India offers far lower prices. Even in such frontier areas as genetically engineered vaccines, Indian companies have managed to slash prices by half. The pharmaceutical industry is now facing new challenges in controlling and preventing environmental pollution as it is expanding**.**

At the same time as we are aware that pharmaceutical industries are one of the highly polluting types of industries and generates strong and high COD wastewater along with hazardous waste which require effective treatment and disposal/reuse of effluents. Minimization of generation of these wastes at the source or recycling of these wastes will benefit Bulk Drug manufacturers by increasing product yields, reducing raw material needs, reducing disposal costs and liabilities associated with Hazardous Wastes.

(03) Description of the process

Pharmaceutical Industry can be divided into two types as per their manufacturing activity. i.e. Active Pharmaceutical Ingredients (Bulk Actives) and Finished Dosage forms (Formulations).

3.1-Bulk drug:

Bulk drug means a pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmaceutical or other standards specified in the second schedule to the Drugs and cosmetics Act 1940 and which is used as such or as an ingredient in any formulation. It is also defined as per Title 21 of Code of Federal Regulations, USFDA defines Bulk Drugs as: **"**Any substance that is represented for use in a drug and that, when used in the manufacturing, processing or packaging of a drug, becomes and active ingredient or a finished dosage form of the drug.**"** The term does not include intermediates used in synthesis of such substances.

Three different methods used for manufacturing Bulk Drugs i.e. Chemical Synthesis, Natural & Biological Product Extraction and Fermentation. Active Pharmaceutical Ingredient (API) goes for "Formulation" to be available as Tablets, Capsules, Liquids and Ointments

Bulk drug manufacturing process description**:**

In a typical Bulk Drug manufacturing unit, one or more batch reactor vessels are used in a series of reaction, separation and purification steps to make the desired end product. Numerous types of chemical reactions, recovery processes, and chemicals are employed in order to produce a wide variety of products.

Chemicals used in chemical synthesis operations range widely and include organic and inorganic reactants and catalysts. In addition manufacturers use a wide variety of solvents. These are used for product recovery, purification and as reaction media.

Waste streams from chemical synthesis operations are complex due to the varied operations and reactions employed. Virtually every step of an organic synthesis generates mother liquor that contains un-converted reactants, reaction by-products and residual product in the organic solvent base. Use of volatile solvents can also result in air emissions, which may be reduced by employing scrubbers or condensers to reclaim the solvent vapours. Waste streams from synthesis process typically have high BOD, COD and TDS. The major steps involved in manufacturing of APIs:

- Raw Material receipt and lot making
- Chemical Reactions (Aqueous & Solvent medium)
- Centrifuging the material & Drying
- Powder Processing (Milling, Sifting, Compaction & Blending)
- Solvent Recovery
- Cleaning of Equipment at all the stages.

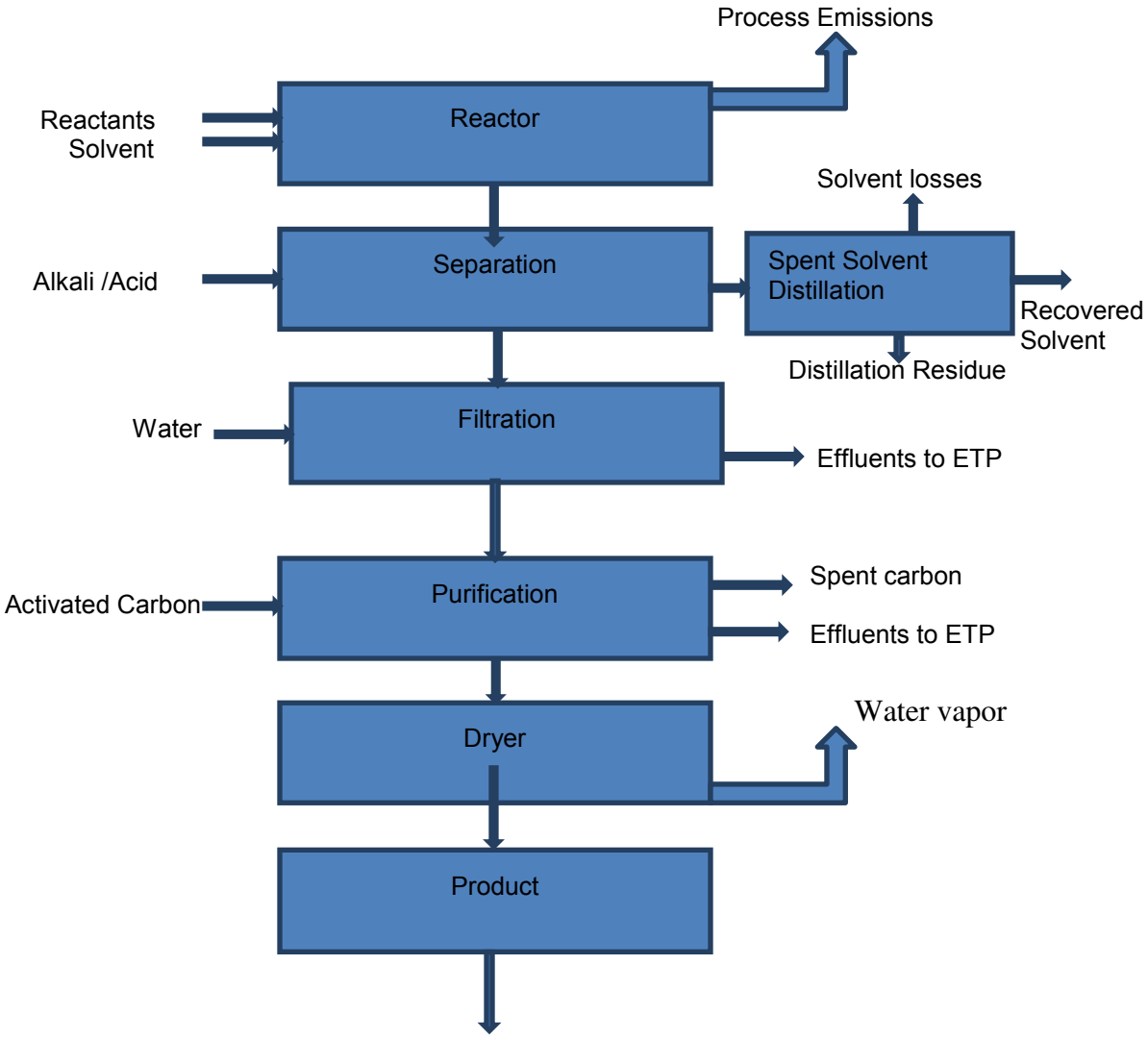
Based on the type of reaction / molecule, different kind of utilities are used to carry out the reaction, centrifuging, drying, powder processing and solvent recovery.

3.2-Formulation:

Formulation means a medicine processed out of or containing one or more bulk drugs with or without the use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation and prevention of disease in human being or animals, but shall not include any medicine include in any bona fide Ayurvedic (including sidha) or Unani (Tibb) system of medicines, any medicine included in the Homoeopathic system of medicine and any substance to which the provisions of the Drugs and Cosmetics Act 1940 don't apply. The Major steps involved in formulation unit:

- Blending the APIs with filler materials
- Making the APIs suitable to formulations (Tablets, Capsules Ointments, Parental& Patents)
- Filling & Packing

Schematic flow chart of process



(04) Effluent Treatment of Pharmaceutical Industry

Pharmaceutical Industry requires very high grade purity of water for its manufacturing process apart from other requirements in support services. At the same time Pharmaceutical industries are one of the highly polluting types of industries among the others and generate strong and high COD wastewater along with hazardous waste.

4.1- Typical Characteristics of Pharmaceutical Effluent:

Purity of final product is very important in Pharma industry. Thus rejects (un-reacted & converted portion of raw materials) contribute to the major pollution load to ETP. The industry involves several batch reactors to get required product and each reaction yields different kinds of pollutants depending upon particular reactants and process. There are number of streams with different characteristics from different sections of the Plant, requiring segregation and corresponding treatment instead of conventional end of pipe treatment system for combined effluent.

4.2- Methods of Treatment of liquid wastes in pharmaceutical industry:

Now a day's most of the pharmaceutical Industries follow the policy of "treatment of effluents and recycling/ reuse of treated effluents". The major potential liquid pollutants generated from the manufacturing plants are from formulation washing effluent, bulk drug washing effluent, mother liquor, utility drain, domestic effluent and Reverse Osmosis plant rejects. These effluent streams are segregated as bio-degradable and non-bio-degradable effluent. The treated bio-degradable wastewater after proper treatment is reused for green belt development and in utilities. The non-biodegradable effluent is further segregated and collected as a

a) Solvent rich mother liquor (ML) which is distilled in distillation plant and recovered solvent is reused, sold to actual user/registered recyclers.
b) Aqueous base (ML) is neutralized in dedicated facility and chemically treated before mixing with common ETP stream after proper analysis for its degradability.
c) High TDS stream from RO reject is taken to MEE for solidification and residue is sent to TSDF site after packing in HDPE bags.

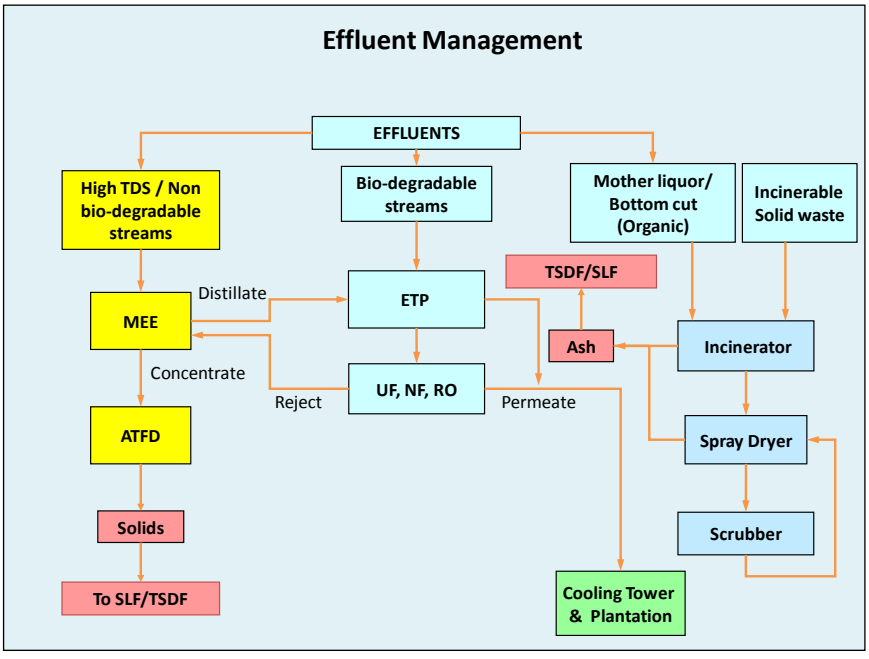
4.3- Segregation of effluent stream and treatment:

a) The high COD / High TDS effluent streams of all production plants are segregated and sent to MEE& ATFD Plants for treatment.
b) The remaining low COD and low TDS effluent streams are collected& treated in conventional effluent treatments plants i.e. Activated Sludge Process (ASP), UASB, Electro-Coagulation, Advance Oxidation etc. which are basically a combination of Primary treatment, Secondary Treatment and Tertiary treatment.

Primary Treatment:-

The effluent form production blocks collected into the collection tank and domestic effluent collected into the domestic collection tank through septic tank. Both the effluents are equalized in the equalization tank.

Raw effluent streams of Low COD and low TDS are first received at the equalization tank wherein flow and mass loading due to various constituents present in the individual streams are equalized so as to attain a composite effluent. This composite effluent is then pumped to neutralization tank, here Acid or alkali is administered to achieve a near neutral pH. Then effluent is pumped to a flash mixer, from there by gravity goes to chemical mixing tank & then to primary clarifier to undergo physico-chemical treatment. Flocculent and coagulant are also added to destabilize charged particulate matter. The effluent leaving the flash mixer



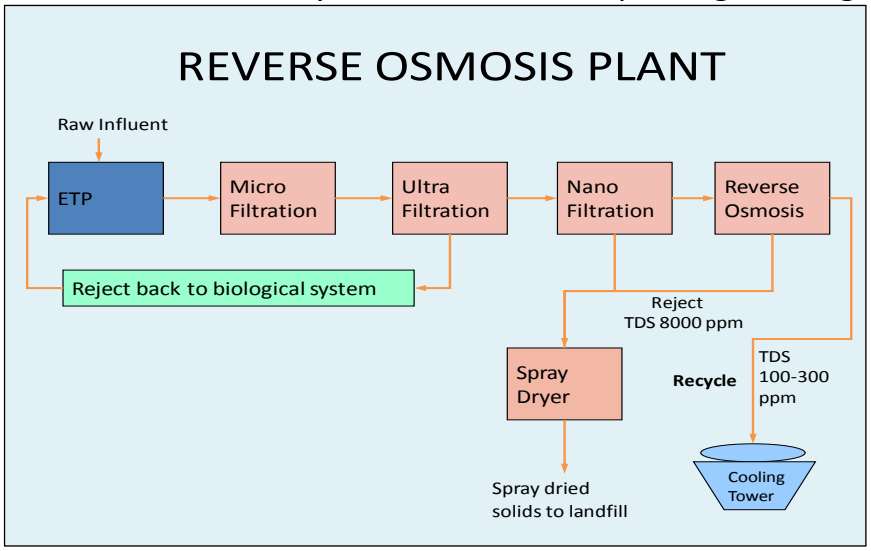
&chemical mixing tank gravitates to a primary clarifier wherein polyelectrolyte aids in the settling of particulate matter by allowing them to agglomerate into large easily settable flocs. Settled solids transferred into the sludge drying beds and the clear effluent is then goes to aeration tank for secondary treatment.

Secondary Treatment:-

The clarified effluent form the primary clarifier is routed two-stage aerobic biological treatment using the activated sludge process. Sewage effluent is also charged in the organic matters in the effluent undergo biological stabilization in the aeration tank to produce by products such as carbon dioxide and water. As a result of organic matter assimilation the population of micro-organism within the aeration tank will increase which need to be removed in a secondary clarifier. A major portion of the settled biomass is re-circulated back to the aeration tank to maintain a viable population of micro-organism within an aerobic environment where efficient oxidation of organic matter can occur. The remaining portion of the biomass depending on the growth kinetics of the population of micro-organism within the reactor is wasted as excesses sludge. This sludge is filtered in a Filter Press and dried on drying beds and finally sent to TSDF site for disposal.

Tertiary Treatment:-

Clarifier effluent from secondary collection tank passing through DMF(Dual Media Filter). Graded Media Sand & Activated Carbon added in the Pressure Dual Media Filter. Provision for Backwashing also provided. The Finally Treated effluent



collected into the Treated Collection tank and treated water used for Horticulture purpose. The treated effluent is transferred to RO Feed Tank for recovery of 80 to 85 % water (permeate) and 15 to 20 % reject is sent to MEE plant for further treatment.

Water Recovery:-

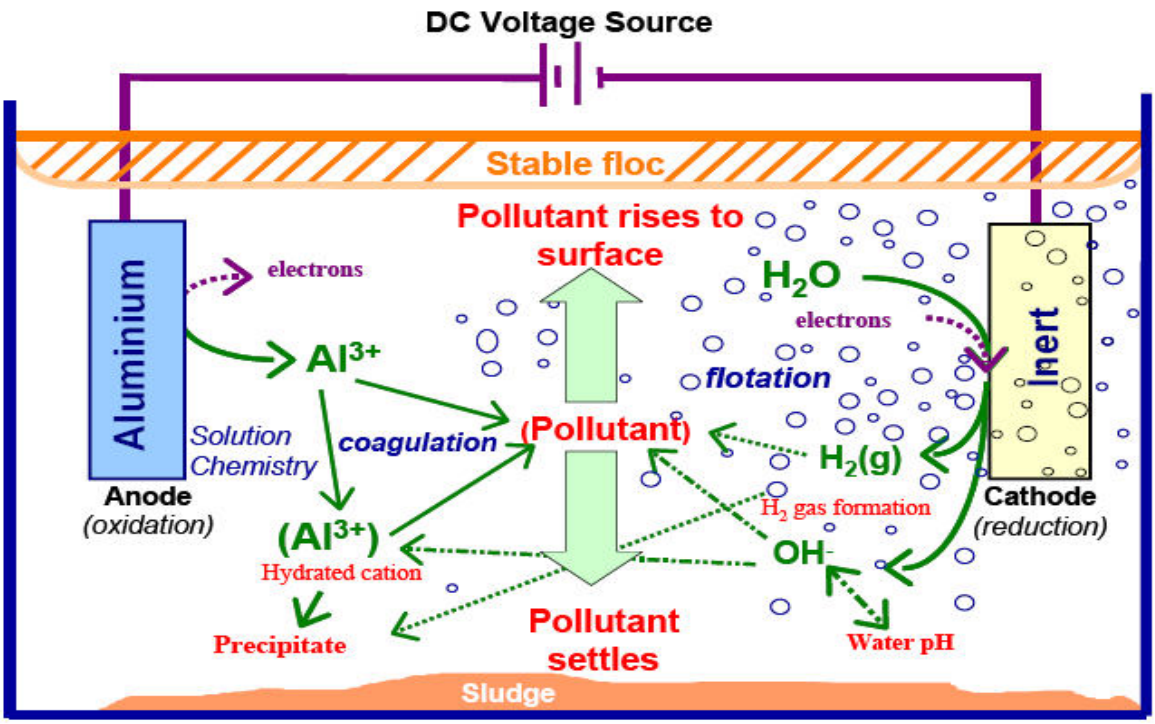
Water is recovered from advanced technology using RO Plant and MEE Plant.

- **Reverse Osmosis Plant:**
  Reverse Osmosis Plant which produces 80-85 % pure water. The pure water is used in utilities. RO Plant also generates 15-20% Reject water. The pressurized effluent is forced through a Semi permeable Membranes of 0.0001 Micron to the fresh water recovery side. The membrane rejects the salt ions present in the effluent water and allows the pure water to pass through the thin membrane material.

- **MEE Plant:**
  MEE Plant for Treatment and recovery of water from High COD effluent of Production Plant and RO reject. The Reject of RO Plant and High COD effluent of production plants are transferred to MEE Plant. MEE Plant comprises of Stripper, four effect forced circulation evaporator and Agitated Thin Film Dryer. The Steam stripper for removing volatile solvents, Multiple Effect Evaporator for concentrating effluent and ATFD for drying concentrated effluent to form solid waste. The distillate of the ATFD is added to the ETP for further treatment and the solids are disposed to Secured Landfill site or TSDF.
- **Spray dryer:**
  The Spray dryer is operated using waste heat of the flue gas where the concentrate of MEE get dried to get solids.

4.4- Electro coagulation

It is possible to identify three basic sciences electrochemistry, coagulation, and flotation - that interact to make electro coagulation work.



Coagulation:-

Coagulation is a key feature of electro coagulation reactor, describing the interaction between the coagulant and any pollutant material. The coagulants role here is to destabilize the colloidal suspension by reducing any attractive forces, thereby lowering the energy barrier and enabling particles to aggregate. Depending on the physical and chemical properties of the solution, pollutant and coagulant, a number of coagulation mechanisms (*e.g.* charge neutralization, double layer compression, bridging and sweep) have been postulated (Thomas *et al.*, 1999; Letterman *et al.*, 1999). For any given electro-coagulation reactor, the dominant coagulation mechanism will vary with the reactors operating conditions, the pollutant type (and concentration) and the coagulant Concentration.

Mechanism:-

The electrochemical reaction occurring at the anode and involving metal M-aluminum is written asAl(s)→Al (aq)3+ + 3e−(Aluminium electrode dissolution).Hydrogen evolution occurs at the cathode depending on pH.

$2H_2O(l) + 2e- \rightarrow H_2(g) + 2OH(aq)-$ (Hydrogen evolution)

$2H(aq)^+ + 2e- \rightarrow H_2(g)$

The generated Al (aq) 3+ ions combine with water and hydroxyl ions to form corresponding hydroxides and/or poly-hydroxides as follow:

- Monomeric species such as $Al(OH)^{2+}$, $Al(OH)_2^+$, and $Al(OH)_4^-$
- Polymeric species such as $Al_2(OH)_2^{4+}$ and $Al_2(OH)_5^+$,
- Amorphous and less soluble species such as $Al(OH)_3$

$Al^{3+} + H_2O \rightarrow Al(OH)^{2+} + H^+$ $\quad$ $Al(OH)^{2+} + H_2O \rightarrow Al(OH)_2^+ + H^+$

$Al(OH)_2^+ + H_2O \rightarrow Al(OH)_3^0 + H+$ $\quad$ $Al(OH)_3^0 + H_2O \rightarrow Al(OH)_4^- + H^+$

Flotation:-

The production of electrolytic gases is an inevitable by-product of electro-coagulation. These gases lift pollutant particles and coagulant aggregates to the surface by a flotation-like process, while encouraging contact between pollutant particles and coagulant by providing a certain amount of mixing action. The main difference between this "electrolytic flotation" and more conventional flotation techniques is the method of bubble production and resultant bubble size. Expertise from other flotation techniques, including electro flotation, dissolved air flotation (DAF) and air-lift reactors can be employed to understand the flotation process in electro-coagulation reactors. Electro flotation describes the production of electrolytic gases for the sole purpose of pollutant removal.

Electrochemistry, coagulation and flotation thus form the three foundation stones for electro-coagulation. Each component is a well-studied technology in its own right. Electro-coagulation is the distinct economical and environmental choice for meeting water treatment discharge standards and compliance requirements. Recover capital and operating costs by eliminating discharge fees and fines, harvesting resources and significantly reducing water replacement costs.

Advantages:-

- Wastewater treated by EC gives clear, colorless and odorless water.
- Sludge formed by EC tends to be readily settable and easy to dewater because it is composed of mainly metallic oxides/hydroxides.
- Flocs formed by EC are similar to chemical floc, except that EC floc tends to be much larger, contains less bound water, is acid-resistant and more stable and therefore can be separated faster by filtration.
- EC produces effluent with less TDS content as compared with chemical treatments.
- The EC process has the advantage of removing the smallest colloidal particles, because the applied electric field sets them in faster motion, thereby facilitating the coagulation.
- The EC process avoids uses of chemicals and so there is no problem of neutralizing excess chemicals and no possibility of secondary pollution caused by chemical substances added at high concentration as when chemical coagulation of wastewater is used.
- The gas bubbles produced during electrolysis can carry the pollutant to the top of the solution where it can be more easily concentrated, collected and removed

4.5- Advance Oxidation as Fenton Treatment for mother Liquor

As the water based mother liquor is highly polluted in comparison to other effluents, but having very low quantity (0.8 KLD to 1.6 KLD depend on batch size) and treated it by advance oxidation as Fenton Treatment which improve the biodegradability of effluent as well reduce the organic load 70 % - 85 % of its initial value. After treatment the organic load is checked and then added it into collection tank gradually. The quantity of treated aquas mother liquor subjected to collection tank depend upon its organic load and organic load already exist in collection tank other than sewage effluent and treated aqua's mother liquor.

- Fenton's Reagent General Chemistry:

$Fe^{2+} + H_2O_2 \rightarrow Fe^{3+} + OH^- + {}^{\cdot}OH$
$Fe^{3+} + H_2O_2 \rightarrow Fe^{2+} + {}^{\cdot}OOH + H^+$

The procedure requires is adjusting the wastewater to pH 3-5, adding the iron catalyst (as a solution of $FeSO_4$) and adding slowly the H_2O_2. If the pH is too high, the iron precipitates as $Fe(OH)_3$.

Reaction rates with Fenton's Reagent are generally limited by the rate of ${}^{\cdot}OH$ generation (i.e concentration of iron catalyst). Typical Fe: H_2O_2 ratios are 1:5-10wt/wt, though iron levels <25-50 mg/l can require excessive reaction times (10-24 hours). This is particularly true where the oxidation products (organic acids) the iron and remove it from the catalytic cycle. Fenton's Reagent is most effective.

- The chemical reactions of the hydroxyl radical in water are of four types**:**

  The OH^- can attack organic molecules found in highly polluted effluents by radical addition, hydrogen abstraction, electron transfer and radical combination.

- Radical addition**:**

  Addition of HO• to an unsaturated aliphatic or aromatic organic compounds (e.g. C_6H_6) results in the production of a radical organic compound that can be oxidized further by compounds such as O_2 or ferrous iron to produce stable oxidized end product

  $R + OH\bullet \rightarrow ROH$, where R = reacting organic compound

- Electron transfer**:**

  Results in the formation of ions of a higher valence

  $R^n + HO\bullet \rightarrow R^{n-1} + OH^-$

- Hydrogen Abstraction**:**

  HO• used to remove a H atom from organic compounds resulting in the formation of a radical organic compound initiating a

chain reaction where the radical organic compound reacts with O_2 producing a peroxyl radicals which can react with other organic compound and so on

$$R + HO\bullet \rightarrow R^{\cdot} + H_2O$$

- Radical Combination**:**

  Two radicals can combine to form a stable product

$$HO\bullet + HO\bullet \rightarrow H_2O_2$$

  In general, the reaction of HO• with organic compounds at completion will produce H_2O, CO_2 and salts.

(05) Scenario of Pharmaceutical units in Central Zone

1. In central zone, Madhya Pradesh is among the leading states in the production of Bulk Drugs. Bulk Drug manufacturing units are mainly concentrated around Indore city. There are 20 (15in MP & 5 in Rajasthan) large and medium scale pharmaceutical industries situated in Madhya Pradesh & Rajasthan States. There was no bulk drug manufacturing unit exist in Chhattisgarh state. The list of pharmaceutical industries in operation in MP and Rajasthan are given in **Table 1**.

2. In central zone 90% of the Bulk Drug manufacturing units are in large or medium scale sector. Most Drugs are manufactured by chemical synthesis. Hence their manufacturing processes and unit operations are similar, though the products in each industry are different. Bulk Drug manufacturing units generate a variety of wastes including Hazardous Wastes. Typical waste streams include mother liquors, spent solvents equipment wash waters, spilled materials, off-spec products and used processing aids. The effluent streams generally contain toxic substances like poly aromatic hydrocarbons and heavy metals.

3. Due to diversity in the products produced it is impractical to provide a general set of wastewater treatment guidelines that would apply to all the Drug manufacturing units. Therefore Zonal Office, Bhopal has taken a project on “Performance evaluation of ETPs & Hazardous waste management in pharmaceutical industries” under Annual Action Plan 2012-13 in all the 20 units. As a part of the project letters

written to all the three SPCBs requesting them to provide list and addresses of pharmaceutical industries which are in operation in the state for planning the field visits. Latter on 15 units were visited and conducted the performance evaluation in some of the ETPs in three phases during September 16th-19th, 2012, November 08th - 09th, 2012 and 27th January to 4th the February 2013 at Bhopal, Dewas, Indore & Gwalior in Madhya Pradesh and Alwar & Bhiwadi in Rajasthan.

4. Under the project 11 Units of MP, 04 units of Rajasthan have been visited and collected composite samples of ETP inlet & outlets to verify the performance of ETPs in some units and verified the hazardous waste management practices adopted by the industries. During the study various type of treatment technologies are being used in pharmaceutical units i.e. ASP, FAB, and UASB, Electro-coagulation, advanced oxidation, MEE, ATFD, RO, incinerator and spray drier. These treatment technologies are used depending on the production and type of wastewater characterises.

5. The industries are generating wastewater from various sections in the plant i.e. Biodegradable Low Inorganic Effluents, High Inorganic Effluents, Organic Effluents (Mother Liquor/Bottom Cut) and Effluents from Utilities (Sand Filter Backwash, Regeneration Effluents from Water Softening and DM Plants, Boiler Blow down, Cooling Tower Bleed Stream, etc.). The biodegradable effluents from process are treated along with effluents from utilities in Effluent Treatment Plants (ETP) consisting of Activated Sludge Process followed by Micro-Filtration (MF), Ultra-Filtration (UF), Reverse Osmosis (RO) Separation, Multiple Effect Evaporation (MEE) and Agitated Thin Film Drying (ATFD). High inorganic effluents from process are treated in a steam stripper to remove maximum quantity of volatile organic chemicals (mostly solvents) before further treating in MEE and ATFD units. In organic effluents which are of hazardous nature are incinerated in incinerators and flue gases leaving the incinerator are scrubbed for control of pollutants concentration in gaseous emissions.

6. During the visit it has been observed that different treatment technology are adopted by the industries like Activated Sludge

Process (ASP), Electro-coagulation followed by ASP, Anaerobic Digesters followed by ASP for treating the wastewater. The final treated wastewater has been passed through the multi-stage RO system for reuse in the in the plant and to maintain zero discharge. The high COD effluent& RO rejects are treated in MEE & ATFD. During the visit different technologies are studied and the analysis report along with load removal and suitability of the treatment technology is given in **Table 1: A to 15: A.**

7. High COD and low COD waste streams were not segregated properly in most of the plants. Both the effluents are being sent to ETPs in open drain instead of HDPE pipe lines or acid proof tiles channels. Moreover the high COD waste streams were not detoxified and treated separately. Most of the industries are not complying the CREP (Corporate Responsibility for Environment Protection) recommendations.

8. Out of 20 only 7 large scale industries have MEE followed spray dryer for treatment of high COD wastes & RO rejects. Whereas small and medium scale bulk drug industries did not have the facilities like MEE for treatment of high COD&TDS effluents.

9. All the large scale industries are having solvent recovery plants. Small scale industries did not have solvent recovery plants and not serious for recovering of solvent and the spent solvent is being discharged along with low COD wastewater and reaching to ETPs for conventional treatment.

10. Out of the 20 industries only 02 industries have waste incinerator facilities within the premises for incineration /final disposal of hazardous waste the remaining are disposing the waste through TSDF.

11. All the twenty units have taken membership from TSDFs for disposing their waste.

12. During the visit the hazardous waste management practices adopted by the industries has been studied especially for spent mother liquor, spent solvent, spent catalyst, Distillation Residues, Spent carbon, Date expired discarded & off specification drugs, Discarded containers, ETP sludge, Incinerated ash and Used oil & waste oil for better management as per the Hazardous Waste (M, H & TM) Rules, 2008. Also verified the wastes being sent for resource recovery and co-processing/ co-incineration by the industries and sorted out the issues related to final disposal of hazardous wastes.Details of disposal are given in **Table 1:B to15:C.**

13. At the time of inspection samples were collected from the ETP inlet & outlet and analyzed for knowing the performance. The range of inlet COD was 3782 mg/lto 114307mg/l and BOD was 964 mg/l to 35100mg/l. The range of COD and BOD in treated effluent was 43 mg/l to 5327 mg/l and 11mg/l to 1205 mg/l respectively. And prescribed limit for BOD- 30 mg/l, COD- 250 mg/l, TSS- 100 mg/l and Ph- 6.0 to 8.5.

Table 1: List of Pharmaceutical Industries in MP and Rajasthan

S No.	Name	Location
01	M/s Medilux Laboratories Pvt. Ltd	Pithampur, MP.
02	M/s Ranbaxy Laboratories Ltd	Dewas, MP.
03	M/s Lupin Pvt. Limited	Mandideep, MP.
04	M/s IPCA Laboratories Ltd	Indore, MP.
05	M/s Symbiotec Pharma lab Ltd	Indore, MP.
06	M/s Symbiotec Pharma lab Ltd	Pithampur, MP.
07	M/s Unichem Laboratories Ltd	Pithampur, MP.
08	M/s Lupin Pvt. Ltd	Pithampur, MP.
09	M/s Teva API India Limited	Malanpur, MP.
10	M/s Ranbaxy Laboratories Limited	Malanpur, MP.
11	M/s Sunil Healthcare Ltd	Alwar, Rajasthan
12	M/s Rajasthan Antibiotics Ltd,	Bhiwadi, Rajasthan

13	M/s Asiatic Drugs & Pharmaceuticals Pvt. Ltd	Bhiwadi, Rajasthan
14	M/s Dalas Bio-tech Ltd	Bhiwadi, Rajasthan
15	M/s IPCA Laboratories Ltd	Ratlam, MP.
16	M/s IPCA Laboratories Ltd	Pithampur, MP.
17	M/s Cure Worth (India) Ltd	Boregaon, Chhindwara,MP
18	M/s Vista Organics	Mandideep, MP
19	M/s CIPLA Ltd	Pithampur, Rajasthan
20	M/s Cachet Pharmaceutical Ltd	Bhiwadi, Rajasthan

(06) Observations

- Interlocking of production process with pollution control devices has not been done in almost all the plants. The interlocking is very much required so that case of none functioning of the pollution control equipment like scrubbers ,solvent recovery process, Incinerator etc. the main production process could stop automatically.

- Majority of the industries installed separate energy meters for pollution control devices like ETP, Incinerator and MEE. The record of electricity consumption for running of pollution control devices was maintained.

- Majority of industries are using V-notch for flow measuring at ETP inlet & outlet but records are not maintained regarding treated and recycled effluent.

- Log book for running hours of effluent treatment plant and record of daily consumption of chemical are being maintained.

- Adequate capacity of effluent holding tank was not provided In few units to store the wastewater in case of failure of any part of treatment plant or non-functional of treatment system.

- Chemical and biological sludge from ETP has not been segregated & collected properly and found stored openly on the land without any covers. Remaining wastes were stored as per the norms. Other solid wastes like poly bags, hand gloves, tissue papers etc. generated in the plant has not been segregated, collected, stored properly and not sending to TSDF for final disposal.

- Laboratory facilities were set up in all the pharmaceutical units for only collection and analysis of wastewater for day to day analysis of consent parameters and not provided adequate laboratory infrastructure facilities for air samples monitoring & analysis.Due to non-availability of proper environmental laboratories with the concerned industries ETP performance could not be cross verified regularly at the level of industry.

- Garland drains were not constructed to prevent mixing of spillages with storm water drains.

- Industries are maintaining good housekeeping in the plant premises as well as at ETP, RO, MEE areas etc.

- Most of the units were not established separate environmental cell with technically qualified personnel who will supervise the environmental activities only.

- It was observed that during visit none of the industries were discharging the treated/untreated effluent outside the factory premises.

- Nitrogen blanketing provided to solvent bulk storage tanks and Solvents transferred through closed pipe line network. Scrubbers provided for absorption of acid/alkali gases.

- Majority of industries are monitoring the ambient air and source emissions once in a month

- The Incinerator consists of Primary & Secondary combustion chamber, Drum Pyrolizers with Spray Dryer absorber, Multiple

Cyclones & Double stage scrubbing system with ID fan. The Spray dryer is operated using waste heat of the flue gas where the concentrate of MEE get dried to get solids.

- The major sources of air pollution are from stationary combustion devices i.e. boiler, DG sets and incinerator stacks. The flue gases from each stationary combustion device are discharged through separate stacks of heights more than 30m. Alkali scrubbers provided in manufacturing areas & at incinerator to control emission of harmful gases in to atmosphere. Stacks of adequate heights have been provided for effective dispersion of the air pollutants in to the atmosphere from emission sources, namely, boilers, incinerator and DG sets. Acoustic enclosures are provided for Diesel Generator sets to take care of Noise pollution.

- Nitrogen blanketing in storage tanks and process equipment to control fugitive emissions and safety measures. Breather valves on storage tanks and process equipment to arrest fugitive emissions. The storage tanks of low boiling solvents are equipped with chilled water utility to avoid fugitive losses. Tanks are insulated and vent condensers are provided as enhanced control.

- Condensers and Heat exchangers provided to control solvent losses from manufacturing processes. Mostly liquids are handled in closed systems to eliminate chances of fugitive emissions. All solvents/liquids are charged mechanically in the closed loop to avoid solvent losses/ fugitive emissions.

- The solvent recovery systems are attached with double stage chilled water/chilled brine condensers to control solvent vapor emissions. Additionally, closed loop auto heating cut-off system in solvent recovery columns to arrest fugitive emissions of solvents.

- Drying of finished goods/intermediate is attached with vacuum driers to arrest the solvent vapors generated during the drying process, traps are also provided in the vacuum line.

- The hazardous waste incinerators are attached with Primary & Secondary combustion chamber, Spray Dryer, Multi Cyclones & scrubbing system with ID fan. The Spray dryer is operated using waste heat of the flue gas where the concentrate of MEE get dried to get solids. Solid & packing wastes has been fed in the Primary chamber with the help of conveying system & liquid waste fed in secondary combustion chamber with the dual burner facility. LNG liquid natural gas and Diesel oil is being used as Auxiliary fuel. The Incinerator is PLC based and conforms to the CPCB guidelines. The operating temperatures of the Primary combustion chambers is 850+-50^{o}C and secondary chamber is 1050+-50^{o}C. The flue gases from the Secondary chamber travels to the Spray Dryer where the RO reject water quenches it. The dried mass comes out from the bottom of the spray dryer. The atomizer rotates at very high speed giving full contact between the flue gas and liquid. The outlet temp of the flue gases from spray dryer is around 170^{o}C. The flue gases pass through the cyclone separator followed by Venture Scrubber. The alkaline solution is circulated in the scrubber which neutralizes the incoming gases. The outlet temp of the scrubber is maintained around 85^{o}C. The vent gases along with water vapors emitted from a 30 m Chimney.

- The hazardous wastes generated in the pharmaceutical industries comprises of chemical and biological sludge from ETP, organic waste from process, discarded medicine, Ash from spray dryer & incinerator, dry powder from ATFD, used oil/ waste oil, spent catalyst, resins, discarded drums etc.

- Many industries have adopted techniques for reduction of the waste generation at source and almost all plants are collecting the spent solvent & some are recycling after reprocessing and some are selling to recyclers. The process residues are being incinerated in two plants and others are in the process of trial run for co-processing in cement industries for utilization for energy recovery. Presently all the units are sending their wastes to TSDF. Some units have already shifted their wastes from own captive SLF to TSDFs and some are under negotiation with TSDF officials.

- It is observed that in majority of units the discarded drums were not stored in one place and sending discarded containers to TSDF for disposal. But some units are sending the barrels to dealers who are supplying the chemicals after cleaning whereas in the authorization it is mentioned that should dispose to TSDF. Therefore the mode of disposal given in the authorization is not being followed which requires change of mode of disposal in the authorization.

- Hazardous display board provided at the temporary storage rooms as well as at the main gate as per the guidelines. Some industries are storing the hazardous wastes more than ninety days in the old SLFs.

- Most of the industries are not labeling and packaging the Hazardous waste properly which may affect its ultimate mode of scientific disposal in TSDF and also for reuse, co-process, land fill disposal etc.

- All the pharmaceutical industries do not have captive incinerators for utilization of hazardous waste as a supplementary resource or for energy recovery. Only two industries have incinerator facilities within the premises for incineration of hazardous waste. The remaining industries are sending their wastes to common TSDF or cement industries for final disposal.

- Majority of industries are giving back the battery scrap to battery supplier. Moreover the industries are not incorporated the battery scrap in the H.W. authorization issued by concerned SPCBs.

- Solvent recovery claimed 95% but no records are being maintained. Mixed solvents and halogen free solvents are being incinerated or selling to recyclers.

- The pharmaceutical units are generates wastewater from various units in the plant i.e. biodegradable low inorganic effluents, high inorganic effluents, organic effluents (mother liquor) and effluents from Utilities (Sand Filter Backwash, Regeneration Effluents from Water Softening and DM Plants, Boiler Blow down, Cooling Tower Bleed Stream, etc.). The biodegradable effluents from process are treated along with effluents from utilities in a effluent treatment

plants (ETP) consisting of Activated Sludge Process/ASB/FAB/ followed by Micro-Filtration (MF), Ultra-Filtration (UF), Reverse Osmosis (RO) Separation, Multiple Effect Evaporation (MEE) and Agitated Thin Film Drying (ATFD). All the industries have established common ETP for industrial and domestic effluent treatment. The effluent is collected in equalization tank where the pH is adjusted from different collection pits. The equalization tanks were equipped with mixing/aeration mechanism for proper mixing. The effluent is transferred to primary clarifier where the coagulants are added for sedimentation of suspended solids. The effluent travels to aeration tanks where the diffused/surface aeration takes place. Thereafter it goes to secondary clarifier from where the active sludge is recycled in to aeration tank to maintain the MLSS. High inorganic effluents from process are treated in a steam stripper to remove maximum quantity of volatile organic chemicals (mostly solvents) before further treating in MEE and ATFD units. In organic effluents which are of hazardous nature are disposed to TSDF or incinerated in incinerators and flue gases leaving the incinerator are scrubbed for control of pollutants concentration in gaseous emissions.

- High COD streams and RO rejects are subjected to thermal evaporation system constituting stripper, multi-effect evaporators and agitated thin film driers. The MEE is operated on need basis as it requires lot of steam. Thermal Evaporation System comprising of steam stripper for removing volatile solvents, Multiple Effect Evaporator for concentrating effluent and ATFD for drying of concentrated effluent to form solids. The distillate of the ATFD has been added to the ETP for further treatment and the solids are disposed to TSDF.

- The RO system is equipped with multi-grade filters, basket filters and ultra filtration. The pre-treated water enters into the RO system for final polishing. Most of the industries are having two stage RO system and few units have three stages. Generally RO-I, RO-II and RO-III. The last stage is for high TDS water. The feed enters in RO-I, the reject of RO-I goes into the RO-II and the reject of RO-II goes into the RO-III. The reject are having high TDS and sent to Incinerator as a feed in atomizer of spray drying unit. RO permeates used in cooling

tower and rejects treated in spray dryer. Some units are using RO rejects in MEE. Other units those who are not having incinerator and MEE the RO rejects are partly using for plantation, dust suppression, ash quenching, taken back in to the biological treatment system , some are doing solar evaporation etc which require further up gradation.

- Except few big units, none of the pharmaceutical industries are providing proper personal protective equipment to the workers who are handling the hazardous wastes including solvents and not conducting occupational health checkups of the workers on regular basis. Even some industries did not taken Public Liability Insurance policy under Public Liability Insurance Act.

- It is observed that small scale units are not following the recommendations of Corporate Responsibility for Environment Protection (CREP) in respect of segregation and treatment of high and low COD wastewater separately. It is found that both the effluents are being collected and treated together. In some units these wastes are segregated and given as pre-treatments like advanced oxidation and electro-coagulation before sending to conventional biological treatment.

- Except one or two units majority of pharmaceutical industries are not monitoring the fugitive & source emissions of VOCs and not even developed the mechanism for them. The industries are not even monitoring the ambient air as per the consent conditions. The ambient air quality monitoring done once in a month for suspended particulate matter only through SPCBs or consultants due to non-availability of air monitoring facilities.

(07) Recommendations

1. All industries should adopt the concept of resource conservation through reduction of the waste generation at source, recycling and reuse of waste. The treated effluent should be recycled /reused in process/cooling/ horticulture to reduce the demand of fresh water.

2. The major pollution control equipment (scrubbers attached with process fumes, incinerator and solvent recovery system) should be interlocked with production process / raw material feeding system.

3. Separate storm water drains should be constructed to avoid mixing of spillages of process waste with storm water. The unit shall provide separate covered channels for process waste and floor washings. The utility effluent should be treated and utilized in plant premises.

4. The industry should provide proper collection and treatment to all the effluent. A holding tank of adequate storage capacity should be provided to store the untreated effluent in case of non-functioning of ETP.

5. Water flow meters should be installed at inlet and outlet of ETP to measure the volume of influent and treated effluent and its record of utilization should be maintained.

6. Continuous running and regular maintenance of ETP should be ensured along with regular sludge removal to avoid the sludge bulking and related problems.

7. The effluent should be treated up to the norms prescribed by SPCBs. Some industry's ETPs needs up gradation (installation of RO and MEE) for treatment of effluent containing high COD and high TDS.

8. All the industries should conduct the comprehensive performance study of effluent treatment plants including RO, Solvent recovery system and MEE once in a year. Industry shall engage qualified environmentalist and NABL/EPA recognized laboratories for performance evaluation. All the corrective measures/ recommendations suggested as a result of performance evaluation should be implemented on priority basis.

9. The gas generated from digester should be utilized instead of flaring.

10. The industries should install & operate the solvent recover system of adequate capacity and initiate necessary measures for controlling of spillages etc. so that solvent recovery shall not be less than 95%.

11. The industries should control the process VOCs emissions from various sources and monitoring mechanism shall also be developed. The source emission and Ambient Air Quality shall be monitored as per the Air Consent Conditions given by SPCB following the guidelines of emission monitoring. The captive incinerator emissions shall also be monitored for general parameters including dioxin and furans as per the HW incinerator guidelines.

12. The industry should provide proper safety device to the workers including occupational health surveillance of the workers on regular basis. The industries should take Insurance under Public Liability Insurance Act applicable according to the provision of Act.

13. All the pharmaceutical industries should comply the recommendations of Corporate Responsibility for Environment Protection (CREP) charter issued by Central Pollution Control Board.

14. The Industry should ensure development of green belt as per the conditions imposed by SPCBs and more trees plantation around the premises along with development of lawns inside the premises.

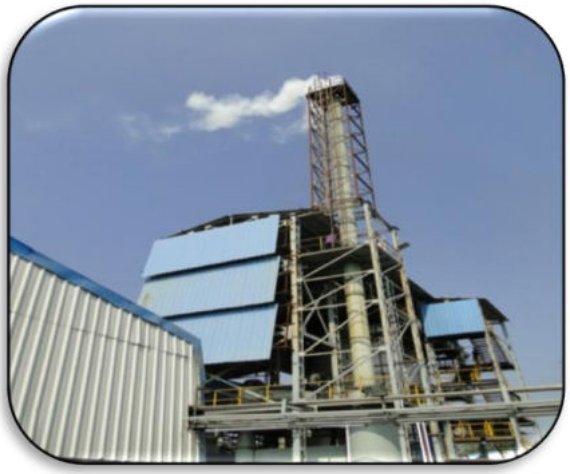
15. The hazardous waste should be stored at centralized storage area designated and developed for storage. Onsite storage and subsequent disposal of waste should be ensured as per the provisions of Hazardous Waste (Management, Handling & Tran boundary Movement) Rules, 2008. Industries should not develop onsite secured land fill facilities to avoid associated environmental problems.

16. Possibility may be explored for co-processing of waste in cement industries for utilization of hazardous waste as a supplementary resource or energy recovery.

17. It is observed that many kind of wastes like battery scrap, discarded containers, chemically contaminated drums are not included in the authorization letter issued by SPCB. Therefore these wastes are not being stored / disposed as per the provisions of Hazardous Waste Rules/ Guidelines issued thereon. The authorization issued by SPCB shall be reviewed and amended w.r.t. other wastes which are covered under the category of hazardous waste and not included in authorization letter.

Some of the Effluent treatment facilities existing in Pharmaceutical industries

View of the Solvent recover, scrubbing and HW storage and incinerator facilities exist in Pharmaceutical industries



Flow measuring system and laboratory analysis facilities in Pharmaceutical industries

Some of the fugitive emission sources in Pharmaceutical industries

(08) Industry-wise Specific Observations

(8.1) M/s Medilux Laboratories Pvt. Ltd, Pithampur, Madhya Pradesh

M/s Medilux Laboratories Pvt. Limited was established in the year 1986 at Pithampur, Indore and involved in producing drugs& drug intermediates. The production capacity of the plant was 300 MT/Year.

Performance Evaluation of ETP:-

- M. P. Audyogik Kendra Vikas Nigam (I) Ltd (AKVN) water supply is the source of water. As per the information provided, total water consumption of the unit is 65 to 70 KLD. The quantity of water used in DM plant/cooling, process, plant vacuum and domestic uses are 35 KLD, 20 KLD, 5 KLD and 10 KLD respectively.

- As per the estimation, maximum 30-35 KLD of wastewater is generated in the process including high and low COD waste water. For the treatment of wastewater the industry has provided ETP with the capacity of 40 KLD. The ETP comprises of equalization, flash mixer followed by primary clarifier, diffused aeration system, secondary clarifier, tube settler, pressure sand filter and ACF. The industry is proposed to upgrade the ETP facility to achieve the better performance by providing aerobic & anaerobic treatment.

- The fumes generated from reactor / centrifugal machine during reaction and filtration of drug intermediate were scrubbed and wastewater generated during the scrubbing is sent to ETP for further treatment. This wastewater having high COD values because it contains sodium sulphite & sodium chloride in dissolved condition.

- The unit has provided the flow meter as well as V-notch at the inlet of the ETP.

- For treatment of wastewater the industry has provided Effluent Treatment Plant with the capacity of 40 KLD, the treated water is

being used for plant floor washing, plantation and coal ash quenching. layout digram of ETP isenclosed at **Annexure-1.** The consent under Water Acts is valid up to30.09.2013.

- The industry has provided separate collection tank for high COD & low COD streams. High COD wastewater generated from scrubbers. Reactor washing and spilled solvent in process area also major source of high COD wastewater. The collection of high COD (In-Organic) and low COD (Organic) stream drainage system from process plants to ETP is separates. Low COD comes through ground level channels and high COD comes through HDPE pipe line. The high COD Effluent is treated in separate tank with help of lime/alum used for pH correction followed by salt formation by poly acryl amide solution, which is subsequently filtered& mixed with low COD effluent. The effluent has been treated with primary treatment, secondary treatment and tertiary treatment technology used for waste water treatment.

- The major portion of treated water recirculation in scrubber and remaining part used for plantation, floor washing, coal ash quenching and dust suppression in the industry.

- The industry has provided one boiler of 1.6 T capacities and one DG set of 320 KVA capacities for power backup. The stack of 30 meter height is attached with 1.6 T capacity coal fired boiler. On the day of inspection the boiler was in operation and coal used as a fuel. Boiler ash stored near the ETP in the covered area from where it is sold to local brick manufacture because it have some calorific value in the form of unborn coal particle.

- The industry has planned to erect a new stack of 30 meter height with spiral ladder & sampling.

- The industry has appointed M/s A To Z Industrial Services as consultant (authorized by MPPCB) with team of competent persons to run an effluent treatment plant to maintain water quality as per norms.

- The industry has established the environment cell to look after the water & air pollution related issues.

- The composite samples were collected from ETP on dated 01.12.2012.The values of ETP inlet was found as pH-7.50, TSS-142.5 mg/l, COD- 5145 mg/l and BOD-1217 mg/l. ETP outlet sample contains pH-7.21, TSS-31 mg/l, COD- 165 mg/l and BOD-28 mg/l. It may be seen from the analysis results that % removals of TSS- 78.24 %, COD- 96.79 %, BOD- 97.69 %.All the monitored values are well within prescribed limit. The detailed analysis report is attached at **Table 01**:**A.**

Hazardous waste management:-

- The authorization under Hazardous Waste (M, H & TM) Rules 2008 is valid up to 31.01.2015. The industry is submitting the monthly HW returns to MPPCB and disposing the HW and maintains the manifest. The records are being maintained. As per the guide lines the unit has provided HW display board at the main entrance gate and found updated at the time of visit.

- M/s Medilux Laboratories Private Limited has obtained TSDF, Pithampur, Dist. Dhar. Membership for disposal of HW as per Authorization having membership no. MPWMP-Hzw-PTM-84 valid up to 31.01.2015.

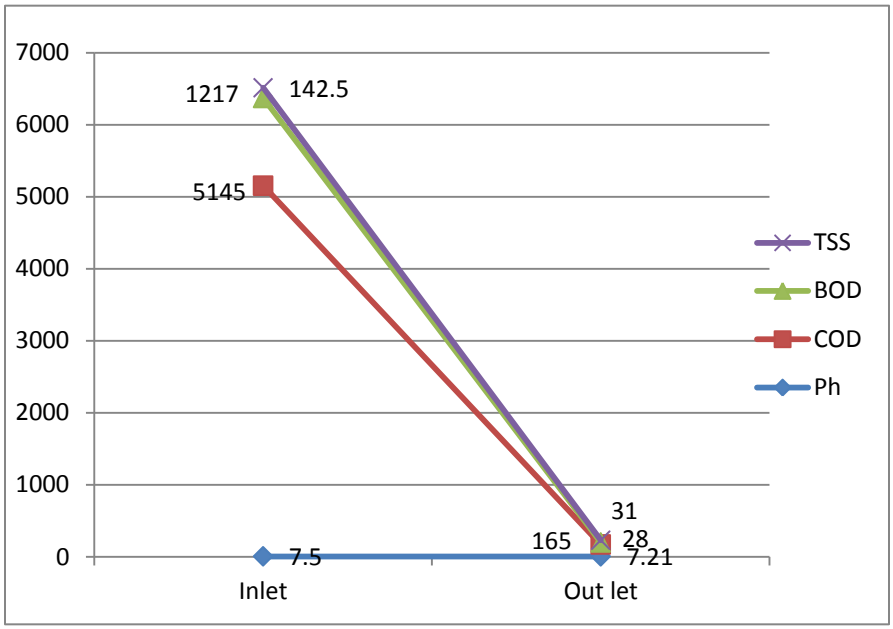
- The unit has provided three sludge drying beds to collect and dry the underflow of PST and SST. Sludge after drying at sludge drying beds has been collected in bags and stored in hazardous waste room. This solid waste is being sent to TSDF (Treatment, Storage and Disposal Facility) for final disposal within 90 days.

- Hazardous waste generation and mode of disposal detailes are enclosed at **Table 01: B.** Other hazardous wastes have been collected properly and stored in hazardous waste room before sending to TSDF Pithampur.

(Table 01:B) M/s Medilux Laboratories Pvt. Ltd, Pithampur, M.P.

HazardousWaste generated			
Source	**Name**	**category**	**Mode of disposal**
DG Set	Used oil & waste oil	5.1	Reuse as lubricant/sold to authorized registered recycler
Drug manufacturing process	Spent solvent	20.2	To be sold to registered recycler
Solvent distillation	Distillation residue from contaminated organic chemicals	20.3	To be sold to authorized re-processor or for disposal to TSDF Pithampur
Drug manufacturing process	Spent mother liquor	28.5	Treated in ETP
Drug manufacturing process	Resin	34.2	TSDF
Drug manufacturing process	containers	33.3	Reused & discarded containers to TSDF
Effluent treatment plant	Chemical sludge	34.3	TSDF
Drug manufacturing process	Spent carbon	35.3	TSDF

(Plate No.01): M/s Medilux Laboratories Pvt. Ltd, Pithampur, M.P.



(Table 01: A) Analysis report of M/s Medilux Laboratories Pvt. Ltd, Pithampur, M.P.

Date of sampling-01/12/2012

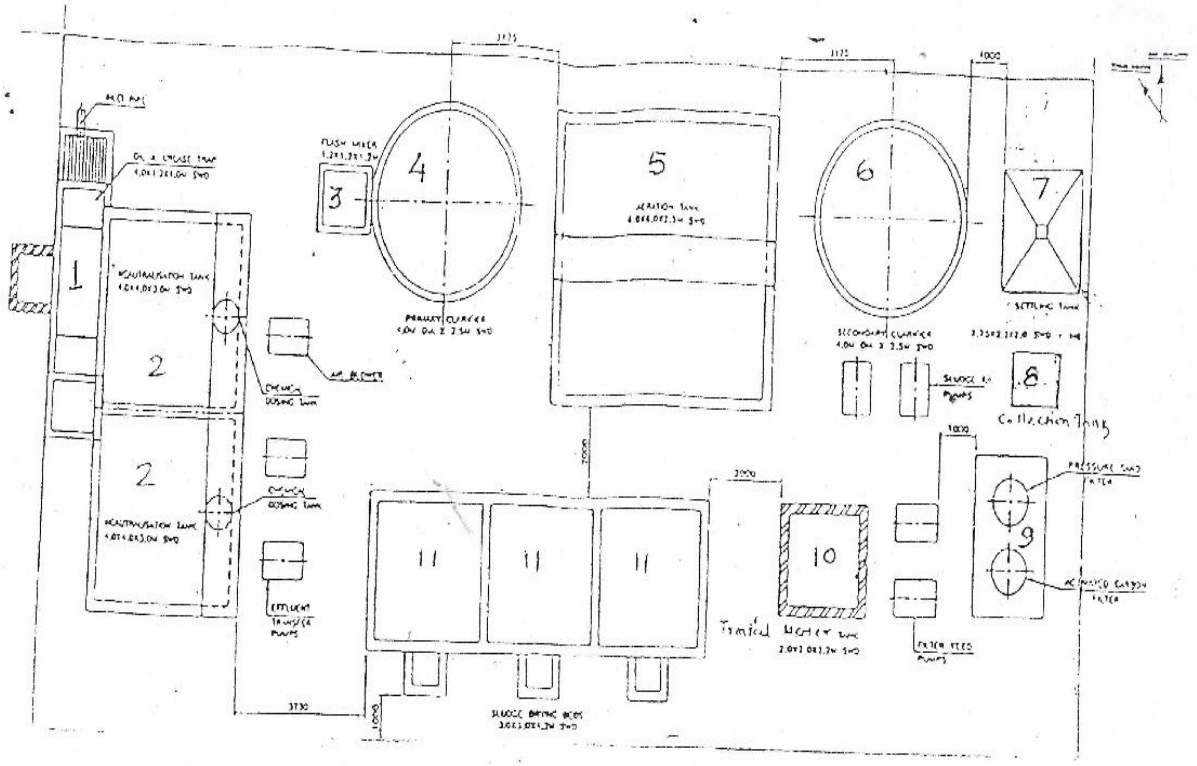
Treatment Technology				
Primary Treatment, Secondary Treatment, Tertiary Treatment				
parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	7.50	142.5	5145	1217
Outlet	7.21	31	165	28
% removal of load		78.24	96.79	97.69

*All values are in mg/l except pH

M/s Medilux Laboratories Pvt. Ltd, Pithampur, M.P.

Procedure For Effluent Treatment Plant [40 KLD]

Layout Diagram of Effluent Treatment Plant



1	SCREEN CHAMBERS	0.5 KL Each	
2	EQUALIZATION TANK 1 & 2	40 KL Each	
3	FLUSH MIXURE	2. KL.	
4	PRIMARY SETTLING TANK	30 KL	
5	AERATION TANK	90 KL	
6	SECONDARY SETTLING TANK	30 KL	
7	TUBE SETLLER TANK	5 KL	
8	HOLDING TANK	10 KL.	
9	MULTIGRADE SAND FILTER & ACTIVATED CARBON FILTER	3 - M^3/hrs	
10	TREATED WATER HOLDING TANK	10 KL.	
11	SLUDGE DRYING BEDS 3 No.	3 KL Each	

M/s Medilux Laboratories Pvt. Ltd, Pithampur, M.P.

(8.2) M/s Ranbaxy Laboratories Ltd, Dewas, Madhya Pradesh

- Ranbaxy Laboratories Limited is located in Dewas Industrial Area No.3, Dewas, M.P and engaged in the manufacture of Active Pharmaceutical Ingredients (APIs) & Dosage form and also manufacturing of formulation products like tablets, capsules, dry syrups, ampoules, vials, liquids, ointments/cream, medicated tape, center wound pad, first aid dressing, corn caps and Plaster of Paris bandage. It is a multi-product manufacturing site. These products are manufactured in campaigns through multi-step organic synthesis using batch processes. A number of formulations are manufactured in this plant. The products are a mix of high volume, low value & low volume, high value potent products. Increasingly, the shift is towards low volume high value potent products, from bulk commodities. The products cover several therapeutic segments, viz., antibiotics, anti-bacterial, cardiovascular, anti-hypertensive, anti-depressants, anti-ulcerants etc. The industry has approval of regulatory agencies from the US-FDA, MHRA-UK, TGA-Australia, WHO and service International Regulated Markets mainly to US and Europe, besides others. Ranbaxy group is serving its customers in over 125 countries and ground operations in 49 countries and manufacturing operations in 8 countries.

- The plant capacity is 850 TPA (bulk drugs). There are 8 bulk drug units consisting of 40 reactors, 30 centrifuges with 6 scrubbers and 4 solvent recovery plants in the industry premises. The industry has centralized caustic scrubbing systems in each units of active pharmaceutical ingredients unit (API).

- Formulation done in four blocks. It was informed that 50% of wastewater comes from formulation units and remaining 50% effluent from API units.

- Unit has obtained Water consent under the Water Act, 1974 is valid up to 30.04.2014 for formulation plant and 31.01.2013 for bulk drug unit. As per the consent the production of tablet, capsules, dry

syrups, injectable vials, injectable ampoules, liquids, ointments creams, fluroquinolones and antiviral acyclovir salts.

Performance evaluation of ETP:-

- The industry has four holding cum neutralization tanks in which the influent is collected from various sections of the plant and neutralized by addition of caustic and fed to primary clarifiers for treatment. Except V-notch, no water flow meters were installed at the inlet and outlet of ETPs.

- Presently the industry is generating wastewater from various units in the plant i.e. Low Inorganic, High Inorganic, Organic Effluents (Mother Liquor/Bottom Cut) and Effluents from Utilities (Sand Filter Backwash, Regeneration Effluents from Water Softening and DM Plant). The biodegradable effluents from process are treated along with effluents from utilities in 700KLD capacity Effluent Treatment Plants (ETP) consisting of Activated Sludge Process followed by Micro-Filtration (MF), Ultra-Filtration (UF), Reverse Osmosis (RO) Separation, Multiple Effect Evaporation (MEE) and Agitated Thin Film Drying (ATFD). High inorganic effluents from process are treated in a steam stripper to remove maximum quantity of volatile organic chemicals (mostly solvents) before further treating in MEE and ATFD units. In organic effluents which are of hazardous nature are incinerated in incinerators and flue gases leaving the incinerator are scrubbed for control of pollutants concentration in gaseous emissions.

- Ranbaxy Laboratories Limited, Dewas has well equipped ETP for industrial and domestic effluent treatment. The effluent is collected in equalization tank where the pH is adjusted from different collection pits provided in plants. The equalization tank is equipped with diffused aeration mechanism for proper mixing. The effluent is transferred to primary clarifier where the coagulants are added for sedimentation of suspended solids. The effluent travels to aeration tanks where the diffused aeration takes place. Thereafter it goes to secondary clarifier where again the flocculent dosing is done. The

active sludge mass is recycled to aeration tanks to maintain the bacteria level. The ETP spreads over in huge area. The ETP is well supported by Environment Laboratory. The data is monitored and recorded. Modern laboratory equipment is provided in the laboratory.

- The RO system is equipped with Multi grade Filters, Basket Filters and Ultra Filtration. The pre-treated water enters into the RO system for final polishing. RO system has three stages. RO I, RO II and RO III. The last stage is for high TDS water. The feed enters in RO-I, the reject of RO-I goes into the RO-II and the reject of RO-II goes into the RO-III. The reject is having high TDS and sent to Incinerator as a feed in atomizer of spray drying unit. The product is sent to Cooling Tower for recycling. RO permeates used in cooling tower and rejects treated in spray dryer (70KLD) and MEE (150KLD).

- The industry has commissioned 150 KLD capacity Thermal Evaporation System in January 2010 and operated on need basis. As per Shri Avanish Verma, Senior Manager (EHS) that it requires 2T of steam. 150KLD RO rejects will be treated in MEE after commissioning the second RO system. Thermal Evaporation System comprising of steam stripper for removing volatile solvents, Multiple Effect Evaporator for concentrating effluent and ATFD for drying of concentrated effluent to form solids. The distillate of the ATFD has been added to the ETP for further treatment and the solids are disposed to Secured Landfill site.

- The industry has installed solvent recovery plant and it was in operation during visit.

- The industry has established environmental laboratory near the ETP for analysis of routine parameters of wastewater, ambient air quality monitoring and stack emission monitoring.

- The collection of high COD (In-Organic) and low COD (Organic) stream drainage system from process area to ETP throw HDPE pipe line is properly separated in two different streams. Primary Treatment, Secondary Treatment and Tertiary Treatment (Two stage

RO, Multi effect evaporator, agitated thin film drying) Technology used for wastewater treatment. RO rejects and MEE treated reject waste sent to spray dryer of incinerator as a feed in atomizer of spray drying unit and MEE and R.O. permeates used in cooling tower.

- High COD streams are subjected to incineration or thermal evaporation system constituting of stripper, multi-effect evaporators, agitated thin film driers. The condensate of MEE is treated in the ETP.

- The composite sample was collected from ETP on dated 17/12/2012. The values of ETP inlet samples contains pH-9.25, TSS-421 mg/l, COD-26179.2 mg/l, BOD-5074 mg/l and ETP outlet sample contains pH-7.31, TSS-32 mg/l, COD- 246.9 mg/l, BOD-19 mg/l. It may be seen that % removal of TSS load 92.39 %, COD load 99.05 %, BOD load 99.62 %. All the monitored values are well within prescribed limit. analysis report is attached at **Table 02**:**A**

Hazardous waste management:-

- M/s Ranbaxy Laboratories Ltd, Dewas obtained authorization under HW (M, H&TM) Rules-2008 is valid up to 23.02.2015. The industry has obtained TSDF Pithampur membership for disposal of HW.

- The hazardous waste incinerator consists of primary & secondary combustion chambers, drum Pyrolizers with spray dryer absorber. Installed 4 TPD a solid-liquid waste handling incinerator. it is PLC operated and has got all APCD, namely Cyclone separators (04 no), venture & pack-bed scrubbers with a stack height of 40m.The incinerator ash is stored and will be sent to the Common Hazardous Waste Disposal Site at Pithampur near Dhar Madhya Pradesh. Other wastes of different categories are disposed as per the Hazardous Waste authorization; containers and liners are decontaminated and sent to authorize recyclers. The used oil is sent to authorize recyclers. Manifesto has been maintained for the hazardous waste transportation.

- In organic effluents which are of hazardous nature are incinerated in incinerators and flue gases leaving the incinerator are scrubbed for control of pollutants concentration in gaseous emission.

- The PM sample was collected from incinerator on dated 17.12.2012. The value of PM is 33 mg/Nm^3. PM Value is well within prescribed limit of 50 mg/Nm^3.

- The hazardous waste generation, handling and disposal record were maintained and displayed the information related to generation, handling, and disposal of hazardous waste on the 6'x4' board at main gate.

- Hazardous waste generation and mode of disposal is given at **Table 02: B.**

- The industry is generating spent oil, contaminated halogen free solvent, distillation residue, spent catalyst/spent carboys, discarded barrel/containers, chemical sludge, date expired/discarded off speedup material, incineration ash and spent organic solvent during the manufacturing process which are falling under hazardous waste category. The contaminated halogen free solvents and the distillation residue have been sold to authorized recyclers. Manifesto has been maintained for the hazardous waste transportation. Annual report submitting to MPPCB. HW stored outside the shed in open area.

- The hazardous waste generated by the plant is disposed in their own captive SLF located within the industry premises and was designed and constructed by M/s Gujarat Enviro Protection & Infrastructure Limited (GEPIL) in February 2006. The SLF has been designed and constructed as per the CPCB guidelines. Permission obtained form MPPCB for construction of SLF. The SLF has been designed for a life of about 45 years. The total capacity of the SLF is 5668 m^3. The industry also has captive incinerator just adjacent to SLF. Ash from incinerator and spray dryer is being disposed in SLF. Cover has been provided on the SLF during rainy season. A total quantity of 199.5MT hazardous waste has been disposed till 22.09.2008. Double liner system with a thickness of 1500 micron HDPE has been provided. The

drainage collection system is provided comprising of leachate collection pit through which leachate is extracted and further transported to the ETP for treatment. The hazardous waste has been packed in bags and stored in shed before sending to secured landfills site during rainy reason. Two types of hazardous waste are stored and the treated hazardous waste is manually disposed to the disposal facility with the proper maintenance of records.

- There are six piezometric holes provided around the SLF to monitor the ground water quality around disposal facility. The depth of these is ranging from 100ft to 275 ft. Bore well is provided in one of the peizometers and the water is continuously drawn in use of plant. Monitoring of water samples and ambient air quality is being done by the industry. The water samples were analyzed through M/s Choksi Laboratories Ltd., Indore. The plant is covered with good infrastructure like approach road, office, shed, change room for workers, telephone and computer connectivity. Thick green belt is developed around the SLF and housekeeping was good at the site.

- The hazardous waste generation, handling & disposal records were maintained and displayed the information related to generation, handling and disposal of hazardous waste on the 6'x4' board at main gate.

Air Pollution control measures:-

- The major sources of air pollution are from stationary combustion devices i.e. boiler, DG and incinerator stacks. The flue gases from each stationary combustion device are discharged through separate stacks of heights more than 30m. Alkali scrubbers provided in manufacturing areas & at incinerator to control emitting of harmful gases in to atmosphere. Stacks of adequate heights have been provided for effective dispersion of the air pollutants in to the atmosphere from emission sources, namely, boilers, incinerator and DG sets. Acoustic enclosures are provided for Diesel Generator sets to take care of Noise pollution,

- Nitrogen blanketing in storage tanks and process equipment to arrest fugitive emissions and safety measures through winterization. Breather valves on storage tanks and process equipment to arrest fugitive emissions. The storage tanks of low boiling solvents are equipped with chilled water utility to avoid fugitive losses. Tanks are insulated and vent condensers are provided as enhanced control.

- Condensers and Heat exchangers provided to control solvent losses from manufacturing processes. Mostly liquids are handled in closed systems to eliminate chances of fugitive emissions. All solvents/ liquids are charged mechanically in the closed loop to avoid solvent losses/fugitive emissions.

- The solvent recovery systems are attached with double stage chilled water/chilled brine condensers to control solvent vapor emissions. Additionally, closed loop auto heating cut-off system in solvent recovery columns to arrest fugitive emissions of solvents.

- Drying of finished goods/intermediate is attached with vacuum driers to arrest the solvent vapors generated during the drying process, traps are also provided in the vacuum line.

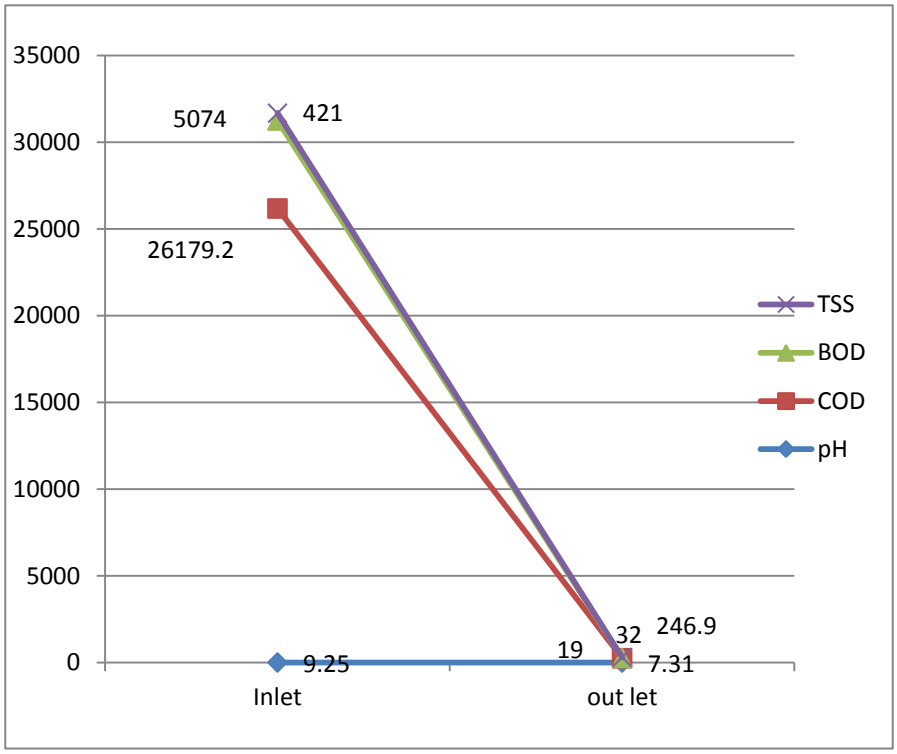
- The hazardous waste incinerator consists of Primary & Secondary combustion chamber, Drum Pyrolizers with Spray Dryer absorber, Multi Cyclones & Double stage scrubbing system with ID fan. The Spray dryer is operated using waste heat of the flue gas where the concentrate of MEE get dried to get solids. Solid & packing wastes has been fed in the Primary chamber with the help of conveying system & liquid waste fed in Primary combustion chamber with the dual burner facility. Diesel oil is being used as Auxiliary fuel. The drum Pyrolizers are used to incinerate tarry semi-solid wastes. The Incinerator is PLC based and conforms to the CPCB guidelines. The Incinerator is supplied, installed and commissioned by M/s Thermax Ltd. The plant has the capacity of 2000 kg/ day solid & Semi Solid waste, 2500 lit/ day organic and aqueous liquid waste. There are three chambers for primary combustion, namely, Primary Chamber & Drum Detoxification Chambers (02 Nos). The operating temperatures of the Primary combustion chambers is 850+-50^{o}C and secondary

chamber is 1050+-50^{o}C. The flue gases from the Secondary chamber travels to the Spray Dryer where the RO reject water quenches it. The dried mass comes out from the bottom of the spray dryer. The atomizer rotates at very high speed giving full contact between the flue gas and liquid. The outlet temp of the flue gases from spray dryer is around 170^{o}C. The flue gases pass through the cyclone separator and then travel to Venturi Scrubber. The alkaline solution is circulated in the scrubber which neutralizes the incoming gases. The outlet temp of the scrubber is maintained around 85^{o}C. The vent gases along with water vapours go out from a 30 m Chimney.

(Table 02:B) M/s Ranbaxy Laboratories Ltd, Dewas, M.P

HazardousWaste generated			
Source	**Name**	**Category**	**Mode of disposal**
DG Set	Used oil	5.1	Sale to authorized registered re-processors
Manufacturing process	Contaminated halogen free solvent	20.1	Captive incineration
Solvent distillation	Distillation residue	20.3	Captive incineration
Manufacturing process	Residues/wastes	28.1	Captive incineration
Manufacturing process	Spent catalyst	28.2	TSDF, Pithampur, Dhar
Manufacturing process	Date expired & off specification drugs	28.4	Captive incineration
Manufacturing process	Spent solvent	28.5	Reuse/Captive incineration
Manufacturing process	Discarded container	33.3	Sale to authorized recyclers
ETP	ETP sludge	34.3	Captive incineration
Captive incineration	Incinerated ash	36.2	TSDF, Pithampur, Dhar

(Plate No.02): M/s Ranbaxy Laboratories Ltd, Dewas, M.P.



(Table 02:A) Analysis report of M/s Ranbaxy Laboratories Ltd, Dewas, M.P.

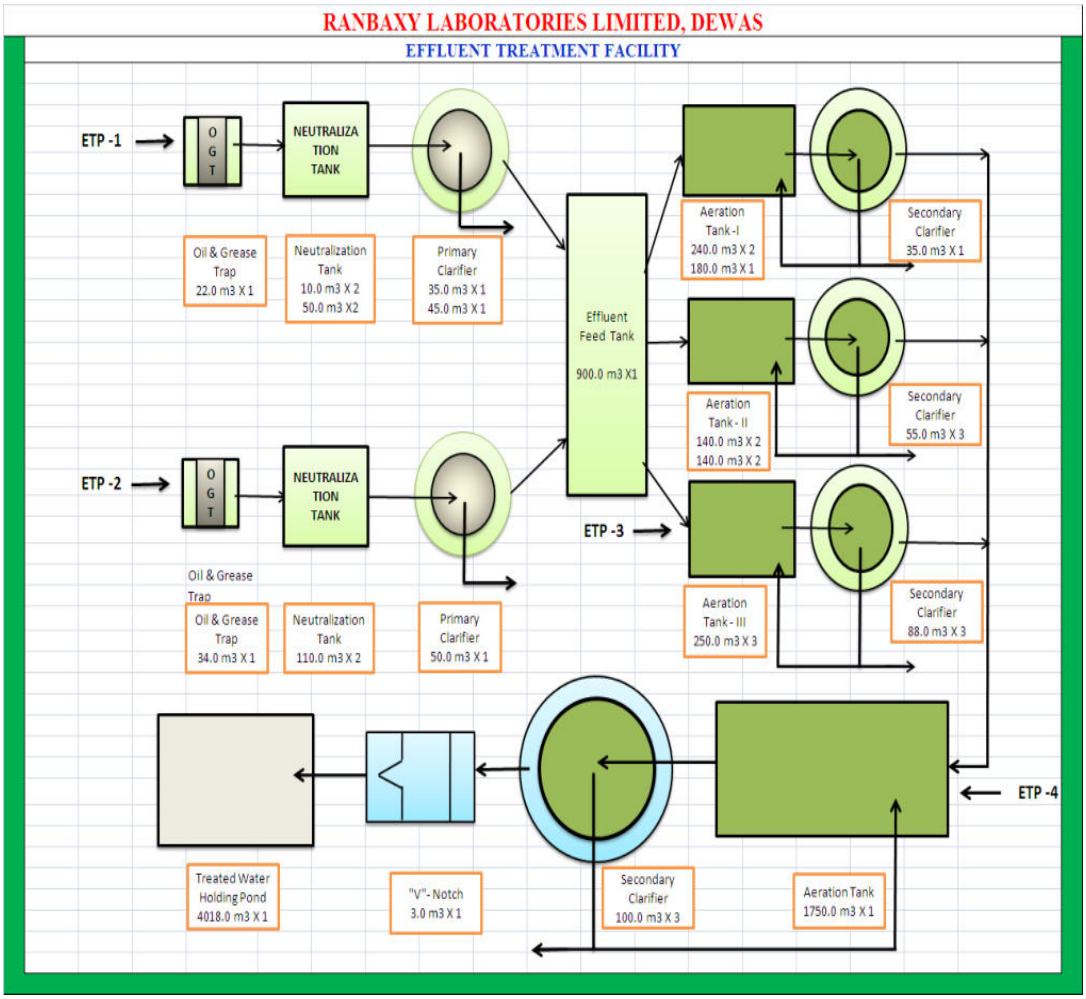
(Date of sampling-17.12.2012)

Treatment Technology				
Primary Treatment, Secondary Treatment, Tertiary Treatment (Two stages R.O., Multi effect evaporator, Agitated thin film drying)				
parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	9.25	421	26179.2	5074
Outlet	7.31	32	246.9	19
%Removal of load		92.39	99.05	99.62

*All values in mg/l accepted Ph

Annexure-2

M/s Ranbaxy Laboratories Ltd, Dewas, M.P.



M/s Ranbaxy Laboratories Ltd, Dewas, M.P.

(8.3) M/s Lupin Limited, Mandideep, M.P.

- M/s Lupin Limited has set up pharmaceutical unit on a 58 acre land in Mandideep industrial area, District. Raisen in Madhya Pradesh. The industry manufacturing bulk drugs like Cephalexin, Cefadroxil, Cefazolin Sodium, Cephradine, Cefuroxime Axetil, Cefatoxime Sodium,Ceftriaxone Disodium and other pharmaceutical formulation products.

- The industry has obtained Water consent under the Water (Prevention & Control of Pollution) Act, 1974 is valid up to 30.11.2014.

- The house keeping in ETPs areas and in plant premises was very good.

- Thick plantation developed around the plant boundary.

Performance evaluation of ETP:-

- The industry has provided ETP-I (for the effluent containing COD more than 2500 mg/L) and ETP-II (for the effluent containing COD more than 2500 mg/L) with the capacity of 100 KLD and 400 KLD respectively. layout digram of ETPs are enclosed at **Annexure-3** and **Annexure-4.**

- Effluent treatment plants consists of the Primary treatment (Neutralization, Flocculation, Primary clarification), Secondary treatment (anaerobic filter, Aerobic treatment, clarification, Extended aeration treatment), Tertiary treatment (Chemical coagulation, clarification, Sand filters, Disc Tube Reverse Osmosis, Spiral reverse osmosis), Recycling unit-Zero discharge facility (Multi Effective Evaporator, Agitated Thin Film Dryer).

- ETP-1 is a conventional biological treatment system and designed for treating low polluted stream generated from cooling tower blow down, boiler below down, canteen and wash rooms. The part of

treated wastewater from ETP-1 goes for gardening, rest is sent to ETP-2 for further treatment.ETP-2 is designed for treating the process wastewater and this system is a combination of physicochemical, anaerobic, aerobic and tertiary level unit operations. The treated waste water is further processed through Reverse Osmosis, Multi Effect Evaporation

- At the time of visit the unit was maintaining the zero discharge of effluent outside the premises.

- DTRO (Disc-Tube R.O. System):-

  It operates effectively and economically in high silt index wastewaters. The disc design dramatically reduces fouling and scaling Suspended solids found in the feed waste water cannot easily settle out on the membrane surfaces due to the short, and turbulent flow system. In the standard DTRO module, hydraulics results in a high flow velocity across the membranes at minimum feed flow. Further, the open feed channel over the membrane surfaces enables optimal membranes cleaning from fouling that are present. In addition, the standard DTRO design allows for more thorough and efficient cleaning.

- SRO (Spiral Reverse Osmosis):-

  Spiral Reverse Osmosis membrane element comprising a plurality of bag-shaped reverse osmosis membranes. The membrane is wound up in a spiral from inside a tube. The spiral winding provides a very high surface area and can bring down TDS below 100 mg/L.

- MEE (Multi Effective Evaporator):-

  The rejects of DTRO is further treated in presence of vacuum to reduce the boiling point and increase the efficiency of condensation in MEE. The concentration of the solute (dissolved solids) in solution is increased by evaporating the solvent (low boiling liquid) from the solution with the help of energy in the form of

steam. The reject of DTRO is preheated to a temperature somewhat above. The temperature in the evaporator, and is fed into the upper section of calendria, through liquid distributor, steam is given on the shell side. The effluent from a thin film over the heat transfer surface while by gravity it is transported downwards and concentrated at the same time. A vapors separator is fitted to the calendria to separate the vapors from the concentrated product. In order to reduce steam consumption, multi-stage evaporation is employed. The vapors generated from the effluent in the first stage can then be used as the heating medium in the second and so on in series for the four stages. Each effect operates at a lower pressure and temperature then the effect preceding it so as to maintain a temperature difference and continue the evaporation procedure. The vapors get separated in the flash vassal and they are condensed in surface condenser using cooling water as the cooling media. One part of the concentrate feed is kept in the circulation while other is transferred to the next effect. The condensate obtained is used as makeup water for cooling towers and the reject of MEE is processed through a dryer.

- ATFD (Agitated Thin Film Dryer):-

  The concentrate from the MEE is further treated with ATFD to get powdered form of the waste. This hazardous waste is handled by TSDF. An ATFD is a specially designed film type dryer for a feed of higher concentration where falling film and rising film evaporator cannot function and aim is to achieve powder. Steam is introduced on the jacket side as the heating medium. The wiper blades mounted on the rotor continuously wipes the feed traveling on the wall inside. The feed starts evaporating and the wipers remove deposition of product on inner wall and try to maintain heat transfer area clan. The dry solid at the bottom of the dryer are discharged under atmospheric condition and collected in a drum. The vapors generated inside flow counter currently to the feed and condense in suitable cooling water condenser. Cooling water is circulated in condenser tube as coolant.

- The composite sample was collected from ETP-2 on dated 18.12.2012. The value of ETP inlet sample contains pH-7.73, TSS-352

mg/l, COD- 15062.4 mg/l, BOD-2862 mg/l and ETP outlet sample contains pH-7.94, TSS-140 mg/l, COD- 691.2 mg/l, BOD-21 mg/l. It may be seen that % removal of TSS load 60.22%, COD load 95.41%, BOD load 99.26%. analysis report is attached at **Table 03**: **A-1**.The pH, BOD monitored values are well within prescribed limit and TSS, COD out of limitbut after R.O., the TSS (02 mg/l) and COD (21.96 mg/l) monitored values are well within prescribed limit .

- The composite sample was collected from ETP-1 on dated 18.12.2012. The value of ETP inlet sample contains pH-7.07, TSS-606 mg/l, COD- 6825.6 mg/l, BOD-1570 mg/l and ETP outlet sample contains pH-7.53, TSS-80 mg/l, COD- 292.3 mg/l, BOD-15 mg/l. It may be seen that % removal of TSS load 86.79 %, COD load 95.71 %, BOD load 99.04 %. analysis report is attached at **Table 03**: **A-2.**The pH, TSS and BOD monitored values are well within prescribed limit and COD out of limitbut after R.O., the COD (21.96mg/l) monitored value is well within prescribed limit.

Hazardous waste management:-

- M/s Lupin Limited, Mandideep obtained authorization under HW (M,H&TM) Rules-2008 is valid up to 12.12.2015.

- The industry has obtained the membership of the TSDF, Pithampur, Dist. Dhar and the member ship no. MPWMP-HzW-MDP-277 dated 01.07.2008 which is valid up to 31.03.2014.

- The disposal of hazardous wastes generated by the industry in different categories is executed as per the authorization to the TSDF at Pithampur, Dist. Dhar.

- The unit has provided “Display Board” as per the Hon’ble Supreme Court order, outside the factory premises with details about hazardous waste quantities & categories.

- The hazardous waste generation, handling and disposal record were maintained.

- The chemical sludge from effluent treatment plant is dewatered in a sludge decanter installed as a part of the effluent treatment facility. This sludge is further dried before its final disposal in TSDF. The transportation of hazardous waste from the industry is being done to TSDF and necessary requirements regarding safety information and labeling are followed.

- Solvent used by the industry in the manufacturing process are recovered and reused in the process and recovery of solvent is monitored closely. All equipment provided in the plant is of flam proof type and the solvents storage tanks are provided with the breather valves as per safety norm. The recovered solvents are mostly reused in the process of subsequent batches of the product while some mixed solvents are sold as by products to perspective users.

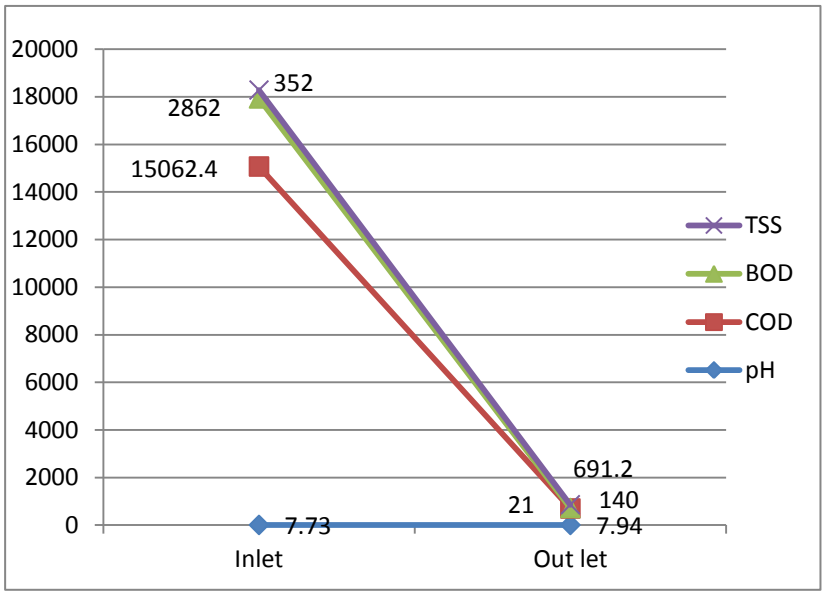
- The industry has dismantled it’s one of the incinerators used for incineration of hazardous waste. The waste is now sending to TSDF for disposal. It is better to dispose the waste at centralized secured facility then to incinerate which leads to air pollution and problem of disposal of ash. The industry has also dismantled its own two captive SLF'S and its hazardous waste sent to TSDF, Pithampur.

- The storage of hazardous waste is done in a properly identified and covered hazardous storage shed, before its final disposal to TSDF. Hazardous waste generation andmode of disposal enclosed at **Table 03: B.**

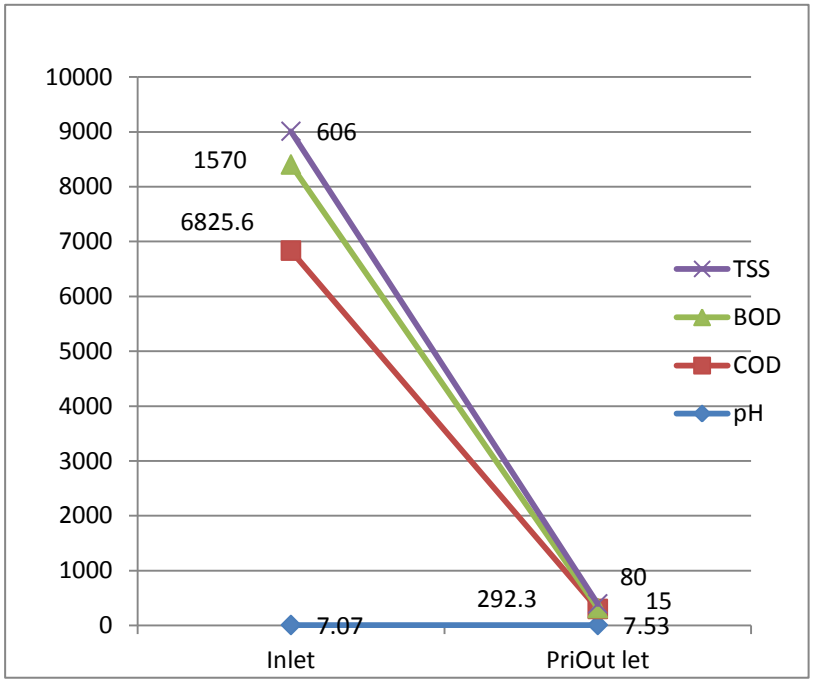
(Table 03: B) (M/s Lupin Limited, Mandideep, M.P.)

HazardousWaste generated			
Source	**Name**	**Category**	**Mode of disposal**
DG Set	Used oil	5.1	Sale to authorized registered re-processors
Manufacturing process	Spent solvent	20.2	Reused/sale to authorized re-processors
Manufacturing process	Residues	28.1	TSDF, Pithampur, Dhar
Manufacturing process	Spent catalyst	28.2	Reuse after activation
Manufacturing process	Spent carbon	28.2	TSDF, Pithampur, Dhar
Manufacturing process	Date expired discarded drugs etc.	28.4	TSDF, Pithampur, Dhar
Manufacturing process	Spent organic solvent	28.5	TSDF, Pithampur, Dhar
Manufacturing process	Discarded container	33.3	Sale/reuse/return to supplier
Effluent treatment plant	Chemical sludge	34.3	TSDF, Pithampur, Dhar
Manufacturing process	Chemical containing water from washing of container	33.1	Treatment through ETP

(Plate No.03): ETP-02 of M/s Lupin Limited, Mandideep, MP.



(Plate No.04): ETP-1 of M/s Lupin Limited, Mandideep, M.P.



(Table 03:A-1) ETP-2 Analysis report of M/s Lupin Limited, Mandideep, MP.

(Date of sampling-18.12.2012)

Treatment Technology				
Primary Treatment, Secondary Treatment, anaerobic filter, Tertiary Treatment (Disc-Tube R.O. system, Spiral Reverse Osmosis Membranes(S.R.O.), Send Filters, Multi Effect Evaporator(MEE), Decanters, Spin flash dryer, Agitated Thin Film Dryer(ATFD))				
Parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	7.73	352	15062.4	2862
outlet	7.94	140	691.2	21
% removal of load		60.22	95.41	99.26

Note: All values are in mg/l except pH

(Table 03:A-2) ETP-1 Analysis report of M/s Lupin Limited, Mandideep, MP.

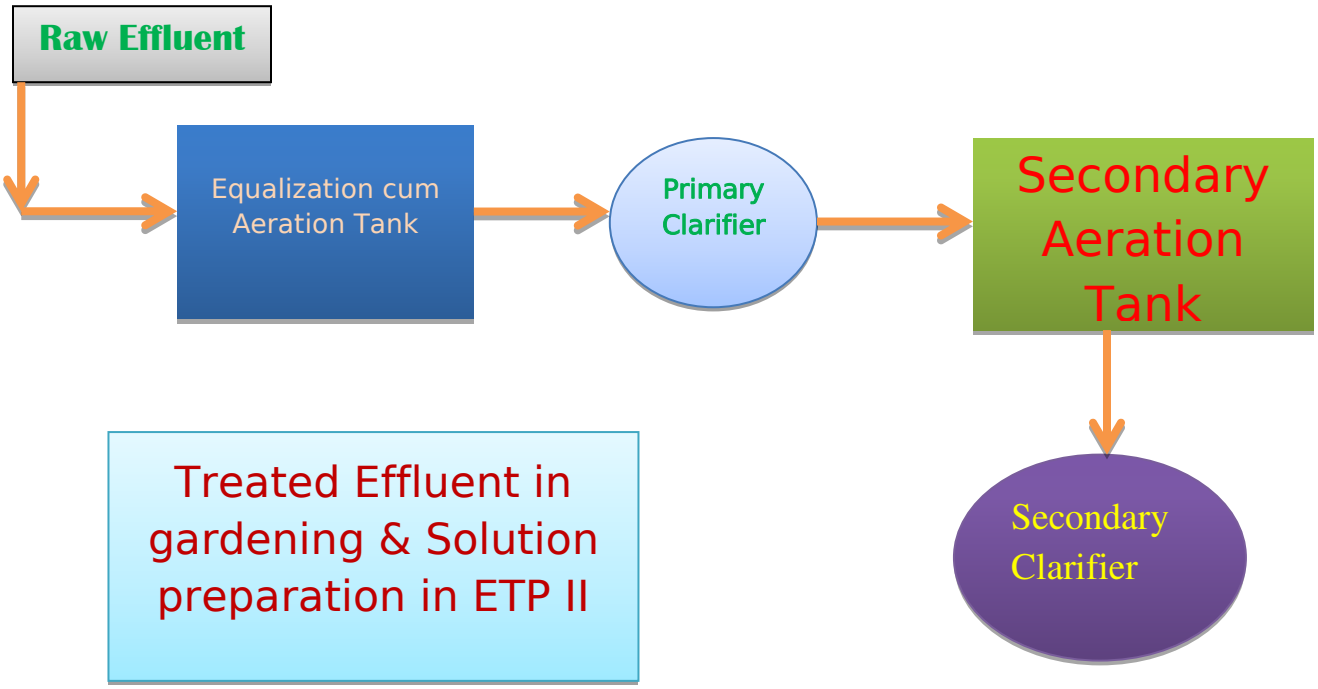
(Date of sampling-18.12.2012)

Treatment Technology				
Primary Treatment, Secondary Treatment, Tertiary Treatment				
Parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	7.07	606	6825.6	1570
Outlet	7.53	80	292.3	15
% removal of load		86.79	95.71	99.04

Note: All values are in mg/l except pH

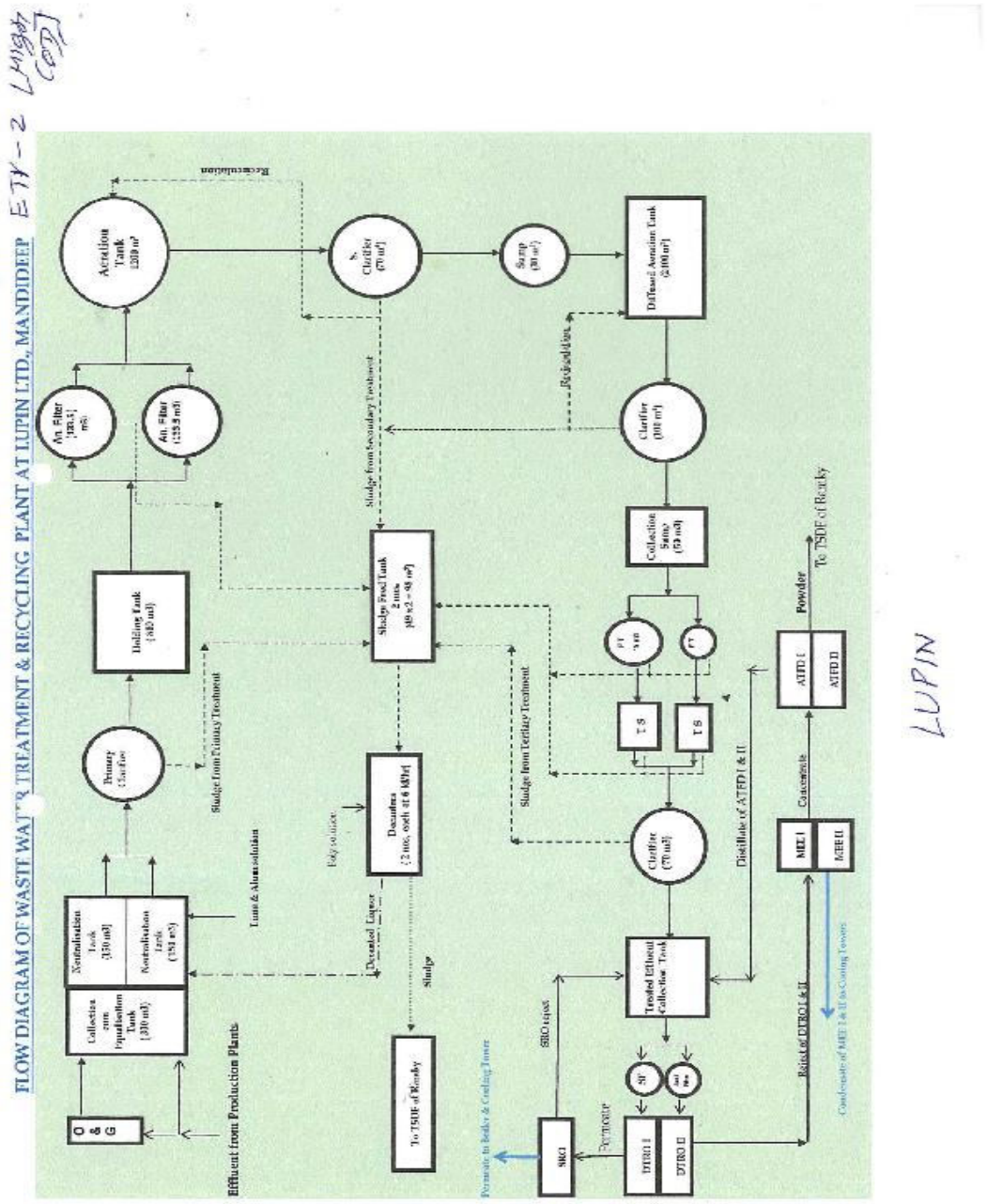
Annexure-3

ETP-1 of M/s Lupin Limited, Mandideep, M.P



Annexure-4

ETP-2 of M/s Lupin Limited, Mandideep, M.P.



M/s Lupin Limited, Mandideep, M.P.


HAZARDOUS WASTE
STORAGE SHED


SPIN FLASH
DRYER


AGITATED THIN FILM DRYER(ATFD-II)

(8.4) M/s IPCA Pvt. Ltd, Indore, Madhya Pradesh

- M/s IPCA laboratories Limited is situated at Polo ground Industrial Area in Indore and engaged in bulk drug manufacturing of Chloroquine phosphate and its derivatives. For more than 60 years, IPCA has been partnering healthcare globally in over 110 countries and in markets as diverse as Africa, Asia, Australia, Europe and the US. IPCA is a fully-integrated Indian pharmaceutical company manufacturing over 350 formulations and 80 APIs for various therapeutic segments. IPCA is a therapy leader in India for anti-malarial.

- The industry is having very congested space for process and wastewater treatment. Due to congested space the industry doesn't have any space for plantation.

- The industry has obtained water consent under the Water (Prevention & Control of Pollution) Act, 1974 which is valid up to 31.08.2013.

Performance evaluation of ETP:-

- The wastewater generation has been estimated as 30 KLD from Reactor washing, Floor washing, Sparkler filter cleaning, Solvent recovery plant, box filter and centrifuge washing and back washing of Scrubber bed in plant 1 & 3 .

- For treatment of wastewater the industry has provided 100 KL/Day capacity Effluent Treatment Plant. The ETP comprising of primary (oil grease trap, equalization tank, coagulation tank, primary settler, sludge settling tank), secondary (pH correction tank, aeration tank, secondary settler, sludge settling tank and holding tank) and tertiary treatment units (sand filter, activated carbon filter followed by RO system). The layout digram of ETP are enclosed at **Annexure-5.**

- The treated wastewater is further processed through Reverse Osmosis, Multi Effect Evaporation (Multi Effective Evaporator, Agitated Thin Film Dryer) and unit is not discharging any effluent from the plant premises. Flow meters were not provided at inlet and outlet of ETP.

- The industry has 80KLD capacity RO plant and installed solvent stripper cum Multi Effect Evaporator for disposal of RO Reject. Entire RO rejects concentrated in MEE and salts are sent to TSDF Pithampur.

- The industry also has solvent recovery plant and as informed, about 98% solvent recovery is achieved for Methanol, 95% for Toluene & 96% for IPAAC**.**

- Filter press provided for dewatering the sludge and the filtrate is taken back to effluent treatment facilities. The sludge has been sent to M/s IPCA, Ratlam for incineration in their own captive HW incinerator for which necessary permission taken from MPPCB.

- The composite sample was collected from ETP on dated 26.12.2012. The values of ETP inlet sample contains pH-7.2, TSS-3233 mg/l, COD-31040 mg/l, BOD-2631 mg/l and ETP outlet sample contains pH-7.6, TSS-157 mg/l, COD- 2391 mg/l, BOD-192 mg/l. It may be seen that % removal of TSS load 95.14%, COD load 92.29%, BOD load 92.70 %.The analysis report is attached at **Table 04**:**A.**The pH monitored value is well within prescribed limit and TSS, COD and BOD out of limit but after R.O., the TSS (26 mg/l), COD (126 mg/l) and BOD (BDL) values are well within prescribed limit.

Hazardous waste management:-

- The industry has obtained authorization under HW (M,H&TM) Rules 2008 and which is valid up to 03.03.2015. The industry has obtained the membership of the TSDF, Pithampur and the membership no. MPWMP-HzW-IND-438 which is valid up to 02.03.2015.

- As per the authorization the industry is generating eleven different categories of HWs. In which eight categories of wastes (Incinerable waste) are sent for incineration at its parent unit located at Ratlam while used oil is sold to authorized recyclers.

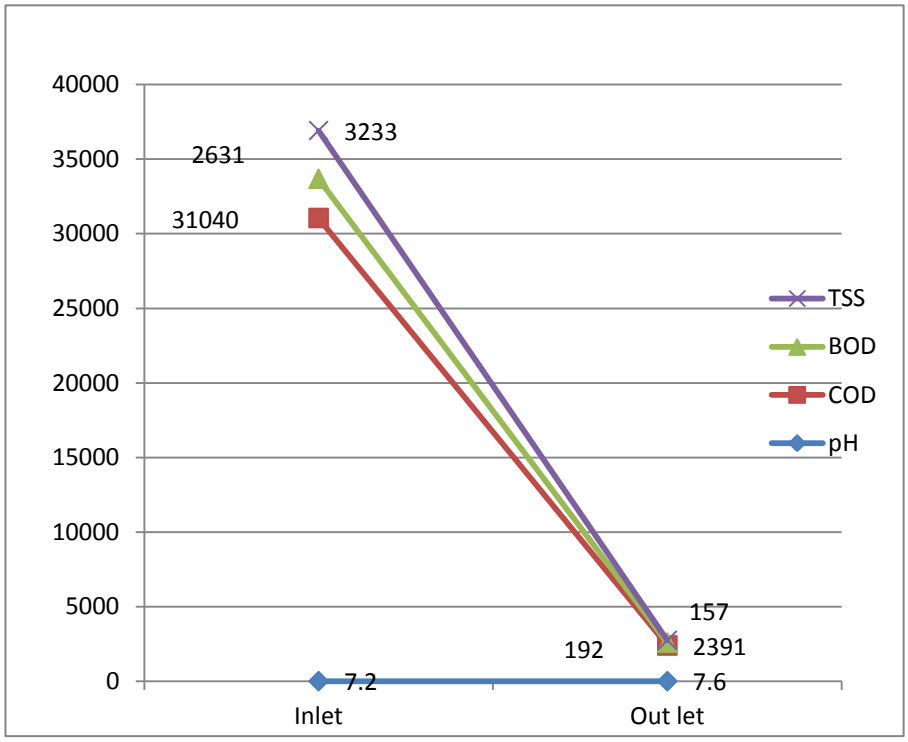
- Chemical and biological sludge stored in the room. Display board provided as per the guidelines at the temporary storage room. Provided the hazardous waste display board of 6’ X 4’ size at the

main gate. The record keeping related to hazardous waste management was systematic.

- The industry has obtained TSDF membership for disposal of HW. However no HW is sent to TSDF for disposal except incinerated ash from Ratlam. The membership no is MPWMP-HzW-IND-438.As per the authorization the industry has to send discarded containers to TSDF for final disposal, where as the industry is selling the barrels to authorized scrap dealers after cleaning. The mode of disposal in the authorization requires to be changed during the next renewal of authorization.

- This mixed sludge after drying collect in the bags and stored in the hazardous waste room. Hazardous waste is being sent to be incinerated at M/s IPCA Laboratories, Ratlam and incinerated ash to TSDF (Treatment, Storage and Disposal Facility) for final disposal.Hazardous waste generation andmode of disposal given at **Table 04:B**.Other hazardous waste collected and stored in hazardous waste room.

(Plate No.05): M/s IPCA Pvt. Ltd, Indore, M.P



(Table 04:A) Analysis report of M/s IPCA Pvt. Ltd, Indore, MP.

(Date of sampling-26.12.2012)

Treatment Technology				
Primary Treatment, Secondary Treatment, Tertiary Treatment(PSF/ACF,R.O.,MEE, ATFD)				
Parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	7.2	3233	31040	2631**
Outlet of secondary clarifier	7.6	157	2391	192
% removal of Organic load		95.14	92.29	92.70

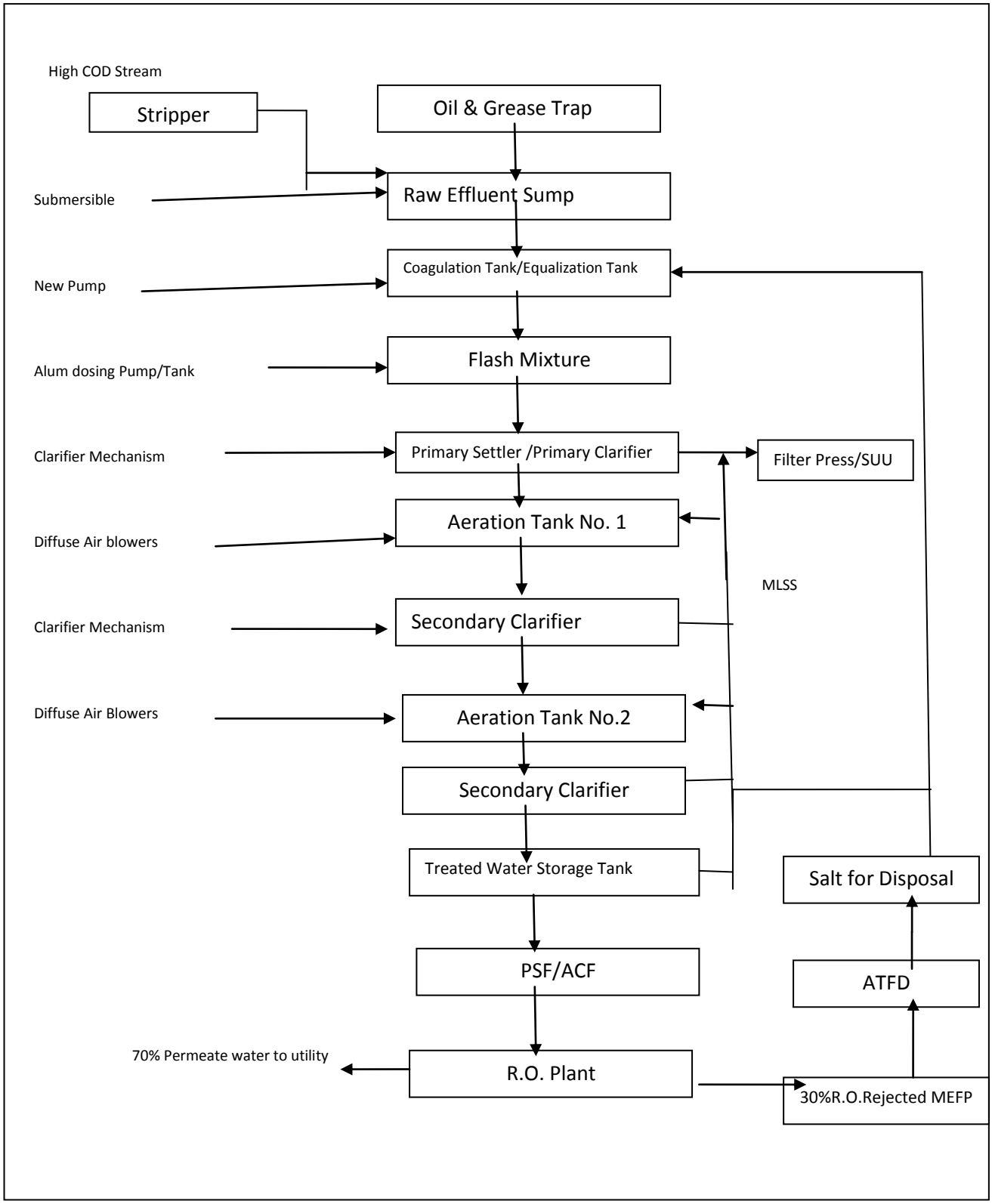
All values in mg/l except pH, **O/L Primary Clarifier.

(Table 04:B) M/s IPCA Pvt. Ltd, Indore, M.P.

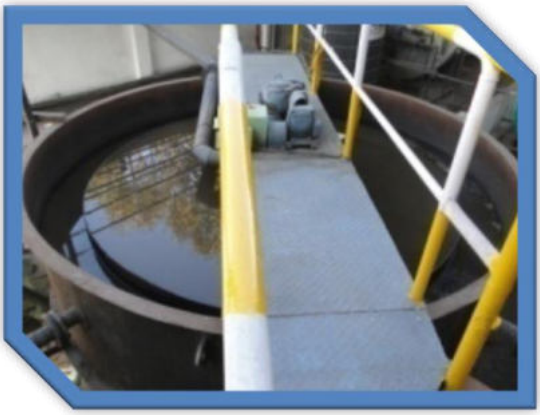
Hazardous Waste generated			
Source	**Name**	**category**	**Mode of disposal**
DG Set	Used oil	5.1	sale to authorized re-processors/re-refiners
Drug manufacturing process	Process residue waste	28.1	To be incinerated at M/s IPCA Laboratories, Ratlam, M.P.
Drug manufacturing process	Spent catalyst & carbon	28.2	To be incinerated at M/s IPCA Laboratories, Ratlam, M.P.
Drug manufacturing process	Date expired/ discarded/ off specification drugs/medicines	28.4	To be incinerated at M/s IPCA Laboratories, Ratlam ,M.P.
Drug manufacturing process	Spent organic solvent	28.5	To be incinerated at M/s IPCA Laboratories, Ratlam,M.P.
Drug manufacturing process	Chemical containing residue	33.1	To be incinerated at M/s IPCA Laboratories, Ratlam, M.P.
Drug manufacturing process	Discarded barrel/container	33.3	TSDF, Pithampur, Dhar
Drug manufacturing process	Fuel gas cleaning residue	34.1	To be treated in ETP
Effluent treatment plant	Chemical sludge from ETP	34.3	To be incinerated at M/s IPCA Laboratories, Ratlam, M.P.
Effluent treatment plant	ETP oil & grease skimming residues	34.4	To be incinerated at M/s IPCA Laboratories, Ratlam, M.P.
Solvent distillation	Distillation residue from organic solvent	36.4	To be incinerated at M/s IPCA Laboratories, Ratlam, M.P.

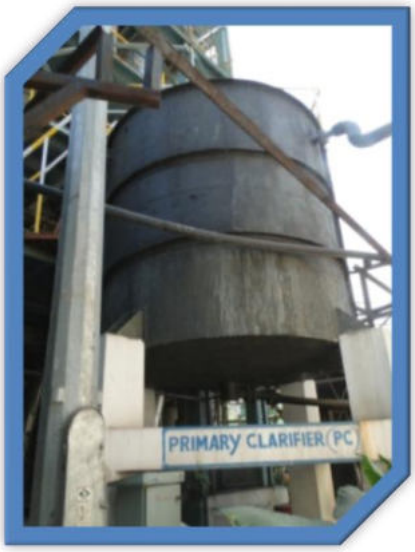
Annexure -5

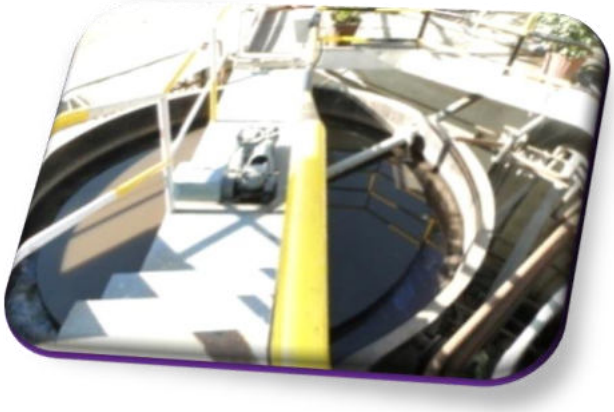
Effluent Treatment Plant (Capacity 100KLD) M/s IPCA Pvt. Ltd, Indore M.P



M/s IPCA Pvt. Ltd, Indore, M.P.







M/s IPCA Pvt. Ltd, Indore, M.P

(8.5) M/s Symbiotec Pharmalab Ltd,Rau, Indore, MP

- M/s Symbiotec Pharmalab Ltd, established at 385, Rau, Indore and involved in producing drug intermediates which are further used in bulk drug formulation.As per the consent the production capacity is 14 MT/Year of bulk drugs intermediates. Symbiotec Pharma Lab Ltd., a cortico-steroids API manufacturing company based at Indore in central India is in the business of development, production and marketing of research-based cortico steroids.

- M/s Symbiotec Pharmalab Ltd, Indore, M.P. has obtained Water consent under the Water (Prevention & Control of Pollution) Act, 1974 is valid up to 30/06/2014.For treatment of wastewater the industry has provided one Effluent Treatment Plant with the capacity of 52 KL/Day. layout digram of ETP are enclosed at **Annexure-6.**

Performance evaluation of ETP:-

- Effluent treatment plants consists of the Primary treatment (Advance Oxidation, Fenton treatment, Neutralization, Primary clarification), Secondary treatment (Aerobic treatment, clarification), Tertiary treatment (Electro Coagulation Unit, Nutsche Filtration, Carbon Filter).Treated water used for irrigation/Equipment washing/Floor washing/Cooling tower make up water.

- Three type of wastewater treated in ETP, first is low COD waste water from equipment washing/floor washing / boiler blow down, second is high COD waste water from aqueous mother liquor/process area, third is sewage. Low COD waste streams collected direct into collection tank, except sewage while high COD containing effluent/waste streams collected in advanced oxidation tank(Fenton Treatment) for pretreatment.

Advance oxidation (Fenton Treatment) :–

Fenton's reagent consists of hydrogen peroxide (H_2O_2) and ferrous ion (Fe^{2+}).this method has been used for wastewater treatment that contains organic pollutant. Chemical reactions of the hydroxyl radical produced by Fenton's reagent

$Fe^{2+} + H_2O_2 \rightarrow Fe^{3+} + OH^- + {}^{\cdot}OH$

$Fe^{3+} + H_2O_2 \rightarrow Fe^{2+} + {}^{\cdot}OOH + H^+$

The chemical reactions of the hydroxyl radical in water are of four types:

The hydroxyl radical (HO•) can attack organic molecules found in highly polluted effluents by radical addition, hydrogen abstraction, electron transfer, and radical combination.

Radical addition: $R + HO\bullet \rightarrow ROH$ where R = reacting organic compound

Electron transfer: Results in the formation of ions of a higher valence

$R^n + HO\bullet \rightarrow R^{n-1} + OH^-$

Hydrogen Abstraction: $R + HO\bullet \rightarrow R^{\cdot} + H_2O$

Radical Combination: $HO\bullet + HO\bullet \rightarrow H_2O_2$

In general, the reaction of HO• with organic compounds, at completion will produce H_2O, CO_2, and salts

Electro Coagulation:-

The Electro coagulation (E.C.) as a post treatment technology for secondary (biologically) treated effluent (STE) by using Aluminium plate as sacrificial anode and stainless steel (SS) plate as cathode without addition of any electrolytes and chemicals for correction in pH. In the E.C. process, the coagulant is generated by electro-oxidation of an aluminium anode known as sacrificial anode The E.C process completes in following steps;

(a) Dissolution of sacrificial anode by releasing the Al^{3+} i.e. electro-oxidation, (b) Generation of hydroxyl ions (OH^-) and H2(g) by splitting of H_2O at the cathode, (c) electrolytic reactions at electrode surfaces i.e. aluminums anode and stainless steel cathode, (d) Interaction among hydrated cations and colloidal, suspended and dissolved pollutants known as adsorption process. (e) Removal of coagulated impurities settled at the bottom of tank and fine sticky floating particles raised at top due H_2 (g) generation at cathode (Canet al.,

2006). The main reactions occurred at electrodes during E.C. process is as follows:

At the anode, aluminum oxidation occurs,

$Al(s) \rightarrow Al^{3+}(aq) + 3e^-$

At the cathode, water reduction occurs,

$3H_2O + 3e^- \rightarrow 3/2H_2 + 3OH^-$

Overall cell reaction,

$Al + 3H_2O \rightarrow Al^{3+} + 3/2H_2 + 3OH^-$

At alkaline conditions, $Al^{3+} + 3OH^- \rightarrow Al(OH)3$,

At acidic conditions, $Al^{3+} + 3H_2O \rightarrow Al(OH)_3 + 3H^+$

The Al^{3+} produced may undergo various reactions in solutions, in other words

Hydrolyze in solution;

$Al^{3+} + H_2O \leftrightarrow Al(OH)^{2+} + H^+$, $Al(OH)^{2+} + H_2O \leftrightarrow Al(OH)_2^+ + H^+$

$Al(OH)_2^+ + H_2O \leftrightarrow Al(OH)_3 + H^+$ $Al(OH)_3 + H_2O \leftrightarrow Al(OH)_4^- + H^+$

Aluminum ions (Al^{3+}) are produced by electrolytic dissolution (electro oxidation) of the anode which generated various monomeric and polymeric species. Al^{3+} (aq) and OH^- ions generated by electrode reactions, reacted to form various monomeric species such as $Al(OH)^{2+}$, $Al(OH)_2^+$, $Al(OH)_4^-$, and polymeric species such as $Al_6(OH)_{15}^{3+}$, $Al_7(OH)_{17}^{4+}$, $Al_8(OH)_{20}^{4+}$, $Al_{13}O_4(OH)_{24}^{7+}$,

- The composite sample was collected from ETP on dated 26/12/2012. The values of ETP inlet sample contains pH-6.1, TSS-186 mg/l, COD-4233 mg/l, BOD-1432 mg/l and ETP outlet sample contains pH-6.2, TSS-170 mg/l, COD- 425 mg/l, BOD-93 mg/l. It may be seen that % removal of TSS load 8.60 %, COD load 89.95 %, BOD load is 93.50 %. The pH monitored value is well within prescribed limit and TSS, COD and BOD out of limit. analysis report is attached at **Table 05**: **A.**

Hazardous waste management:-

- M/s Symbiotec Pharmalab Ltd has obtained the authorization under HW (M, H&TM) Rules 2008 and valid up to 24.07.2014. The industry has obtained the membership of the TSDF, Pithampur and Dist. Dhar and the member ship no. MPWMP-HzW-IND-154 dated 01.04.2010 which is valid up to 31.03.2014.

- Dedicated room for hazardous waste storage available and hazardous waste send to land filing and incineration done by Ramky Enviro Projects, TSDF, Pithampur. At the Hazardous waste storage site danger sign board not provided with all safety devices also at the storage site. This mixed sludge after drying collect in the bags and stored in the hazardous waste room.

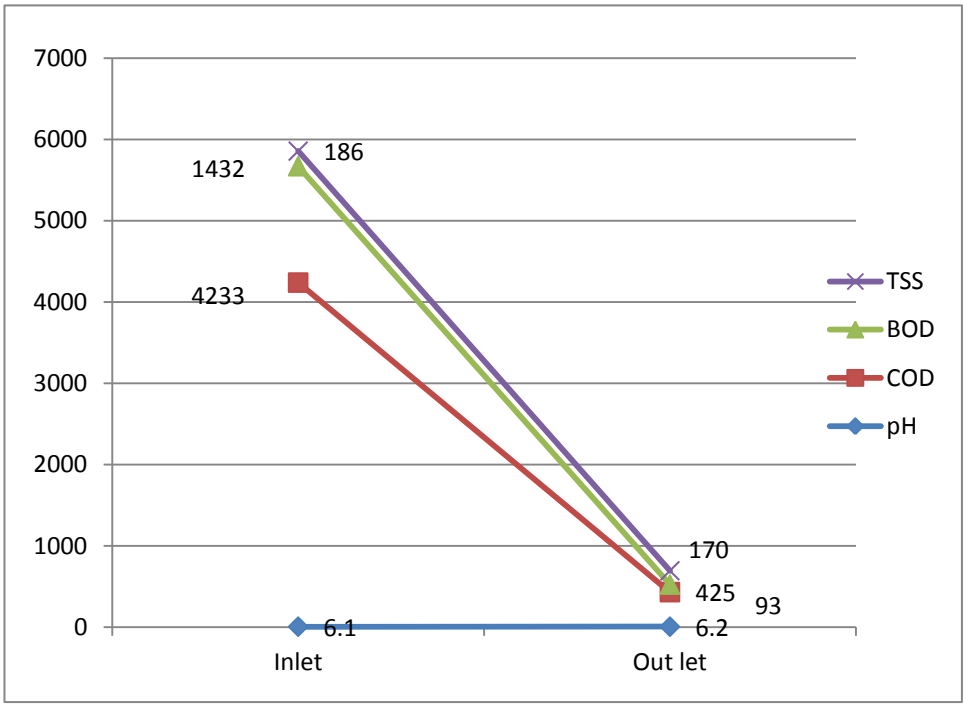
- The hazardous waste generation, handling and disposal record were maintained and displayed the information related to generation, handling, and disposal of hazardous waste on the board at main gate. The disposal of hazardous wastes generated by the industry in different categories is executed as per the authorization to the TSDF at Pithampur, Dist. Dhar.

- Hazardous waste generation and Mode of disposal enclosed at **Table 05: B.** Other hazardous waste collected properly and stored in hazardous waste room. Hazardous waste is being sent to for final disposal.

(Table 05:B) M/s Symbiotec Pharmalab Ltd, Rau, Indore, MP

Hazardous Waste generated			
Source	**Name**	**category**	**Mode of disposal**
DG Set	Used oil	5.1	Sale to authorized re processors/refiners
Solvent distillation	Distillation residue	20.3	TSDF Pithampur, Dhar
Drug manufacturing process	Process residue and waste	28.1	TSDF Pithampur, Dhar
Drug manufacturing process	Spent catalyst & carbon	28.2	TSDF Pithampur, Dhar
Drug manufacturing process	Off specification products	28.3	TSDF Pithampur, Dhar
Drug manufacturing process	Date expired/ discarded/ off specification drugs/medicines	28.4	TSDF Pithampur, Dhar
Drug manufacturing process	Spent organic solvents	28.5	To be recover in house solvent plant & waste disposed in to TSDF Pithampur, Dhar
Drug manufacturing process	Discarded barrel/container	33.3	Sale to authorized vender
Drug manufacturing process	Chemical Containing Residue	33.1	To be treated in ETP
Drug manufacturing process	Discarded Barrel / Container	33.3	Sale to authorized vender
R.O.	Spent ion exchange resin containing toxic metals	34.2	TSDF Pithampur, Dhar
Effluent treatment plant	Chemical sludge from ETP	34.3	TSDF Pithampur, Dhar
Effluent treatment plant	oil & grease skimming residues from ETP	34.4	TSDF Pithampur, Dhar

(Plate No.06) M/s Symbiotec Pharmalab Ltd, Rau, Indore, MP



(Table 05:A) Analysis report of M/s Symbiotec Pharmalab Ltd, Rau, Indore, M.P

Date of sampling-26/12/2012

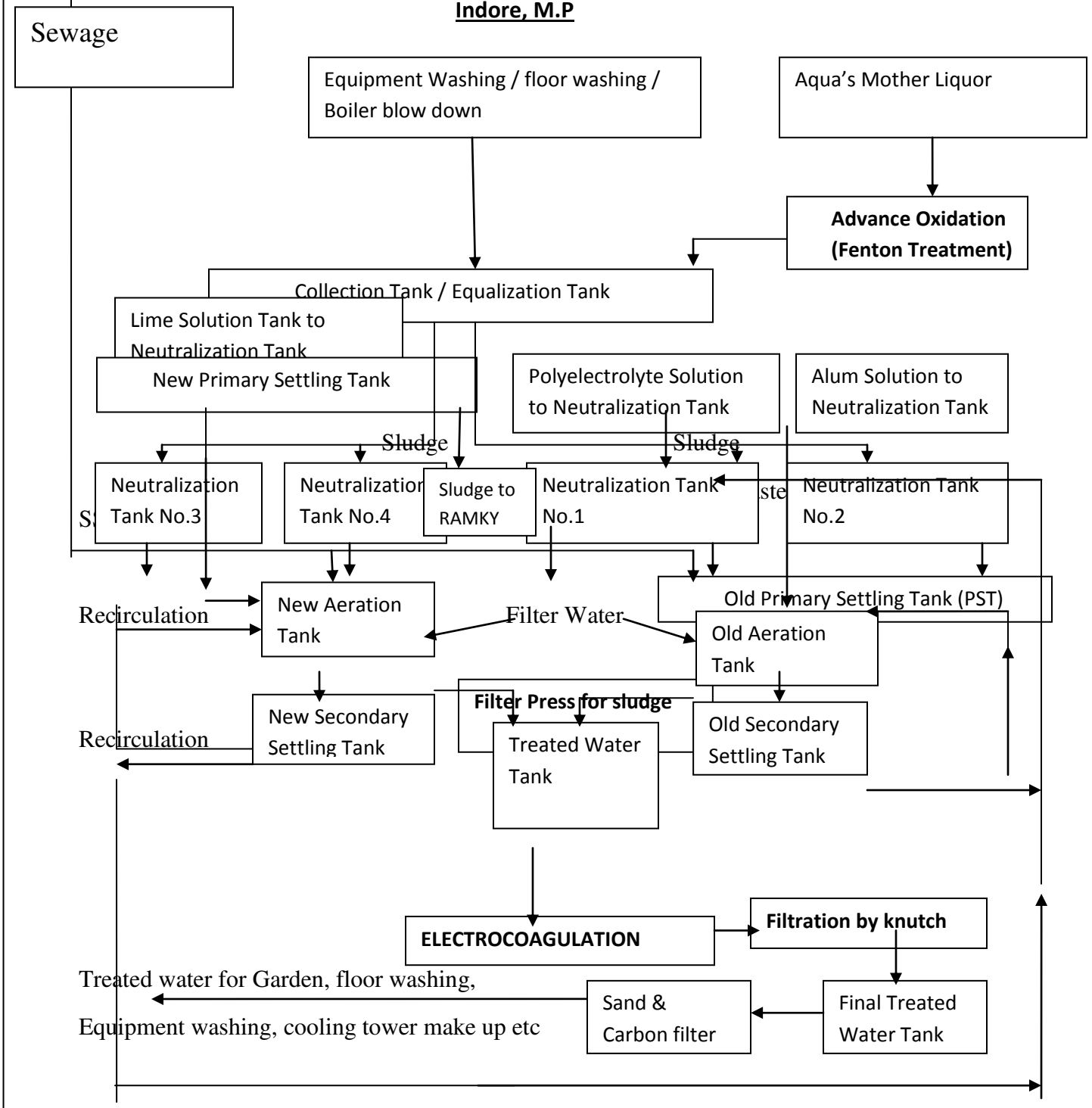
Treatment Technology				
Primary Treatment(Advance oxidation, Fenton Treatment), Secondary Treatment, Tertiary Treatment(electro coagulation, Nutsche Filtration)				
Parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	6.1	186	4233	1432
outlet	6.2	170	425	93
% removal of load		8.60	89.95	93.50

*All values in mg/l accepted pH

Annexure-6

M/s Symbiotec Pharmalab Ltd, Rau, Indore, M.P.

Schematic diagram of Effluent Treatment Plant of M/s Symbiotec Pharma lab Ltd,Rau, Indore, M.P



M/s Symbiotec Pharma Lab Ltd, Rau, Indore, M.P

(8.6) M/s Symbiotec Pharmalab Ltd, Pithampur, MP

- M/s Symbiotec Pharmalab Ltd was established in the year 2009 at Pithampur and involved in producing drug intermediates which are further used in bulk drug formulation. As per the consent the production capacity is 48 MT/Year of bulk drugs intermediates. Symbiotec Pharma lab ltd., a cortico-steroids API manufacturing company based at Indore in central India is in the business of development, production and marketing of research-based cortico steroids.

- M/s Symbiotec Pharmalab Ltd, Pithampur, Dist. Dhar, M.P. has obtained Water consent under the Water (Prevention & Control of Pollution) Act, 1974 is valid up to 30.09.2015.For treatment of wastewater the industry has provided one Effluent Treatment Plant with the capacity of 200 KL/Day. layout digram of ETP are enclosed at **Annexure-7.**

Performance evaluation of ETP:-

- Effluent treatment plants consists of the Primary treatment (Advance Oxidation, Fenton treatment, Flash Mixer, Primary clarification), Secondary treatment (Aerobic treatment, Clarification), Tertiary treatment (Sand filter, Carbon Filter).Treated water used for irrigation/Floor washing.

- Low COD waste streams collected direct into collection tank, except sewage effluent while high COD waste streams collected in advanced oxidation tank(Fenton Treatment) for pretreatment and after treatment it is allowed to mix with low COD waste streams in to collection tank.

Advance oxidation (Fenton Treatment):

Fenton's reagent consists of hydrogen peroxide (H_2O_2) and ferrous ion (Fe^{2+}).this method has been used for wastewater treatment that contains organic pollutant. Chemical reactions of the hydroxyl radical produced by Fenton's reagent

$Fe^{2+} + H_2O_2 \rightarrow Fe^{3+} + OH^- + {}^{\cdot}OH$

$Fe^{3+} + H_2O_2 \rightarrow Fe^{2+} + {}^{\cdot}OOH + H^+$

The chemical reactions of the hydroxyl radical in water are of four types:

The hydroxyl radical (HO•) can attack organic molecules found in highly polluted effluents by radical addition, hydrogen abstraction, electron transfer, and radical combination.

Radical addition: $R + HO\bullet \rightarrow ROH$ where R = reacting organic compound

Electron transfer: Results in the formation of ions of a higher valence

$R^n + HO\bullet \rightarrow R^{n-1} + OH^-$

Hydrogen Abstraction: $R + HO\bullet \rightarrow R^{\cdot} + H_2O$

Radical Combination: $HO\bullet + HO\bullet \rightarrow H_2O_2$

In general, the reaction of HO• with organic compounds, at completion will produce H_2O, CO_2, and salts

- The composite sample was collected from ETP on dated 27.12. 2012. The values of ETP inlet sample contains pH-5.7, TSS-90 mg/l, COD-5566 mg/l, BOD-1896 mg/l and ETP outlet sample contains pH-7.2, TSS-50 mg/l, COD- 137 mg/l, BOD-39 mg/l. It may be seen that % removal of TSS load 44.44 %, COD load 97.53 %, BOD load 97.94 %. The pH, TSS and COD monitored values are well within prescribed limit and BOD out of limit. analysis report is attached at **Table 06**: **A.**

Hazardous waste management:-

- M/s Symbiotec Pharmalab Ltd, Pithampur, Dist. Dhar, M.P. Obtained authorization under HW (M, H&TM) Rules2008 is valid up to 20.10.2014. The industry has obtained the membership of the TSDF, Pithampur, and Dist. Dhar. (Member ship no. MPWMP-HzW-PTM-369) which is valid up to 31.03.2014.

- Dedicated room for storage of different categories hazardous waste available and hazardous waste send to TSDF, Pithampur. Hazardous waste storage site danger sign board not provided with all safety devices also at the storage site. This mixed sludge after drying collect in the bags and stored in the hazardous waste room.

- The hazardous waste generation, handling and disposal record were maintained and displayed the information related to generation, handling, and disposal of hazardous waste on the board at main gate. The disposal of hazardous wastes generated by the industry in different categories is executed as per the authorization to the TSDF at Pithampur, Dist. Dhar.

- Solvent used by the industry in the manufacturing process are recovered and reused in the process and recovery of solvent is monitored closely. The recovered solvents are mostly reused in the process of subsequent batches of the product while some mixed solvents are sale to authorized re-processor/recycler. Distillation residues send to TSDF, Pithampur.

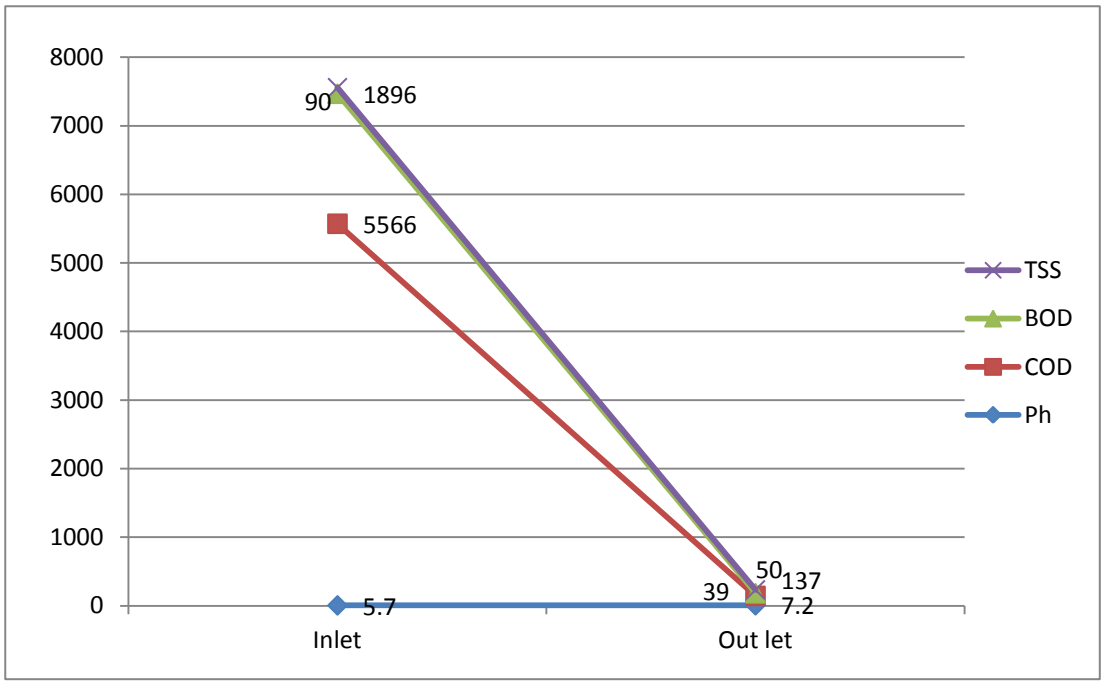
- Discarded container sale to authorized traders after decontamination.

- Hazardous waste generation and Mode of disposal enclosed at **Table 06: B.**

(Table 06:B) M/s Symbiotic Pharmalab Ltd, Pithampur, M.P.

Hazardous Waste generated			
Source	**Name**	**category**	**Mode of disposal**
DG set	Spent oil	5.1	To be sold to authorized re processors/recycler
ETP	oil & grease	5.2	
Solvent distillation	Distillation residue	20.3	TSDF, Pithampur
Drug manufacturing process	Other solid wastes(poly bags, hand gloves, tissue papers and butter papers)	28.1	TSDF, Pithampur
Drug manufacturing process	Spent mother liquor	28.1	TSDF, Pithampur
Drug manufacturing process	Spent carbon	28.2	TSDF, Pithampur
Drug manufacturing process	Date expired & off specification drugs	28.4	TSDF, Pithampur
Drug manufacturing process	Spent solvents	28.5	Distillation and reuse or sale to authorized re-processor. Distillation residue to TSDF
Drug manufacturing process	Discarded container	33.3	Sale to authorized traders after decontamination
ETP	ETP sludge	34.3	TSDF, Pithampur

(Plate No.07): M/s Symbiotic Pharmalab Ltd, Pithampur, M.P.



(Table 06:A)Analysis report of M/s Symbiotic Pharmalab Ltd, Pithampur, MP

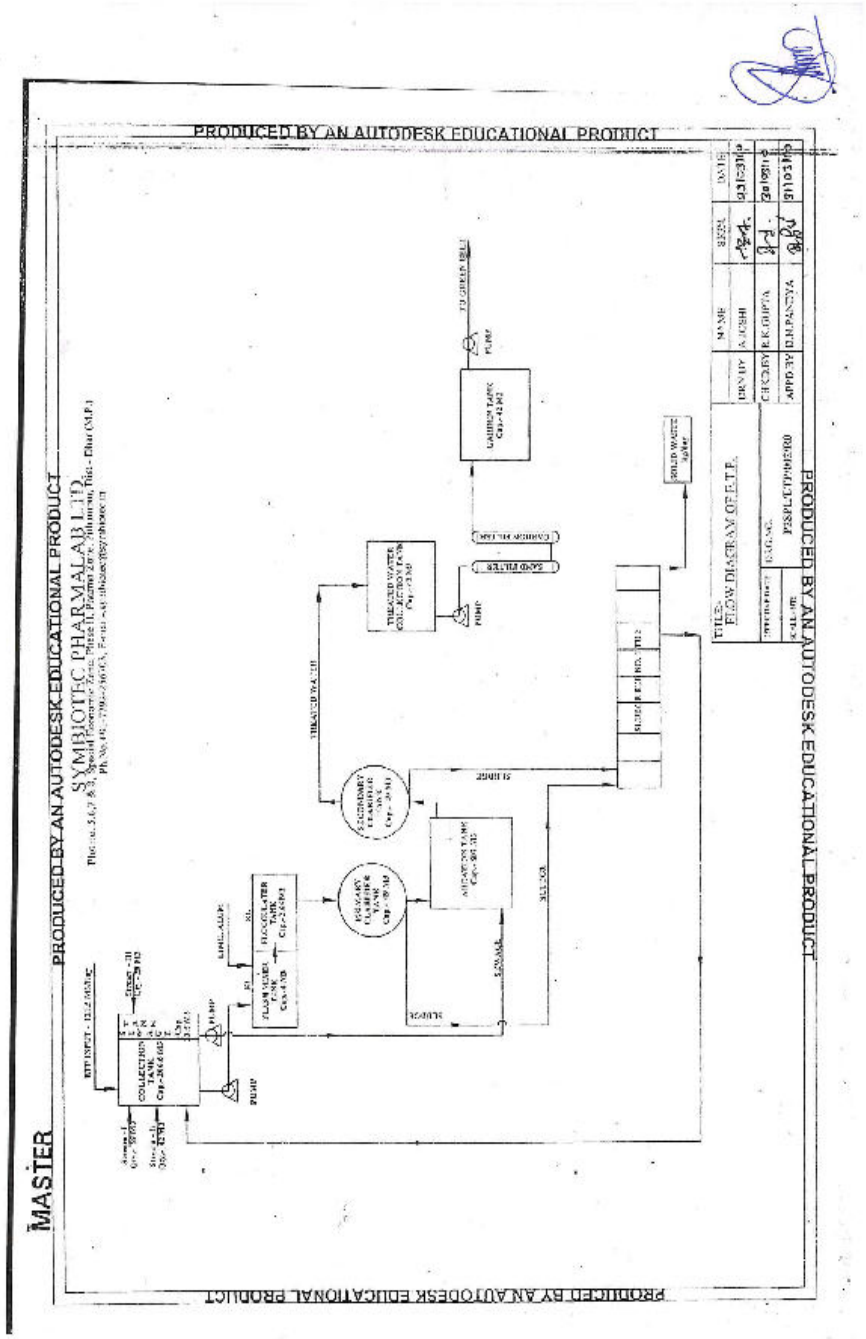
(Date of sampling: 27.12.2012)

Treatment Technology				
Primary Treatment(Advance oxidation, Fenton Treatment), Secondary Treatment, Tertiary Treatment(Sand Filter, Carbon Filter)				
Parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	5.7	90	5566	1896
outlet	7.2	50	137	39
% removal of load		44.44	97.53	97.94

*All values are in mg/l except pH.

Annexure-7

M/s Symbiotic Pharmalab Ltd, Pithampur, M.P.



M/s Symbiotec Pharmalab Ltd, Pithampur, M.P.

(8.7) M/s Unichem Laboratories Ltd, Pithampur, MP

- The industry is located at Pithampur Industrial Area and commissioned in 1992.Unichem has taken over the plant of Pithampur from Biotech synergy limited in the Year 2005-06. The unit is involved in manufacturing of life saving drugs & drugs intermediates. The industry is not manufacturing all products concurrently, some of the products manufactured on a continuous basis while others are manufactured as per market requirements. As per the records about 34 MTA bulk drugs produced against the consent capacity of 155 MTA.

- Air consent is valid up to 28. 02.2014. The unit has one boiler. One stack of 35m height is provided for these boilers. Standby boiler will be installed after Environmental clearance by the board. There were two operational DG sets of 500 KVA capacities installed in common room.

- The industry has not procured any air quality monitoring equipment. The ambient air quality monitoring at two locations and source emissions were monitored once in three months by the regional office laboratory of MPPCB, Indore.

- The house keeping in the premises is good. Green belt was maintained in and around the plant. Plantation was also seen in the open patches near ETP area and process plant area.

- The industry has obtained Water consent under the Water (Prevention & Control of Pollution) Act, 1974 and is valid up to 28.02.2014.For treatment of wastewater the industry has provided one Effluent Treatment Plant with the capacity of 40 KL/Day. Layout diagram of ETP are enclosed at **Annexure- 8.**

Performance evaluation of ETP:-

- Water consent under water Act is valid up to 28.02.2014. It was estimated that a total 18 KLD of wastewater generated from the unit as the unit was operating at very less production capacity. V-notch has been provided to measure the inlet ETP flow.

- ETP of capacity 40 m^3/day is provided to treat the effluent. The effluent is passed through screening and O&G removal and collected in equalization cum neutralization tank. Then the effluent comes to flocculation tank where chemicals were dosed for coagulation and the settling is carried out in primary settling tank. The supernatant overflows to biological aerobic treatment consisting of diffused aeration system. The treated effluent is passed through tertiary treatment comprising of Gravity Sand Filter, Activated Carbon Filter, and reverse osmosis system and was being utilized for gardening and plantation.

- The chemical sludge settled in primary settling tank and the biological sludge generated in secondary & tertiary settling tanks was dried separately. The chemical sludge was sent to TSDF Pithampur for disposal while the biological sludge was being utilized as manure for plantation.

- 90 KLD capacity new ETP i.e. anaerobic digestions followed by two stage aeration & tertiary treatment and reverse osmosis system is under construction in the premises which will be commissioned tentatively by 1st week of December 2013. It was informed except equalization, neutralization and aeration; all other structures will be dismantled in the old ETP after commissioning of new ETP.

- The unit has provided separate ETP laboratory to monitor routine parameters. The records of inlet flow and consent parameters were maintained in the logbooks.

- The composite sample was collected from ETP on dated 27/12/2012. The value of ETP inlet sample contains pH-4.2, TSS-351 mg/l, COD-12544 mg/l, BOD-3660 mg/l and ETP outlet sample contains pH-6.3,

TSS-242 mg/l, COD- 313 mg/l, BOD-38 mg/l. It may be seen that % removal of TSS load 31.05%, COD load 97.50%, BOD load 98.96%. analysis report is attached at **Table 07**: **A**. The pH monitored value is well within prescribed limit and TSS, COD and BOD out of limit but after R.O., the TSS (54 mg/l), COD(100 mg/l) and BOD(BDL) monitored values are well within prescribed limit.

Hazardous waste management:-

- Hazardous waste authorization is valid up to 13.03.2015. The unit has obtained TSDF membership for disposal of HW of category 20.3, 28.2, 29.1 & 34.3.The membership No is MPWMP-HzW-PTM-008

- The chemical sludge from PST and Biological Sludge from two SSTs is dried separately. The biological sludge used as manure for plantation while the chemical sludge sent to TSDF.

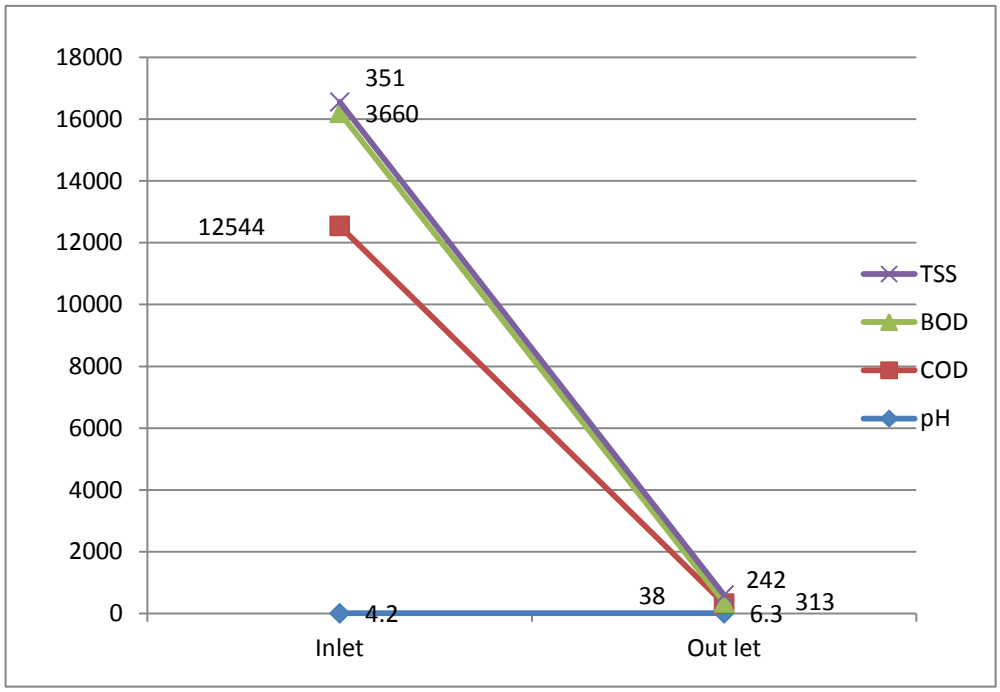
- The hazardous wastes are stored in isolated covered shed size 15 m x 05 m. All the wastes are stored separately, category-wise in the shed.

- The industry has provided isolated room of 15 m x 05 m size for secured storage of hazardous wastes. The category-wise HW was stored separately in the shed. It has maintained the records on generation, storage, treatment and disposal of Hazardous Wastes. On the day of visit 490 Kg of organic residues, 2938 kg ETP Sludge and 1411 of spent carbon were in storage. Hazardous waste generation andMode of disposal enclosed at **Table 07: B.**

(Table 07: B) M/s Unichem Laboratories Ltd, Pithampur, M.P.

HazardousWaste generated			
Source	**Name**	**Category**	**Mode of disposal**
DG Set	used oil	5.1	sold to authorized vendor
Solvent distillation	Distillation residue	20.3	Dried & stored as hazardous waste & send to common site for final disposal
Drug manufacturing process	Spent activated carbon	28.2	TSDF
Drug manufacturing process	Date expired / off specification Product	28.3	TSDF
Drug manufacturing process	Spent organic solvents	28.5	Taken for solvent distillation immediately for reuse.
Drug manufacturing process	Discarded container	33.3	Reused in own premises or send back to party.
Effluent treatment plant	Chemical sludge	34.3	TSDF

(Plate No.08): M/s Unichem Laboratories Ltd, Pithampur, M.P.



(Table 07:A) Analysis report of M/s Unichem Laboratories Ltd, Pithampur, MP

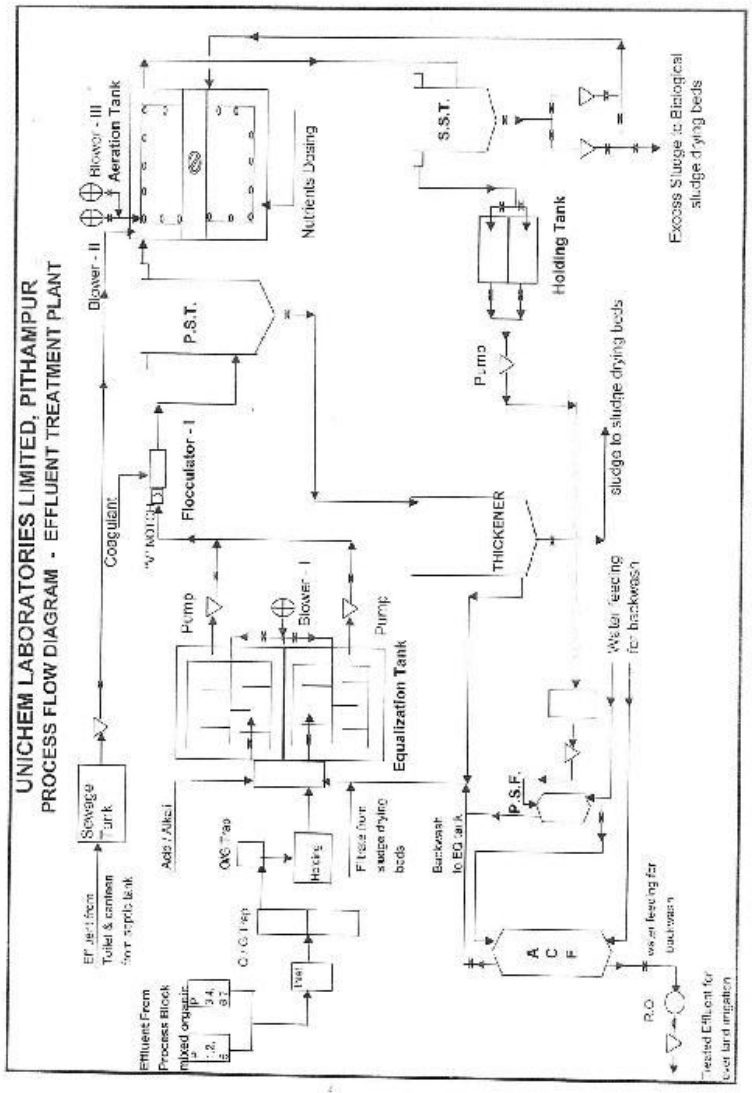
(Date of sampling-27.12.12)

Treatment Technology				
Primary Treatment (Equalization tank, Primary clarification), Secondary Treatment (Aerobic treatment, Secondary Clarification), Tertiary Treatment (Sand Filter, Carbon Filter, R.O.)				
Parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	4.2	351	12544	3660**
outlet	6.3	242	313	38
% removal of load		31.05	97.50	98.96

*All values are in mg/l except pH, **out let: Primary clarifier.

Annexure-8

M/s Unichem Laboratories Ltd, Pithampur, M.P



M/s Unichem Laboratories Ltd, Pithampur, M.P.

M/s Unichem Laboratories Ltd, Pithampur, M.P.

(8.8) M/s LUPIN Limited, Pithampur, MP

- M/s Lupin Limited is located in SEZ Pithampur, Dist-Dhar in Madhya Pradesh. The industry involved is manufacturing of active pharmaceutical ingredient (API). The industry has obtained Water consents under the Water (Prevention & Control of Pollution) Act, 1974 and which are valid up to 30.06.2015 for oral contraceptives, 31.01.2014for OSD & Ophthalmic and 30.06.2013 for API plant.

Performance evaluation of ETP:-

- Separate effluent treatment plants (ETP-1 and ETP-2) for formulation plants (Low pollution load) and ETP-3 for API manufacturing plat (High pollution load). The capacity of Effluent Treatment Plant -3 is 150m^3/Day. ETP-3 is designed for high pollution load wastewater. The treated waste water is further processed through Reverse Osmosis (RO), Multi Effect Evaporator (MEE) followed by Agitated Thin Film Dryer (ATFD). The waste water is treated and recycled completely in this treatment and called as Zero Liquid Discharge Plant (ZLD) which consist the operational systems as below.ETP layout digram of ETP is enclosed at **Annexure-9.**

- Effluent Treatment Plant: Consists of the Primary treatment (Neutralization, flash mixer, Clari-flocculation), Secondary treatment consisting Activated Sludge process (ASP) extended aeration system (aerobic biological oxidation), Tube settler, Tertiary treatment consisting Reverse Osmosis (R.O.), Multi Effect Evaporator (MEE) Agitated Thin Film Dryer (ATFD).

- Reverse Osmosis (R.O.): Treated Effluent from ETP is further treated in Reverse Osmosis Plant. Permeate (Pure Water) generated is used for makeup of the Cooling Towers and the Reject is further treated in MEE.

- Multi Effect Evaporator (MEE): The RO Reject (Concentrated Effluent) is further evaporated in the MEE plant by using Steam as heating medium. The

condensate is used for makeup of the Boiler and Concentrated Effluent is further treated in ATFD.

- Agitated Thin Film Dryer (ATFD): The concentrate from MEE is completely evaporated to dryness and the Powder is collected in bags and sent for the final disposal at TSDF.

- The entire treated Effluent is recycled and reused inside the premises as make up water in Cooling Tower and Boiler.

- The composite sample was collected from ETP-3 on dated 27/12/2012. The values of ETP inlet sample contains pH-7.2, TSS-20 mg/l, COD- 5488 mg/l, BOD-1208 mg/l and ETP outlet sample contains pH-7.6, TSS-18 mg/l, COD-1513 mg/l, BOD-64 mg/l. It may be seen that % removal of TSS load 10 %, COD load 72.43 %, BOD load 94.70 %. analysis report is attached at **Table 08**:**A.** The pH and TSS monitored values are well within prescribed limit and COD and BOD values out of limit but after R.O., the COD (35 mg/l) and BOD (BDL) monitored values are well within prescribed limit.

Hazardous waste management:-

- M/s Lupin Limited, Pithampur, obtained authorization under HW (Management, Handling and Tran's boundary Movement) Rules, 2008 and valid up to 01.07.2017. The industry has obtained the membership of the TSDF, Pithampur and the member ship no. MPWMP-HzW-PTM-263 dated 30.11.2011 which is valid up to 01.01.2015.

- The hazardous waste generation, handling and disposal record were maintained and displayed the information related to generation, handling, and disposal of hazardous waste on display board at main gate. The disposal of hazardous wastes generated by the industry in different categories is send to the TSDF at Pithampur, Dist. Dhar.

- Sludge generated from the ETP collected in sludge holding tank. The cake from sludge dewatering equipment (Decanter) has been disposed off to TSDF site.

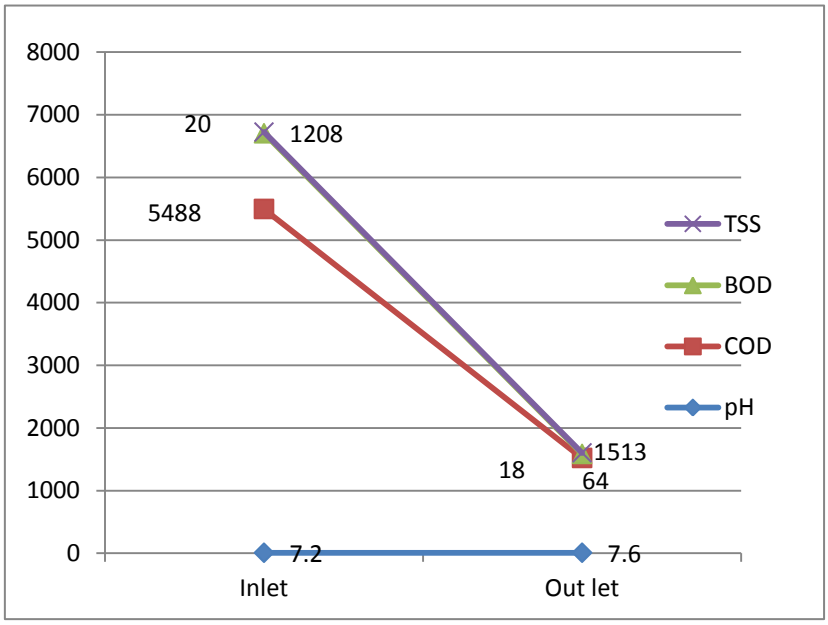
- The powder is collected from MEE store in closed bags and sends to TSDF for disposal. The transportation of hazardous waste from the industry is being done to TSDF and necessary requirements regarding safety information and labeling are followed.

- Used oil sale to authorized re- processer registered with CPCB/SPCB. Spent carbons /date expired discarded and of specification drugs/medicine send to M.P. Waste Management Project, TSDF, Pithampur for final disposal.

- During the Drug manufacturing process, discarded container/barrels decontaminated and reused/returned to the supplier/sale to authorized re-processors.

- Hazardous waste generation and mode of disposal is enclosed at Table **08: B.**

(Plate No.09): ETP-3 of M/s LUPIN Ltd, Pithampur, MP.



(Table 08:B) Hazardous Waste generation details of M/s Lupin Limited, Pithampur, M.P.

Source	Name	category	Mode of disposal
DG Set	used oil	5.1	sale to authorized re processors
Drug manufacturing process	Spent solvent	20.2	TSDF
Drug manufacturing process	Distillation residues	20.3	TSDF
Drug manufacturing process	Process waste residue	28.1	TSDF
Drug manufacturing process	Spent carbon	28.2	TSDF
Drug manufacturing process	Spent catalyst	28.2	TSDF
Drug manufacturing process	Date expired/ discarded/ off specification drugs/medicines	28.4 & 28.3	TSDF
Drug manufacturing process	Discarded container /barrels, liners used for hazardous waste/regular chemicals	33.3	To be decontaminated & reused/returned to supplier/sale to authorized re-processors
Drug manufacturing process	Chemicals containing residue	33.1	TSDF
Drug manufacturing process	Spent resin	34.2	TSDF
Effluent treatment plant	ETP sludge	34.3	TSDF
Drug manufacturing process	Filter media & molecular sieves	35.1	TSDF
MEE	Salt from MEE	36.2	TSDF

(Table 08:A) Analysis report of ETP-3, M/s Lupin Ltd, Pithampur, MP.

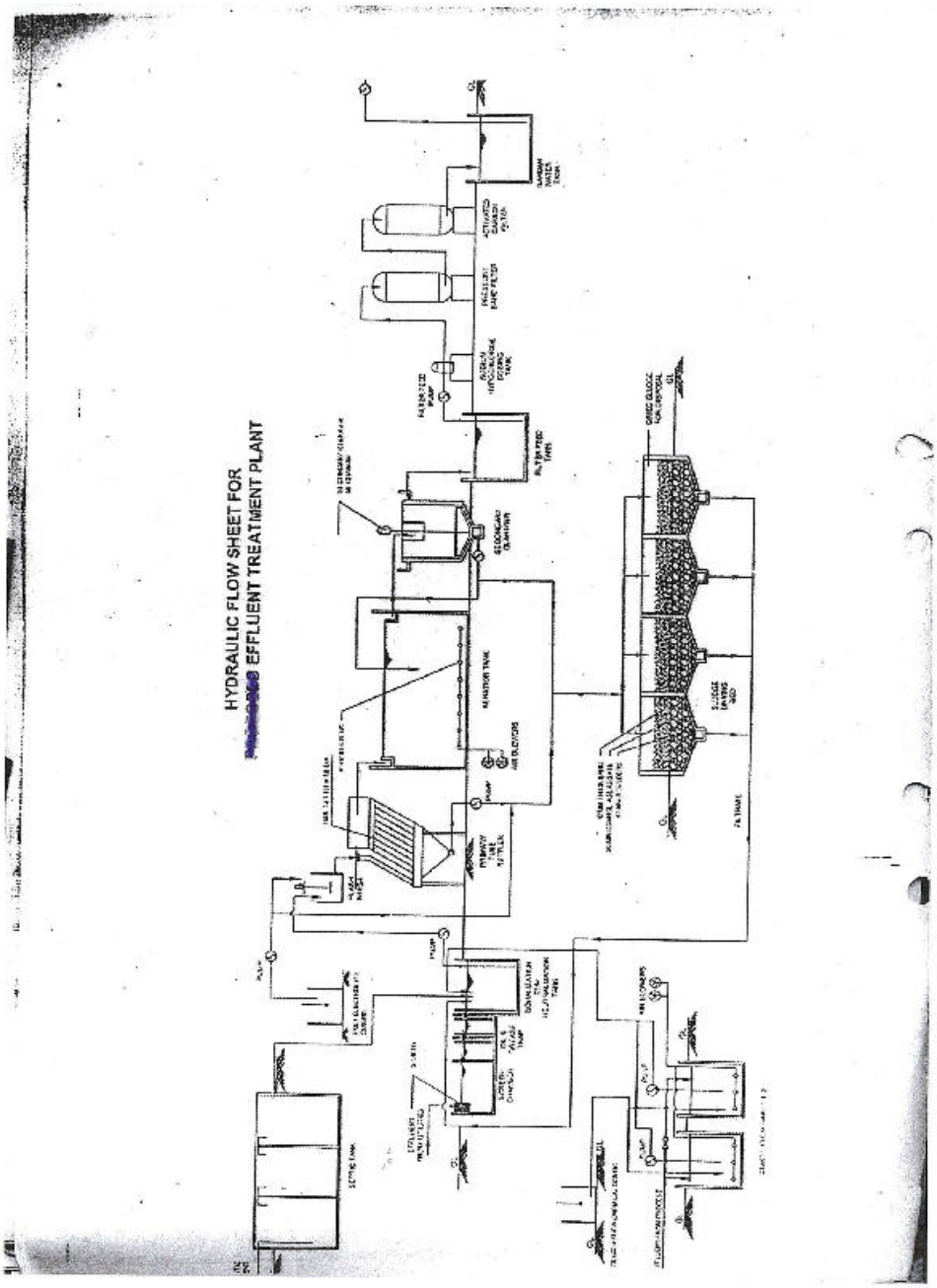
(Date of sampling-27.12.20120)

Treatment Technology				
ETP-03-Primary Treatment (Neutralization, flash mixer, Clari-flocculation), Secondary Treatment (anaerobic biological oxidation, Tube settler), Tertiary Treatment (Pressure Sand filters, R.O., Multi Effective Evaporator.				
Parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	7.2	20	5488	1208**
outlet	7.6	18	1513	64
% removal of load		10	72.43	94.70

Note: All values are in mg/l except pH, **O/L clari-floculation

Annexure-9

M/s Lupin Limited, Pithampur, M.P



M/s Lupin Limited, Pithampur, M.P.

(8.9) M/s Teva API India Limited, Malanpur, Gwalior, MP

- M/s Teva API India Limited was established in 2009 at Malanpur, Gwalior, M.P. and involved in manufacturing of API Drugs, Hypertension, Anti-coagulants, Pharmaceutical ingredients. As per the consent the production capacity is 155 MT/Year.

- M/s Teva API India Limited, Malanpur, Gwalior,M.P. has obtained Water consent under the Water (Prevention & Control of Pollution) Act, 1974 is valid up to 31/01/2013.For treatment of wastewater the industry has provided one Effluent Treatment Plant with the capacity of 250 m^3/day. layout digram of ETP are enclosed at **Annexure-10**

Performance evaluation of ETP:-

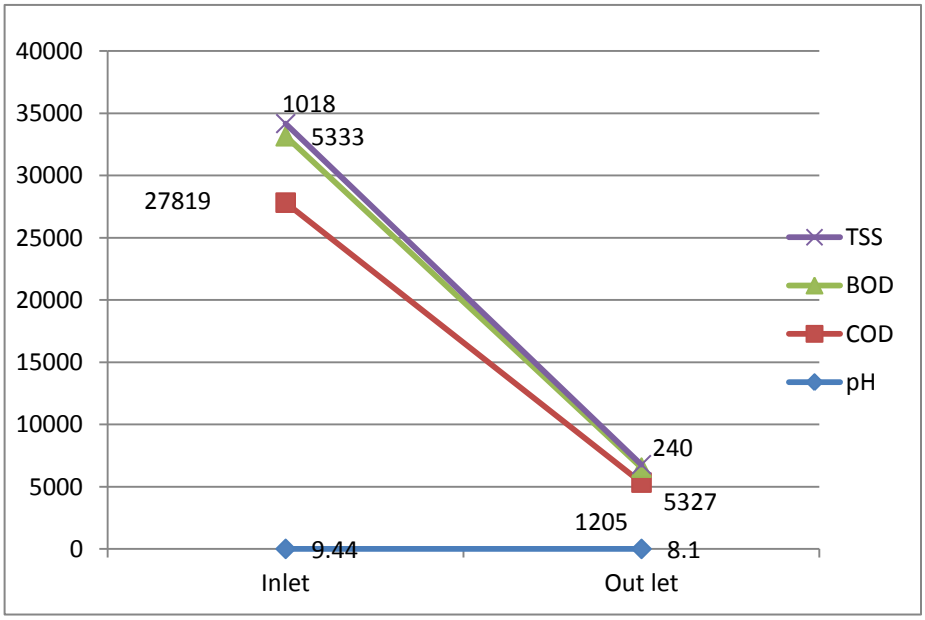
- Effluent treatment plants consist of the Primary treatment (Flash Mixer, Clari-flocculator), Secondary treatment (UASBR, Aerobic Reactor, Clarifier), Tertiary treatment (DMF, R.O, MEE). R.O. permeate and MEE condensate used for irrigation and cooling tower make-up water.

- The composite sample was collected from ETP on dated 28/01/2013. The value of ETP inlet sample contains pH-9.44, TSS-1018 mg/l, COD-27819 mg/l, BOD-533 mg/l and ETP outlet sample contains pH-8.1, TSS-240 mg/l, COD- 5327 mg/l, BOD-1205 mg/l. It may be seen that % removal of TSS load 76.42 %, COD load 80.85 %, BOD load 77.40 %. The detailed analysis report is attached at **Table 09**: **A.**The pH monitored value is well within prescribed limit and TSS, COD and BOD out of limit but after R.O., the TSS-22 mg/l and COD-233 mg/l monitored values are well within prescribed limits and BOD-45 mg/l is out of limit.

Hazardous waste management:-

- M/s Teva API India Limited has obtained authorization under HW (M, H&TM) Rules 2008 is valid up to 09.02.2015. The industry has obtained the membership of the TSDF, Pithampur, Dist- Dhar.
- The hazardous waste generation, handling and disposal record were maintained and displayed the information related to generation, handling, and disposal of hazardous waste on the board at main gate. The disposal of hazardous wastes generated by the industry in different categories is executed as per the authorization to the TSDF at Pithampur, Dist. Dhar.
- Spent organic Solvent used by the industry in the manufacturing process are recovered in house solvent plant and reused in the process. Solvent distillation residue dried and stored in Hazardous waste and send to TSDF, Pithampur. Date expired/discarded/Off specification drugs/medicines, collected and stored in separate room and send to TSDF, Pithampur.
- Used oil is being sold to authorized re-processors/refiners. Discarded container/barrelsare also sending to authorized vender. Chemical sludge in the form of solid waste collected and packed in polythene bags & send to TSDF, Pithampur.Hazardous waste generation and mode of disposal is enclosed at **Table 09: B.**

(Plate No.10): M/s Teva API India Limited, Malanpur,Gwalior, MP.



(Table 09: B) M/s Teva API India Limited, Malanpur, Gwalior, M.P.

Hazardous Waste generated			
Source	**Name**	**Category**	**Mode of disposal**
DG Set	Used oil	5.1	sale to authorized re processors/refiners
Drug manufacturing process	Process residue waste	28.1	TSDF
Drug manufacturing process	Spent catalyst & carbon	28.2	Sale to authorized vender
Drug manufacturing process	Date expired/ discarded/ off specification drugs/medicines	28.4	TSDF
Drug manufacturing process	Spent organic solvent	28.5	Recover in house solvent plant
Drug manufacturing process	Chemicals containing residue	33.1	TSDF
Drug manufacturing process	Discarded barrels /container	33.3	Sale to authorized vender
Drug manufacturing process	Spent ion exchange resin containing toxic metals	34.2	TSDF
Effluent treatment plant	Chemical sludge from ETP	34.3	TSDF
Effluent treatment plant	oil & grease skimming residues from ETP	34.4	Incinerated in TSDF
Drug manufacturing process	Filters & Filter material which have organic liquids in them	35.1	TSDF
wet scrubber	Sludge from wet scrubber	36.1	Treated in ETP
Drug manufacturing process	Distillation residue from contaminated organic solvent	36.4	TSDF

(Table 9: A) Analysis report of M/s Teva API India Limited, Malanpur, Gwalior,MP.

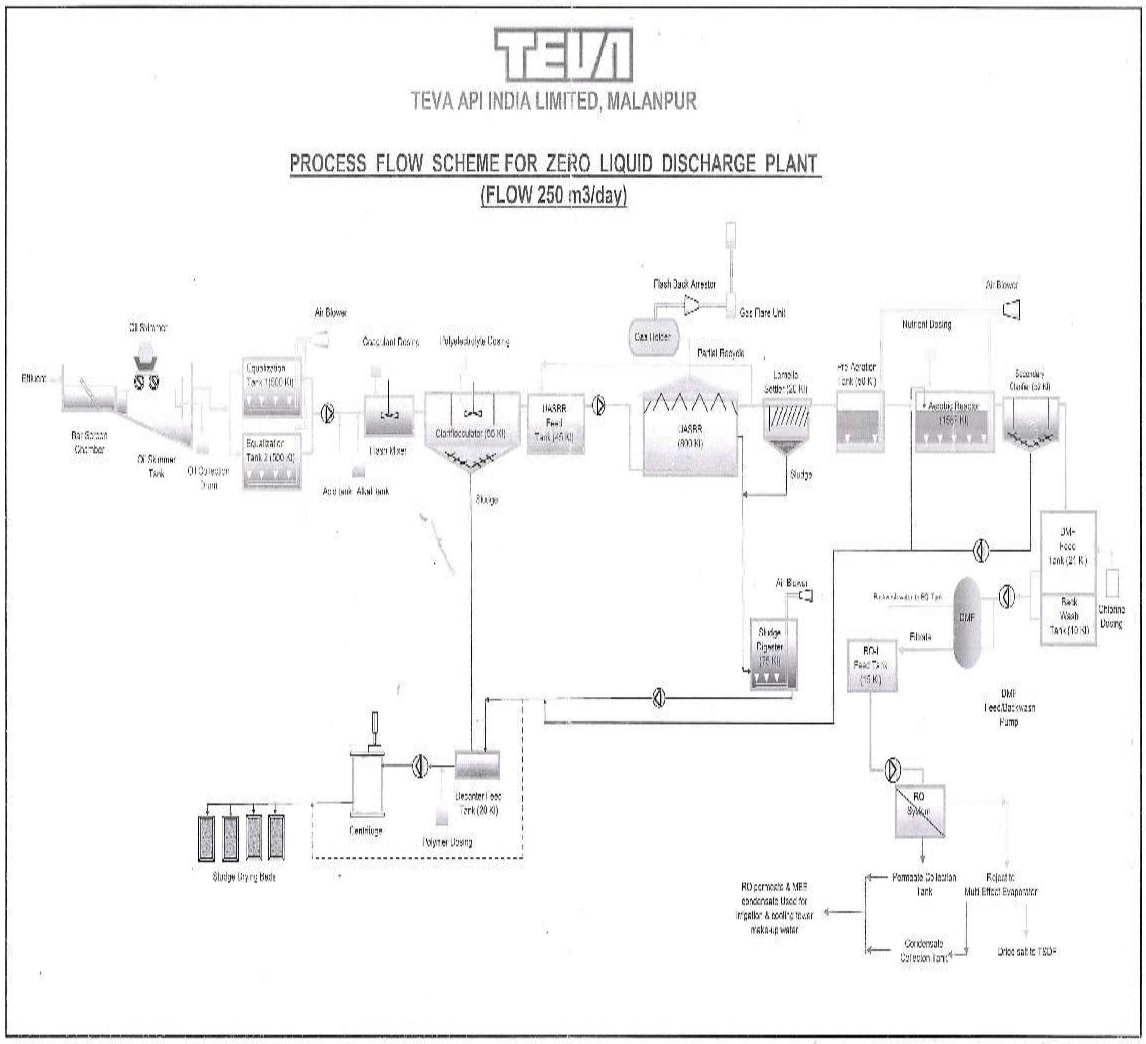
(Date of sampling-28.01.2013)

Treatment Technology				
Primary Treatment (Flash Mixer, Clari-flocculator),Secondary Treatment(UASBR, Aeration , Clarifier) and Tertiary Treatment (DMF,RO,MEE)				
Parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	9.44	1018	27819	5333
outlet	8.1	240	5327	1205
% removal of load		76.42	80.85	77.40

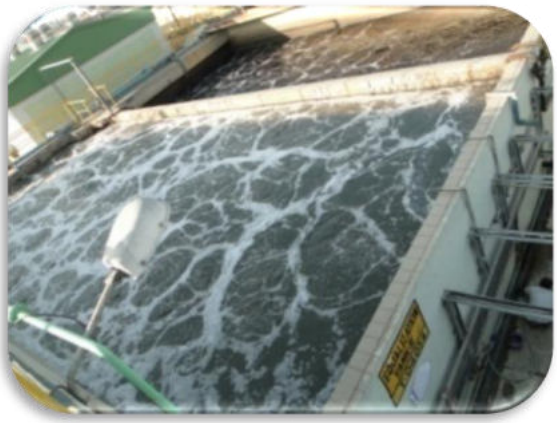
Note: All values are in mg/l except pH

Annexure-10

M/s Teva API India Limited, Malanpur, Gwalior, M.P.



M/s Teva API India Limited, Malanpur, Gwalior, M.P.



(8.10) M/s Ranbaxy Laboratories Limited, Malanpur, MP

M/s Ranbaxy Laboratories Limited was established at Malanpur industrial area, M.P. as a Bulk drug unit& formulation plant. Unit has obtained Water consent under the Water (Prevention & Control of Pollution) Act, 1974is valid up to 31/08/2013.As per the consent the production of Alpha ketoester, Bi-cycloketone, Imipenems, Other, carbapenems & Enolphosphate. As per the consent the production capacity is 102 TPA.

Performance evaluation of ETP:-

- For treatment of wastewater the industry has provided one Effluent Treatment Plant with the capacity of 100KLD and the layout digram of ETP is enclosed at **Annexure-11.**

- The collection of high COD (In-Organic) and low COD (Organic) stream drainage system from process area to ETP throw HDPE pipe line is properly separate in two different streams. Primary Treatment (Neutralization tank, Flashmixer, Tube settler), Secondary Treatment (Aeration tank) and Tertiary Treatment (ACF/MGF, MEE, ATFD) Technology used for waste water treatment. Inorganic stream are separately neutralized and send to MEE/ATFD and solid salt generated from this process has been sent to TSDF. Treaded water used for utility makeup. It was informed that RO will be has installed in future and the treated water has been used for gardening purpose in the plant.

- The composite sample was collected from ETP on dated 28/01/2013. The value of ETP inlet was found as pH-1.7, TSS-919 mg/l, COD- 114307 mg/l and BOD-35100 mg/l. The values of ETP outlet found as pH-7.74, TSS-151 mg/l, COD- 229 mg/l, BOD-51 mg/l. It may be seen that % removal of TSS load is 83.56 %, COD load -99.79 %, BOD load- 99.85 %.The pH and COD monitored values are well within prescribed limit and TSS, BOD out of limit. Analysis report is attached at **Table 10**:**A**

Hazardous waste management:-

- M/s Ranbaxy Laboratories Limited obtained authorization under HW (M,H&TM)Rules-2008 is valid up to 09.12.2014. The industry has obtained TSDF Pithampur membership for disposal of HW as per Authorization.

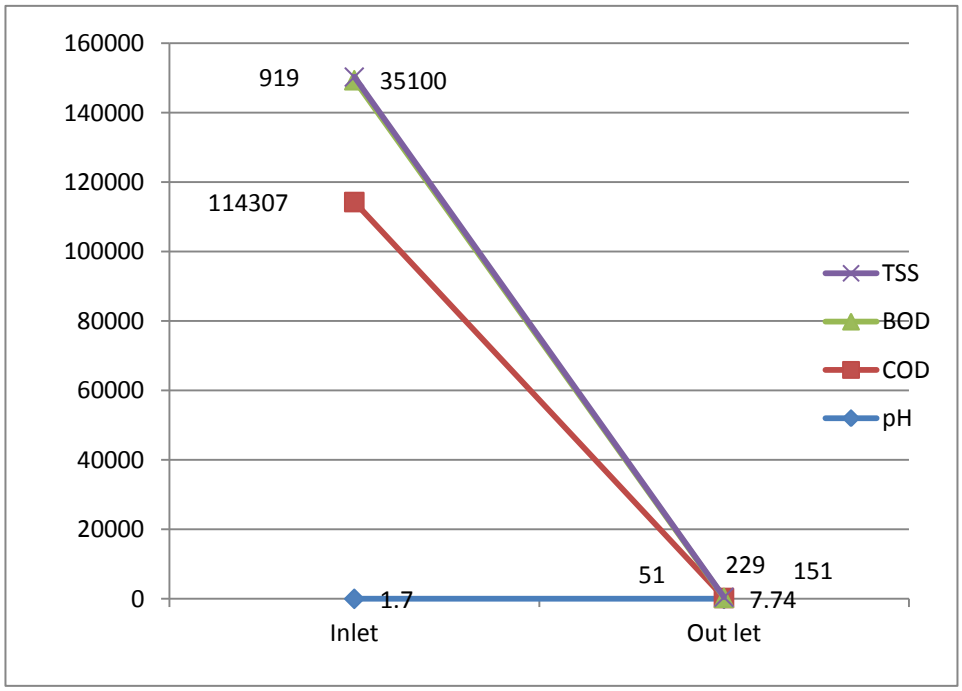
- The hazardous wastes of different categories are disposed as per the Hazardous Waste authorization; discarded barrel/containers are decontaminated and sent to TSDF, Pithampur. The used oil is sent to authorize and registered recyclers/Re-processors. Manifesto has been maintained for the hazardous waste transportation.

- The hazardous wastes of different categories are disposed as per the Hazardous Waste authorization; discarded barrel/containers are decontaminated and sent to TSDF, Pithampur. The distillation residue and process residue waste are sent to TSDF, M.P. Waste management project, Pithampur, Dist. Dhar.

- The hazardous waste generation, handling and disposal record were maintained and displayed the information related to generation, handling, and disposal of hazardous waste on the 6'x4' board at main gate.

- This mixed sludge after drying collect in the bags and stored in the hazardous waste room.Hazardous waste generation andMode of disposal enclosed at **Table 10: B.**

(Plate No.11): <u>M/s Ranbaxy Laboratories Limited, Malanpur, M.P</u>.



(Table 10:A) Analysis report of M/s Ranbaxy Laboratories Ltd, Malanpur, MP.

(Date of sampling-28/01/2013)

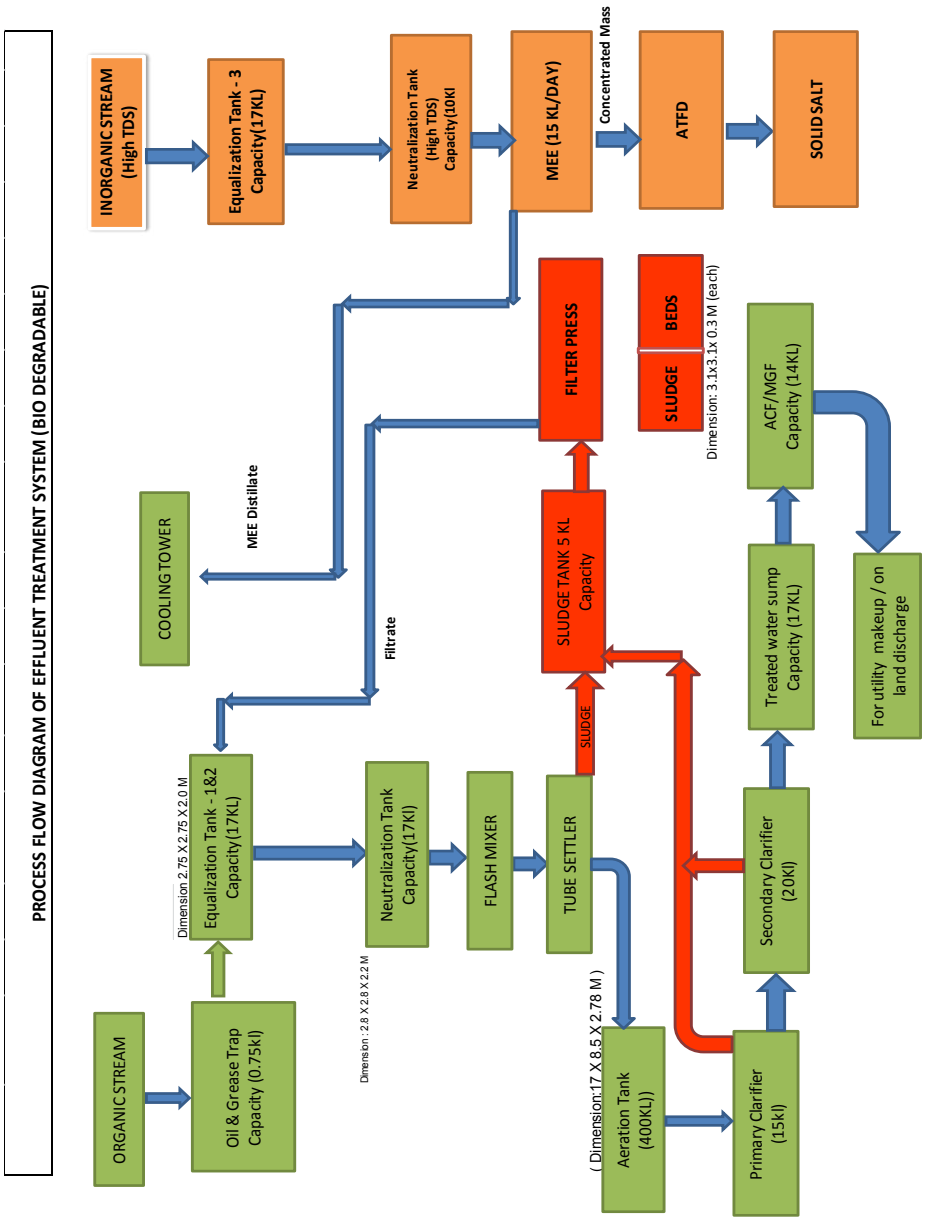
Treatment Technology				
Primary Treatment(Neutralization tank, Flash mixer, Tube settler), Secondary Treatment(Aeration and settling tank), Tertiary Treatment(ACF/MGF,MEE,ATFD				
Parameter	pH	TSS	COD	BOD
Inlet	1.7	919	114307	35100
outlet	7.74	151	229	51
% removal of load		83.56	99.79	99.85

*All values are in mg/l except pH

(Table 10:B) M/s Ranbaxy Laboratories Limited, Malanpur, M.P.

HazardousWaste generated			
Source	**Name**	**category**	**Mode of disposal**
DG Set	Used oil	5.1	sale to authorized & registered recycler/ re processors
Drug manufacturing process	Distillation residues waste	20.3	TSDF, Pithampur
Drug manufacturing process	Process residue waste	28.1	TSDF, Pithampur
Drug manufacturing process	Discarded barrels /container	33.3	TSDF , Pithampur
Effluent treatment plant	Chemical sludge from ETP	34.3	TSDF, Pithampur

M/s Ranbaxy Laboratories Limited, Malanpur, M.P.



M/s Ranbaxy Laboratories Limited, Malanpur, M.P.

(8.11) M/s Sunil Healthcare Ltd, Alwar, Rajasthan

- M/s Sunil Healthcare Ltd is located in Alwar, Rajasthan and engaged in production of empty gelatin capsules. As per the consent the production capacity is 18 million capsules/ day.

- Unit has obtained Water consent under the Water (Prevention & Control of Pollution) Act, 1974 is valid up to 31/10/2016. As per the consent the production of Empty hard gelatin capsule shell, I.P.

Performance evaluation of ETP:-

- For treatment of wastewater the industry has provided one Effluent Treatment Plant with the capacity of 25 KLD, layout digram of ETP is enclosed at **Annexure-12.**

- Primary Treatment (Bar screen chamber, Oil& Grease trap, Equalization tank), Secondary Treatment (fluidized aerobic bio reactors, Flocculator cum tube settler) and Tertiary Treatment (Color removal unit, Dual media filter) Technology used for waste water treatment. The effluent passed through a bar screen chamber and oil & grease trap. The effluent collected in an equalization tank. The equalized effluent was pumped to Fluidized aerobic bio reactors (FAB) where COD&BOD reduction by virtue by aerobic microbial activities. The oxygen required will be supplied through air bubble diffusers. The excess bio solids formed in the biological are separated in the downstream Flocculator cum tube settler tank. The clear supernatant will pass through chlorination tank for disinfection followed by color removal unit and dual media filter. The biological sludge generated from the FAB, which is settled in the tube settler, will be drained to the sludge drying beds and filtrate sent back to the equalization tank. Treaded water used for utility makeup/land discharge.

- The effluent generated was segregated in three streams. Domestic sewage was being sent to septic tanks, process effluent was being

treated in a compact ETP and the wastewater from utilities was being collected separately for neutralization.

- The process effluent was being utilized for in house gardening after treatment. While the utility effluent was directly discharged to the drain outside the factory premises.

- The collection pits for the process effluent & utility effluent were located next to each other. Thick layers of scum were floating in both the pits indicating intermixing of effluent from two different streams. Even the color of the effluents was same.

- On the day of visit, it was observed that only negligible quantity of sludge was seen in the two sludge-drying beds. The less generation of sludge may be due to irregular operation of ETP and pre-settlement of solids in collection pit.

- The solid wastes generated including process rejects were stored separately in specified area. The crushed capsules cutting scrap were sold to other industries, being used as raw materials.

- The house keeping in process area and plant premises was good.

- The composite sample was collected from ETP on dated 30/01/2013. The value of ETP inlet sample contains pH-7.27, TSS-231 mg/l, COD-4374 mg/l, BOD-964 mg/l and ETP outlet sample contains pH-7.08, TSS-59 mg/l, COD- 638 mg/l, BOD-98 mg/l. It may be seen that % removal of TSS load 74.45 %, COD load 85.41 %, BOD load 89.83 %. The pH, TSS monitored values are well within prescribed limit and COD, BOD out of limit. analysis report is attached at **Table 11**:**A.**

Hazardous Waste Management:-

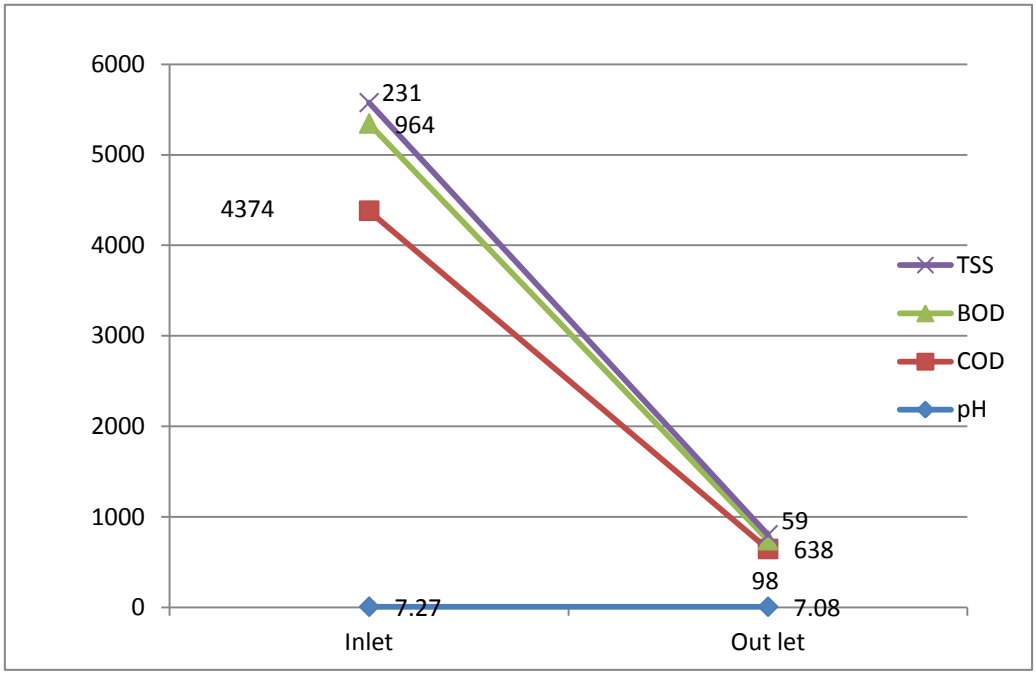
- M/s Sunil Healthcare Ltd. authorization application submitted for renewable under HW (M, H&TM) rules-2008 on dated 07/12/2009.The industry has obtained UCCI & TSDF, Udaipur membership.

- The unit constructed a room specified for storage of Hazardous waste .Sludge generated from the ETP plant send to TSDF. The used oil is sale to authorize and registered recyclers/Re-processors.

- The hazardous waste generation, handling and disposal record were not properly maintained and displayed the information related to generation, handling, and disposal of hazardous waste on the board at main gate.

- This mixed sludge after drying collect in the bags and stored in the hazardous waste room.Hazardous waste generation andMode of disposal enclosed at Table **11: B.**

(Plate No.12): <u>M/s Sunil Healthcare Ltd, Alwar, Rajasthan</u>



(Table 11:A) Analysis report of M/s Sunil Healthcare Ltd, Alwar, Rajasthan

(Date of sampling: 30.01.2013)

Treatment Technology				
Primary Treatment, Secondary Treatment (fluidized aerobic bio reactors, Flocculate cum tube settler), Tertiary Treatment (Color removal unit, Dual media filter.				
Parameter	pH	TSS	COD	BOD
Inlet	7.27	231	4374	964
outlet	7.08	59	638	98
% removal of load		74.45	85.41	89.83

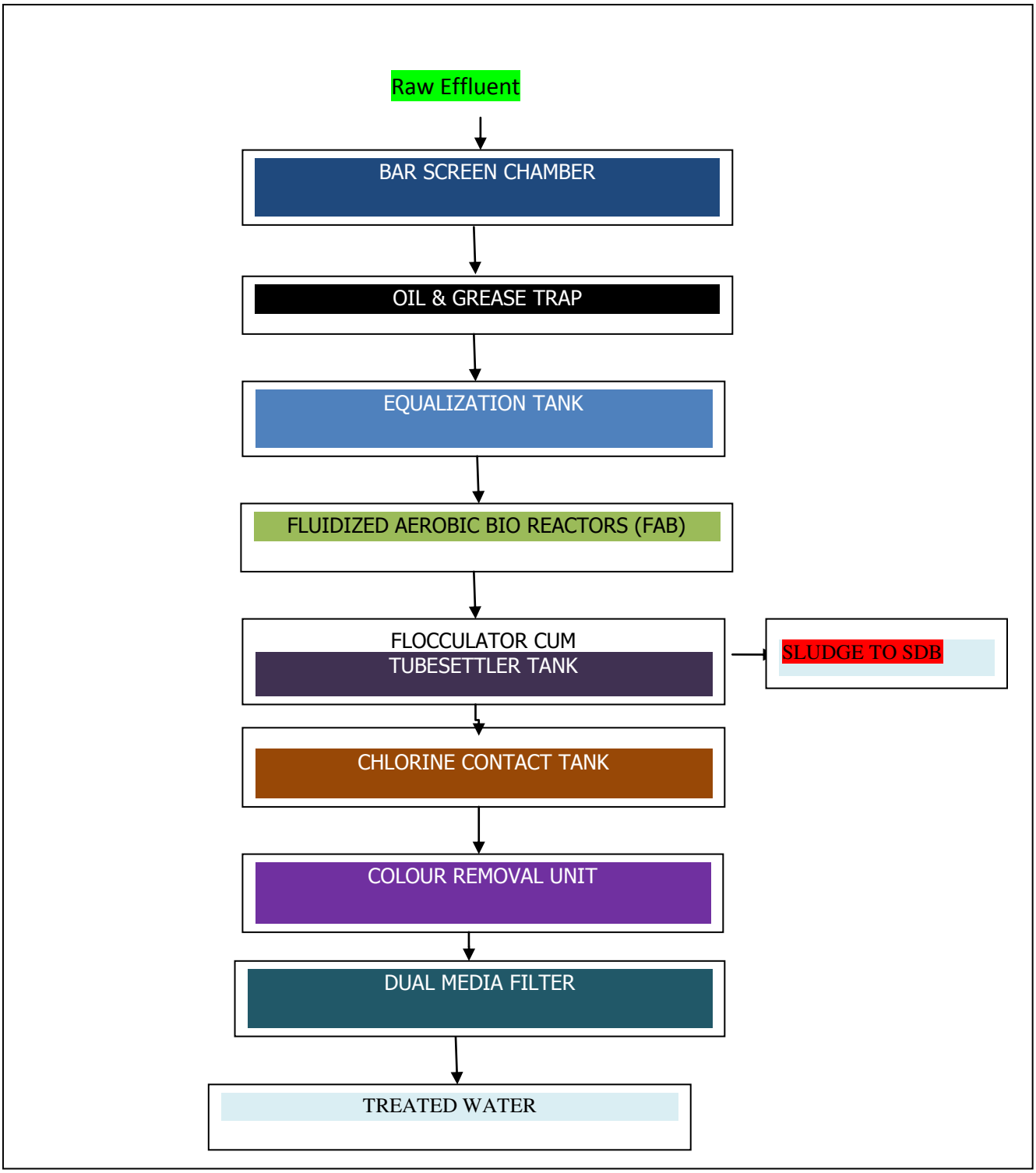
*All values are in mg/l except pH

(Table 11:B) M/s Sunil Healthcare Ltd, Alwar, Rajasthan

HazardousWaste generated			
Source	Name	category	Mode of disposal
ETP	ETP sludge	34.3	TSDF
DG Set	Used oil	5.1	sale to authorized & registered recycler/ re processors

Annexure-12

ETP Block Diagram of M/s Sunil Healthcare Ltd, Alwar, Rajasthan



M/s Sunil Healthcare Ltd, Alwar, Rajasthan

(8.12) M/s Rajasthan Antibiotics Ltd, Bhiwadi,Rajasthan

- M/s Rajasthan Antibiotics Ltd. set up pharmaceutical unit in Bhiwadi industrial area (Rajasthan), plot no-A-619&630, RIA, Bhiwadi, Tehsil: Tijara, District: Alwar. The company manufacturing drugs i.e. Pantaprazole sodium sterile, Omeprazole sodium sterile, Esomeprazole sodium sterile and Rabeprazole sodium sterile.

- Unit has obtained Water consent under the Water (Prevention & Control of Pollution) Act, 1974 is valid up to 30.06.2014.

- The unit has maintained good house-keeping in process areas of plant.

- The unit has not done adequate tree plantation in and around the unit.

Performance evaluation of ETP:-

- For treatment of wastewater the industry has provided Effluent Treatment plant with the capacity of50 KLD.The effluent treatment plant consisting of the primary treatment, secondary treatment (aerobic treatment, clarification) and tertiary treatment (dual media filter).the line digram of ETP is enclosed at **Annexure-13.**

- The unit has not provided separate channels for process water and floor washings.

- As informed by industrial representative, very less quantity of wastewater has been generated from the process. Wastewater generated from Chilling unit, Cooling tower and DM plant were re-circulated for cooling purpose. At the time of visit no discharge of effluent from the factory premises was observed.

- The composite sample was collected from ETP on dated 01/02/2013. The values of ETP inlet sample contains pH-6.6, TSS-52 mg/l, COD-3782 mg/l, BOD-992 mg/l and ETP outlet sample contains pH-6.9,

TSS-14 mg/l, COD- 43 mg/l, BOD-11 mg/l. It may be seen that % removal of TSS load 73.07 %, COD load 98.86 %, BOD load 98.89 %. The all monitored values are well within prescribed limit. analysis report is attached at **Table 12**: **A.**

Hazardous waste management:-

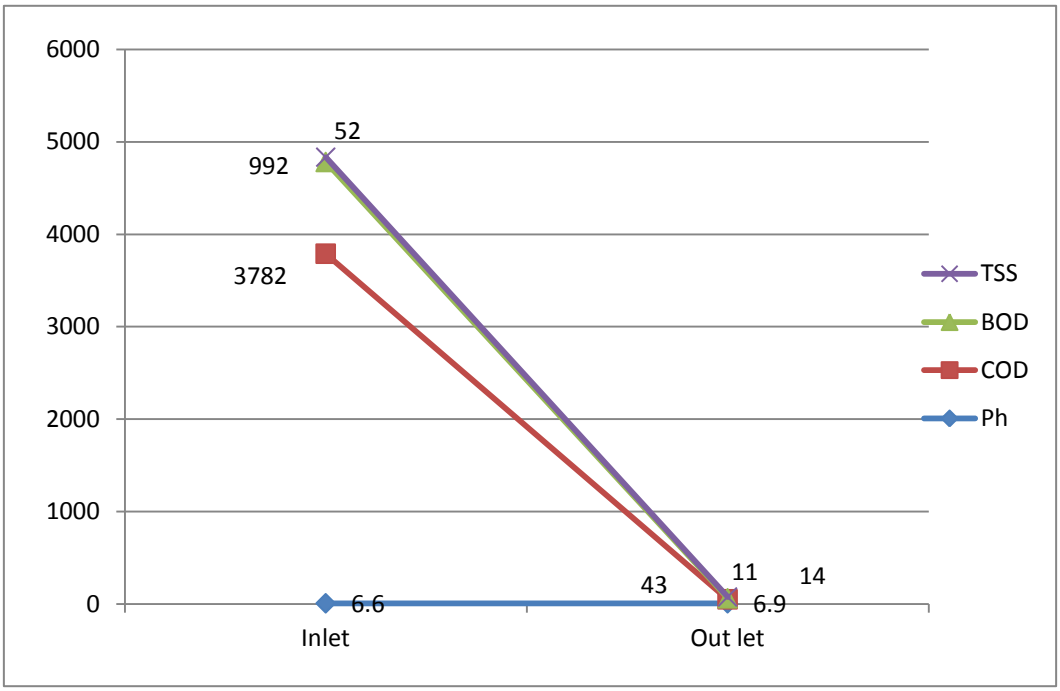
- M/s Rajasthan Antibiotics Ltd obtained authorization under HW (M, H&TM) Rules2008 is valid up to 30.09.2014. The industry has obtained the membership of the TSDF, Udaipur.

- The hazardous waste generation, handling and disposal record were maintained and displayed the information related to generation, handling, and disposal of hazardous waste on the 6'x4' board at main gate and the details about hazardous waste quantities & categories are updated.

- This sludge is further dried before its final disposal in TSDF. The transportation of hazardous waste from the industry is being done to TSDF and necessary requirements regarding safety information and labeling are followed. The used oil has been sold to registered recyclers. Discarded containers are decontaminated and sent to TSDF, Udaipur. Process residues wastes send to TSDF Udaipur.The hazardous waste generation and mode of disposal enclosed at **Table 12:B.**

- Empty containers are stored on ground in open area in the premises. Covered sheds was provided for storing hazardous wastes of different categories before its final disposal to TSDF.

(Plate No. 13): M/s Rajasthan Antibiotics, Bhiwadi, Rajasthan



(Table 12:B) M/s Rajasthan Antibiotics, Bhiwadi, Rajasthan

HazardousWaste generated			
Source	**Name**	**category**	**Mode of disposal**
Drug manufacturing process	Process residues waste	28.1	TSDF
Drug manufacturing process	Discarded container s	33.3	TSDF
DG Set	Used/spent oil	5.1	Sale registered recycler

(Table 12 : A) Analysis report of M/s Rajasthan Antibiotics, Bhiwadi, Rajasthan

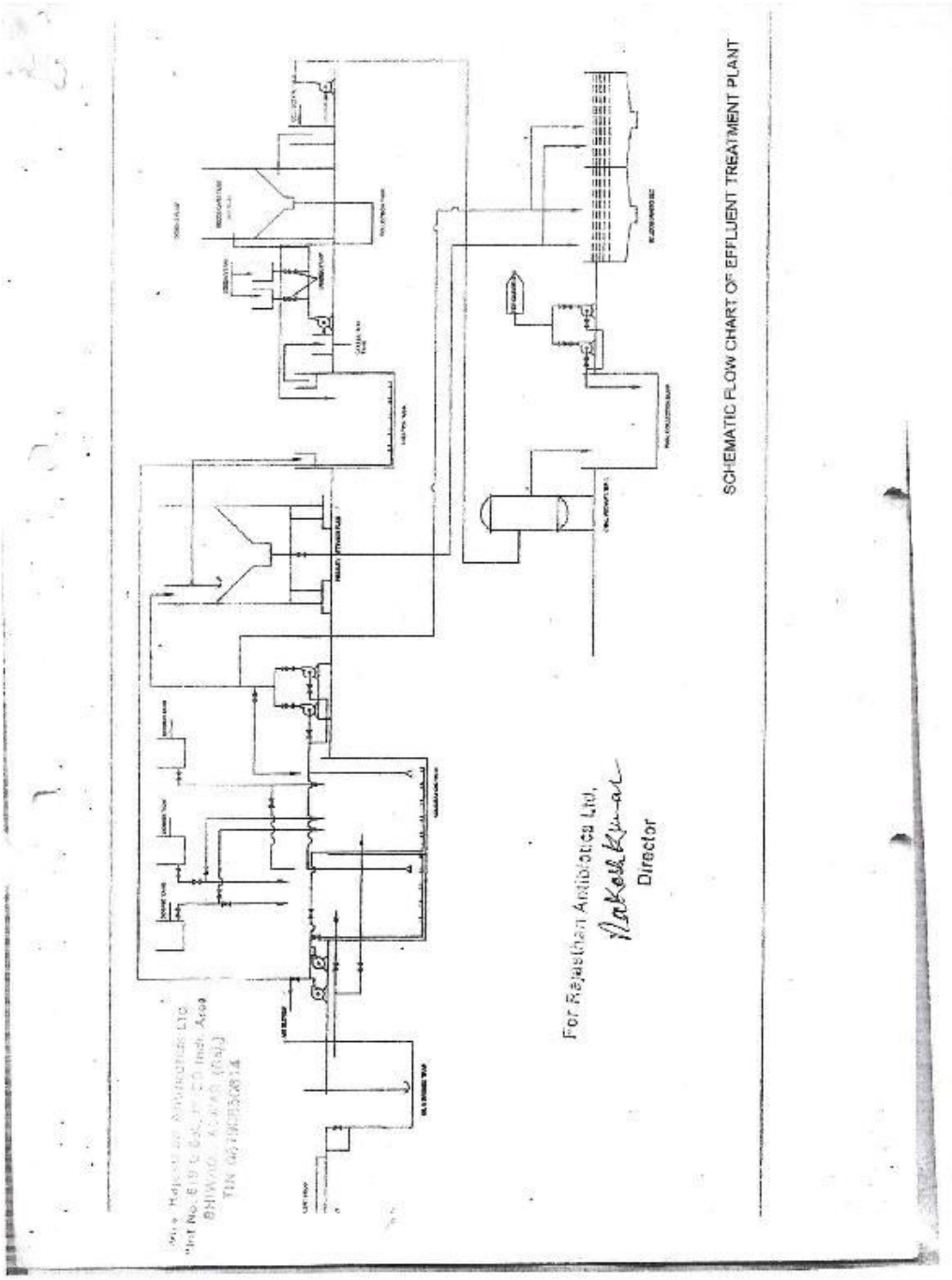
(Date of sampling-01/02/2013)

Treatment Technology				
Primary Treatment, Secondary Treatment(Aeration treatment, clarification), Tertiary Treatment(Dual media filter)				
Parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	6.6	52	3782	992
Outlet	6.9	14	43	11
% removal of load		73.07	98.86	98.89

*All values are in mg/l except pH

Annexure-13

M/s Rajasthan Antibiotics, Bhiwadi, Rajasthan



M/s Rajasthan Antibiotics, Bhiwadi, Rajasthan

(8.13) M/s Asiatic Drugs & Pharmaceuticals Pvt Ltd , Bhiwadi, Rajasthan

- M/s Asiatic Drugs Pharmaceuticals Pvt. Ltd was established in the year 1998 at RIICO Industrial area, Phase-II,Bhiwadi, Dist-Alwar, Rajasthan as a producing 6 API Intermediate, 7ADCA, Amoxycillin rihydrate, Ampicillin trihydrate, Cephalaxin monohydrate. Unit has obtained Water consent under the Water (Prevention & Control of Pollution) Act, 1974 is valid up to 31.12.2013.As per the consent the production capacity is 395.6 TPA.

Performance evaluation of ETP:-

- For treatment of wastewater the industry has provided one Effluent Treatment Plant with the capacity of 25 KLD, layout digram of ETP is enclosed at **Annexure-14.** Primary Treatment (Bar screen chamber, Equalization tank, Neutralization tank), Secondary Treatment (aerobic treatment) and Tertiary Treatment, Technology used for waste water treatment.

- The industry has provided ETP having clarifier / settler, aeration tank and sludge drying beds. The clarifier was being used as primary settler for 4-hrs and as secondary settler for next 4 hrs. It was observed that the chemical sludge generated in the primary clarifier was deposited in one of the sludge drying beds. There was no presence of biological sludge in SDBs.

- The liquid effluent generated in the process is collected in collection tank. The PH of the effluent is made neutral by adding alkali/acid. The neutral effluent is pumped to primary clarifier and then to the aeration tank. The effluent from aeration tank is taken to secondary clarification and then to sludge drying bed. The treated effluent is then used for irrigation purpose. High and Low COD not properly segregated and treated.

- The composite sample was collected from ETP on dated 02/02/2013. The value of ETP inlet sample contains pH-8.3, TSS-306 mg/l, COD-

9209 mg/l, BOD-1642 mg/l and ETP outlet sample contains pH-7.4, TSS-60 mg/l, COD- 864 mg/l, BOD-177 mg/l. It may be seen that % removal of TSS load 80.39 %, COD load 90.61 %, BOD load 89.22 %. The pH, TSS monitored values are well within prescribed limit and COD, BOD out of limit.analysis report is attached at **Table 13**:**A.**

Hazardous waste management:-

- M/s Asiatic Drugs Pharmaceuticals Pvt. Ltd. authorization application submitted for renewable under HW (M, H&TM) rules-2008 on dated 30/09/2014.The industry has obtained TSDF, Udaipur membership.

- The unit constructed a room specified for storage of Hazardous waste. Sludge generated from the ETP plant send to TSDF. The used oil is sale to authorize and registered recyclers/Re-processors.

- The hazardous waste generation, handling and disposal record were properly maintained and displayed the information related to generation, handling and disposal of hazardous waste on the board at main gate.

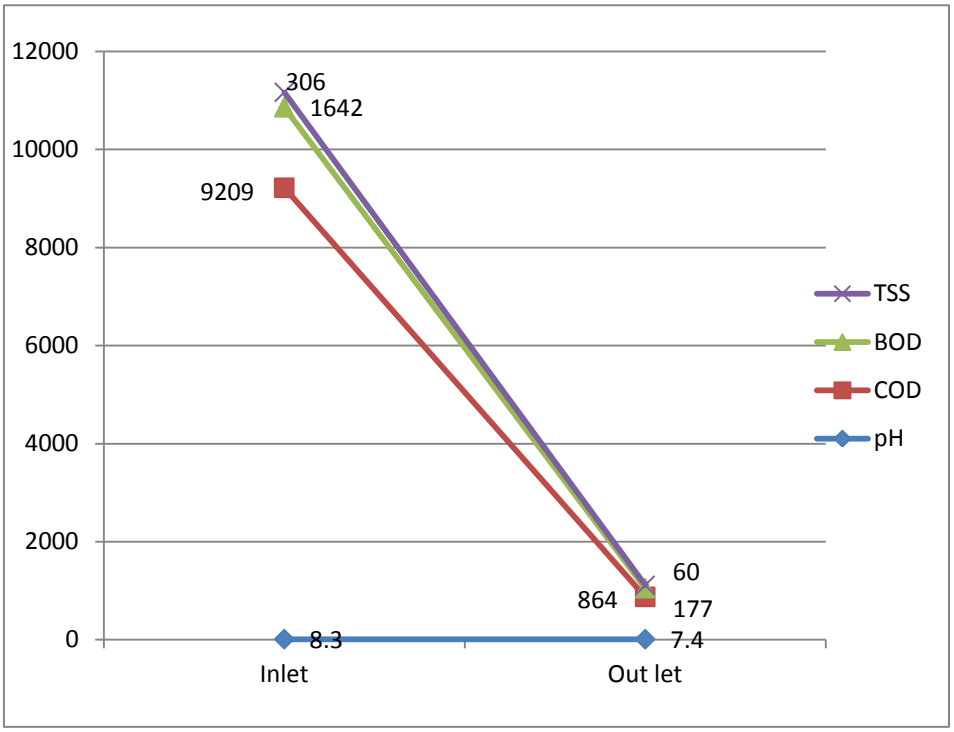
- The chemical containers and other empty containers were stored in open without any shelter.

- Chemical and biological sludge mixed to each other during the treatment process. This mixed sludge after drying collect in the bags and stored in the hazardous waste room.Hazardous waste generation and Mode of disposal enclosed at **Table 13:B.**

(Table 13: B) M/s Asiatic Drugs & Pharmaceuticals Pvt.Ltd., Bhiwadi, Rajasthan

HazardousWaste generated			
Source	**Name**	**category**	**Mode of disposal**
DG Set	Used/spent oil	5.1	TSDF
Effluent treatment plant	Chemical sludge from ETP	34.3	TSDF

(Plate No.14) M/s Asiatic Drugs &Pharmaceuticals Pvt. Ltd., Bhiwadi, Rajasthan



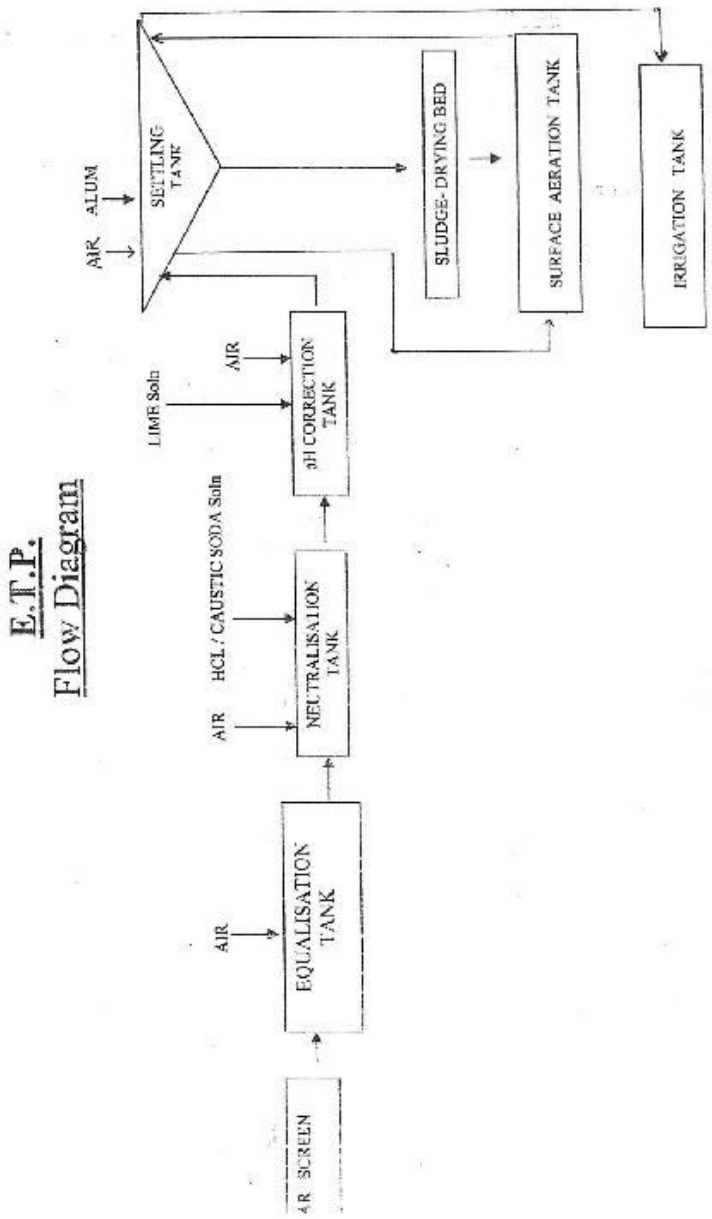
(Table 13:A) Analysis report of M/s Asiatic Drugs &Pharmaceuticals Pvt. Ltd., Bhiwadi, Rajasthan

(Date of sampling-02.02.2013)

Treatment Technology				
Primary Treatment(Bar screen chamber, Equalization tank, Neutralization tank), Secondary Treatment(aerobic treatment), Tertiary Treatment				
Parameter	pH	TSS	COD	BOD
Inlet	8.3	306	9209	1642
outlet	7.4	60	864	177
% removal of load		80.39	90.61	89.22

All values are in mg/l except pH

M/s Asiatic Drugs Pharmaceuticals Pvt. Ltd., Bhiwadi, Rajasthan




E.T.P.
Flow Diagram


HAZARDOUS WASTE
STORAGE TANK

(8.14) M/s Dalas Biotech Ltd, Bhiwadi, Rajasthan

M/s Dalas Biotech Ltd is a leading biotechnology and pharmaceutical health care company based in India. M/s Dalas Biotech Ltd. was established at RIICO Industrial area, Phase-I, Bhiwadi, Dist-Alwar, Rajasthan as a producingbulk drugs and drug intermediate, Amoxycillin, Ampiciline, Cefixime, Cephadroxil, Cephalexin, Cloxacillin, Pgaenenzyme, Simvastatin. Unit has obtained Water consent under the Water (Prevention & Control of Pollution) Act, 1974 is valid up to 19.01.2013. As per the consent the production capacity is 466.05 MT/A.

Performance evaluation of ETP:-

- For treatment of wastewater the industry has provided one Effluent Treatment Plant with the capacity of 15 KLD. layout digram of ETP are enclosed at **Annexure-15**.An effluent treatment plant consists of the Primary treatment (Equalization, Chemical treatment, Primary settling tank), Secondary treatment (Aerobic treatment, Secondary settling tank) and Tertiary Treatment (Send filter, ACF).

- Effluent Treatment is manly Primary Treatment, Secondary treatment and Tertiary Treatment. First stage of waste water treatment plant. Collected the waste water into the Equalization/Holding Tank and then collect the water with feed pump into the Flocculation Tank. In this tank use the dosing method of chemical for water treatment as like Poly, Alum and Lime. After dosing of chemical water bypass into the Primary settler tank. Water goes to Primary settler tank to Aeration tank. Aeration tank to secondary settler tank and secondary settler tank to buffer tank and Buffer tank to ACF tank for filtering and then goes to final outlet tank. Final outlet tank to gardening and washing of floor/Toilet.

- The composite sample was collected from ETP on dated 02.02.2013. The values of ETP inlet sample contains pH-4.4, TSS-302 mg/l, COD-4001 mg/l, BOD-1429 mg/l and ETP outlet sample contains pH-7.2, TSS-60 mg/l, COD- 1470 mg/l, BOD-371 mg/l. It may be seen that % removal of TSS load 80.13 %, COD load 63.25 %, BOD load 74.03 %.

The pH, TSS monitored values are well within prescribed limit and COD, BOD out of limited. analysis report is attached at **Table 14:A.**

Hazardous waste management:-

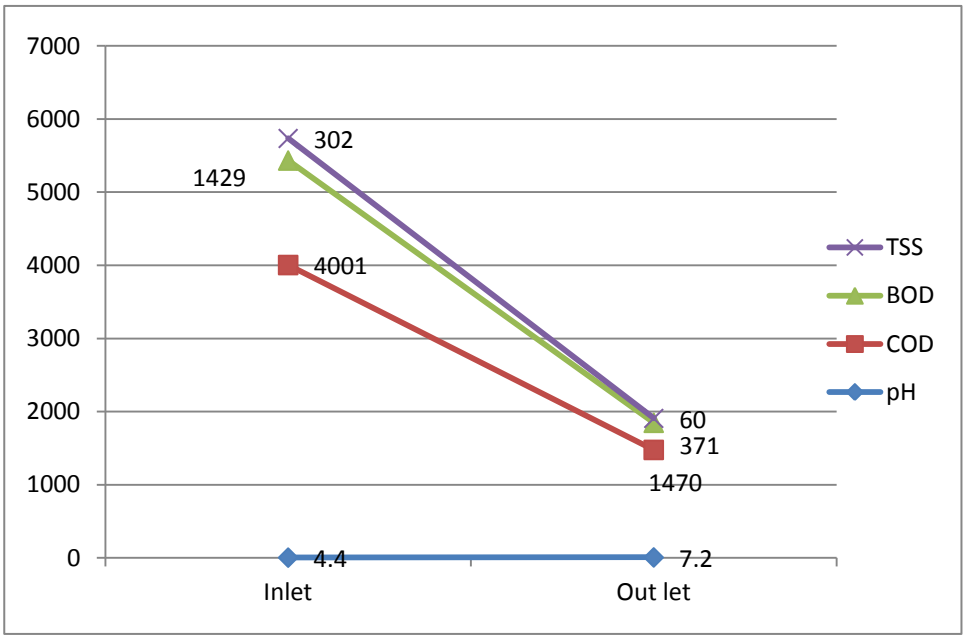
- M/s Dalas Biotech Ltd, Bhiwadi, Rajasthan obtained authorization under HW (M,H&TM) Rules2008 is valid up to 09.03.2007 and application apply for renewal of authorization under HW (M,H&TM) Rules2008 on dated 28.02.2012.The industry has obtained the membership of the TSDF,Udaipur,Rajasthan.

- The hazardous waste generation, handling and disposal record were not maintained properly and displayed the information related to generation, handling, and disposal of hazardous waste on the board at main gate not available. Storage of hazardous waste in the RCC room.

- This mixed sludge after drying collect in the bags and stored in the hazardous waste room for final disposal within 90 days. Sludge generated from the ETP plant send to TSDF. The waste oil is sale to authorize and registered recyclers/Re-processors. Residues& waste generated during the Drug manufacturing process send to TSDF, Udaipur.

- Hazardous waste generation andMode of disposal enclosed at **Table 14:B.** The industry has not taken some steps for reduction of the waste generated.

(Plate No.15): M/s Dalas Biotech Ltd, Bhiwadi, Rajasthan



(Table 14:B) M/s Dalas Biotech Ltd, Bhiwadi, Rajasthan

HazardousWaste generated			
Source	**Name**	**category**	**Mode of disposal**
Effluent treatment plant	Chemical sludge from ETP	34.3	TSDF
DG Set	Waste oil	5.1 & 5.2	Sale registered recycler
Drug manufacturing process	Residues & waste	28.1	TSDF

(Table 1 4:A) Analysis report of M/s Dalas Biotech Ltd, Bhiwadi, Rajasthan

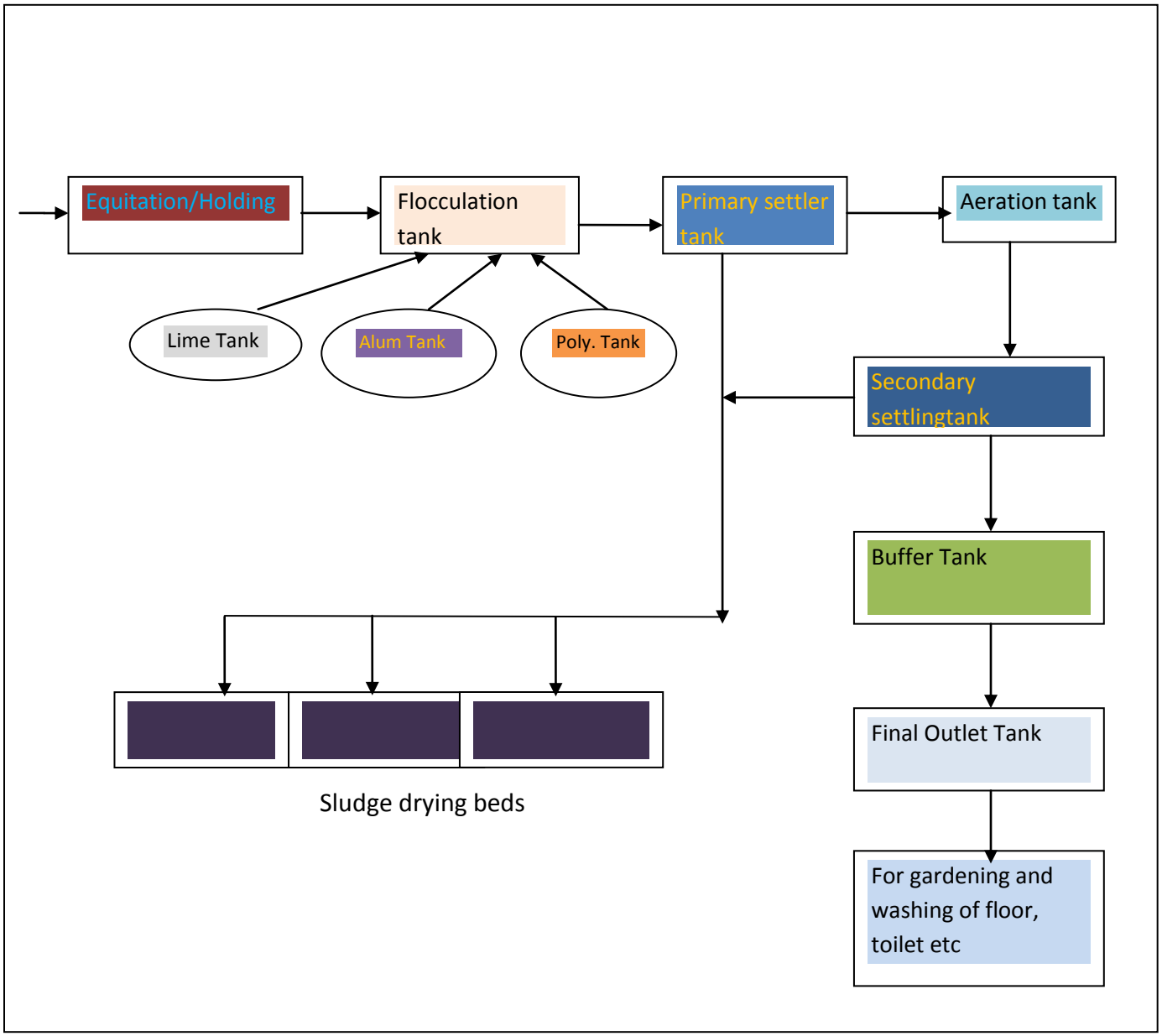
(Date of sampling-02.02.2013)

Treatment Technology				
Primary Treatment(Equalization, Chemical treatment, Primary settling tank), Secondary Treatment(Aerobic treatment, Secondary settling tank),Tertiary Treatment(Send filter, ACF)				
Parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	4.4	302	4001	1429
outlet	7.2	60	1470	371
% removal load		80.13	63.25	74.03

All values are in mg/l except pH

Annexure-15

ETP flow chart of M/s Dalas Biotech Ltd, Bhiwadi, Rajasthan



M/s Dalas Biotech Ltd, Bhiwadi, Rajasthan

(8.15) M/s IPCA Laboratories Ltd, Ratlam, MP

M/s IPCA Laboratories Ltd was established at Ratlam as a Bulk drugs unit and Formulations. For more than 60 years, Ipca has been partnering healthcare globally in over 110 countries and in markets as diverse as Africa, Asia, Australia, Europe and the US. Ipca is a fully-integrated Indian pharmaceutical company manufacturing over 350 formulations and 80 APIs for various therapeutic segments. Unit has obtained Water consent under the Water (Prevention & Control of Pollution) Act, 1974 which is valid up to 31.07.2017.As per the consent the production capacity is 2551.5 MT/Year.

The house keeping in the premises was good. Though the industry has planted trees in one side of plant area, there was scope to increase the plantation near boiler & incinerator area.

Performance evaluation of ETP:-

- For treatment of wastewater the industry has provided Effluent Treatment Plant with the capacity of 495 KLD, layout digram of ETP is enclosed at **Annexure-16.**

- The collection of high COD (In-Organic) and low COD (Organic) stream drainage system from process area to ETP has been separated in two different streams. High COD/TDS streams sending directly to the MEE for treatment.

- The low COD effluents treated in Primary Treatment consisting of equalization, neutralization, chemical treatment, primary clarifier and Secondary Treatment consisting of Bio-Reactor-I &II, Secondary clarifier and Tertiary Treatment (Multi Media Sand Filter, ACF, Two stages Reverse Osmosis) Technology used for wastewater treatment. The Reverse Osmosis ejects are treated along with high COD waste in Multi Effect Evaporator.

- The composite sample was collected from the ETP on 05.02.2013. The value of ETP inlet sample values fond as pH-7.2,TSS-1174 mg/l, COD- 11025 mg/l, BOD-2233 mg/l and ETP outlet sample vales fond

as pH-7.1, TSS-40 mg/l, COD-337.9 mg/l, BOD-24 mg/l. The % removal of TSS- 96.59 %, COD- 96.93 %, BOD- 98.92 %. The analysis report is attached at **Table 15**:**A.** The pH, TSS and BOD monitored values are well within prescribed limit and COD out of limit but after R.O., the COD(22.50 mg/l) value is also well within prescribed limit.

Hazardous waste management:-

- M/s IPCA Laboratories Ltd obtained authorization under HW (M,H&TM) Rules2008 is valid up to 02.03.2015. The industry has obtained TSDF Pithampur membership for final disposal of HW as per Authorization. Hazardous waste generation and mode of disposal enclosed at **Table 15: B.**

- The unit has Installed 4 TPD a solid-liquid waste incinerator. The hazardous waste incinerator consists of primary & secondary combustion chamber, drum pyrolizers with spray dryer absorber. It is PLC operated and has got all APCD, namely Cyclone separators(04 no), venture& packed-bed scrubbers with a stack height of 40m.The incinerator ash has been sending to the Common Hazardous Waste Disposal Site at Pithampur near Dhar Madhya Pradesh. Other wastes of different categories are disposed as per the Hazardous Waste authorization.

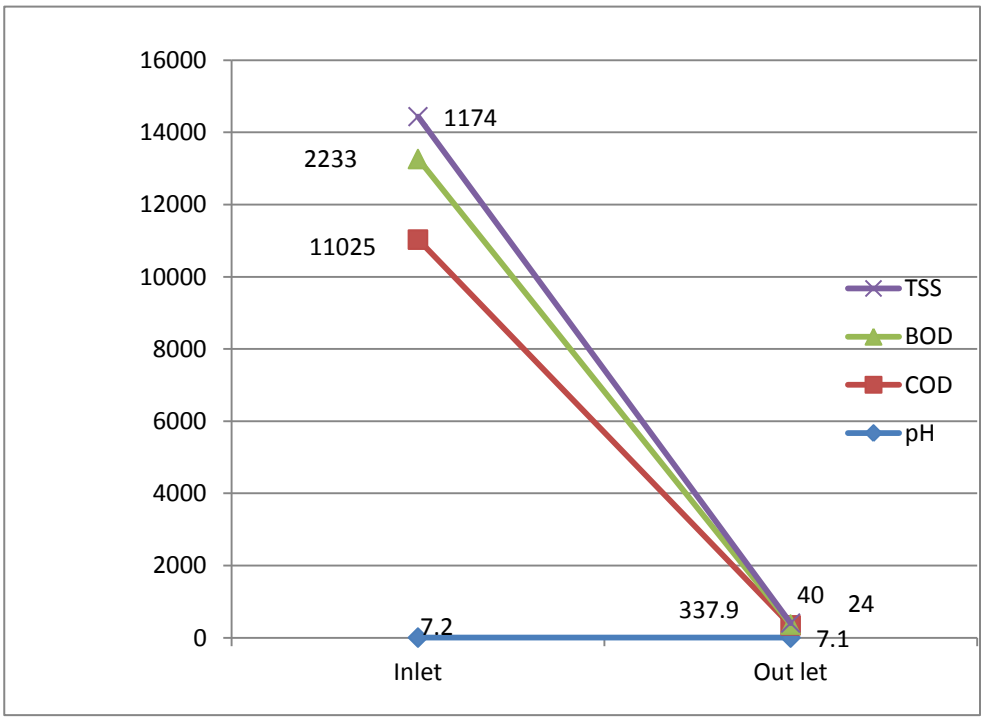
- Discarded containers are decontaminated and sent to authorize parties. The used oil is incinerated in captive incinerator. Manifest has been maintained for transportation of Residue wastes, spent catalyst, spent carbon, date expired medicines, Chemical containing residue, Oil & Grease.

- In organic effluents which are of hazardous nature are incinerated in incinerators and flue gases leaving the incinerator are scrubbed for control of pollutants concentration in gaseous emission.

- The PM sample was collected from incinerator on 05.02.2013. The value of PM was fond as 29 mg/Nm^3. PM Value is well within prescribed limit of 50 mg/Nm^3.

- The hazardous waste generation, handling and disposal record were maintained and displayed the information related to generation, handling, and disposal of hazardous waste on the 6'x4' board at main gate.

(Plate No.16): M/s IPCA Laboratories Ltd, Ratlam, M.P.



(Table 15 : A) Analysis report of M/s IPCA Laboratories Ltd, Ratlam, MP

(Date of sampling-05.02.2013)

Treatment Technology				
Primary Treatment, Secondary Treatment, Tertiary Treatment,(Bio reactor, R.O.,MEE)				
Parameter	**pH**	**TSS**	**COD**	**BOD**
Inlet	7.2	1174	11025	2233
outlet	7.1	40	337.9	24
%removal		96.59	96.93	98.92

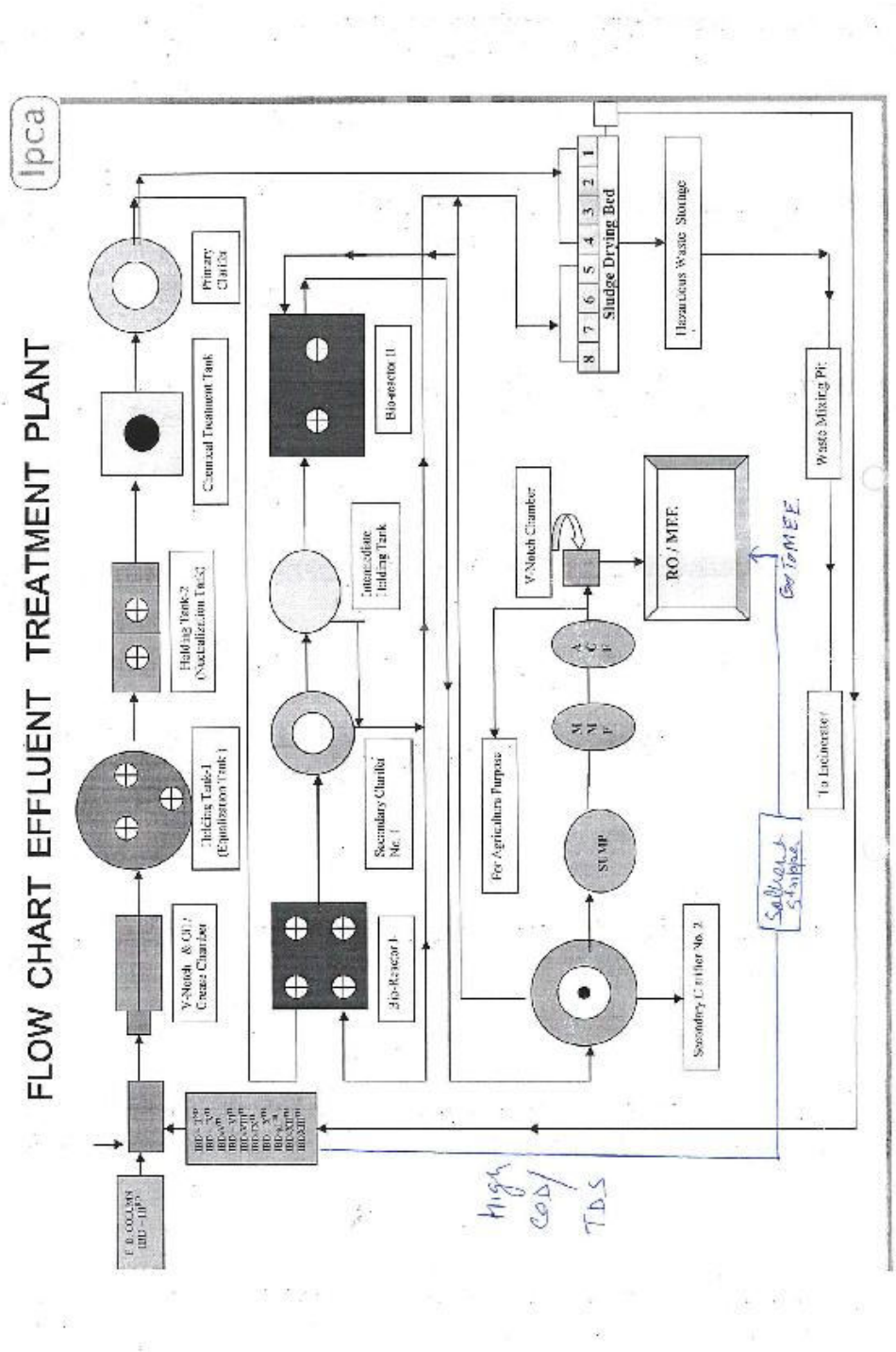
*All values are in mg/l except pH

(Table 15 :B) M/s IPCA Laboratories Ltd, Ratlam, M.P

Hazardous Waste generated			
Source	**Name**	**category**	**Mode of disposal**
DG Set	Waste oil	5.1	Incineration in captive incinerator
Drug manufacturing process	Residues & waste	28.1	Incineration in captive incinerator
Drug manufacturing process	Spent catalyst & carbon	28.2	Incineration in captive incinerator
Drug manufacturing process	Date expired/ discarded medicines	28.4	Incineration in captive incinerator
Drug manufacturing process	Spent organic solvent	28.5	Incineration in captive incinerator
Drug manufacturing process	Chemicals containing residue	33.1	Incineration in captive incinerator
Drug manufacturing process	Discarded container s	33.3	Sale to authorized party
Drug manufacturing process	Flue gas cleaning residue	34.1	Incineration in captive incinerator
Drug manufacturing process	Spent ion exchange resin	34.2	TSDF
Effluent treatment plant	Chemical sludge from ETP	34.3	TSDF
Effluent treatment plant	oil & grease skimming residues from ETP	34.4	Incineration in captive incinerator
Incinerator	Incineration ash	36.2	TSDF
Effluent treatment plant	Evaporation sludge	33.2	TSDF
Drug manufacturing process	Distillation residue	36.4	Incineration in captive incinerator

Annexure-16

M/s IPCA Laboratories Ltd, Ratlam, M.P




EFFLUENT
TREATMENT PLANT


HOLDING TANK
No. 01
CAP. 300 KL


NEUTRALIZATION TANK
No. 02 CAP. 100 KL


PRIMARY CLARIFIER


BIOREACTOR No.1
CAP. 1000 K.L.

M/s IPCA Laboratories Ltd, Ratlam, M.P

M/s IPCA Laboratories Ltd, Ratlam, M.P

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