CENTRAL POLLUTION CONTROL BOARD
Parivesh Bhawan, East Arjun Nagar
Delhi-110032

CPCB Project on "Preparation of COINDS document on Pharmaceutical industry and Development of Emission standards including VOC"

The Central Pollution Control Board (CPCB) intends to take up a project on "Preparation of COINDS document on Pharmaceutical industry and Development of Emission standards including VOC" for execution through engagement of outside Expert agency on Grant in aid/MoU/Agreement basis. The background, objectives, scope of work, time schedule is given below for your perusal and reference please**.**

Expert agencies/Organization have similar type of experience may send their detailed Technical bid (project proposal)and financial bid for the aforesaid study on or before September 30,2011 in separate envelopes to the I/C PCI-I, Central Pollution Control Board, Parivesh Bhawan, East Arjun Nagar, Delhi-110032.

TERMS OF REFERENCE

1.0 Background

National Environmental Policy (NEP) 2006 of India demands that Environmental Standards must reflect the economic and social development situation in which they apply. Standard adopted in one society or context may have unacceptable economic and social costs if applied without discrimination in another society or context. Setting Environmental Standards would evolve several considerations i.e. risk to human health, risk to other environment entities, technical feasibility, cost of compliance, and strategic considerations. It is also understood that environmental standards cannot be universal, and each country should set standards in term of national priorities, policy objectives, and resources. These standards, may, of course, vary (in general, become more stringent) as a country develops, and has greater access to technologies and financial resource for environmental management. CPCB over the decades is therefore, in the process of developing industry specific standards for discharge of effluent and emission so as to protect the recipient environment. Development of such standards essentially depends on the understanding of actual / realistic data / information for the concerned industries, which are located / operating in different parts of the country. Consequently, CPCB conceived preparation of Comprehensive Industry Documents (COINDS), which act as a base for developing environmental standards with reference to a particular industry sector.

COINDS for Pharmaceutical sector was first prepared covering liquid effluents in the year 1988-89. But, no document has been brought out to address the control of air pollutants. Though some efforts were made to prepare a report to deal with emission aspects of this industry sector initially through NEERI in the year 1995 and later by an individual expert but the studies remained incomplete. Since then the sector has undergone changes in terms of raw material consumption, technological up-gradation, demand growth potential, and diverse product range. Also there is a need to relook into the critical pollutants generated from pharmaceutical industries other than the conventional pollutants. The existing document therefore needs to be upgraded to include new and developing technologies and their efficacy to treat various pollutants, also to include status of Pharmaceutical industries.

Like many chemical industries, the pharmaceutical industry has also environment concerns, especially in the manufacturing of active pharmaceutical ingredients (API). In batch-based

manufacturing processes, the possible sources of environmental impact can emerge from synthesis at various steps. A number of transformations and intermediaries are created during the synthesis, and in each step a byproduct is created. If the by-product is used it does not act as an environment overhead otherwise it becomes one. A large number of processes are involved in manufacturing and each process has an environmental overhead. Environmental overheads exist for the pharmaceutical sector just like any other manufacturing sector, which impact the environment negatively. These negative impacts could be in the form of degradation of natural habitat, through land, air and water pollution. The Pharmaceutical companies which are engaged in production of APIs and their intermediates are perceived as polluting industries. It has brought new challenges in protection of the environment. One of such challenges is to control odour and volatile organic compounds including toxic air and water pollutants.

Wastewater streams in pharmaceuticals and biotechnology manufacturing depend on the specific process and may include: chemical reactions streams; product wash water; spent acid and caustic streams; condensed steam from sterilization and strippers; air pollution control scrubber blow downs; equipment and facility wash water; and clean-in-place wastewater. The main conventional pollutants of concern in these wastewater streams from primary manufacturing (e.g. fermentation, chemical synthesis, crystallization, purification, and biological / natural extraction) are biochemical oxygen demand (BOD), chemical oxygen demand (COD), total suspended solids (TSS), ammonia, toxicity, biodegradability, and pH. The chemical compounds that may be present includes solvents such as methanol, ethanol, acetone, isopropanol, and methyl-ethyl ketone etc, organic acids such as acetic acid, formic acid, organic halides, ammonia, cyanide, toluene, and active pharmaceutical ingredients (API).

Air emissions from the industries could be either from point sources or diffused in nature. Usually, the point sources are provided with control equipment, thus emissions from these sources are corresponding to their efficiency of control system. Whereas, the diffused emissions are usually dispersed by the natural ventilation, but in few facilities induced draft through hoods and ducts collects them and subjected to terminal control device. Emission, which exert impact in terms of following are of concern for control i.e. toxicity; odor; photochemical oxidation creation potential; ozone depleting potential; global warming. Prevailing public concern in respect of air pollution in industrial estates are odor and toxic emissions. For the purpose of management of VOC in industry due to use of varieties of solvents, it is essential to know the pollutants which emanate, prevailing control practices, appropriateness & efficiency of the control system, additional measures needed for control etc.

The revision of COINDS is required to include the status of pharmaceutical industries with production details of different types of bulk drugs with therapeutic use, number of units and their locations, type of pharmaceuticals and process adopted, raw materials used and effluent generation from different streams, segregation & its treatment presently adopted by industrial units, mode of disposal of wastewater, reduction & recycling of effluent, Best treatment technologies available, by- product recovery / utilization, solvent recovery, type and source of emissions from processes, BAT for control of emission, Cost of Treatment both for waste water as well as emission etc.

Therefore, the central Board has now taken-up a project to revise the COINDS for Pharmaceutical sector and the details are given in subsequent sections.

2.0 Objectives

Project objectives include:

- To review the existing effluent standards and add new parameters such as VOCs and other organic pollutants
- Develop emission standards for both inorganic and Volatile organic pollutants emanating through process vent/stack and suggest measures for fugitive emission
- Prepare COINDS document on status of pharmaceutical industry

3.0 Scope of work

To prepare COINDS for Pharmaceutical Industry on various aspects of environmental pollution & its control, covering following scope of work

Phase I - Collection, collation of information on Pharmaceutical industry

1. Inventory of pharmaceutical industries on products manufacturing for various Therapeutic class, scale of operation, their capacity and location through questionnaire
2. Types of Pharmaceuticals synthetic, semi synthetic, fermentation etc (Installed/ Actual Production capacity).
3. Description of manufacturing process, material balance, pollution control technologies for pollution abatement for the therapeutic class of analgesics and antipyretic (Paracetamol,Ibuprofen etc), Antibiotic(Amoxycilline, Ampicilline etc), Anti dysentery(tinidazole etc), anti TB(ethambutol etc), Gastrointestinal(Ranitidine etc) and drugs under the class.
4. Production and consumption pattern of all therapeutic class of drugs.
5. Drugs identified in which is maximum number solvents used for manufacturing
6. Characteristics of wastewater of different streams, management practices etc.
7. Possible emission sources i.e. point and non-point sources and priority pollutants from pharmaceutical industries at various and technologies adopted to control.
8. Green processing, green engineering and green chemistry i.e. phase out of halogenated solvents by adopting Enzymatic route
9. Preliminary field visits to 25 selected industries covering all products and process adopted.

PHASE-II Collection, collation of information with respect to pollution potential and control

It is proposed to conduct in-depth studies at 15 selected industrial units. However, the number of representative units will be determined after completion of Phase I study. It will cover all major types of drugs manufactured in India with major therapeutic use, with different size at various locations, practices adopted for treatment of effluent & control of air emissions and disposal system followed. The detailed study would involve:

- Sources of pollution, identification of pollutants in effluents and emission.

- Characteristics & quantum of gaseous emissions, effluent discharges and solid waste generation.
- General description of manufacturing process with detailed flow diagram for all types of drugs & pharmaceuticals including all unit processes and unit operations.
- Preparation of material balance, water balance, with specific information to solvent consumption and its recovery in identified industries.
- Listing of solvents and their consumption in the pharmaceutical industry and identifying possible sources of fugitive emissions.
- Development of emission standards for both inorganic parameter like HBr,HCl,Cl,NH3,HCN,Heavy Metals and organic pollutants like Benzene, Toluene, Carbon tetra chloride, IPA, Methylene chloride, Methanol, MIBK ,Active ingredient and emission factors for these identified pollutants.
- Development of effluent standards for organic parameters like Benzene, Toluene, Methylene chloride, Methanol, IPA, Active ingredients and review of existing effluent standards including heavy metals and Bio assay test.
- Identification of waste streams having high COD, high TDS, and high BOD for adopting suitable technologies.
- The pollution aspects of soil and groundwater, surface water bodies of the surrounding area etc.
- Characteristics of wastewaters before and after treatment of different streams by adopting composite sampling.
- The emission monitoring at the vent will be carried based on peak of the reaction period of different batch process.
- Specific water consumption and wastewater generation.
- Source of generation of solid waste including hazardous waste and treatment & disposal practices.
- Microbiological tests need to be adopted to test the presence of antibiotics, therefore tests need to be validated which will be included in monitoring and testing protocols

Phase III: Preparation of COINDS & Formulation of Revised Standards

- Identification of appropriate treatment method/ technologies for water pollution and its reduction & control and the possibility of achieving ZERO discharge.
- Cost on achieving effluent standards and its relevant treatment schemes for existing practices and for proposed.
- Identification of appropriate technologies to control air pollutants (fugitive) emission as well as source emission and cost of APCDs.
- Effluent and emission standards in terms of concentration and load base.
- Setting of Environmental Standards would evolve several considerations i.e. Risk to Human Health, Risk to Other Environmental Entities, technical feasibility, cost of compliance and strategic considerations etc. The report shall cover the health and environment aspects based on detailed literature survey.
- The rationale for fixing of standards and scope of their achievability will also be described.
- The report should also include hazardous waste generation and its disposal methods adopted by the industry

- International environmental standards followed in the pharmaceutical category
- Review of Indian industry and chemical use profile to identify the priority chemicals in respect of odour control (listing of pollutants on priority chemicals in respect of odour control (listing of pollutants on priority based on odour threshold, use, spatial distribution of the issue); and proven hazardous air pollutants (classification into proven carcinogens and others etc
- Classification of pollutants into toxic air emissions, volatile organic compounds, odorous pollutants etc. and to short list pollutant specific concerned industries and to prioritize industries & activities for further control/improvement
- Protocol for leak detections & repair programme (LDAR)for pharmaceutical industry

4.0 Review/Development of Standards

Standards for effluents are to be modified, if necessary, and also new parameters may be added based on the project outcome. The emission standard should be developed including VOCs .The standards are desired in terms of concentration as well as load based.

5.0 Time Schedule

A maximum of two years time is allotted for the submission of final draft report to the Central Pollution Control Board from the date of receipt of first installment. The final report shall be submitted within a month after review of the report by the Board.

6.0 Mode of Execution

The project can be executed on MOU/Agreement basis. The Private firms and their consortium /Reputed Institute including CSIR lab or IITs/International reputed firms may indicate the concept and submit an approach paper along with estimated cost of project, break-up in different heads i.e. manpower, analysis charges, transportation, laboratory facilities etc.

7.0 Mode of Payment

The payment will be made in the following terms

(i) 10 % of the consultancy fee after award and signed the MOU/agreement.

(ii) 10 % of the consultancy fee after submission of inception report.

(iii) 10% of the consultancy fee after completion of Phase – I and submission of dry study report.

(iv) 30 % of the consultancy fee after completion of Phase – II and submission of in-depth study report.

(v) 30 % of the consultancy fee after completion of Phase – III and submission of draft report.

(vi) 10 % of the consultancy fee after acceptable the report to the Peer and core Expert committee of CPCB.