Executive Summary
(English)

Proposed Drug Intermediates Manufacturing Plant
by
M/s R. P. Intermediates
at
Village - Shernagar, District - Muzaffarnagar (Uttar Pradesh)

Submitted to:
R. P. Intermediates

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Prepared by:

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EXECUTIVE SUMMARY

Background & Objective of the Study

M/s R.P. Intermediates proposes to establish a small scale pharmaceutical raw materials manufacturing facility at 8th km, Jansath Road, near Rana Papers, Muzaffarnagar and has acquired land for the same The proposed intermediate raw materials are L base, D base, Chloramphenicol Powder and Chloramphenicol Palmitate These raw materials are used in pharmaceutical industries and the number of pharmaceutical industries is increasing day by day due to heavy demands of Medicines by the public. The increase in population is instrumental in these demands. A large number of Pharmaceutical Units have also been established in the State of Uttarakhand recently and the proposed raw materials would also be in demand there.

Project Description

The proposed Drug intermediate to be manufactured are L base, D base, Chloramphenicol Powder and Chloramphenicol Palmitate These intermediates are used as raw materials in pharmaceutical industries and the number of pharmaceutical industries is increasing day by day due to heavy demands of Medicines by the public.

Land Requirement

Land Measuring 0.179 Hectare was purchased in the year of 2001. The deed of execution of the land was done in 2001 and soon after purchase declaration u/s 143 was obtained from the district court.

Raw Material Requirement

A list of the Raw Material required and its quantity is sketched in the following Table.

Raw Material	**Quantity / Month**
S-Base	2000Kg
HCl	18 Kg
NaOH	60Kg
M.D.C.A.	434 Kg
Methanol	603Kg
Powder Activated Carbon	48Kg
Acetone	480Kg
Pyridine	50Kg
Palmitoyl Chloride	164Kg

Water Requirement

The source of water shall be tubewell that is to be installed in the unit's premise. It is estimated that a maximum of 200 litres per day will be required as process water. A part of this will be recycled. Besides 2.0 KLD is the domestic water requirement.

Power Requirement

A power load of 30 kva is required for functioning of proposed project. The proponent has already applied to State Electricity Board for the connection.

A DG Set of Capacity 30 KVA will be installed. The consumption of HSD in the DG Set will be around 25-30 litre per day.

A baby boiler having a rated capacity of 20 kg of steam per hour based on Diesel fuel will be installed for production of steam for process. Tha daily consumption of diesel would be around 40-50 litre per day.

Manpower Requirement

The details of manpower requirement are given in following Table.

No. of Personnel	9
Working hours per shift	8
No. of shift per day	One
No. of Working Days per year	300

Sources of Pollution and Control

Air Pollution

The main air pollution sources from the proposed unit are Baby boiler and DG set. The baby boiler having a rated capacity of generating 20 kg of steam per hour would be based on diesel fuel. The stack of the boiler would be kept 10 m above the roof top.

Regarding the DG Set there would not be any air pollution problem since this would be fitted with catalytic converter as OEM component and the stack height would be 2 m above the building roof top so that the Particulate Matter, SO_2 and NO_x, if any, get dissipated in the atmosphere

Water Pollution

The total wastewater generated from the unit shall not exceed 200 litres per day level. This will be treated in an On-site ETP. The treated effluent will be discharged in the nearby nallah. The sludge shall be dried on sludge drying beds and periodically the sludge cakes shall be removed and disposed off suitably.

Domestic wastewater shall not be allowed to mix with plant effluent and a separate septic tank along with soak pit shall be provided.

Noise Pollution

The main sources of noise pollution from the proposed unit are DG Set, Boiler and rotating equipments.

The DG Set shall be housed in a closed chamber having provision for the fresh air.

The blower of the boiler and all the rotating equipments shall be mounted on vibration packing.

Waste Generation

The solid and hazardous wastes generated from the plant operations will be of four different categories as per the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008. The company will provide adequate separate storage area for the storage of each type of hazardous/ solid wastes proposed to be generated from the plant. The hazardous waste storage area will have RCC flooring and covered roof to avoid rainwater mixing with the same. A leachate collection system will be provided for the treatment and disposal of leachate, which will be generated from the storage area..

Description of the Environment

Primary baseline environmental monitoring studies were conducted during summer season of Year 2010 (March to June) and details are as follows:

Site Environs

The site is located at Village : Shernagar, Muzaffarnagar on State Highway 12 A (Jansath Road) between Muzaffarnagar-Jansath Section having Latitude and Longitude of 29°25'28.12" N and 77°45'33.44" E respectively. The project area consists of Industrial, Semi Urban as well as Rural Environment.

Topography & Geology

The Study area is part of Alluvial Belt made up of undifferentiated quarternary sedimentation. These mainy comprise of sand and Clay with kankar. The sand beds constitute highly rich aquifers.

The area slopes towards southwest with an average gradient of 1.5m/km. The general elevation of the alignment varies between 245 m to 260 m above mean sea level. However, the elevation of the project site and surroundings varies between 242m to 248 m.

Climate

It is found that the Study Area has predominantly four seasons namely – Summer (mid-March to June), Monsoon (July to mid-September), Post-monsoon (mid-September to November) and Winter (December to February). It has a subtropical climate characterized by high temperature, low humidity, and medium to scanty rainfall.

Micro-Meteorology

As per the Secondary Data Collected from IMD for the Study Area, the month of August seems to be the most wet month and the month of April the driest month of the year. The study area receives the maximum rainfall during July and August.

As per the secondary data collected from IMD for the study Area, the hottest month in the study area is May and the coldest month is January. The Temperature of the study area varies from 5.8°C in January to 35.4°C in May.

The analysis of the average wind pattern shows predominant winds from W, WSW, WNW and NW with wind frequencies of 9.75 %, 10.1 %, 8.03 % and 8.15 % respectively. The calm conditions were prevailed for 18.08 % of the total time. Average wind speed of the Study Area is 2.73 m/s.

Soil Characteristics

In the proposed study soil quality are influenced to a very limited extent by the topography, vegetation and parent rock. However, the variations in soil profile are much more pronounced because of the regional climatic differences. The soil of this zone has developed under semi-arid condition. The sub-surface geological formations of the buffer area (7 km radius) comprise of sand, silt, clay and kankar in various proportions . Its characteristics in the districts of Uttar Pradesh is part of Gangetic alluvium while in Yamuna Nagar, Ambala, Patiala and Ludhiana these are non-calcareous and sandy loam on the surface, and loam to clayey loam at depth and placed under the classification as Udipsamments/Udorthents

Soil samples were collected from the project site as well as from nearby areas to access the soil characteristics in the study area. The soil samples collected from the project site reveal sandy loam characteristics and brown in color.

Landuse

The prevalent landuse of the study area is agricultural (61.73 %). Rest of the land is either fallow land or human settlements. The region has a mix of medium and high fertility soils. The soils of medium fertility are single croplands, while the highly fertile soils are suitable for double crops. The main agricultural produce of the area is food grains (wheat, barley, gram, rice, maize), sugar cane, tilhan, and potato. Both Rabi and Khariff crops are harvested.

Water Environment

The proposed project site is located at Upper Ganga Basin (Upstream of Gomti in Confluence to Muzaffarnagar). The flow in the basin is largely contributed by the south-westerly monsoon winds from July to September, as well as on the flow from melting Himalayan snows in the hot season from April to June. Tropical Cyclones originating between June and October in Bay of Bengal also contribute to water flows in the basin.

Groundwater is an important resource for meeting the water requirements for irrigation, domestic and industrial uses. It is annually replenishable resource but its availability is non-uniform in

space and time. The project area is underlain by thick pile of quaternary sediments which comprises sands of various grades, clays and *kankar*. The depth of ground water varied from 10-40 metre from the ground level as per the ground water survey report by Central Ground Water Authority (CGWA) conducted for different districts.

Water sampling and subsequent analysis were carried out to determine both the groundwater and surface water quality of the study area. Ground water samples were collected from 6 locations during the study period and analyzed for a number of physico-chemical parameters. The samples were taken from the borewells at Project Site, Bhandoor, Nairana, Sandhawli, Dhandara and Nai Mandi.

The pH of the Groundwater in the study are ranges from 7.15-7.44. Total Dissolved Solids ranges from 146-374. Overall it may be said that the groundwater quality of the study area is good and suitable drinking.

Surface water samples were collected from 3 locations during the study period and analyzed for a number of physico-chemical parameters. The samples were taken from the Dhandhera Datiyana Drain, Upper ganga Canal and Makhiyali Distributary.

Hardness, Dissolved Solids, COD and Coliforms are much higher than standard in Muzaffarnagar main drain. The water quality of upper ganga canal and Makhiyali Distributary are however slightly exceeds the permissible limits.

Air Environment

Preliminary air sampling and monitoring was carried out in the months of March, April and May, 2010 to establish the air quality of the study area. The main sources of pollution in the study area are industrial and vehicular emissions, suspended dust from the paved and unpaved tracks, fuel burning for domestic requirements and windblown dust from the open agricultural and waste land.

Six air sampling locations were selected at Project Site, Village : Nairana, New Mandi of Muzaffarnagar Town, Village : Sandhwali, Village : Dhandhera, Village : Bhandaur

The highest $PM_{2.5}$ level was observed at the Project Site (70.4 µg/m^3), while the lowest level was observed at New Mandi of Muzaffarnagar Town (20.3 µg/m^3). PM_{10} levels were found ranging from 54.0 to 162.0 µg/m^3. The highest RSPM levels were found at the Project Site (162.0 µg/m^3) while the lowest levels was found at New Mandi (54.0 µg/m^3). The highest level of SO_2 was found at the Project site (25.4 µg/m^3) whereas lowest level was found at Village: Bhandaur (6.6 µg/m^3). The SOx level of the Study area is well under the NAAQS Standard (New) of 80 µg/m^3. The highest level of NOx was found at the New Mandi (38.2 µg/m^3) whereas lowest level was found at Village: Sandhawli (14.4

μg/m^3). The NOx level of the Study area is well under the NAAQS Standard (New) of 80 μg/m^3. The highest level of HC was found at Project Site (425.0 μg/m^3) and the lowest level was found at Village : Dhandhera (160.0 μg/m^3). All values of CO at all the monitored locations were found within the permissible levels of 2000 μg/m^3. The highest level was found at Project Site (940.0 μg/m^3) and the lowest level was found at Village : Dhandhera (400.0 μg/m^3).

Noise Environment

Noise monitoring was carried out at seven locations, namely, Project Site, Near SH-12a (Jansath Road),Village : Nairana,Village : Bhandaur, Village : Dhandhera, Village : Sandhawli and Kambal wala Bagh in Muzaffarnagar Town.

The results of the monitoring are provided in. Monitored levels were compared against Ambient Noise Standards prescribed under Gazette Notification 643 of Ministry of Environment and Forests, Government of India. The project site falls in designated industrial area and the noise levels at all the locations were found within the ambient noise standards.

Maximum Sound level is observed both during Day and night is near SH-12 a. The other Noise sampling location being situated near by the highway, the noise level was observed to be on the higher side.

Biological Environment

The study area do not have any ecological sensitive attribute, such as, national park, wild life sanctuary/ game reserve, tiger reserve/ elephant reserve/ turtle nesting ground, breeding grounds, core zone of biosphere reserve, habitat for migratory birds, mangrove area, area with threatened (rare, vulnerable, endangered) flora/fauna, protected corals, wetlands, zoological gardens, gene banks, reserved forests, protected forests, any other closed/ protected area under the Wild Life (Protection) Act, 1972. Flora and fauna of the study area has been studied through secondary sources data as well as from site survey.

Socio-economic Environment

The Study Area of 10 km radial Zone mainly falls in the Muzaffarnagar and Jansath Sub-district of District Muzaffarnagar There are Total 29 Villages in Study Area, out of which, 10 villages belongs to Jansath Sub district and rest 19 village are in Muzaffarnagar Sub-district.

Total Population of the Study area as per Census of India, 2001 is 495843, the total number of Household being 76872. Rural population constitutes 33.11 % and Urban Population constitutes 66.89 % of total population. Total Male Population of the Study area is 262578 and total Female Population of the Study Area is 233265.

Literacy Rate of the study area is 57.85%. Distribution of male and female literacy rate in the study zone is 64.18% and 50.73% respectively

As revealed from Census of India 2001, a huge percentage (72%) people is non-workers in the Study Area.

Anticipated Environmental Impacts

During Construction Phase

It shall be noted that all the civil work for establishment of proposed unit was already completed in the Year 2001. The project implementation activities involved in this project are now limited to installation of machinery and pollution control equipments along with development of greenbelt.

Potential Impacts during Operation Phase

Some of the potentially significant environmental impacts from the proposed project will be in Air Environment, Water Environment, Land Environment, and Socio-economics.

Impact on Soil vis-à-vis Solid Waste

The total plot area for the development is about 1,790 m^2, half of which has already been constructed for the plant. The remaining portion is at present vacant and is under green cover with tree plantation in the periphery. There is no adverse impact envisaged due to the operation of the plant.

Solid and hazardous waste generated from the plant operation will be in the form of used oil, ETP sludge, Discarded containers/ barrels/liners used for hazardous wastes/ chemicals, packaging and domestic solid waste.

Hazardous waste generated from the facility shall be disposed off in suitable manner as per the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008. The used oil generated from the proposed project shall also be collected in barrels and shall be sold to the authorized recyclers identified by the UPPCB/ CPCB. Non-hazardous solid waste will be segregated and sold to the recyclers.

Impact on Air Quality

The main sources of air pollution due to the operation of the plant will be baby boiler with 20 kg/hr capacity and a DG set of 30 KVA capacity. In addition to that, there will be some process emissions as well from reactors, for which proper ventilation system has been provided. Major pollutants emitted from the boiler and DG set are in the form of air pollutants, *viz., NOx,* SO_2 and PM from the stacks.

ISCST-3 Model with the following options has been employed to predict the ground level concentrations due to the proposed plant emissions from baby boiler stack and DG set.

The contribution to GLCs for the pollutants i.e. SPM, SO2 and NOx were predicted over the study area due to the proposed project

considering the worst scenario. The maximum Ground Level Concentration for NOx, SOx and PM is predicted to be 0.21,0.31 and 0.05 μg/m^3 respective at a distance of only 0.2 km at the west direction. Therefore it can be said that the impact on air environment due to the proposed project is negligible.

Impact on Noise Levels

Considering all the noise generating sources, the dissipation of noise away from the source points is predicted. The cumulative noise level near the sources as calculated with the help of above equations was calculated as 80 dB(A). From the predictions, it is clear that the noise drops to 40 dB(A) level at a distance of 100 m from the proposed project site. The existing ambient noise levels near the project site are in the range of 45 to 56 dB(A). Therefore, the future noise impacts on the environment are not expected to be significant. Due to the masking effect, the ambient noise level in the nearby areas will not increase during the operation of the plant. It shall also be noted that the plant will be operational only in one general shift, and hence, there would not be any noise generation at night time from the plant. Hence, there would not be any adverse impact due to the operation of the plant on the residents of the nearby areas.

Impacts on Water Environment

Liquid effluent will be generated from processes, utilities, equipment washings, floor washings and domestic usage. It is estimated that out of the total demand of 0.5 KLD for various industrial & domestic purposes during the operation phase of the project. Total industrial effluent generation will be about 0.2 KLD and domestic effluent of about 0.24 KLD. Remaining water will be either utilized in the processes or get evaporated.

All the industrial wastewater will be treated in an effluent treatment plant (ETP). Treated wastewater will be used for horticulture purposes. The sludge will be dried on sludge drying beds and periodically the sludge cakes will be removed and disposed off suitably.

The domestic wastewater generated from lavatories, will not be mixed with the plant effluent. A separate septic tank along with soak pit will be provided for treatment of it.

Impacts on Socio-Economic Environment

The proposed drug intermediates project will have a significant impact on the industrial growth in the region as there are a number of pharmaceutical units in Muzaffarnagar as well as nearby state of Uttarakhand. It is anticipated that during the operation phase, the proposed project will generate a total direct employment for 10 people. In addition to that, the project will also generate some opportunities for indirect benefits through casual work, sub contracts, transportation, trading etc.

Impacts on Ecology and Biodiversity

The project activity does not require tree cutting during land clearing. Also, the study zone does not have any ecologically sensitive location and hence, the plant activities are not expected to have any impact on the ecology and biodiversity.

Environmental Management Plan

The purpose of the environmental management plan (EMP) is to minimize the potential environmental impacts from the proposed project and to mitigate the consequences. EMP reflects the commitment of the project management to protect the environment as well as the neighboring populations.

Construction Phase

All the civil construction work of the project was already completed in Year 2001. However, machinery and installation of pollution control equipments has yet to be done. There would not be any signicant impact during this phase, which requires additional environmental management plan.

Operation Phase

Air Environment

In the proposed plant, there will be 2 stacks only, which will be conacted with a baby boiler and a DG set. The DG set will be used only during the power failure. Also, the plant operation will be limited for 1 shift in a day. The project site is away from human settlements. To maintain the greenery a thick betl of medium height trees have been put along with the boundary of the factory premises. A total of 20% of area will be earmarked for greenbelt. The premises would also have lawns, flower gardens.

Noise Levels

The statutory national standards for noise levels at the plant boundary and at residential areas near the plant will be met. The selection of all new plant equipments will be made with specification of low noise levels. Noise suppression measures such as enclosures, buffers and/or protective measures may be provided (wherever noise level is more than 90 dB(A) and exposure limits to workers is more than 8 hours a day) to limit noise levels within occupational exposure limits.

Water Environment

In the proposed project, the water requirement for process is of the magnitude of about 2.7 KLD. No impact of ground or surface water is envisaged due to the project and hence, no mitigation measures are required. However, use of treated water for greenbelt development and rainwater harvesting is proposed in the project.

The wastewater from the proposed project will be treated in an On-site Effluent treatment plant and the treated effluent, which will have the quality of rainwater will be discharged in nearby nallah.

Rainwater harvesting is also proposed in the project to tap effectively the rainfall runoff and subsequently recharging to the aquifer systems. 1 recharge structures will be required for the same. The probable location of these sites will be finally decided as per the layout of storm water drains.

Land Environment

Solid wastes like process waste and organic waste etc. in process, packaging is to be separately collected & sent for incineration. ETP Sludge and incinerable wastes are to be separately collected in polythene/HDPE bags or drums and stored temporarily onsite on an impervious floor at a specified place before final disposal.

Environmental Monitoring Programme

A well defined environmental monitoring programme would be employed with trained and qualified staff of EMC to monitor the ambient air as well as stack gas quality to check whether the quality of emissions/ effluents are maintained within the permissible limits or not.