

## **EXECUTIVE SUMMARY**

### **1.0 PROJECT DESCRIPTION**

#### **1.1 GENERAL INTRODUCTION**

M/s. Ipca Laboratories Ltd. is a reputed name in the Indian Pharmaceutical & healthcare industry. It is a public limited organization engaged in manufacturing pharmaceutical products since 1984 in various plants located in India. Currently, M/s. Ipca Laboratories Ltd. has contemplated a major expansion of its products & production capacity of the plant at Ratlam. The company has been pioneers in development & market headers in most of the products made by them.

The plant at present manufactures 35 Bulk Drugs & is having formulation. The Existing Production capacity of Bulk Drug is 1202 MT/year+ Existing formulation consists of:-

Tablet – 800 Million nos. /year

Injection – 20 Million nos. /year

Liquid orals 2500 KL/year

The proposed project will increase the Bulk Drugs from 35 to 65 (i.e. new 30 products) production will go up from 1202 MT/year to 2551.5 MT/year.

#### **1.2 BRIEF PROJECT DESCRIPTION**

Ipca Laboratories Ltd. Plant is a public limited organization engaged in manufacturing pharmaceutical products since 1984 in various plants located in India.

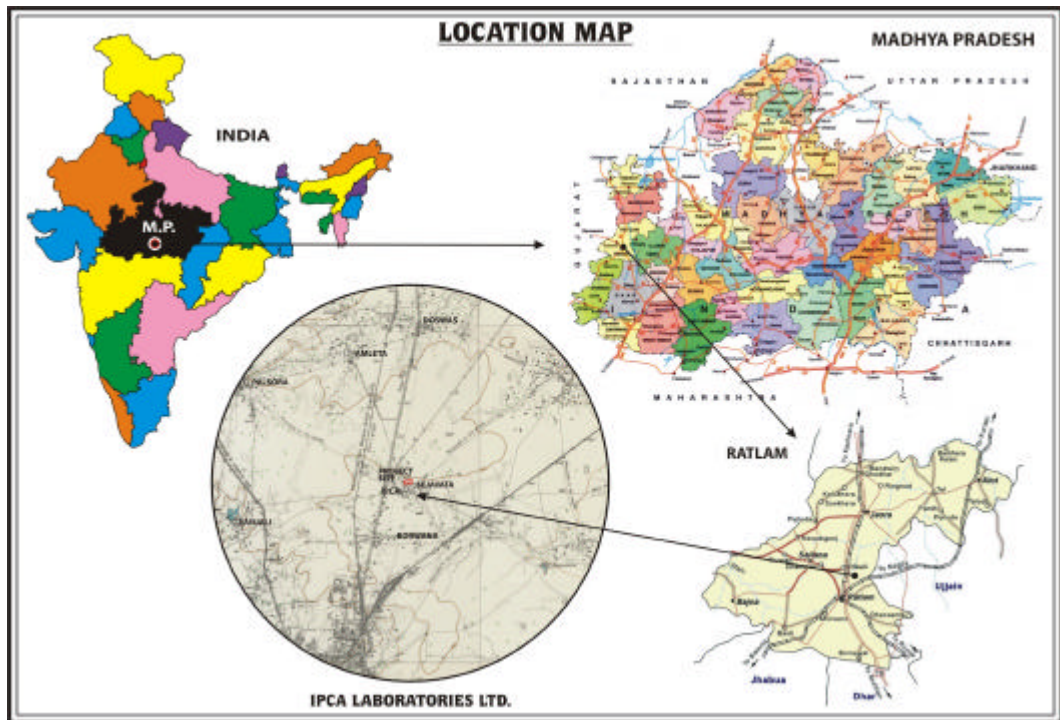
1.	Name & Address	<b>Ipca Laboratories Ltd.</b> At-Village-Sejavta, Tehsil-Ratlam, District-Ratlam (M.P.)
2.	Area of the project	68.0 Acres & out of this approx. 1600 m <sup>2</sup> area in the existing premises will be constructed to fulfill the requirement of the enhancement production capacity
3.	Latitude	23°19' N
4.	Longitude	75°03'E
5.	Products	<b>35 to 65 Bulk Drugs</b> Tablet–800 Million nos. /year Injection–20Million nos./year Liquid orals- 2500 KL/year
6.	Production Capacity	<b>1202 MT/Year to 2551.5 MT/Year</b>
7.	Capacity of Boiler	6 Tonnes/hr. each (3 nos.-2 Regular+1 Stand by)
8.	Total water Requirement	1050 m <sup>3</sup> /day (Existing + After Enhancement)

9.	Total Power Requirement	4450 KVA
10.	Total Fuel Requirement	Coal (40 TPD), LSHS (800 LPD), LDO (1000 LDP), HSD (500 LDP)
11.	Transportation	Trucks
12.	Manpower	Direct employment - 603 (Permanent Staff) 432(Permanent Workers) Indirect Employment- 1200(Contract Workers)

**1.3 LOCATION OF THE PROJECT**

The Ipca Laboratories Ltd. plant is situated in North – East direction of village Sejavta which is approximately 7 kms away from Ratlam district headquarter on the Madhya Pradesh National Highway No. 79 connecting Mhow & Neemuch. The city of Ratlam is situated on the main broad gauge rail route of western railway connecting Mumbai & Delhi. It is also connected to state capital Bhopal and Rajasthan by rail.

Mumbai & Kandla are the nearest sea ports. Both are connected with rail route from Ratlam. Indore is the nearest airport & domestic flights for Ahmedabad, Bombay & Delhi are available from here.



**1.4 EXISTING & NEW PRODUCT DESCRIPTION**

The plant at present manufactures 35 Bulk Drugs & is having formulation. The Existing Production capacity of Bulk Drug is 1202 MT/year + Existing formulation consists of:-

Tablet – 800 Million nos. /year

Injection – 20 Million nos. /year

Liquid orals 2500 KL/year

The plant will manufacture the bulk drugs from 35 to 65(i.e, new 30 products) production will go up from 1202 MT/year to 2551.5 MT/year.

The Reaction Details, Efficiency, Reaction conditions and recovery and molecular weight etc for the products manufacturing are also given in detail in EIA report in Chapter No -2.

In the manufacturing process various kinds of solvents will be used so the quantity of different solvents used, recovered, lost and solvent balance cycle is also mentioned in the EIA report in the chapter no -2.

**The List of Existing & New Product is given below.**

**[List of Existing Products]**

Sr. No	Product Name	Proposed consent Qty. in MT / Year
1.	FLUMEQUINE	40
2.	METOCLOPRAMIDE HCl	10
3.	TRIMETHOPRIM	30
4.	ATENOLOL	400
5.	CHLOROQUINE PHASPHATE / SULPHATE	20
6.	PYRANTEL PAMOATE / TARTRATE	125
7.	MORANTEL CITRATE / TARTRATE	50
8.	FUROSEMIDE	125
9.	N-AMYL META CRESOL	01
10.	ACECLOFENAC	20
11.	ARTEMISININE AND SALTS	15
12.	BALSLAZIDE DISODIUM DI HYDRATE	40
13.	CETIRIZINE Di HCl	5
14.	CHLORTHALIDONE	10
15.	CILOSTAZOLE	02
16.	CITALOPRAM HYDROBROMIDE	02
17.	CLOPIDOGREL B-SULPHATE	05
18.	FLUCONAZOLE	10
19.	GLIMEPIRIDE	02
20.	HYDROXY CHLOROQUINE SULPHATE	60
21.	HYDROCHLOROTHIAZIDE	100
22.	LISINOPRIL DI HYDRADE	02
23.	LOSARTAN POTASSIUM	100

24.	2-MERCAPTO-5-METHOXY BENZIMIDAZOLE	10
25.	METOPROLOL TARTRATE / SUCCINATE	60
26.	METHYLPHENIDATE -HCI	01
27.	NABUMETONE	30
28.	OXANTEL PAMOATE	05
29.	PROPRANOLOL HCI	150
30.	PENTOXIFYLLINE	10
31.	PAROXETINE HYDROCHLORIDE HEMIHYDRATE	05
32.	TRICLABENDAZOLE	25
	<b>TOTAL</b>	<b>1470</b>

**LIST OF PROPOSED PRODUCTS**

<b>Sr. No</b>	<b>Product Name</b>	<b>Proposed consent Qty. in MT / Year</b>
33.	METFORMIN HCL	1000
34.	LUMEFANTRINE	10
35.	AMODIAQUINE HCL	15
36.	MESALAMINE	5
37.	ONDANSETRON HCL/ DIHCL	1
38.	BENDROFLUMETHIAZIDE	1
39.	PERINDOPRIL TERT BUTYLAMINE / ERBUMINE	0.5
40.	VALSARTAN	2.0
41.	CARVEDILOL	10
42.	RAMIPRIL	0.5
43.	QUETIAPINE HEMIFUMARATE	5.0
44.	SODIUM ALENDRONATE	1.0
45.	Butanedioic acid, mono[2-methyl-2-[4-( spiro[tricyclo3.3.1.1 <sup>3,7</sup> ]- decane-2,3'-[1,2,4]trioxan]- 6'.ylethenyl)phenoxy]propyl]ester (CDRI-97/78)	1.0
46.	RITALINIC ACID	1.0
47.	INDAPAMIDE	0.5
48.	PROGUANIL HCL	5.0
49.	DIMETHOXY METHYL HYDROQUINONE	1.0
50.	TRAMADOL HCL	10
51.	SULFADOXINE	1.0
52.	ALLOPURINOL	1.0
53.	BISOPROLOL FUMARATE	1.0
54.	ENALAPRIL MELEATE	1.0
55.	ETODOLAC	1.0
56.	WARFARIN SODIUM CLATHRATE	1.0
57.	ATOVAQUONE	1.0
58.	EZETIMIBE	1.0
59.	FENOFIBRATE	1.0
60.	ISOTRETINOIN SODIUM	1.0
61.	RESPERIDONE	1.0
62.	GABEPENTIN	1.0
	<b>TOTAL</b>	<b>1081.5</b>
	<b>TOTAL QTY. PROPOSED FOR EXISTING</b>	<b>1470</b>

	<b>PRODUCT</b>	
	<b>QTY. OF ADDITIONAL CAPACITY PROPOSED</b>	<b>1081.5</b>
	<b>TOTAL QTY. FOR CONSENT</b>	<b>2551.5</b>

### FORMULATION

<i>TABLET ( MILLION/YEAR)</i>	800
<i>INJECTION (MILLIONS NO. / YEAR</i>	20
<i>LIQUID ORALS (KL/YEAR)</i>	2500

## 2.0 DESCRIPTION OF THE ENVIRONMENT

### 2.1 TOPOGRAPHY

The entire study area lies on the Malwa Plateau, with Aravalli Range to its northwest and the Vindhya Range to its south. The Rivers Mahi on its west & Chambal to its east.

The region can be divided in to two geomorphic units as under:-

1. High Relief hilly area
2. Plain

### 2.2 PHYSIOGRAPHY

The rocks exhibit a tendency to spheroidal withering through the exploitation of roughly concentric shells & hence rounded masses called boulders are common. These are generally observed in the step like series of perpendicular escapements on the hill sides & slopes of the valleys. These are well marked on low table lands of hilly region on the western side of Ratlam i.e. in Sailana Tehsil.

### 2.3 CLIMATE CONDITION

The minimum and maximum temperatures of the study area during study period were 14.3°C and 43.8°C respectively. The area receives its maximum rainfall by South-West Monsoon, which commences from the middle of June and ends in September. The normal annual average rainfall of Ratlam district is 1000-1100 mm.

### 2.4 WATER QUALITY

Depth of the open wells in the study area range from 8 m to 20 m below ground level with an average depth of 13.2 m. Water sample were collected from 6 stations and the analysis of the samples shows that the concentration of total dissolved solids ranges between 266.0 mg/L, to 1650.0 mg/L; pH various from 7.58 to 8.28 and Total Hardness from 92.82mg/L to 807.20 mg/L.

### 2.5 AIR QUALITY

Ambient air quality monitoring has been carried out at 10 stations in the study area of 10 Km radius on 24 hourly bases. While The maximum and minimum concentrations for all the locations of SPM range between 285 to 102  $\mu\text{g}/\text{m}^3$  RPM range between 38 to 88  $\mu\text{g}/\text{m}^3$ , SO<sub>2</sub> range between 6 to 26  $\mu\text{g}/\text{m}^3$  and NO<sub>x</sub> range between 6 to 34  $\mu\text{g}/\text{m}^3$ .

## 2.6 NOISE QUALITY

Noise monitoring in the study area at 10 stations shows that the noise level varies in Leq value ranges from 48 Leq dB (A) to 61Leq dB (A) in Daytime and 37Leq dB (A) to 48Leq dB (A) in Nighttime.

## 2.7 SOIL QUALITY

Samples collected from identified locations indicate that the soil is alkaline, pH value ranging from 8.3 to 8.9 the other main parameters are given below:

Organic Carbon (%)	–	0.28 to 0.48
Phosphorus (Kg/ha)	–	90 to 95
Potassium as K (Kg/ha)	–	340 to 345

## 2.8 BIOLOGICAL ENVIRONMENT

There are no national parks, wild life sanctuaries or biosphere reserves within 10 km radius of the study area. The soil in the area is low to medium fertile with reference to its agriculture potential.

### Flora:

A survey was done to have an overview of the eco-system of the core area. The biodiversity of vegetation in the area is not very high due to intense biotic pressure. The area is predominantly agro-system with poor irrigation facilities. The Main Species of Flora found in the region are:- Karanj (Pongamia pinnata), Khair (Acacia catechu), Teak (Tectona grandis), Amla (Emblica officinalis), Babul (Acacia arabica), Mahua (Madhuca indica), Shisham (Dalbergia sissoo), etc.

### Fauna:

There is no suitable habitat for occurrence ecologically important fauna in the area. No significant endangered species have been reported in the study area. The fauna mostly constitute domesticated animals etc. The rodent includes, rats and Other Species are Mongoose, Hare etc. Many birds like Crow, Sparrow, Myna, and Kingfisher.

## 3.0 ANTICIPATED ENVIRONMENTAL IMPACTS AND MITIGATION MEASURES

### 3.1 AIR ENVIRONMENT

The use of comparatively cleaner fuel like LSHS for boiler generates much lesser suspended particulate and SO<sub>2</sub> on combustion.

Therefore, there shall be no significant impact on air quality due to the project and its expansion also no major air polluting equipment is envisaged in the expansion project. The existing boiler and diesel generator shall be utilized for the expansion.

### **3.2 NOISE ENVIRONMENT**

There is no major noise generating operations\space machinery envisaged in the project. The only noise generating sources are motors and rotating machinery like pumps\ blowers \compressors etc. Noise generating units like boiler house and D.G. sets room are isolated and sensitive areas like canteen administration building and formulation unit are provided with enclosure doors.

The findings indicate that no significant impacts due to noise pollution are expected, due to the project or its expansion.

### **3.3 WATER ENVIRONMENT**

The proposed expansion will marginally increase the quantity of effluent and it shall not alter the composition of treated effluent.

The storage of treated water in a concrete lined lagoon prevents any possibility of soil and ground-water contamination due to leakage. The ground-water and soil sample analysis in the vicinity of the dairy farm shows that there has been no contamination of soil or ground water.

The biological monitoring of organisms and plant life in the water bodies and in the vicinity of lagoon has not revealed any obvious noticeable changes. Therefore, it can be deduced that there shall be no significant impact on water quality in the area due to the project expansion.

### **3.4 LAND ENVIRONMENT**

The proposed expansion is planned in the existing plot area and no further land acquisition is necessary. Therefore, the Ipca Laboratories Ltd. plant activities, due to proposed expansion are unlikely to alter the agricultural and land-use pattern in the study region.

### **3.5 SOLID WASTE**

The solid waste will be 12.5 Tonnes/month, which will be generated in the form of sludge from ETP after treatment. This sludge is dried in sludge drying beds and burnt in Incinerator. The incinerator ash will be stored separately in drums and disposed at TSDF i.e. a secured landfill site of Pitampura, Indore (M.P)

### **3.6 SOCIO-ECONOMIC ENVIRONMENT**

The Ipca Laboratories Ltd. project has generated a fair amount of direct and indirect employment in the study region. The local economy has received a boost due to employee spending and services generated by Ipca Laboratories Ltd.

Migration into the existing area or displacement of existing population is insignificant. Housing, transport, water, power supply, medical, educational and other civic amenities are not adversely affected nor appear to get affected in future.

#### **4.0 ENVIRONMENTAL MONITORING PROGRAMME**

For ensuring that the emission loads do not exceed stipulated limits and ambient air quality is satisfactory, the following monitoring schedule is recommended:

<b>S.No.</b>	<b>Description</b>	<b>Frequency of Monitoring</b>
1.	Ambient Air Quality at boundary of the project	Once in a month
2.	Stack Emissions	Once in a month
3.	Work Environment Air Quality	Once in a month
4.	Meteorological data	Once in a quarter
4.	Noise Level Monitoring	Once in month
5.	Health Check-up	Once in six months

#### **5.0 PROJECT BENEFITS**

Adequate plantation is proposed on the site inside and outside the plant. The trees should maintain regional ecological balance and conform to soil and hydrological conditions. Indigenous species would be preferred.

The management is to support the local administration and other form of assistance for the development of public amenities in this region. Mainly they are providing the basic amenities of the nearby villagers for water distribution, building of schools, hospitals etc. The health programme outlines a routine monitoring of health and safety of the Ipca Laboratories Ltd. work force. A regular medical check up of each worker will be carried out once per six months.

Ipca Laboratories Ltd. has generated direct and indirect employment from the nearby villages due to local labours for approx. 2500 persons, out of which 603 persons are permanent staff, 432 persons are permanent workers and 1200 persons will be contractual labour, which will contribute in increasing the social status of the villagers..

Adult Education programmes are proposed to be organized for up-gradation of literacy level.

Transport, Post and telegraph facilities have been improved in this area due to rapid industrialization.

#### **6.0 ENVIRONMENT MANAGEMENT PLAN**

##### **6.1 AIR ENVIRONMENT MANAGEMENT**

Gaseous emission from fuel burning, which consists of common pollutants like SO<sub>2</sub>, NO<sub>x</sub> and SPM, would be discharged into atmosphere through stacks of suitable height. The hazardous chemicals and volatile organic solvents are

carefully handled in a closed system, thereby preventing any discharge of these chemicals into the air.

Development of Green Belt within the premises of the plant will help in attenuating the pollutants emitted by the plant.

Ambient air quality and stack emission would be regularly monitored to ensure that ambient air quality standards and suggested limits on stack emission loads would be met honestly all the time.

## 6.2 **WATER MANAGEMENT**

In order to reduce the water consumption by plant, it is recommended to carryout a water audit every year. The study shall focus on water consuming operations and measures to reduce water use.

Efforts should be made to conserve as much water as possible by recycling and reusing. Water table levels shall be measured at the baseline stations once every season.

It is also observed that the effluent which get generated from the processing have following characteristic so as they do not show as significant change on surrounding environment.

- Discharge effluent meets the MPPCB /CPCB norms.
- High COD streams are collected separately and distilled for recovery of solvents. After recovering the solvents the effluent is sent to ETP for treatment and solid waste is sent to incinerator for incineration.
- The Composite Untreated Effluent Analysis report and Monthly Effluent Analysis (final discharge carried out by the Board year 2006-07 and performance of ETP is given in the EIA report in chapter no -5, and its is visible from the mentioned data that we meet the prescribed norms.

### **Waste Water Management**

It is found that none of the raw material which will being used in the manufacturing process, contain chromium and lead and the products are free from these toxic element so as such no measures are required to remove chromium and lead from the discharged effluent in Effluent Treatment Plant .

The municipal and industrial wastewater will be treated in the Effluent Treatment Plant (ETP) and the treated water is sent to Lagoons from where it is utilized in Green belt Development and irrigation within the premises, as there is Zero discharge outside the boundary.

The sewage from Effluent Treatment Plant is dried in Sludge drying beds and the dried sludge is burnt in the Incinerator. The incinerator ash is collected and stored in drums till it is finally disposed in the TSDF.

## 6.3 **NOISE MANAGEMENT**

There is no danger of noise pollution from Ipca Laboratories Ltd. which is controlled by proper maintenance and compact technology.

The green belt will help in reducing noise levels in the campus as a result of attenuation of noise generated due to plant operations, and transportation.

#### **6.4 SOLID WASTE MANAGEMENT**

The solid wastes some of them are hazardous as well are generated from the different stages of the products ,like distillation /Centrifuging /Layer separation/ Precipitation/scrubber etc. and the primary and secondary operations of ETP. There shall be an appreciable increase in the quantity of solid, wastes after the expansion.

All hazardous and solid waste are incinerated in Thermax make incinerator as per the guidelines of state & central pollution control boards .as per list enclosed in EIA report and also primary & bio-sludge from the ETP. This will ensure complete destruction of all organic/ inorganic solid wastes without creating any secondary effects. The only residue from the incinerator is incinerated ash is sent for disposal at the common TSDF site at Pithampur, which is approved by the pollution control board.

#### **6.5 GREEN BELT DEVELOPMENT**

Presently, 20000 plants survive within and around Ipca Laboratories premises which were planted in past years and the total area covered under green belt is 11 Hectare. It is proposed to plant approx. 21000 trees in about 10.0 Hectare areas. Thus, the total area under green belt will be 21.0 Hectare.

Tolerant species should be selected for the Green belt development. The planting should be in appropriate alternate rows around the proposed site to prevent lateral pollution dispersion.

#### **6.6 SOCIO-ECONOMIC MANAGEMENT**

Ipca Laboratories Ltd. has generated direct and indirect employment for approx. 2500 persons, out of which 603 persons are permanent staff, 432 persons are permanent workers and 1200 persons will be contractual labour.

Medical and educational facilities for rural population in the vicinity are poor and the management of project is ready to undertake an appropriate contribution towards their improvement.

