Pre- Feasibility Report

For

Manufacturing of Pharmaceutical Formulations in Keron Life sciences Pvt. Ltd.

At

Plot No- D-5, Sara Industrial Estate Rampur, Dehradun, Uttarakhand

1. EXECUTIVE SUMMARY

1.1 **M/s Keron Life sciences Pvt. Ltd. (KLPL)** a private limited company under the companies Act 1956 was incorporated on 09-6-2012. The registered office of the company is located at sahaspuranshik, Sahaspur Vikas Nagar Dehradun Uttarakhand India. The Company is promoted by Shri Arvind Kumar Jha and Shri Mukesh Mrinal of the Delhi.
M/s Keron Life sciences Pvt. Ltd. (KLPL, Selaqui, Dehradun (UK) will start manufacturing of Tablets, Capsules, Ointment, Liquid Oral, Dry Powder, Herbal and Cosmetic & Food only, under orange category in Doon Valley.

1.2 INTRODUCTION

History of the Company:
KLPL is proposed to be established as an ISO 9001:2000 and WHO- GMP/USFDA certified company engaged in development , production marketing distribution and export of pharmaceutical , Herbal, Cosmetic & Food Products in specialized areas, i.e. cardiovascular/urological medicines,

1.3 Salient Features of The Project

Proponent Name	**Keron Life sciences Pvt. Ltd.**
Location	Plot No- D-5, Sara Industrial Estate Rampur, Dehradun, Uttarakhand.
Latitude	30° 22' 47.56" N
Longitude	77° 50' 14.59" E
Land use	Industrial area
Nearest Habitat/ Town	Rampur, 1 Km (S)
Nearest Railways Station	Dehradun Railway Station 21 Km(SE)
Nearest Airport	Jolly Grant Airport, 39 Km (SE)
Nearest Highway	NH 72, 1 km (SW)
Water Demand and Supply source	8 KLD Supply of Bore well
Nearest Tourism Place	Mussoorie 52 Km
Seismic Zone	Zone – IV
Altitude	516 meters
Proposed Production process	Tablets, Capsules, Ointment, Liquid Oral, Dry Powder, Herbal and Cosmetic & Food.
Estimated Project Cost	INR 24,250,000
Working Days	26
Man Power	40

2. PROJECT /BACKGROUND INFORMATION

A. Identification of the project and project proponent.

Category of Project: Category B2 (Doon Valley). The project proponent is **M/s Keron Life sciences Pvt. Ltd.** is a limited company.

B. Brief Description of Nature of Project.

M/s Keron Life sciences Pvt. Ltd; proposes to manufacture Pharmaceutical formulations such as Tablets, Capsules, Ointment, Liquid Oral, Dry Powder, Herbal and Cosmetic & Food.

C. Need for the Project & Importance to the Country

The Proponent has expertise in the manufacture of above medicines. There is a growing demand for the pharmaceutical products internationally as well as in the domestic market. A need has therefore been felt to establish the unit for manufacturing.

D. Demand and supply gap

These products are having National market and still demand is more than supply so manufacturing of these items are feasible. The Proposed Company does not see any difficulty in marketing their products as the two essential points in marketing a product i.e. product quality & packing and experience are reasonable in favour of the Promoters.

E. Export Possibility

Product shall be of export quality also and possibilities of export will be explored.

F. Domestic/Export Markets

There is domestic market of this product but export shall also be done.

G. Employment Generation (Direct & Indirect) due to the project

With this proposed project direct employment generation of40persons will be there in worker/supervisor/ managerial category. Indirect generation of employment will also be there in way of contractors, transportation, suppliers, other service providers with continues chain of employment.

3. PROJECT DESCRIPTION

A. Type of Project including Interlinked and Interdependent Projects, if any

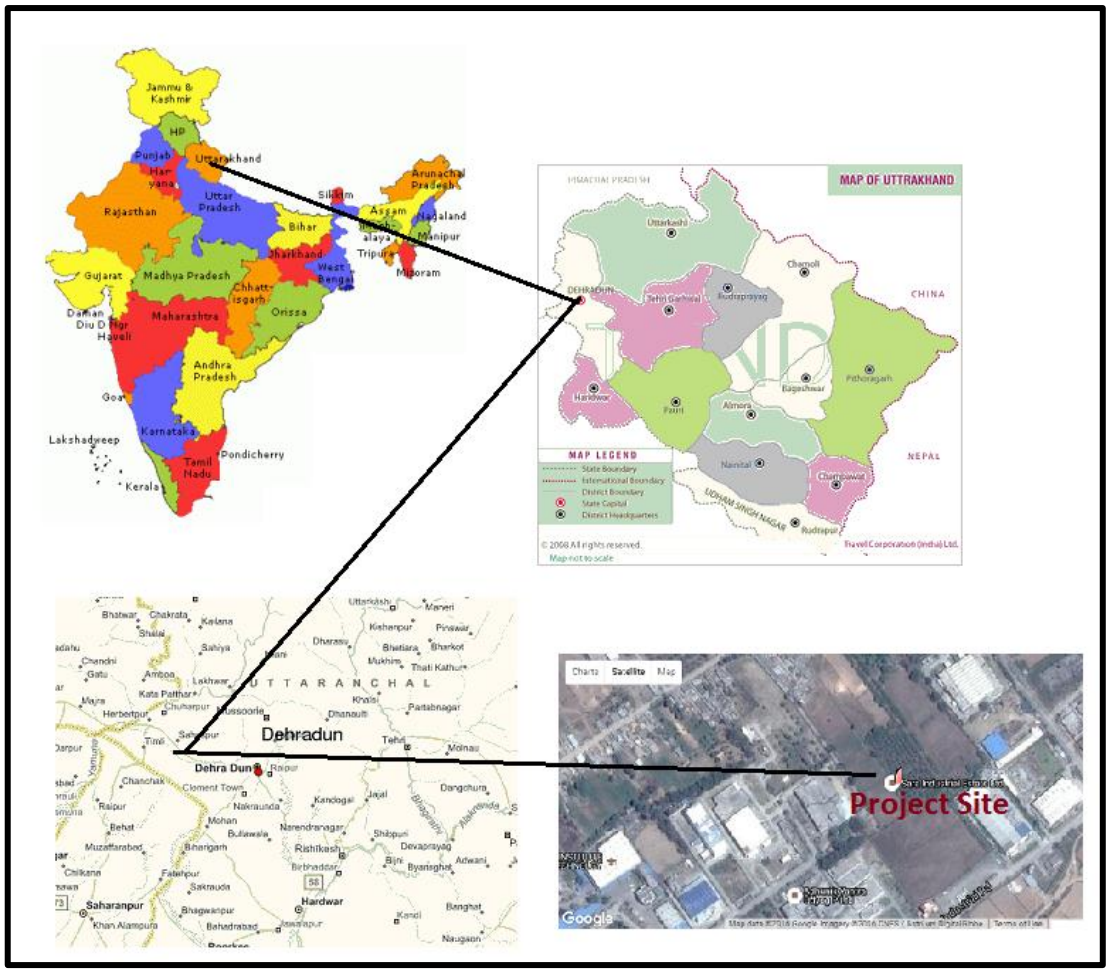
There is no interlinked and/or interdependent project linked with it. No other allied activities and/ or services will be carried out with this project.

B. Land allocation within plant

The total land area for project is 2000 m^2 in which (33%) will used for green belt.

C. Location (map showing general location, specific location, and project boundary & project site layout) with coordinates.

The unit situated at Plot No- D-5, Sara Industrial Estate, Rampur, Dehradun, Uttarakhand is a well-defined and developed industrial area in Tehsil of Vikas Nagar and District of Dehradun at a distance of 28Km west of Dehradun on National Highway No 72 to Chandigarh.



Location map

D. Details of alternate sites considered and the basis of selecting the proposed site, particularly the environmental consideration gone into should be highlighted.
No alternate site.

E. Size and Magnitude of the operation.

S.No.	Items of Manufacture/ Type of Service	Quantity per annum Nos
1.	TABLETS & CAPSULE	20 Crore Nos
2.	OINTMENT	20qtl
3.	LIQUID ORAL	50 KL
4.	DRY POWDER	10 MT
5.	HERBAL COSMETIC & FOOD	200MT

F. Project description with process details (a schematic diagram/flow chart showing the project layout, components of the project etc. should be given)

The process involves following steps for various pharmaceuticals product.

1. TABLETS:

A) GRANULATION: The raw material (various ingredients), viz the powder is sieved through a “sifter” so as to have the powder of equal mesh sizes after which, it is finely grind (through a Multi Mill) and mixed homogenously in a Mass- Mixer. This mass is then kept for drying (in a fluid bed dryer) for varying time and temperatures depending upon the quality of the product. The dried powder is ready to be converted in tablet form in the compression department.

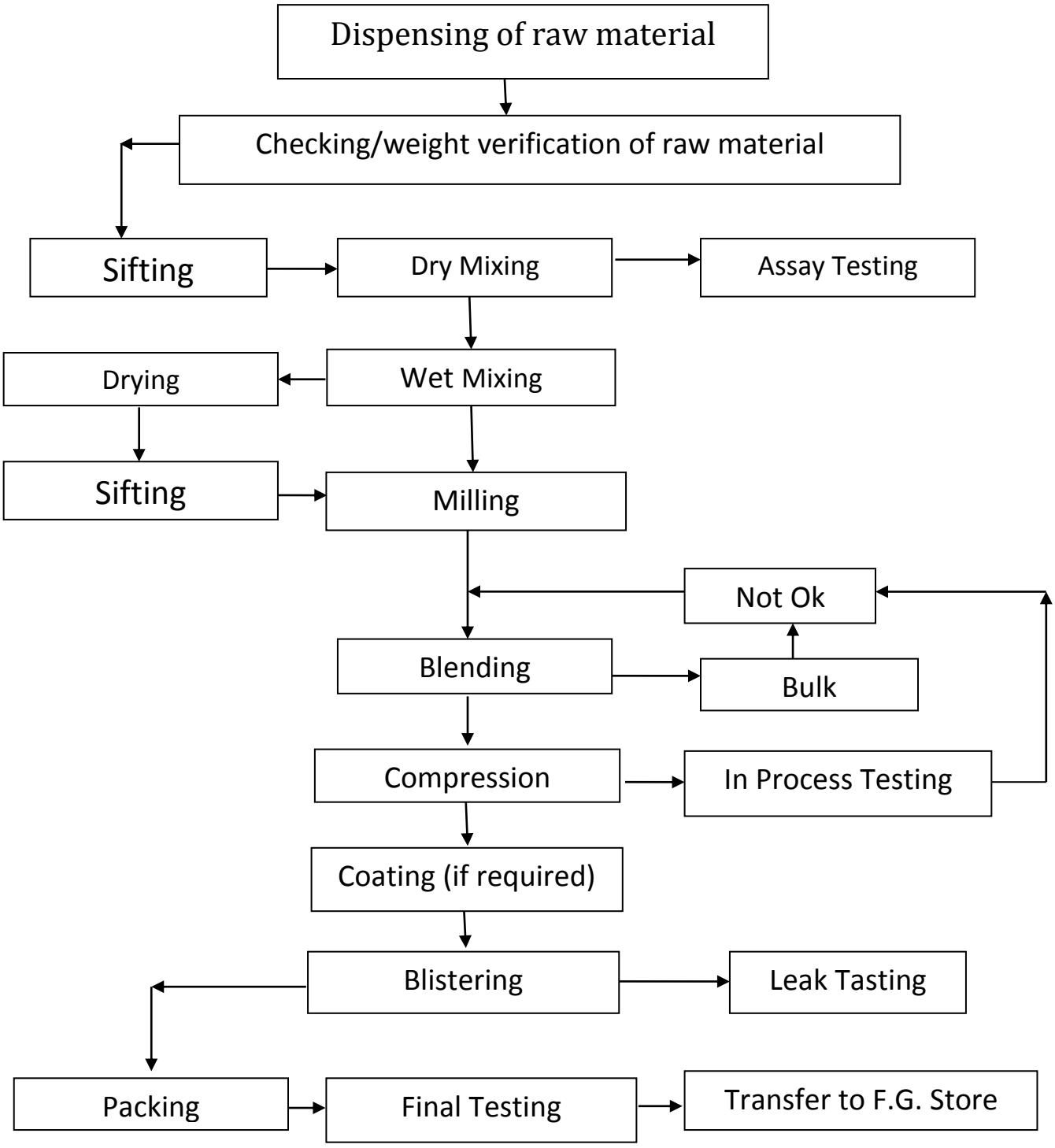
B) COMPRESSION: The dried powder from the granulation department is fed through a hopper to a Rotary Tableting machine where it is compressed into tablets, which can be of different sizes depending upon the requirements. The process is carried out under controlled temperature, which is done by Air- conditioning.

C) COATING: This is an optional process depending on the customer’s requirement. At the same time it is also essential in order to maintain highest quality standards. In this process, the compressed tablets are coated (in a Tableting machine) with the help of a compressor. The tablets may be coated by sugar, material cellulose or any other material. Again the work area shall be Air-conditioned. The tablets are ready for packing which is done in a “Blister Pack Machine”. The general pack size is of ten tablets.

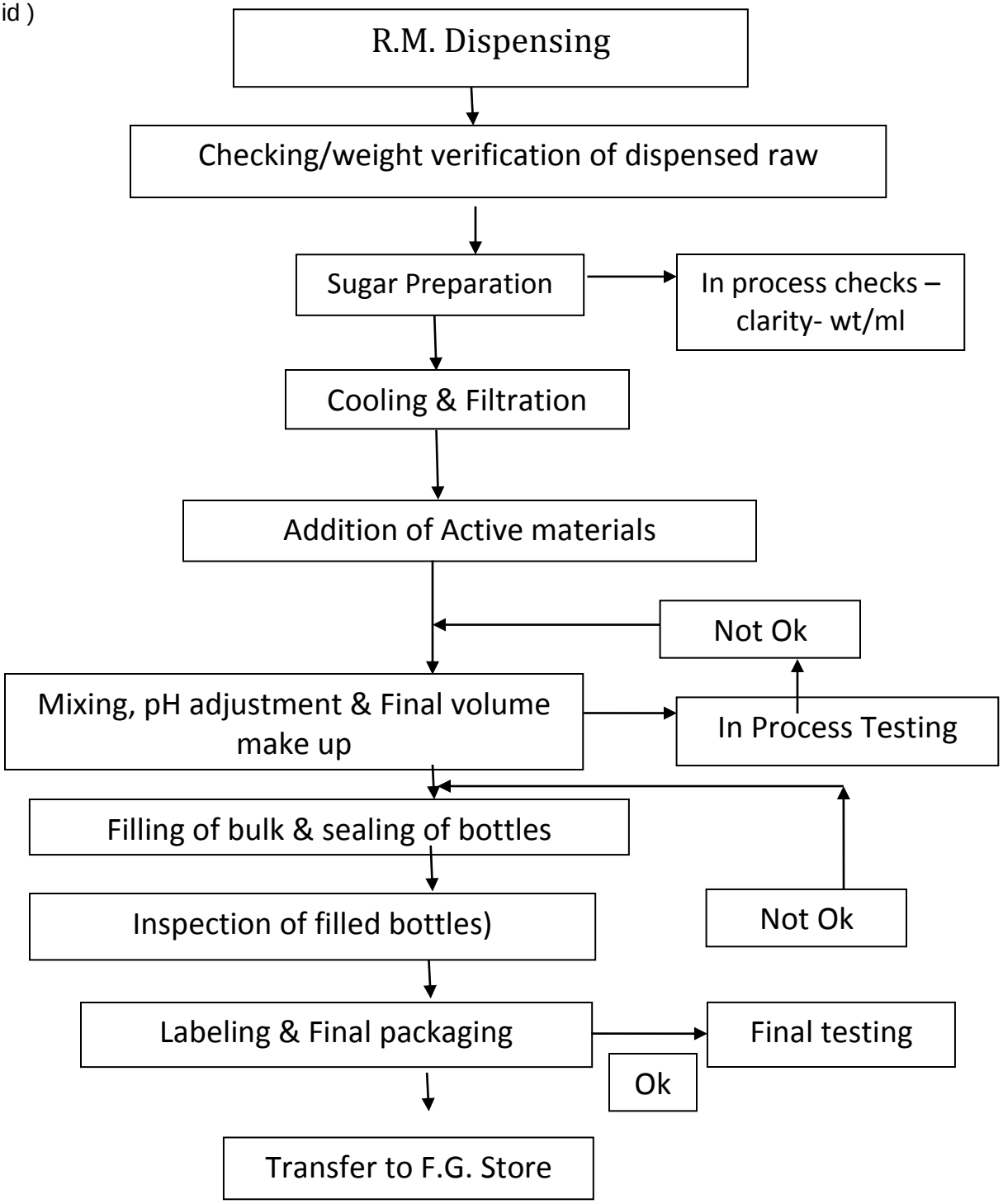
2. **CAPSULES:** In order to maintain “Good Manufacturing Practices” (GMP) standards, it is necessary to have two capsule sections. One is for general capsules and the other is for sensitive penicillin or ampicillin group capsules. Both the sections are separate with proper Air-conditioning and controlled relative humidity with the help of de- humidifier. In both the cases, the process is the same. The powder of various pharmaceutical raw materials is thoroughly mixed in a double cone blender for a fixed length of time. After mixing is complete, the powder is filled in empty capsules on a capsule filling machine which after fillings are closed and sealed. The capsules are then ready for packing on the Blister Packing Machine. Again the pack sizes if generally of ten capsules.

3. **LIQUIDS:** In preparing Liquid, utmost care is taken in purifying the water. The water s purified with the help of de-mineralizer plant. Only then it is used for manufacturing purposes. From the demineralizer the water is collected in a stainless steel tank. The necessary ingredients are added into it and mixed with the help of an electric stirrer. If suspensions are to be manufactured, then it is churned with the help of homogenizer. Further, they are also churned by a Colloid Mill, which mixes the fine particles of water insoluble compound into an emulsion. After sometime, the stirred/churned liquid is passed through a volumetric filling machine into bottles/jar as required. The Bottle is then sealed with the help of a sealing machine. It is then visually checked under light for any foreign particles in the syrup. After labeling the bottle is ready for dispatching. The bottles used in filling the liquids are thoroughly washed with the help of Bottle Washing machine and then dried in Bottle Dryer for sterilization. This is a very important process for the product to be of best quality.

(Tablets)


Dispensing of raw material
Checking/weight verification of raw material
Sifting
Dry Mixing
Assay Testing
Drying
Wet Mixing
Sifting
Milling
Not Ok
Blending
Bulk
Compression
In Process Testing
Coating (if required)
Blistering
Leak Tasting
Packing
Final Testing
Transfer to F.G. Store

(Liquid)


R.M. Dispensing
Checking/weight verification of dispensed raw
Sugar Preparation
In process checks – clarity- wt/ml
Cooling & Filtration
Addition of Active materials
Not Ok
Mixing, pH adjustment & Final volume make up
In Process Testing
Filling of bulk & sealing of bottles
Inspection of filled bottles)
Not Ok
Labeling & Final packaging
Final testing
Ok
Transfer to F.G. Store

G. PLANT AND MACHINERY

Production section

S.N.	NAME OF EQUIPMENT	CAPACITY
4.	Starch Paste kettle	50 Ltrs with stirrer.
5.	Geometrical blender	60 kg
6.	RMG	80 kg
7.	Fluid bed drayer	60 kg
8.	Octagonal blender	100 kg
9.	Rotary machine	27 station double
10.	Dust collector	300 cfm
11.	Autocoater	60 kg
12.	Double track blister machine	7 lack tablet per shift
13.	Alu-Alu packing	1 lack per shift
14.	Drum blender	100 kg
15.	Semi Automatic capsule filling machine	2.5 lack capsule per shift
16.	Capsule polishing and inspection machine	30000 capsule per houre
17.	Manual Capsule filling machine	30000 per shift
18.	Capsule Loader	30000 per shift
19.	Capsule Polishing & Inspection machine	40000/Hr.

UTILITY SECTION

S.N.	NAME	CAPACITY
1.	BOILER	200 kg per hour
2.	D.G SET	250 KW
3	DOUBLE R.O.	250 LT/Hr.
4	AIR COMPRESSOR	1.812M3/MIN
5	LOOP SYSTEM	6 kg per minute

H. Raw Material Required Along Estimated Quantity, Likely Source, and Marketing Area Of Final Product/s Mode Of Transport Of Raw Material And Finished Product.

LIST OF RAW MATERIAL

Paracetamol	5000kg
Starch	20000kg
DCP	5000kg
Methyl parabean	20kg
Propylparabean	5kg
Talcum	500kg
Magnesium	500kg
Sorbitol	1000kg
Glycerine	1000kg
Propyl Glycol	1000kg
Vit.B1	5kg
Vit. B2	5kg
Vit.B6	2kg
Folic Acid	5kg
Ferrous fumerate	20kg
Niacinamide	10kg
Zinc sulphate	10kg
Maltose	1000kg
Asprin	100kg
Ammonium chloride	100kg
CPM	10kg
Sodium citrate	20kg
Guafensine	20kg

Levamisole	5kg
Bromhexine	5kg
Ibubrofen	10kg
Terbutaline sulphate	5kg
Phenylepherine	5kg
Oxyclozanide	10kg

Availability of Raw materials: The raw materials such as basic salts and excipients are freely available in the open market in almost all commercial cities. There are no price controls or distribution controls on the same. They can be manufactured indigenously and can be procured directly from the manufacturers in case of bulk purchases. As regards the cost of raw materials, the rates of different basic salts and excipients are different and fluctuating.

Availability of Packing Materials: The presentation of any product is an important factor. However, this factor assumes special attention in Pharmaceutical Industry due to various reasons such as shelf-life, hygiene, quality, stability, durability, easy to use etc., as also steady flow of finished product as per the requirement of market. Keeping these factors in mind there are many methods of packing too viz glass bottles, strips & blisters (in foils & PVC's), plastic pouches, tubes etc. Because of the variety and different types of methods used in packing pharmaceutical products, it is difficult to ascertain the exact cost of packing per unit.

I. Power Requirement:

Total Power requirement is 300 KVA and will be met from Uttarakhand electricity board, also DG set of 250 KVA is proposed. DG set shall be used at the time of power failure only.

J. WATER REQUIREMENT AND SUPPLY SYSTEM

Water requirement in industrial process shall be 8 KLD which will be met from bore wells. Water required for domestic consumption shall be around 7 KLD, most of this shall be met from recycling of treated effluent.

Water Requirement (Quantity)

Use Of Water	Quantity of Water Required	Waste Water Generation	Treatment Method	Reuse Of Water
From Process	8 KLD	7 KLD	ETP	Gardening & Flushing
Domestic	2 KLD	1.6 KLD	Septic Tank And Soak Pit.	-------

SITE ANALYSIS

A. Connectivity

Well connected with Road, Rail and air service

Nearest Railways Station	Dehradun Railway Station 21 Km(SE)
Nearest Airport	Jolly Grant Airport, 39 Km (SE)
Nearest Highway	NH 72, 1 km (SW)

B. Land form, Land use and Land owner ship

Plain and flat land having Industrial use falling SARA Industrial Estate Rampur, Sahaspur, Dehradun.

C. Topography –

Land is plane and flat with inclination towards South

D. Existing land use pattern

The existing land use is Industrial.

E. Existing Infrastructure

All infrastructures have been developed by SARA Industrial Estate Selaqui, Dehradun. .

F. Climatic data from secondary sources

Monthly mean maximum & minimum temperature and total rainfall based upon 1961-1990 data:

Month	Mean Temperature ^{o}C		Mean Rainfall in mm
	Maximum	**Minimum**	
January	19.3	6.0	55.0
February	25.1	7.8	58.8
March	26.4	12.0	49.0
April	32.1	16.7	22.5
May	35.6	20.7	41.7
June	34.8	23.0	201.8
July	30.5	22.8	672.6
August	29.4	22.4	728.2
September	29.7	20.8	296.5
October	28.5	15.7	49.8
November	25.0	10.4	8.6
December	21.1	6.8	24.4

Source- http://www.imd.gov.in/doc/climateimp.pdf

G. Social Infrastructure

The area is under Vikas Nagar Tehsil, Entire social infrastructure has been developed by State Govt.

H. Drinking Water Management (Source & Supply of water)

The source of the drinking water is Borewell

I. Sewage System.

Soak pit and septic tank arrangement shall be provided for the waste generated from toilets and domestic use.

J. Industrial Waste Management.

Effluent Treatment Plant is proposed for industrial waste. Capacity of ETP shall be 10 KLD

K. Solid Waste Management

1. Solid waste generated from sludge drying beds of ETP shall be disposed to TSDF as per the norms of State Pollution Control Board.
2. Used oil shall be disposed to authorized recycler.
3. Expired drugs shall be disposed as per HWM rule R regulation.

L. Power Requirements & Supply/ source.

Total Power requirement is 300 KVA and will be met from Uttarakhand electricity board, capacity DG set of 250 KVA is proposed. DG set shall be used at the time of power failure only.

5.0 PLANNING BRIEF

A. Planning concept (type of industries, facilities, transportation etc.) town and country planning/Development authority Classification.

The proposed industry is small scale and established in a developed SARA Industrial Estate Rampur, Sahaspur, and Dehradun.

6.0 PROPOSED INFRASTRUCTURE

A. Industrial Area (Processing Area) No additional infrastructure is proposed

B. Resident Area (Non Processing Area) as only local person will be given employment, no residential area/ housing is proposed.

C. Green Belt - 33% area has been reserved for green belt Company has been developed dense green belt around the plant premises with plant species.

D. Hazardous waste Management: Company shall get the Authorization under “Rule-5” of the Hazardous Waste (Management, Handling & Trans-boundary Movement) Rule, 2008, and maintain proper storage & safety management for Hazardous material. All Hazardous waste shall be disposed through authorized vendor .Quantities of various hazardous wastes are given below:

S. No	Schedule	Particulars	Quantity
1	5.1	Waste Oil	175 Ltr/annum
2	34.2	Dried ETP sludge.	0.1 MTA
3	28.4	Expired finished product and raw materials	0.2 MTA

7.0 REHABILITATION AND RESETTLEMENT (R & R) PLAN

The unit is in developed industrial estate, so R & R plan is not required.

8.0 PROJECT SCHEDULE AND COST ESTIMATES

- Project is expected to be complete in next 3 - 4 months
- Funds requirement shall be Rs 2.42 Crore/- including the machinery and plant.

9.0 ANALYSIS OF PROPOSAL (FINAL RECOMMENDATIONS)

The Indian pharmaceutical industry is a success story providing employment for millions and ensuring that essential drugs at affordable prices are available to the vast population of this subcontinent. Also Improvement of infrastructure as well up-liftment of social structure in the area. The people residing in the nearby areas have been benefited directly & indirectly.