PRE – FEASIBILITY REPORT

For
Expansion in Manufacturing of Pharmaceutical Formulations

IN

RUSAN PHARMA LIMITED

AT

122 MI, Central Hope Town

Behind Pharma city, Selaqui

Tehsil – Vikasnagar,

Distt. Dehra Dun – 248197

(UTTARAKHAND)

1. EXECUTIVE SUMMARY

1.1 **M/S RUSAN PHARMA LTD.,** established in 1994, started with R & D and formulation development center (Approved by Department of Science & Technology, Government of India) at Mumbai. Rusan specializes in projects for contract research, method development, and drug master file development & stability studies. Further to cross the competitive edge, Rusan has extended its activities by establishing an API manufacturing facility at Ankleshwar. Rusan has three formulation units, two at Kandla (Gujrat) and third at Dehra Dun (Uttarakhand)

At present **M/S RUSAN PHARMA LTD** is engaged in manufacturing of Tablets, Capsules and Injections. As such project proponents are now looking forward for capacity enhancement in their products and incorporation of some new products; hence this report is being presented for seeking the clearance accordingly.

1.2 INTRODUCTION

1.2.1 Salient Features of The Project

Proponent Name	**M/S RUSAN PHARMA LTD.**
Location	Khasra No 122 I, Central Hope Town, Selaqui, Dehra Dun.
Latitude	30° 22' 25.41" N
Longitude	77° 51' 38.51" E
Land use	Industrial area
Nearest Habitat/ Town	Selaqui, 1 Km
Nearest Railways Station	Dehradun Railway Station, 35 Km
Nearest Airport	Jolly Grant Airport, 75 Km
Nearest Highway	NH 72, 2 km
Water Demand and Supply source	17 KLD Supply of source shall be Bore well
Nearest Tourism Place	Mussoorie, 52.4 Km
Seismic Zone	Zone – IV
Altitude	1692 ft.
Proposed Production process (Expansion)	Tablets, Capsules, Injections – Ampoules, Vials, Transdermal Patch, Liquid Line & Pre Filled Syringe
Working Days (monthly)	26
Man Power	400

COST OF THE PROJECT: The total cost of the project is **Rs. 49.15 Cr Existing and 10.85 Cr Proposed = 60 Cr .**

2. PROJECT /BACKGROUND INFORMATION

A. Identification of the project and project proponent.

Category of Project: Category B2 (Doon Valley). The project proponent **M/s Rusan Pharma Limited** is a limited company.

B. Brief Description of Nature of Project.

M/s Rusan Pharma Limited had been working in the pharmaceutical industry for the last 25 years. Rusan has extended its activities by establishing an API manufacturing facility at Ankleshwar. Rusan has three formulation units, two at Kandla (Gujrat) and third at Dehra Dun (Uttarakhand)

C. Need for the Project & Importance to the Country

In the last few decades we have witnessed the rapid growth of population all around the world and particularly in India, due to which there has been change in the living habits of the people and various factors emerged affecting the health of human being, as such this stimulated the demand of every person to overcome health related issues, hence consumption of medicines are increasing day by day in both Indian and International market. In view of the above Rusan Pharma has proposed enhance its production capacity for Tablets & Injections – Ampoules and incorporating new products like Vials, Transdermal Patch, Liquid Line & Pre Filled Syringe to meet the demand of medicine which is feasible in all respect.

D. Demand and supply gap

The Pharmaceuticals products are having National market and still demand is more than supply so manufacturing of these items are feasible. The Proposed Company has no difficulty in marketing their products as they have an expertise in the field.

E. Export Possibility

Manufacturing and export of pharmaceuticals product for various commonwealth of independent states (CIS) countries Russia, Ukraine, Uzbekistan, Kazakhastan, Cost – Rica, Bangladesh, Myanmar, Morocco, Mauritius, Iraq, Kenya, Armenia, Bhutan, Vietnam, Namibia, Taiwan, Zambia, Zimbabwe and other countries.

F. Domestic/Export Markets

The Pharmaceutical industry in India ranks 3rd in the world in terms of volume and 14th in terms of value. As such having so much demand it has vast opportunity in domestic market as well as in international market.

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

The company at present is having 100 people working in different category. Indirect generation of employment is also there in way of contractors, transportation, suppliers. As such after expansion 400 more employees will be added as the total strength of

manpower will reach to 500 nos. and there will be more generation of employment for other service providers accordingly.

GOVERNMENT INITIATIVES

The Government of India has unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. It has reduced approval time for new facilities to boost investments.

Further, the government has also put in place mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority to address the issue of affordability and availability of medicines. Romania is keen to tie up with the Indian pharmaceutical companies for research and develop new drugs. Romania will collaborate with India for license acquisition to sale India's drugs in Europe. The country will tie up with Indian pharmaceutical companies for research and develop new drugs.

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 is being carried out with this project.

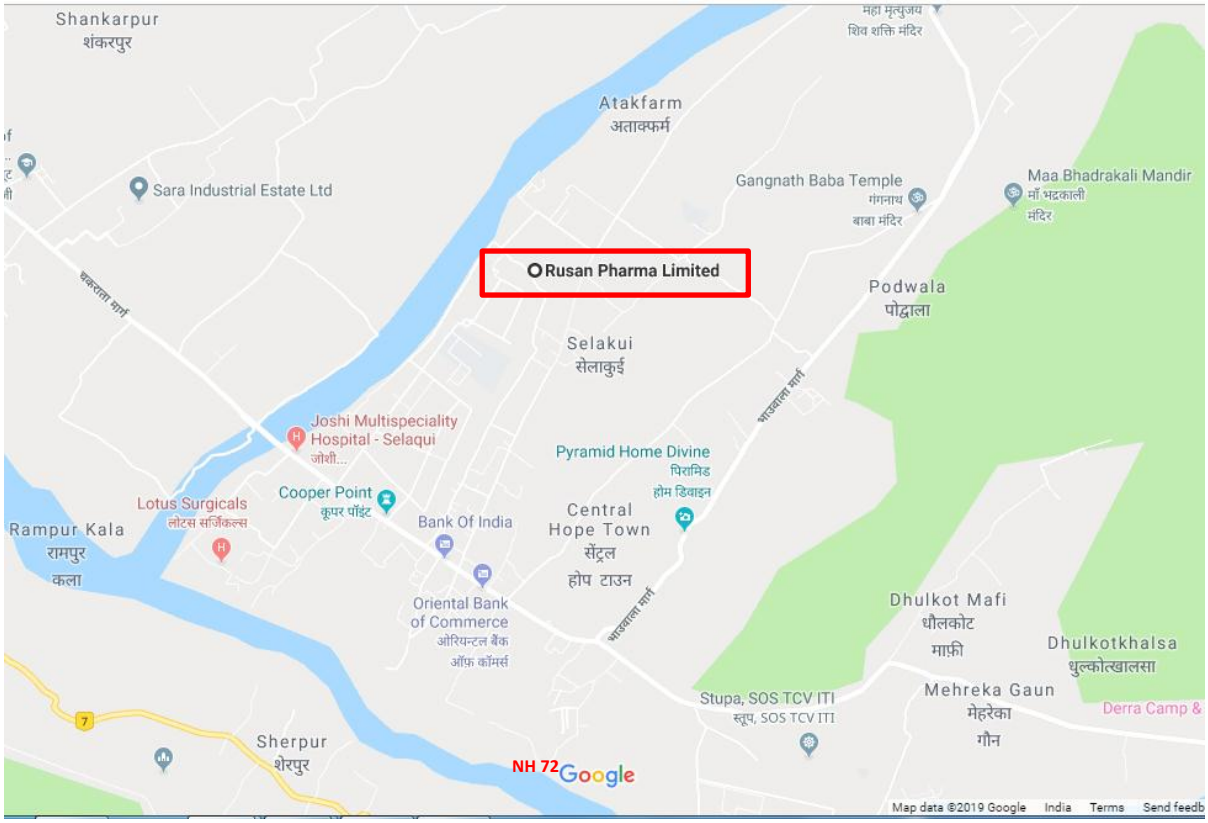
B. Land allocation within plant

The total land area for project is 6092 sqm in which (33%) will be used for green belt.

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

The unit situated at Khasra No 122 I, Central Hope Town, Selaqui, Dehradun. Selaqui is a well-defined and developed industrial area in Tehsil of Vikas Nagar and District of Dehradun at a distance of 35 Km west of Dehradun 2 Km off National Highway No 72 to Chandigarh.

LOCATION MAP



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.

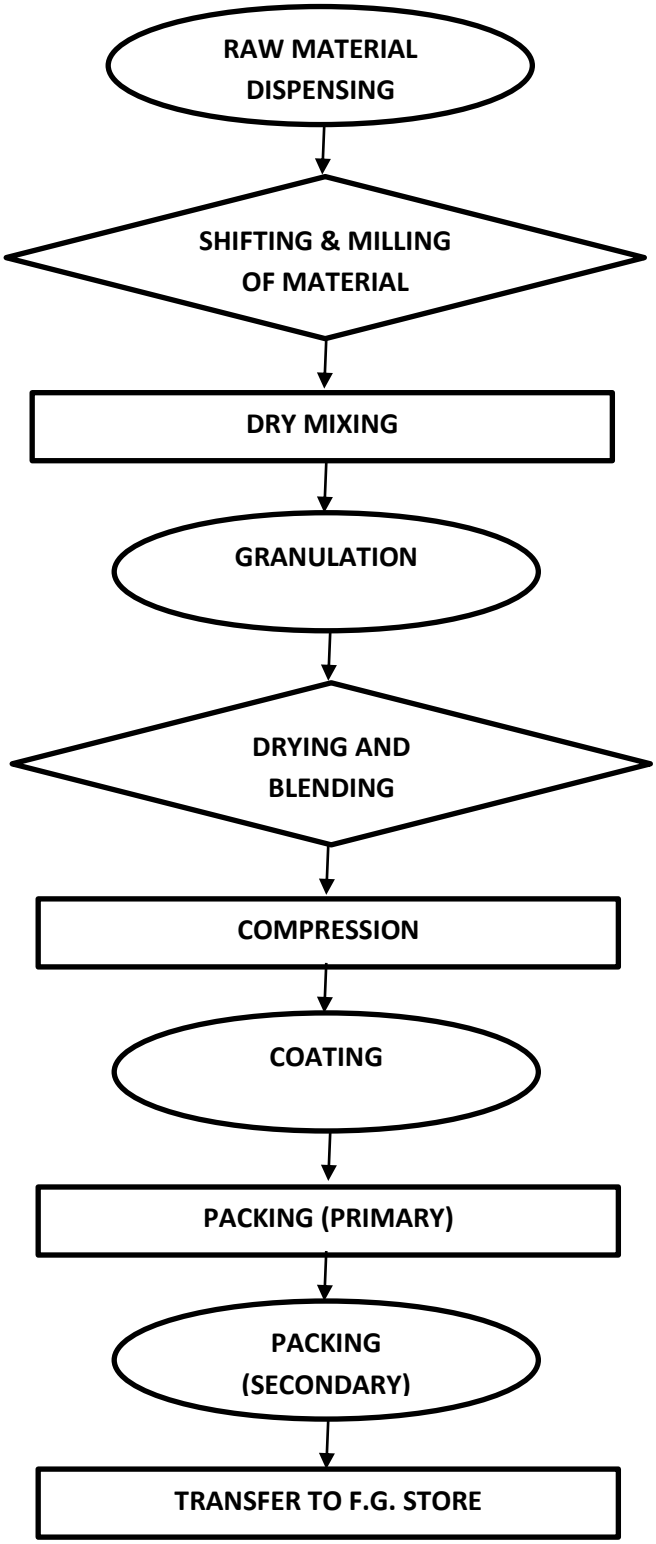
D. Size and Magnitude of the operation.

M/s Rusan Pharama Ltd. has proposed expand its production capacity and incorporation of some new products as follows:-

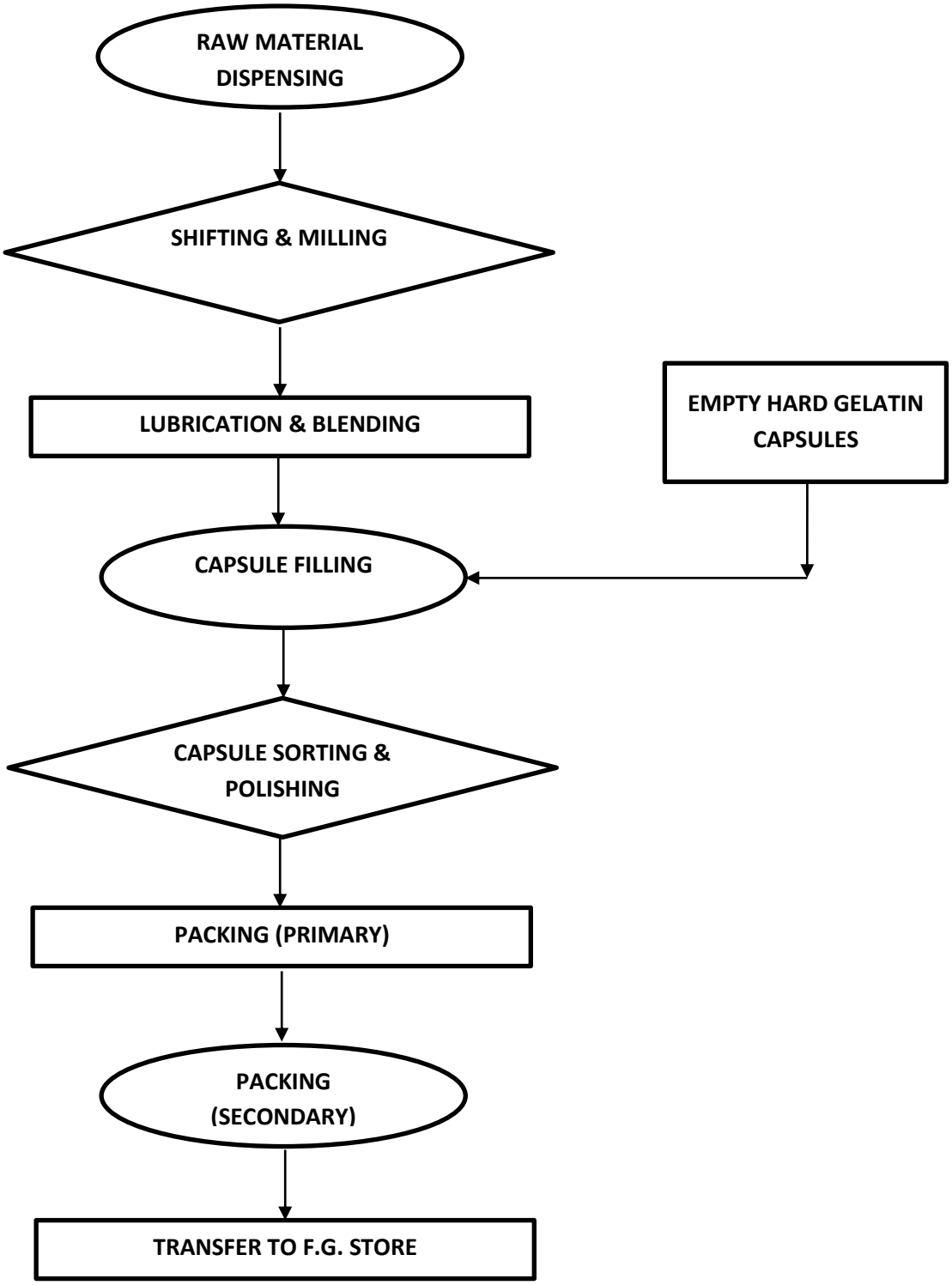
S. No.	PRODUCTS	Existing Capacity	Proposed Capacity	Total Capacity
1.	Tablets	93.0 lacs/ day	50.33 lacs/day	143.33 lacs/day
2.	Capsules	18.0 lacs/day	NIL	18.0 lacs/day
3.	Injections - Ampoules	1.40 lacs/day	2.66 lacs/day	4.066 lacs/day
4.	Vials	NIL	1.334 lacs/day	1.334 lacs/day
5.	Transdermal Patch	NIL	28,800 nos/day	28,800 nos/day
6.	Liquid Line (no. of bottle)	NIL	31,200 nos/day	31,200 nos/day
7.	Pre Filled Syringe	NIL	50,000 nos/day	50,000 nos/day

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

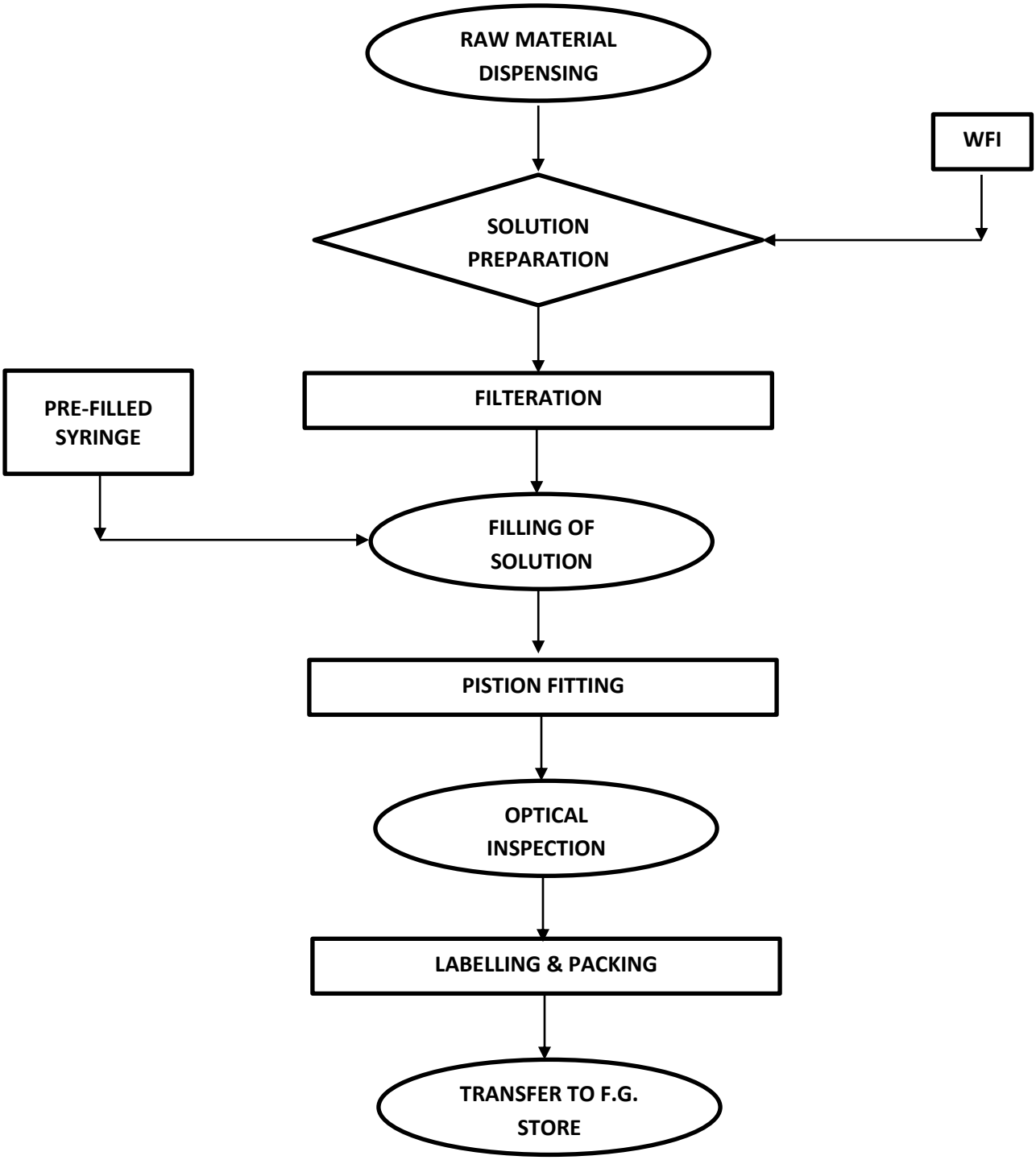
TABLET MANUFACTURING PROCESS FLOW CHART



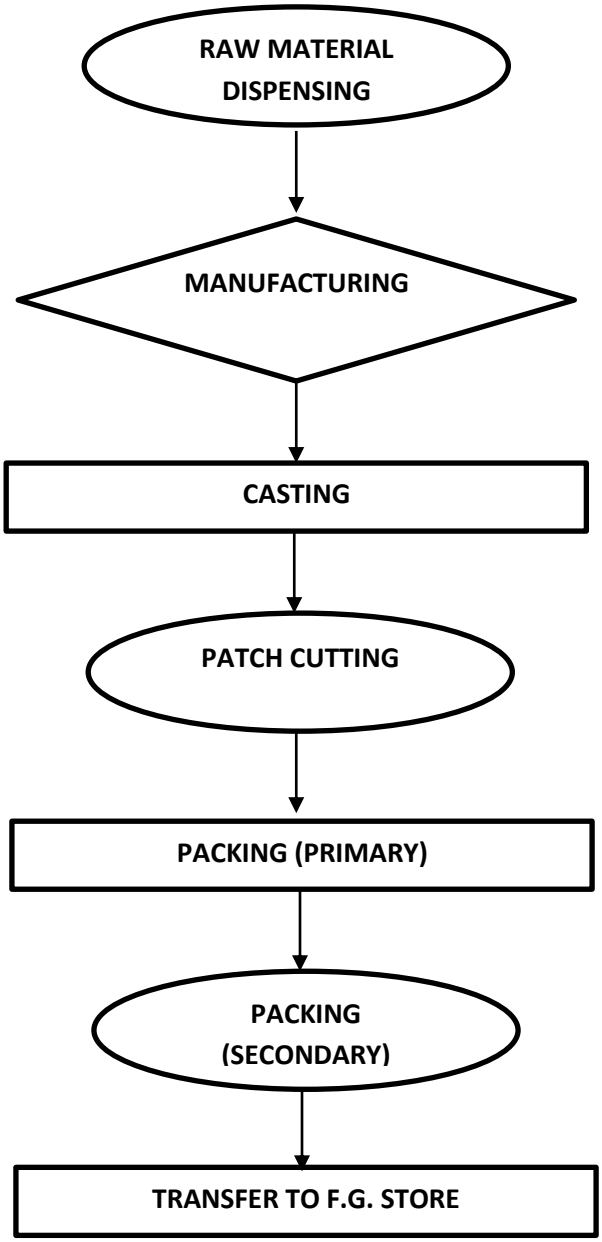
CAPSULES MANUFACTURING PROCESS FLOW CHART



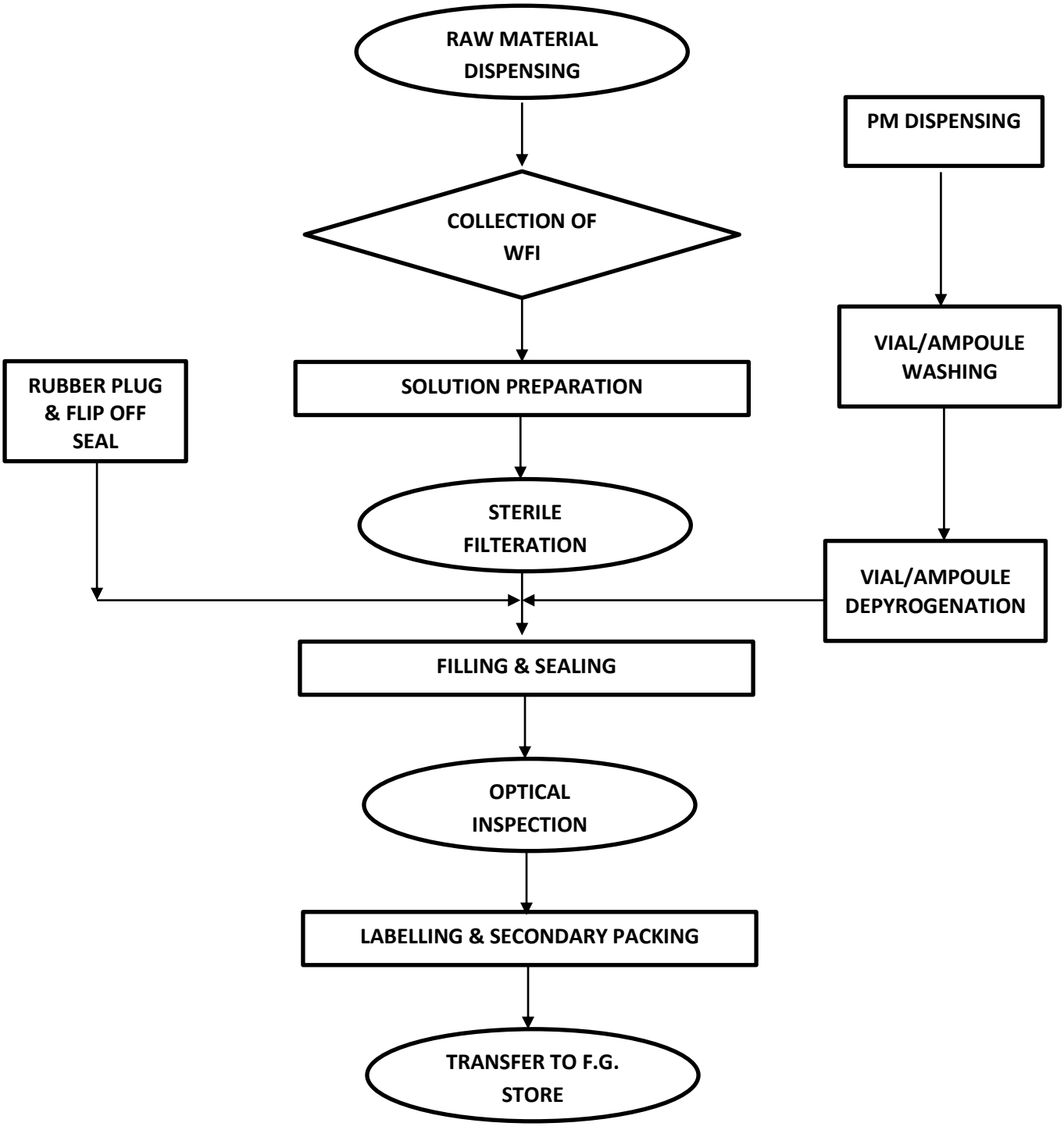
PFS MANUFACTURING PROCESS FLOW CHART



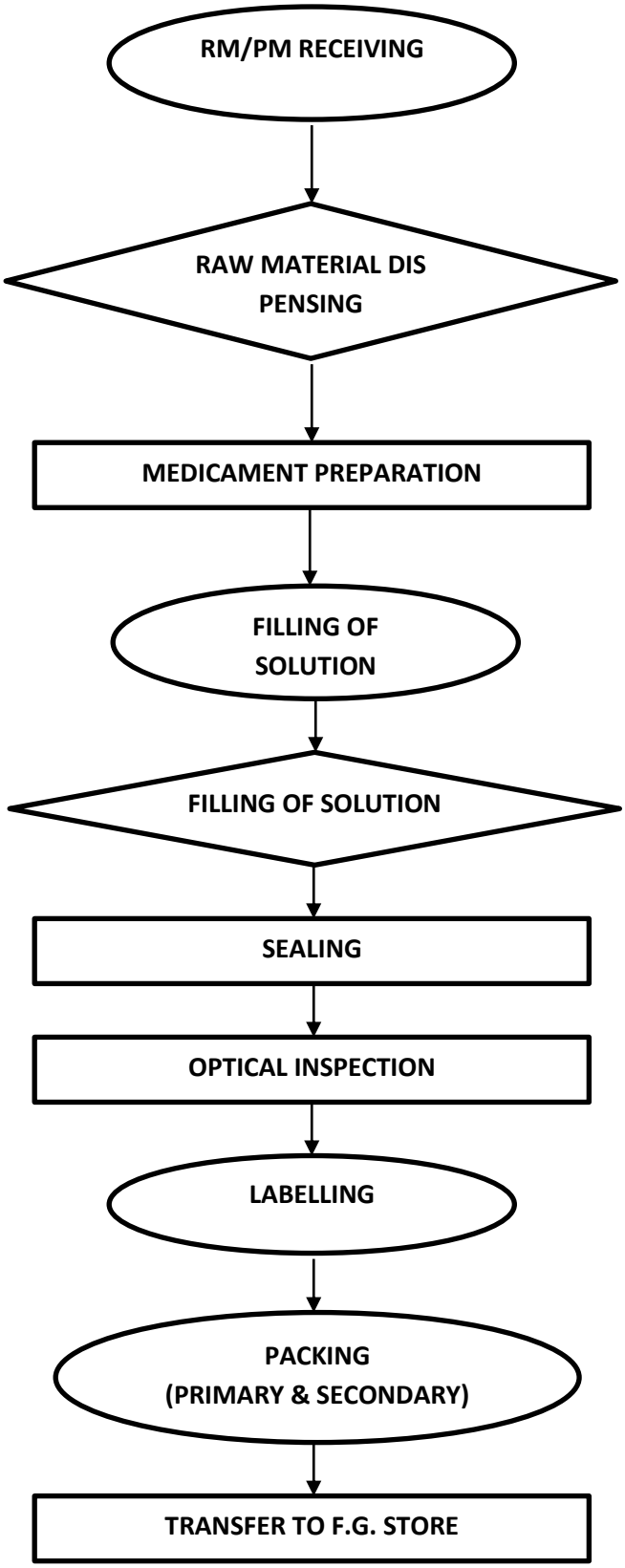
TRANSDERMAL PATCH MANUFACTURING PROCESS FLOW CHART



SMALL VOLUME PARENTERNALS MANUFACTURING PROCESS FLOW CHART



ORAL LIQUID MANUFACTURING PROCESS FLOW CHART



F. 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 ACTIVE PHARMACEUTICAL INGREDIENTS (API)

Sr. No.	Name of API	Sr. No.	Name of API
1.	Calcium Dobesilate Monohydrate	34.	Buprenorphine Base
2.	Loperamide Hydrochloride	35.	Promedol (As Hydrochloride)
3.	Tramadol Hydrochloride	36.	Chlorpheniramine Maleate
4.	Buprenorphine Hydrochloride	37.	Betamethasone Sodium Phosphate
5.	Diclofenac free acid	38.	Noradrenaline Bitartrate
6.	Bisoprolol Fumarate	39.	Bromhexine Hydrochloride
7.	Diazepam	40.	Phenylephrine Hydrochloride
8.	Haloperidol	41.	Lidocaine Hydrochloride
9.	Metformin Hydrochloride	42.	Opium
10	Cinnarizine	43.	Ethanol
11.	Domperidone	44.	Codeine Phosphate
12.	Naltrexone Hydrochloride	45.	Bupivacaine HCl
13.	Propranolol Hydrochloride	46.	Dextrose
14.	Methadone Hydrochloride	47.	Cotrimoxazole
15.	Folic Acid	48.	Dexamethasone
16.	Morphine Sulphate	49.	Furosemide
17.	Sotalol Hydrochloride	50.	Hyoscine-N-Butyl bromide
18.	Paracetamol	51.	Neostigmine
19.	Sulfamethoxazole	52.	Pethidine
20.	Trimethoprim	53.	Sufentanil
21.	Naltrexone base	54.	Verapamil
22.	Fentanyl	55.	Alfentanil
23.	Nicotine	56.	Clonazepam
24.	Nalbuphine hydrochloride dihydrate	57	Diclofenac sodium
25.	n- Butylcyanoacrylate	58.	BetamethasoneDipropionate
26.	Atropine Sulphate	59	Etomidate
27.	Enoxaparin Sodium	60.	Ketamine
28.	Fentanyl Citrate	61.	Lorazepam
29.	Metoclopramide Hydrochloride Monohydrate	62.	Phenytoin
30.	Midazolam	63.	Propofol
31.	Nadroparin Calcium	64.	Trenaxamic acid
32.	Naloxone Hydrochloride	65.	Zuclopenthixol acetate
33.	Rivastigmine	66.	Zuclopenthixol deaconate

G. Power Requirement:

At present total Power requirement of 750 KVA is being met from Uttarakhand Power Corporation Ltd. As such additional 250 KVA is required to meet the demand which is proposed to get from UPCL, as such after expansion Total Power will be 1000 KVA from UPCL.

The existing & proposed capacity of DG Set & Boiler is given as under:-

Sr. No.	Particular	Existing Capacity	Proposed Capacity	Total Capacity
1.	Boiler	850 Kg/Hr	850 Kg/Hr	1700 Kg/Hr
2.	DG Set	500 KVA	1000 KVA	1500 KVA

DG set shall be used at the time of power failure only.

H. WATER REQUIREMENT AND SUPPLY SYSTEM

Water requirement in industrial process shall be 30 KLD which will be met from bore wells. Water required for domestic consumption shall be around 25 KLD most of this shall be met from recycling of treated effluent.

Water Consumption (Quantity)

Use Of Water	Existing Qty of Water Required	Proposed Qty of Water Required	Total Qty of Water Required
For Process Purpose	10 KLD	**20 KLD**	**30 KLD**
For Domestic Purpose	05 KLD	**20 KLD**	**25 KLD**

Waste Water Discharge (Quantity)

Use of Water	Existing Discharge	Proposed Discharge	Total Discharge	Treatment Method	Reuse of Water
From Process	06 KLD	**10 KLD**	**16 KLD**	ETP 20 KLD (Existing)	Gardening & Flushing
From Domestic	04 KLD	**16 KLD**	**20 KLD**	STP 20 KLD (Proposed)	Road Washing

SITE ANALYSIS

A. Connectivity

Well connected with Road, Rail and air service

Nearest Railway Station	Dehradun Railway Station 35 Km
Nearest Airport	Jolly Grant Airport, 75 Km
Nearest Highway	NH 72, 2 Km

B. Land form, Land use and Land owner ship

Flat and barren land having Industrial use falling at Khasra No 122 I, Central Hope Town, Selaqui, Dehra Dun.

C. Topography –

Land is flat and barren with inclination towards South

D. Existing land use pattern

The existing land use is Industrial.

E. Existing Infrastructure

Industrial Land for has been purchased by this company on which all infrastructure has been constructed and developed by the company itself.

F. Climatic data from secondary sources

Monthly mean maximum & minimum temperature and total rainfall data have been given below:

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 Bore well.

I. Sewage System.

Already soak pit and septic tank arrangement has been provided for the waste generated from toilets and domestic use. As such during expansion STP has been proposed.

J. Industrial Waste Management.

Effluent Treatment Plant is in existence to treat industrial waste water.

K. Solid Waste Management

1. Solid waste generated from sludge drying beds of ETP is being disposed to TSDF as per the norms of State Pollution Control Board.
2. Used oil is being disposed to authorized recycler.
3. Expired drugs are being disposed as per Hazardous Waste & Management Rules & Regulation.

L. Power Requirements & Supply/ source.

At present total Power requirement of 750 KVA is being met from Uttarakhand Power Corporation Ltd. As such additional 250 KVA is required to meet the demand which is proposed to get from UPCL, as such after expansion Total Power will be 1000 KVA from UPCL. In absence of Electricity D.G. Set is there and Existing D.G. Set capacity is 500 KVA and proposed capacity is 1000 KVA **Required capacity will be 1500 KVA** and Existing Boiler capacity is 850Kg/Hr and proposed capacity is 850 Kg/Hr **Required capacity will be 1700Kg/Hr.**

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 industry and is established in an Industrial Area.

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, 2016, 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	1.4MT/annum
2	34.2	Dried ETP sludge.	0.8 MTA
3	28.4	Expired finished product and raw materials	0.6 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 enhance its capacity after expansion within 6 Months.
- Funds requirement is **(49.15 Cr Existing + 10.85 Cr Proposed)** including the machinery and plant.

9.0 ANALYSIS OF PROPOSAL (FINAL RECOMMENDATIONS)

The expansion in product capacity and incorporation of new products by M/s Rusan Pharma Ltd. is being proposed keeping in view the ever growing demand of pharmaceutical products in the market. The company is having vast experience and expertise in this field and having three formulation units, two at Kandla (Gujrat) and third at Dehra Dun (Uttarakhand). Due to this expertise it has been exporting its products to various countries. The expansion program by M/s Rusan Pharma is feasible from all aspects after going through the capabilities and experience of the company. The expansion will also contribute in the generation of employment and 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.