MEDICAL GRADE PETROLEUM JELLY

1. INTRODUCTION

The project proposes to establish a small scale unit to manufacture Petroleum Jelly. This would mainly be of pharmaceutical grade.

Petroleum Jelly works by creating a sealing barrier between cells in dry or damaged skin which locks in moisture and speeds up your skin's natural recovery process, helping it to heal from within. Its occlusive function allows it to protect dry skin, cracked skin, minor cuts, scraps, and burns. It also helps to reduce the appearance of fine, dry lines. Petroleum Jelly can also be used to protect your skin and lips against dryness and chapping.

Petroleum jelly, petrolatum, white petrolatum, soft paraffin/paraffin wax or multi-hydrocarbon, is a semi-solid mixture of hydrocarbons (with carbon numbers mainly higher than 25), originally promoted as a topical ointment for its healing properties.

2. PRODUCT AND ITS APPLICATION

Petroleum Jelly is also known as Mineral Jelly or Petrolatum. It is mostly used in emulsion form in cosmetics & pharmaceutical for the preparations of various creams, ointments, lotions etc. Commercial Petroleum Jelly is used in the manufacturing of lubricants & Grease. Petroleum Jelly of good quality is used in Vaseline manufacturing. It is also used as a moisturizer in good quality toilet soaps. It also finds its use as an anti-rusting agent for iron goods like blade, wire surgical instruments etc.

It is available in the market in various forms. It may be white, yellow, and green or may be of some color depending upon ingredients used.

This project is prepared for white petroleum jelly, which can be used in cosmetics and pharmaceuticals. Hence strict quality control is required for the manufacturing of this item.

After petroleum jelly became a medicine chest staple, consumers began to use it for many ailments as well as cosmetic purposes, including toenail fungus, genital rashes (non-STD), nosebleeds, diaper rash, and chest colds. Its folkloric medicinal value as a "cure-all" has since been limited by better scientific understanding of appropriate and inappropriate uses. It is recognized as an approved over-the-counter (OTC) skin protectant, and remains widely used in cosmetic skin care.

The product mix varies depending upon quality and use of final product.

The suggested product mix is as follows

Sr. no	Product	Quantity
1	Paraffin Wax	20 %
2	Microcrystalline Wax	20 %
3	White Oil	60 %

Petroleum jelly is a mixture of hydrocarbons, having a melting point usually within a few degrees of human body temperature, approximately 37 °C (99 °F). It is flammable only when heated to liquid; then the fumes will light, not the liquid itself, so a wick material like leaves, bark, or small twigs is needed to ignite petroleum jelly.

It is colorless, or of a pale yellow color (when not highly distilled), translucent, and devoid of taste and smell when pure. It does not oxidize on exposure to the air and is not readily acted on by chemical reagents. It is insoluble in water. It is soluble in dichloromethane, chloroform, benzene, diethyl ether, carbon disulfide and oil of turpentine.[1] [5]

Depending on the specific application of petroleum jelly, it may be USP, B.P., or Ph. Eur. grade. This pertains to the processing and handling of the petroleum jelly so it is suitable for medicinal and personal care applications.

3. DESIRED QUALIFICATION FOR PROMOTER

The promoter preferably should be having formal qualifications in the field of pharmacy (B.Pharm. or D. Pharm). A science graduate would also be fine. Further he / she should have experience of working in a unit manufacturing such product.

4. INDUSTRY OUTLOOK/TREND

Petroleum & related industries in India is growing at about@ 7-10 % per annum. The products in pharmaceuticals & cosmetics are well developed and growing. The present trend is to go for environment friendly products.

5 MARKET POTENTIAL AND MARKETING ISSUES, IF ANY

The product under consideration would be mainly be used by the Pharmaceutical and cosmetics industry. In some cases, pharmaceutical grade Petroleum Jelly can be used directly also.

In today's business word, more and cosmetics industries are coming up and thereby increasing the demand for the raw materials like petroleum jelly. Hence it can be assumed that the petroleum jelly is having very good market potential in view of development of cosmetic & pharmaceutical industry in India. Present demand for petroleum jelly including export demand is around 70000 metric tons per annum Growth rate in demand for 2021 @ 7% per annum.

The Indian Pharmaceutical industry is highly fragmented with about 24,000 players (around 330 in the organised sector). The top ten companies make up for more than a third of the market. The Indian pharma industry accounts for about 1.4% of the world's pharma industry in value terms and 10% in volume terms.

Besides the domestic market, Indian pharma companies also have a large chunk of their revenues coming from exports. While some are focusing on the generics market in the US, Europe and semi-regulated markets, others are focusing on custom manufacturing for innovator companies.

The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, as per a report by Equity Master. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume. Of late, consolidation has become an important characteristic of the Indian pharmaceutical market as the industry is highly fragmented.
The Indian pharma industry, which is expected to grow over 15 per cent per annum between 2015 and 2020, will outperform the global pharma industry, which is set to grow at an annual rate of 5 per cent between the same period. The market is expected to grow to US$ 55 billion by 2020, thereby emerging as the sixth largest pharmaceutical market globally by absolute size, as stated by Mr. Arun Singh, Indian Ambassador to the US. Branded generics dominate the pharmaceuticals market, constituting nearly 80 per cent of the market share (in terms of revenues).

India is primarily a retail-based branded generic market with 80% dispensed through pharmaceutical outlets. As in most emerging economies, acute therapies dominate and account for close to 70% of the market. Acute Therapies – target short duration diseases – cough & cold, fever, pain – such as anti-infective, analgesics, pain-killers.
Various Cosmetics and pharmaceuticals are used by the large number of people in general for wounds, cuts, burns, skin diseases.
In today’s business word, more and cosmetics industries are coming up and there by increasing the demand for the raw materials like petroleum jelly. Hence it can be assumed that the petroleum jelly is having very good market potential in view of development of cosmetic & pharmaceutical industry in India

The project is for manufacture of petroleum jelly in very small scale. There are many such units all over India. These include Unicorn Petroleum, Mumbai, Krishna Chemicals, Ahmedabad, Arjun Beeswax Company, Baroda, Kunduz petrochem, Kolkata, etc.

6 RAW MATERIAL REQUIREMENTS

The unit would require Paraffin Wax, Microcrystalline Wax, White Oil and such other active ingredients.

The project would also require packaging materials and consumables.

All of the above are easily available in India.

7 MANUFACTURING PROCESS

Petroleum waxes are broadly classified into two types paraffin and microcrystalline. Paraffin waxes distill at temperatures less than about 8500F and are thus components of light paraffin distillates. The higher boiling intermediates and heavy paraffin distillates and paraffin residual oils contain microcrystalline waxes.

When light paraffin distillates are cooled, the wax separates in large, plate-like crystals. Cooling of the heavier distillates and residual oil does not produce obvious crystals; the wax separates as very small particles (micro crystals) which cause the oil to set to a paste or a jelly. A mixture of 30 to 50 percent heavy oil and microcrystalline wax forms petrolatum or petroleum jelly.

Petrolatum is a colloidal suspension of microcrystalline waxes in heavy oil with melting points ranging from 1100 to 1350F.

First of all, the ingredients are weighed as per the formulations. Now paraffin wax is taken in to reaction vessel with electrical heater (Jacketed). Now micro crystalline wax is added in to reaction vessel. Both the waxes are then melted with continuous mixing and the temperature is maintained between 1200 – 1300 C.

Now liquid paraffin is added with continuous stirring (150-200 rpm) at constant temperature, so that ingredients are mixed together to form emulsion or jell. The whole mass is cooled down and sample is taken for testing. After testing, material is packed in suitable containers

The products would have to be manufactured as per standards laid down in IP, BP and such book of standards.

Further it would be under the Food and Drugs Control Authority (FDCA).

The Drugs and Pharmaceutical Industry in general is highly regulated in India. Regulatory authorities at the Central level and the State level monitor the same.

At the Central level, the **Central Drugs Standard Control Organisation (CDSCO**), Ministry of Health & Family Welfare, Government of India is the apex organisation. At the state level the **Food and Drugs Control Authority (FDCA**) is the regulatory authority.

Drugs & Cosmetics Act and Schedule M

These authority monitor and control the production of Drugs and Pharmaceutical products under the provisions of **the Drugs and Cosmetics (amendment) Act, 2005 & 2008** and guidelines (July 2015).

The revised **Schedule M** under this Act is the main basis which specifies the detailed norms for location; building premises plant lay out, building, plant & machinery, manufacture, sterilization, packaging, quality control and such other key components.

Good Manufacturing Practices (GMP)

The Drugs and Pharmaceutical Industry in general is highly regulated in India. Regulatory authorities at the Central level and the State level monitor the same.

The revised **Schedule M** under this Act is the main basis which specifies the Further the pharma units in general and such sterile products manufacturing units in particular would also have to comply with following

- Good Manufacturing Practices (GMP),
- Current Good Manufacturing Practices(cGMP) and
- WHO-GMP

Good manufacturing practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

WHO-GMP certification is essentially for the plant set up, manufacturing facilities and related aspects. However **Certificate of Pharmaceutical Products (CoPP**) is also required for each of the products to exporting the same. This is given only after six months (stability period) of getting WHO-GMP Certificate.

Current GMP (cGMP) is essentially an updating of the systems and facilities as per the requirement of regulated pharma market at the international level

The above are in the form of guidelines and not part of any Act (except basic GMP). However they are essential to follow and implement to fulfill the requirement of the industry and the international market.

Further highly systematic documentation and record keeping is a must as per the requirement of concerned authorities.

It is to be noted that the Department of Health and Family Welfare proposes to introduce the **Drug and Cosmetics (Amendment) Bill, 2015**. This is in process. As and when this is passed and put into effect by way of an Act, all the Drugs and Pharmaceutical units (existing and new) would have to follow the norms under the amended act.

8 MANPOWER REQUIREMENTS

Sr. No.	Designation	Number	Approx. Salary Total (Rs. Per month)
1	Manufacturing chemist	1	12000
2	Production supervisor	1	10000
3	Manager	1	10000
4	Office staff & marketing executive	3	20000
5	Skilled workers	7	25000
6	Unskilled workers	5	10000
7	Sub total		87000
	Perks @ 15 %		13050
	Total		100500/-

9 IMPLEMENTATION SCHEDULE

The implementation time required for this project will be approximately 9 months after arranging the finance from the bank.

Sr. No	Activity	Time
1	Preparation of Project report	One month
2	E M Registration & approval from FDCA	One month
3	Financial/Loan from Banker or Financial Institutions	Two months
4	Power connection/Building construction Six months	One month
5	Machinery procurement & Trial run.	Two months
6	Recruitment of Staff & Labour	One month
7	Actual commercial production	One month

10 COST OF PROJECT

The total cost of project is estimated as below:

Sr. No	Component	Particulars	Cost (Rs. Lakhs)

1	Land	700 sq. mts	3.50
2	Building	250 sq mts	5.00
3	Plant & Machinery including QC		10.00
4	Other Assets		0.50
5	P & P Expenses		0.50
6	Contingencies		1.50
7	WC Margin		1.20
	Total		22.20

11 MEANS OF FINANCE

- Term Loan : Rs.15. 00 lakhs
- Promoter own contribution : Rs.7.20 lakhs

12 WORKING CAPITAL CALCULATION

Sr. No	Particulars	Duration	Total Estimated cost (Rs. Lakhs)
1	Raw materials/ Packing materials	15 days	**1.50**
2	Working expenses	1 month	**0.70**
3	Finished goods	7 days	**0.50**
4	Receivable	15 days	**1.00**
	Total		**3.70**

13 LIST OF MAIN MACHINERY REQUIRED & SOURCES

Sr. no.	Machine	Number	Approx. Total Cost (Rs. Lakhs)
1	Cylindrical Aluminum jacketed Reaction Vessel	2	3.00
2	Aluminum Storage Vessels Cap:250 Kg each	4	4.50
3	motor & stirrer	1	0.50
4	Quality Assurance & Quality Control equipments		2.00
5	**Total**		10.00

Indicative Sources:

- Harsidhdha Engineers, Kathwada, Ahmedabad
- Filmatic Systems, Thane(West), Mumbai
- Bhavani Engineering Works, Vatva, Ahmedabad

Note: All machinery to be of GMP standards

14 PROFITABILITY CALCULATIONS

Basis & Presumptions:

a. The production is based on single shift of eight hours and 300 working days per annum.

b. The cost in respect of Plant & Machinery has been taken at the time of preparation of Project Profile, which may vary from place to place and time to time.

c. Labour charges have been taken as per Govt. norms.

d. It is presumed that plant will work at 50% efficiency in the first year, 60% in the second year and 70% in the third year.

- **Annual production capacity Recommended**

  150 M.T. per Annum

  At assumed 100% capacity utilization (indicative):

  - Total Sales turnover: 120.00 lakhs
  - Cost of production & other expenses:100.00 lakhs
  - Profit : 14.00 lakhs

Profitability projections (Indicative only)

Particulars	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
Capacity utilisation (%)	**60**	**75**	**80**	**80**	**80**
Production (TPA)	90	112.50	120	120	120
Sales	72.00	90.00	96.00	96.00	96.00
Expenses	60.00	75.00	80.00	80.00	80.00
Gross profit	12.00	15.00	16.00	16.00	16.00
Profit to Sales (%)	16.50	17.00	18.00	18.00	18.00

Key Assumptions and The basis of profitability calculation:

As mentioned above, The Unit will have capacity of 150 M.T. of **Patroleum Jelly (medical grade)** per Annum. The capacity build up is taken considering the sales related from OEM/ Retail network that is built up by the entrepreneur based on his prior experience in the industry.

This project has to have group of products of different specifications. The sales prices of these products vary. Accordingly an average sales price of Rs.1.25 lakh per ton has been assumed. The cost of production, inclusive of major cost heads such as raw materials, labour & power has been considered based on prevailing industry standards and assumed @ 80 %.

On indicative basis, power Costs are considered at Rs 7/- per Kwh and fuel cost is considered at Rs. 50/- to 60/- per litre. The depreciation of plant is taken at 10-12 % and Interest costs are taken at 12 %- 14% depending on type of industry. All these are wherever applicable.

It may be kindly noted that basis / assumptions for such kind and size of the projects in a profile can be on indicative basis only. At the same time it does provide a reasonably accurate scenario.

15 BREAKEVEN ANALYSIS

FC X 100: 15.00 X 100 = 1500

FC + Profit: 15.00 +16.00 = 31

BEP = 45.00 %

16 STATUTORY/ GOVERNMENT APPROVALS

There is no specific statutory requirement. However MSME & GST registration, IEC Code for Export of end products and local authority clearance may be required for Shops and Establishment, for Fire and Safety requirement and registration for ESI, PF and Labour laws may be required if applicable. And promoter has to take approval from Pollution Control Board.

17 BACKWARD AND FORWARD INTEGRATION

As forward integration, Entrepreneur may think of going for the production of Cosmetics.

18TRAINING CENTERS/COURSES

For such industry training and short term courses may be availed from the Chemical engineering department's o reputed Universities. Also EDPs of respective states.

Udyamimitra portal (link : www.udyamimitra.in ☒) can also be accessed for handholding services viz. application filling / project report preparation, EDP, financial Training, Skill Development, mentoring etc.

Entrepreneurship development programs help to run businesses successfully and are available from Institutes like Entrepreneurship Development Institute of India (EDII) and its affiliates all over India.

Disclaimer:

Only few machine manufacturers are mentioned in the profile, although many machine manufacturers are available in the market. The addresses given for machinery manufacturers have been taken from reliable sources, to the best of knowledge and contacts. However, no responsibility is admitted, in case any inadvertent error or incorrectness is noticed therein. Further the same have been given by way of information only and do not carry any recommendation.

Source:- Udyami Mitra/Sidbi