

UNIVERSITY OF COCHIN

B. TECH. COURSE

IN RUBBER PROCESSING AND TECHNOLOGY

PROJECT REPORT ON

A SMALL SCALE UNIT TO BE ESTABLISHED
IN KERALA

FOR MANUFACTURING

PHARMACEUTICAL CLOSURES

DISSERTATION

SUBMITTED BY:-

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FOREWORD

This Project Report has been prepared and submitted in the form a dissertation unlike project reports to procure loans to start new Industries. The primary mission of this dissertation is the partial fulfilment of my B.Tech. degree. From the point of view of a dissertation work I believe that the extra details given on technical aspects are justifiable.

However, I do not claim this report to be exhaustive and complete in all respects. But I hope that this will serve as a guideline for action to be followed.

I take this opportunity to express my thanks to all persons who helped me in my endeavour and in particular to Mr. C.M. George, Project Officer; Mr. E.V. Thomas, Dy. Director, Mr. M.K. Balagopalas Nair, Chemical Engineer; and Mr. P.W. George, Cost Accounts Officer of Rubber Board and Rubber Research Institute of India.

KOTTAYAM -9,
18TH MARCH, 1977.

T.N. VIJAYAN.

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HIGHLIGHTS OF THE PROJECT

NUMBER OF SHIFTS 2.

1. TOTAL INVESTMENT	4,97,500.00
2. TOTAL FIXED ASSETS	3,57,000.00
3. OWN CAPITAL	93,000.00
4. BUILT UP AREA REQUIRED	1800 Square Feet
5. WORKING CAPITAL	1,40,500.00
6. PERSONNEL REQUIREMENT	32
7. ANNUAL OUT PUT	30 Million Closures
8. BREAK - EVEN PRODUCTION	15.9 Million Closures
9. ANNUAL COST OF PRODUCTION	6,56,000.00
10. ANNUAL INCOME FROM SALES	8,12,250.00
11. NET PROFIT	1,09,375.00

THIS PROJECT IS INTENDED

FOR

THE MANUFACTURE OF

30 MILLION PHARMACEUTICAL

CLOSURES PER ANNUM.

SECTION.A. INTRODUCTION

1. GENERAL

Rubber has got vast applications in the medical field. Natural and synthetic rubbers are being used in this field. Some are used in contact with medicines while others actually find place inside the human body. Naturally the human body is reluctant in accepting foreign bodies. This posed a big problem to the Surgeons in the replacement of certain parts of the body with some artificial substitutes. Considerable work is reported in this field using various synthetic rubbers especially Silason rubber, which was found to be acceptable to the human body. Thus in modern days it has even become possible to replace the valves of human heart with rubber valves made of Silicon. These are instances where rubber actually occupies a position in the interior of the body. No less is the significance of situations where rubber is used in contact with medicines that are taken in. Here rubber is found as pharmaceutical moulded items like closures for various pharmaceutical preparations, injections etc. and extruded items like transfusion tubing etc. A critical combination of a list of properties are required for these items. Rubber is put to these challenging requirements solely due to the highly versatile nature of the item - rubber. Rubber has got the majority of the properties called for for application in this field.

2. PRODUCT DESCRIPTION

Medical and pharmaceutical products are specifically designed for introduction into the human body by injection.

(v) Swelling (vi) Compression Set (vii) Extraction of accelerator residues (viii) Toxicity (ix) Friction.

A number of natural and synthetic elastomers provide a unique combination of properties which enable them to be compounded into products which meet special requests for pharmaceutical closure for parenteral products. These materials permit easy passage of a hypodermic needle through the closure without damaging the point, and without requiring undue force to insert, and it maintains sufficient resilience to provide immediate resealing after withdrawal of the needle.

Natural rubber is still widely used as a general purpose elastomer for closures. Since these closures are an integral part of the drug product package, this must come under the same rigid control and standards as the product itself.

I.S.I. has laid down specifications for pharmaceutical closure. This is given in Annexure 6.

For successful production of the item, the following are required (i) Complete record of incoming raw materials - grade, type, lot number, quantity, supplier's name etc. (ii) Lab. testing of all raw materials (iii) Records of analysis of all raw materials

After the purchase of closures, the manufacturer's of pharmaceutical items subject these closures to some treatments. The closures should, therefore, be designed so as to enable them to be subjected to these treatments. Common treatments are discussed below

1. Washing is the first treatment. This is to remove the surface dirt, lint, fibres etc with which closures become contaminated during

shipping and handling. Some types of non-toxic detergents are also used for this. These should have a pH range of 5.5 to 7.5 and should have good surface tension and surface activity and good solubility in water.

2. Drying and Sterilization is the next operation. This is usually conducted in hot air dryers at 100 to 110°C for 3 to 5 hours.

Surface treatments:

Various surface treatments are also given to obtain certain special properties. Some of these are (i) Silicon treatment- Here a thin film of inert Silicon lubricant is given to reduce surface friction. (ii) Halogenation:- This is a chemical treatment which results in slightly hardened surface having a reduced coefficient of friction. Although this treatment does harden the surface and reduce the coefficient of friction thus improving the feeding rate of closures in automatic stoppering equipment, it also may cause sealing problem. Closures which have been treated in this manner require more head pressure for sealing than untreated or Silicon treated closures. (iii) Conditioning:- When closures are to be used with aqueous products containing preservatives such as phenol, Sodium bisulphate, Benzyl alcohol etc. it has been found that it is often beneficial to soak closures for 10 to 12 hours in a dilute solution of preservatives after washing and rinsing. When this procedure is used, the stoppers may be drained and used without an excessive drying process. This small unit is intended for the manufacture of Pharmaceutical Closures made from natural rubber. According to this plan the unit is intended to produce 30 Million closures per annum. Two shift working is envisaged. The annual consumption 45 To

3. PROSPECTS

The developments in the field of medicines need no emphasis. It is ever on the increase. New medicines are being launched into the market everyday. Also the production of medicines, as the quantity produced is concerned, is increasing tremendously. More and more people now has begun to depend on such medicines which have already proved their efficacy in curing various diseases. Thus consumption is on the increase which in turn calls for increased production. Pharmaceutical closures have wide use in the field of medicine. These are being consumed in millions every day by the medicine manufacturers. So far no major substitute has come to the scene for replacing rubber closures, especially closures for various kinds of injectable medicines. Rubber has got its superiority in this field. So an ever increasing trend in the production of medicines clearly shows the increasing demand for this item. From the above, it is very clear that there is very bright prospects in the future for such a unit.

4. PRODUCT DIVERSIFICATION:

In this small project, the major machinery employed are mixing mill, Hydraulic presses, Boiler etc. In fact these are all basic rubber machinery. No specialised machines are employed here. These make it highly flexible. A diversification in the product line is not at all difficult in this case. Without any change in the existing set up it is possible to manufacture the variety of moulded goods. Only the moulds need to be changed. In a wider sense, this is a highly flexible unit in which product diversification can be effected easily, without much losses,

Even though there is so much flexibility it seems that product diversification needs not much consideration in the immediate future since there is very good demand for the proposed product.

SECTION.B. MARKET SURVEY

1. User/Customer Analysis

The sole consumers of this item are the manufacturers of medicines. At present there are more than 50 major units in India engaged in the manufacture of medicines. These are all very big consumers of the item. They, themselves consume millions of closures per day for their products. There are a large number of smaller units also engaged in the production of medicines. They also require these closures in huge quantities. Also, more and more new units are coming up. Now-a-days the capacities of the existing units are also being enhanced. The major consumption of Pharmaceutical closures is in the manufacture of injectable items like Penicillin, Streptomycin, Kanamycin, Tetracycline, Oxytetracyclines, Tetra Cycline hydrochloride etc. A long list of such medicines can be made where this type of closures are used. Apart from these injectable items, a large number of other items like ear drops, eyedrops etc, also use this type of closures in their packing.

The production of Penicillin and Streptomycin by two large units in our country is given below:-

Producer	Item	Quantity
Hindustan Antibiotics Ltd.	Penicillin	85.84 MMu
"	Streptomycin	80, Tons
Indian Drugs and Pharmaceuticals	Antibiotics	71.76 Tons
"	Penicillin	63.3 MMu

A survey conducted showed that most of the injectable items are coming to the market in small glass bottles containing about 3 to 4 grams of the medicine in each bottle. One closure is essential for each bottle. The production figures of such medicines show that they are of the order of Tons/year. These huge quantities are being packed in small individual bottles each containing as little as 3 to 4 grams. Considering that each bottle contains approximately 4 grams of medicine, one Ton of medicine will require approximately 3 lakhs of closures.

Now consider the production of streptomycin alone for a rough estimation. Here the production of Streptomycin at the two major units alone are considered i.e. at Hindustan Antibiotics and at Indian Drugs and Pharmaceuticals. Their total production of Streptomycin alone comes to about 150 Tons per year at present. This will require approximately 3.5 crores of closures. This is only for a single item -- Streptomycin -- produced by only two major units. Likewise considering the total production of all types of such medicines by all the manufacturers, it can be seen that the requirement of closures is of the order of hundreds of crores per year.

2. FEASIBILITY

The present project is intended for the manufacture of only 3 crores of closures per year. This will be only a very very small fraction of the total requirements. Such a unit has got good feasibility.

3. COMPETITIVE SITUATION

Though plastics have also found good use in the medical field it has not become a serious threat yet for rubber closures. As regard the existing production, about 25 units are engaged in the production

ingestion or infusion. Once present in the body, they are intended to initiate, alter or terminate some change in existing body chemistry. It is obvious, therefore, that great care needs to be exercised to control the identity, purity, potency, sterility, toxicity and therapeutic efficacy of the preparation. In the carefully controlled environment of today's leading pharmaceutical plants, manufacturing practices are designed to achieve these aims.

Once prepared in the desired form the preparations must be preserved unaltered as they are transported from the place of manufacture to the point of administration. It is, therefore, necessary to put this material into a proper container, the openings of which are made secure by some type of closure or seal. The primary use of rubber in this field of application may be classified under the general heading of "CLOSURES".

A closure is used in packaging pharmaceuticals to establish a seal in the open end or ends of the container, to confine the contents within a given volume, and to protect the product from contamination. In addition to its function as a closure, it must also permit the removal of the product when needed or required. This is frequently done by means of a hypodermic needle using therein a single or multiple penetration through the closure.

The pharmaceutical requirements for rubber closures include many properties peculiar to their specialised application. Some of these properties are (i) Coring and resealability (ii) Moisture, Vapour & Gas transmission (iii) Absorption rate of the closure and its ability to absorb certain type of chemicals (iv) Hardness

of Pharmaceutical closures. But none of these units is solely intended for this item alone. So if a small unit is set up for the manufacture of this item alone it will be very easy for the unit to conquer its share of the market. The main reasons for its success are (i) Being engaged in the production of a single item alone, it will be able to bring down the cost of production through various ways such as increased production through improved methods etc. (ii) Better quality standards can be set up and maintained through regular quality inspections and testings. (iii) Ability to supply the customers in large quantities without delay and according to their requirements and specifications. (iv) Ability to adjust production according to demand.

Also, bestowed with cheap and abundant power, Labour and raw materials a new entrepreneur from Kerala will be in a commanding position as far as competition in this field is considered.

4. SPECIFIC MARKET

The consumers of this product are the producers of medicines. Major units producing medicines are concentrated in the areas of Bombay, Hyderabad, Calcutta etc. Recently a new unit has come up in Kerala also — Kerala State Drugs and Pharmaceuticals, Alleppey.

5. GEOGRAPHICAL EXTENT OF THE MARKET

Most of the market is within the country. Overseas orders can be obtained. But export is not of much practical consideration as far as a small unit is concerned because of its difficulty to export and satisfy the large demands of importers. This can however, be realised through organisations dealing with the export of a large variety of items in bulk amounts.

SECTION.C. PRODUCTION REQUIREMENTS

1. Location

Location of the plant is a very important factor because (i) a plant is relatively immobile, and once it is established, it is permanent

(ii) Location has a considerable influence on operating cost and productivity.

Plant site is selected after consideration of the following factors:-

- (i) Availability of Raw Materials
- (ii) Availability of Labour
- (iii) Availability of Water, Power etc.
- (iv) Facilities of Transportation, Communication etc.
- (v) Satisfactory climate.

An Industrial Estate in Kerala is selected for implementing the project because of the following advantages.

(i) The Industrial Estate kindles the dormant capabilities of a potential industrial mind, always stimulating to start new Industries.

(ii) The little capital of the entrepreneur need not have to be locked up in bricks, mortar and other buildings materials. Land and building are available at cheaper rates.

(iii) Undue delay in getting electricity connection, water, transport facilities etc. are avoided.

(iv) Reduces over head expenses to the minimum

(v) Industrial Estate provides accommodation for Banks, Post and Telegraph Office, Canteens, Shops, Dispensaries, Recreation facilities, Reading Rooms etc.

(vi) The proximity to a wide variety of Industries will facilitate inter-

trading and inter-servicing.

(vii) Labour will be available in the grade and quantity needed.

(viii) Training facilities are available at less cost.

(ix) Through association, observations and consultations, the management problems could be understood and handled more efficiently in an Industrial Estate.

2. LAND AND BUILDING

In this proposed project the land and building is rented from an Industrial Estate.

The Industrial Estates in Kerala are providing 4 types of buildings usually. The type, size, area and rent are given below:-

Type	Size (in feet)	Area (in Sq.Ft.)	Rent (Rs.P.M)
A	76 x 46	3496 "	413.00
B	66 x 31	2146 "	290.00
C	47 x 22	1074 "	133.00
Special	124 x 63	7812 "	917.00

The requirements of the built up area for this small unit are given in details below:-

<u>Details</u>	<u>Area in Sq. Ft.</u>
Raw Material Storage & Compounding	300
Mixing, Blank preparation & Moulding	600
Office	200
Finishing and Inspection; Packing and storage	400
Laboratory	200
Toilet facilities	100
TOTAL	1800 Square feet.

According to this a 60'x30' size is sufficient. But the nearest type available from an Industrial Estate is the B type having an area 2146 Sq.Ft. size is 66'x31'. So this, type B, is selected for this unit. The rent is Rs.290/- per month.

3. PLANT LAY OUT

Various aspects are to be considered before fixing a layout.

The important points are

- (i) Materials handling (both internal and external) should be minimum.
- (ii) It should ensure continuous flow of materials.
- (iii) Storage capacities and their location.
- (iv) Expansion at a later date which should dovetail into the existing operations.

A typical layout for the proposed unit is given in the Annexure 3.

4. REQUIREMENTS OF MAIN ITEMS OF RAW MATERIALS

(i) Polymer: Polymers used in the manufacture of Pharmaceutical closures are NR, Synthetic Polyisoprene, Butyl, Silicon etc. Among these NR is the major polymer used. For this item pale crepe natural rubber is required. This is locally available with an uninterrupted supply. The annual requirement is approximately 23,500 Kg.

(ii) Fillers: The fillers used are Calcium Silicate and first quality China-clay. The requirements of these items per annum are

<u>Item</u>	<u>Annual Requirement Kg.</u>
Calcium Silicate	6,000
China-clay	12,000

(iii) Process Aids: To improve processing characteristics, process oil is used. Here paraffinic oil is recommended. About 700 Kg. of oil is required per annum.

(iv) Vulcanising System: This consists of the vulcanising agent sulphur, Accelerators and Activator. Their requirements per annum are as follows

<u>Item</u>	<u>Kg.per year</u>
Sulphur	350
MBTS	240
TMT	35
Zinc Oxide	700

A list of the suppliers of various raw materials is given in the annexure 9.

(v) Terms of Purchase of Raw Materials. All negotiations are done through banks. On a margin money of 30% the bank will spend 70% for the purchase of materials. The amount has to be paid back in 70 days with interest. The purchased material will be kept in the bank's godown and materials in small quantities are withdrawn whenever required, on payment of cash.

(vi) Requirements of Main Items of Machinery: The selection of appropriate machines is important since maximum utilisation of machinery gives better return for the money spent. The selection of machinery is based on the following considerations.

- a) Targetted Capacity B) Nature of the product c) Type of Production
- d) Its effect on the utilisation of all other machinery.

Based on these considerations the following machinery are selected for the production of Pharmaceutical closures from pale crepe rubber. The annual consumption of compound is about 45 Tons.

In this project a two shift operation is proposed. The number of working days per year is taken to be 300.

Mixing Mill A 12"x30" mixing mill will be of adequate capacity. The batch size is about 15 to 16 Kg. Here we use only one mill. The same mill will be used for warming up, reworking etc. Hence

there is adequate utilization of the mill.

Hydraulic Press: Two 4-Daylight hydraulic presses of size 18" x 18" are required. One moulding Cycle is adjusted to be of 10 minutes duration. In 10 minutes about 2 kg. of the compound has to be handled. Since the item is very small and hence larger in number two presses will be required to handle the quantity fixed. Thus there is maximum utilisation of Press.

Boiler: Steam heating of the platens is advocated for the presses since this enables very close temperature control. A 100 S Boiler is required.

Air Compressor: A small air compressor is required for the cleaning of the moulds. This results in quick mould cleaning operation.

Moulds: Suitable moulds are required for the manufacture of closures according to the specifications.

Dies: Dies can be conveniently used for the preparation of blanks from compounded sheets. This helps in reducing flash loss since it enables the correct loading of the mould cavities.

Suitable dies can also be used for the deflashing of the moulded item.

Weighing Balances: A platform balance for checking bulk arrivals of raw materials and despatches; a pan type balance for use in the laboratory (Chemical balance is preferable); Two dial type balances.

The major equipments for use in the laboratory are

1. A Thermostatically controlled air oven
2. A colorimeter and other miscellaneous lab-equipments.

A list of machinery suppliers is given in the Annexure 9.

TERMS OF PURCHASE

1. Quotations are made and satisfactory quotations are confirmed.
2. Price quoted are exclusive of packing, transportation costs, Sales Tax, Octroi, excise duty etc.
3. 30% of the price should be paid in advance and the remaining at the time of purchase. Payment can be done through banks.
4. Purchaser has the right for inspecting machinery.
5. Supplier possesses the right for cancellation, changing delivery time and price due to unforeseen reasons.
6. Warranty against manufacturing defects is assured.
7. Liabilities passes on to customer immediately after despatch and shortages should be notified within one week.

7. MAN POWER REQUIREMENTS: The Man power Requirements may be divided into 3 catagories.

- a) Managerial
- b) Clerical
- c) Technical (both skilled & unskilled)

The total personnel requirement for this unit for a two shift operation is 32.

Training Programme For the efficient functioning of the firm experienced and well-tained Technologists, Supervisors, Mill-men and Press Operators are needed. Small Industrialists cannot afford to have elaborate training programmes as it is a costly affair. However, the government is giving considerable assistance in this field by arranging training programmes at institutions like Common Facility Centres etc. at affordable expenses.

DETAILS OF THE MAN POWER REQUIREMENTS IS GIVEN BELOW

Staff	Working shift	Unskilled	Semi Skill- skilled ed	Oth- ers
I. Managerial				
1. Manager/Technologist	1	..	..	1
II Clerical				
1. Typist/Accountant	1	..	..	1
2. Peon/Watchman	2	..	..	2
3. Lab-Technician	1	..	..	1
III Technical				
1. Supervisor	2	..	..	2
2. Mill operators	2	..	..	2
3. Press operators	2	..	..	8
4. Blank preparation	2	4	..	..
5. Deflashing	2	8	..	..
6. Boiler Attendant	2	..	..	2
7. Packing	1	1	..	..
TOTAL		13	..	12
				7

INFRASTRUCTURE AND OTHER FACILITIES: Roads.

(a) For the successful functioning of any Industry, big or small, transport facilities is essential. To bring the raw materials to the factory premises and to haul the manufactured products to the market, transport facilities are unavoidable. This pre-supposes the availability of good roads or canals. The question of transportation is not a problem in the present case as it is proposed to locate the project in an Industrial Estate which will definitely have good accessibility.

(b) Water Supply: Water is an important indirect raw material for

almost all products. The material, the processes, the machinery and the workers need water. In Kerala water is adequately available in all seasons. So this, also, is not a major problem regarding this small unit.

(c) Electricity: The most important driving power behind machines is electricity. Adequate supply of electricity is an essential requirement for all industries. Only a few states in India (including Kerala) are out of the grips of power cut. Even in places where power is available, the small Industrialist has to face several problems. He has to spend much time and money in getting connections, drawing 3 phase line, installation of transformers etc. In this case also Industrial Estates prove helpful to a small Entrepreneur.

SECTION -D. TECHNOLOGY AND PROCESS OF MANUFACTURE

The flow diagram of the manufacture of Pharmaceutical closures is given in Annexure 7.

1. DETAILS

Compounding: As far this particular item is concerned, compounding is the stage where maximum skill and care are required. This is an item which should meet stringent specifications since it is coming in direct contact with medicines. So in this case cost factor is having only a secondary importance. The most important requirement is that the item should not contain any material that is toxic. Other requirements are coring and resealability, Swelling, Friction, Hardness Compression Set Extraction of accelerator residues etc.

The elastomeric Polymer does not furnish the optimum desirable properties and is incapable of maintaining its original properties when exposed to heat, light, pressure, ozone and chemical attack. It must be modified with suitable agents to achieve these required character-

istics and to maintain them while performing its function as a Pharmaceutical closure. The art of choosing these modifying agents, determining the percentage to incorporate, and the method and conditions of incorporation is called compounding. Herein lies the art and science of rubber formulation. A typical formulation usually contains the following classification of materials.

1. Elastomers: To furnish the desired elastic properties eg. NR, Butyl, Neoprene etc. Here pale crepe NR is taken.
2. Vulcanising Agent: To effect cross-linking of the base polymer eg: Sulphur, Resins etc.
3. Accelerators: To promote cross-linking reactions eg: Organic Sulphur containing materials such as Mercaptans disulphide.
4. Activators: To increase the efficiency of the accelerator reactants eg: Zinc and Magnesium Oxide.
5. Reinforcing Agents: To achieve desired physical and mechanical properties. eg: Barium Sulphate, Carbon Black, Clays, Silica.
6. Plasticizers: To increase plasticity and workability of the stock. eg: Naphthene and Aliphatic oils, Esters, Silicon oils etc.
7. Stabilizers: To protect against deterioration from oxygen or ozone attack. eg: Paraffin and various mineral waxes.
8. Pigments: To produce colour to finished items. eg: Carbon Black, Iron Oxide, Chrome green, Cadmium Sulphide, Titanium Dioxide, Organic pigments.
9. Special Purpose Additives. Eg: Teflon for reduced friction, Paraffin for external lubrication

The choice of elastomers is governed by the final properties desired and the availability of the raw elastomers in a form where a

minimum of undesirable contaminants is present. Pale crepe is a good choice from NR.

The choice of vulcanising agents is limited to materials effective in promoting cross-linking of the elastomers and the application of the finished closures. Activators, accelerators and vulcanising agents are part of the "Cure System" and are subjected to the same limiting qualifications. The question of toxicity is always present when considering raw materials and systems containing such materials as Lead, Selenium and Tellurium, although widely used in mechanical goods, they cannot be used in closures.

Reinforcing agents are materials which give desired physical effects like Hardness, Tensile Strength etc.

Plasticisers are chosen from materials which will aid in the wetting and dispersion of the dry compounding ingredients. Toxicity should also be considered in their selection. Paraffinic oil is a good choice in this field.

Antioxidants and Antiozonants prevent physical deterioration. Most of these cannot be used due to the toxicity of the materials. Paraffin wax is a good choice here.

Pigments used must be selected with care.

Some, or even all, of these materials may be present in a formulation, depending on the desired end requirements.

The formulation employed here is given below

FORMULATION

<u>Ingredients</u>	<u>Parts by weight</u>
Pale crepe Rubber	100.0
Zinc Oxide	3.0
Stearic Acid	1.0
Calcium Silicate	25.0
First Quality China Clay	50.0
Diethylene Glycol	1.0
Paraffinic Oil	3.0
Paraffin wax	1.0
Sulphur	1.5
M B T S	1.0
T M T	0.15
Titanium Dioxide	5.0
Colour	0.20

Mixing is done on a 12" x 30" mill. The same mill is used for all requirements such as mastication, mixing, sheeting, warming etc.

First the rubber is masticated and this is followed by the addition of stearic acid, Zinc oxide, fillers, oil, wax etc. Towards the end of the mixing cycle the accelerators are added. Then, finally, Sulphur is added and then the compound is sheeted out. Thorough dispersion of the ingredients must be ensured during mixing. Wastage and losses should be controlled as far as possible. The mixing cycle time is proposed to be 30 to 35 minutes per batch.

Maturing: Maturing of the compound is done for 24 hours.

Pre-Warming: The matured compound has to be warmed before moulding. The addition of Sulphur, if not done during mixing, can also be done at this stage. The temperatures of mixing and warming must be well controlled. Otherwise scorch problems will shoot up.

Blank Preparation: This is done using dies. Compounded sheets are laid on a worktable and the blanks are cut using dies. The use of dies for cutting blanks helps in making blanks of the correct size for feeding the moulds. This results in reduced flash loss during mouldings.

Moulding: Moulds are heated to the cure temperature of 155°C . These are then taken out. A mould lubricant is applied. The blanks are then kept in the moulds and the mould is closed. It is kept on the platen and the press closed and pressure applied. It remains under these conditions for a specified period of time — the cure time. Here the cure time is 6 minutes at 155°C . In this unit the number of people suggested for moulding is 4. This is because of the Labour content of this particular process. Here the item is very small and hence to feed a large number of cavities during each cycle increased number of persons is a must. Here two presses are employed. While one press is closed for curing, these people can attend the other press. Thus a total of 4 persons is sufficient for moulding. After the specified cure time the press is opened and moulds are removed. The moulded pieces are removed. The mould is cleaned with the air jet and it is now ready for a second cycle of operation.

Inspection: The moulded pieces are inspected for major defects, immediately after moulding.

Finishing/Deflashing

Deflashing is the finishing operation. It is a major problem for this unit since a large number of small pieces are to be deflashed. Various methods are available for the removal of flash from moulded pieces. The important among them are 1) Hand trimming 2) Die cutting 3) Cold tumbling 4) Buffing etc.

Cold tumbling is a method highly suited for deflashing large numbers of small items at a time. Here, the moulded items are put into a chamber which can be rotated. Then a spray of liquid Carbon dioxide is introduced into the chamber. This is followed by a stream of abrasives. The thin flashings become rigid at the low temperature while the thicker portions still retain the rubbery or elastic nature. These stiff flashings are easily broken and removed by the abrasives. This is a very convenient machine which is highly suited for the deflashing of such simple items like closures. This will also save a good deal of Labour cost. But the high cost and the non availability in the indigenous market does not permit us to adopt such a machinery right at the start. In the present scheme, however, manual deflashing itself is suggested. About 4 persons will be required for this operation. But in future the unit can switch over to mechanical deflashing methods as described above.

Packing: The finished goods are packed in Polythene bags.

2. PROCESS LOSS

Since this is a small item the wastage due to flash is more in compression moulding. However using correct blanks this can be controlled to a very great extent. Flash losses can also be minimised by adopting other moulding methods like a) transfer moulding b) Injection moulding, etc.

But these methods are more expensive. Injection moulding is the best method for moulding this item. But, however, the machine is highly expensive and not common and is not available in the indigenous market. In this project compression moulding technique is suggested. Other methods of production as described above can be considered in future when the unit attains such a commanding position in the field. This will enhance the production tremendously and the Labour costs will be

minimised. But much more sophisticated technology will be a must.

In the present situation losses can be considered to occur from the following a) Flash loss: This cannot be completely eliminated in compression moulding but can be controlled by using suitable blanks. b) Scraps: These are defective items after moulding. c) During handling: The ingredients may also be lost during weighing, compounding, mixing etc.

Maximum care should be taken to minimise the process loss. The anticipated process loss is about 10 to 15% in this case.

3. QUALITY CONTROL MEASURES: Quality is the surest foundation of success. It is not the best quality that matters, but is the right quality. Every product should have a certain level of quality, worth of its price. By quality what is meant is a certain characteristics assigned to a product. These characteristics are Highly variable. Consistency of quality means, these variations are within fixed tolerance and in order to keep variation the minimum, within tolerance, quality control measures are necessary. Quality control should be there from the very start of purchase of raw materials to the final despatch of finished products.

First the raw materials are tested for the desired level of purity and these tests need not be repeated frequently, once an agreement with an established supplier has been made.

Strict supervision of the machinery and processes are to be made. Finally the finished products are tested according to the I.S.I Procedures. Statistical quality control is followed.

SAMPLING OF CLOSURES AND PERMISSIBLE NUMBER OF DEFECTIVES.

No. of Closures in the lot	No. of Closures to be selected	Permissible No. of defectives	No. of test to be per- formed.
1	2	3	4
Up to 3000	90	2	1
3001 to 10000	180	4	2
10001 to 35000	270	6	3
35001 and above	450	8	5

Sampling: It is recommended that at least 10% of the packages should be selected and an equal number of closures drawn at random from each package selected to give the required number of closures in accordance with column 2 of the above Table.

Workmanship and Finish: The closures shall be non-porous, evenly and smoothly finished and free from embedded foreign matter, smears of grease or pigment, and substantially free from blisters, adventitious dust, fibres and loose particles of rubber. In the case of plugs, the top shall be concentric to the plunger. The closures of each batch shall be of uniform colour. The requirements for Pharmaceutical rubber closures are also given in Annexure 6.

TESTS FOR PHARMACEUTICAL RUBBER CLOSURES.

1. **Sterilization test:** Pack sufficient number of prepared closures in silk or Nylon bag or in a stainless steel perforated container and autoclaves them at a temperature of 120 to 125°C for 30 minutes. Cool the contents and dry the closures in a hotair oven at 100 to 102°C for 2 hours. Cool and examine the closures.

2. Test for Extractable Matter: Place an appropriate number of prepared closures to weigh about 20 grams in a conical flask. Add 200 ml. of distilled water to the flask. and cover the flask with a beaker or with aluminium foil which has been previously washed with acetone. Also add 200 ml. of distilled water to another conical flask and cover the flask with a beaker or with aluminium foil as in the case of first flask. This serves as a control blank. Autoclave both the flasks for 30 minutes at 120 to 125°C. At the end of 30 minutes remove the flasks and allow to stand at room temperature for 3 to 5 hours. Examine the colour of the extracted solution. Preserve these extracts for tests in expt. (8), (9), (10).

3. Fragmentation Test: Half fill 20 vials with water free from extraneous matter. and seal in the appropriate manner. Using a 0.8mm regular point hypodermic needle, pierce each closure five times, normal to the surface, flushing the needle after every puncture into the vial, ensuring that all the five piercings are made within a circle of 5 mm. in diameter and as equidistant from each other as possible. Then remove the needle and examine it carefully for any sign of blunting. If blunting is evident, discard the vial and its contents and substitute by a fresh one. Repeat the above test on the remaining 19 vials. Filter the contents from each vial together with suitable washings through a filter funnel using filter paper of a contrasting colour. Count the number of fragments on the filter paper without any artificial aid.

4. Test for self-sealability: Half-fill with water 5 vials for which the closures are intended. Apply the sterilised closures and seal

in the appropriate manner. Take each vial in turn, invert and inject through the closure a volume of air equal to the volume of air in the vial by means of a 0.8 mm regular point needle (38 mm long) fitted to a hypodermic syringe. Withdraw the needle rapidly and note whether any leakage occurs.

5. Accelerated Ageing Test: Suspend the sterilized rubber closures to be tested in a thermostatically controlled airoven maintained at a temperature of $70 \pm 1^{\circ}\text{C}$ for a period of 168 hours so that the rubber closures are free from strain and exposed to air on all sides but not exposed to light. Remove the closures, cool to room temperature and examine visually.

6. Determination of Free Sulphur Content The reagents used are Bromine, Barium Chloride solution (10%), Acetone and Hydrochloric acid. Using clean forceps transfer 10 closures to a round bottomed flask. Add 100 ml. acetone and keep overnight. Connect the flask to an efficient reflux condenser, boil and reflux for 8 hours. Cool and transfer the acetone extract completely from the flask to a clean tared platinum crucible of suitable size by washing with acetone. Evaporate carefully to dryness on a steam bath and dry at 100°C to constant mass. Add to the dried acetone extract, 50 ml. of water and 1 to 3 ml. of Bromine and cover with a watch glass. Allow the vessel to stand in a water bath at about 70°C for at least 30 minutes, remove the watch-glass and heat continuously without boiling till the solution is almost colourless. Add 1 ml. of hydrochloric acid, filter the solution and dilute it to 250 ml. with water. Heat the solution to boiling, and slowly a slight excess of hot barium chloride solution,

continue to boil the liquid for 5 to 10 minutes and allow it to stand for one hour at 90 to 100°C. Filter the liquid through a sintered glass or Silica crucible which has been previously washed, dried and weighed. After the filtration has been completed, wash the crucible and the precipitate with hot water till the washings are free from chloride, dry at 100°C for one hour, cool in a desiccator and weigh. Make a blank determination with the reagent, using the same quantities and under the same conditions of test, and apply the correction, if any, to the mass obtained.

Free Sulphur content, % by mass = $\frac{13.73 B}{M}$

Where

B=Corrected mass in grams of the Barium Sulphate precipitate and

M=Mass in grams of the closures taken.

7. Determination of pH of aqueous extract. From each lot, cut 10 caps into 2mm pieces. Autoclave the pieces for 5 minutes at a pressure of 40 to 50 kN/m² with 200 ml of water. Discard the first extract and repeat the process with another 500 ml of water for 40 minutes. Decant the extract, cool and determine the pH with a standard pH meter.

8. Test for Reducing Substances. Pipette 50 ml. aliquots of the extracted solution of the sample of closures obtained in expt (2) and the control blank solution into two 250 ml conical flasks, add 2 ml. of starch solution (1%) and titrate with 0.01N Iodine solution to the first permanent blue colour as the end point. The difference between the two titration values is the measure of the reducing substances in the sample solution.

9. Transmission Test: Using a suitable colorimeter and using 1 cm cell, read percent transmission of the aqueous extract obtained in expt.(2) at 620 nm, using control blank solution as a reference.

10. Test for Heavy Metals: Reagents; Standard Lead solution containing 0.01 mg. of Lead/ml, Acetic acid --33%, Freshly prepared Hydrogen Sulphide solution.

Pipette 10 ml of the aqueous extract from expt.(2) into a Nessler cylinder; add 10 ml of boiled and cooled distilled water and 1ml. of dilute solution of lead into another Nessler cylinder. Add 2 ml. of acetic acid to each of the cylinders. Add 10 ml of solution of hydrogen sulphide to each tube. Dilute to 50 ml mark, mix and allow to stand for 10 minutes. Compare the colours obtained by viewing the light reflected from the white tile through the cylinder. Colour of the aqueous extract thus treated should not be darker than the standard.

11. Determination of Hardness: Perform this test on a press cured rubber slab of the same compound as used for the closures and cured under the same conditions. The minimum dimensions of the slab shall be 75 x 75 x 6.5 mm. Hardness of this is determined using a hardness tester.

12. Determination of Total Ash: Cut the sample rubber closures into small pieces and weigh accurately about 1 gram of the sample pieces in a Silica crucible. Ignite at 650°C , 250°C till ashing is complete and constant mass is obtained.

4. UTILISATION OF BYE PRODUCTS, IF ANY:

In many chemical Industries in addition to the main product

so many bye-products are also obtained. These can be either used as much or maybe used for manufacture of other useful products. But as far this product is concerned there is no formation of any bye-products.

5. WASTE DISPOSAL: Wastes are always losses and these must be minimised. In this unit the major portion of waste is contributed by the flashings. These are quite useless as such also the quantities of flashings are less. But these flashings can be collected and stored and when a reasonable quantity is obtained, this can be given for reclaiming.

SECTION.E. SELLING AND DISTRIBUTION ARRANGEMENTS

The marketability of the product is the driving forces behind every industry. All the articles produced should be sold out at a reasonable price which will fetch adequate return on the investment.

The two most commonly adopted procedures namely Direct Sales by opening depots and sales through agents on commission basis are not applicable for the sales of pharmaceutical closures. Here the best method is to enter into long term contracts with important medicine manufactures. Nowadays production of medicine is increasing more and more units are coming up. All these demand increased supply of pharmaceutical closures. Thus, as far as this small unit is concerned, selling will not be a big problem. Since the entrepreneur can supply quality items at lower costs, he can easily enter into such contracts, provided he can supply the item according to their specifications. Also he should be prompt in despatching consignment. Delivery Arrangements: Supply by railway wagons will be cheaper.

SECTION . F. CAPITAL REQUIREMENTS

The total capital employed for the project may be divided into Fixed capital and working capital.

1. Fixed Capital:

The fixed capital includes amount spent for purchase of land, construction of building, purchase, erection and installation of machinery etc. Preliminary and pre-operative expenses for a definite period which can be capitalised also comes under fixed capital. Fixed capital also includes expenses incurred on office furniture and machineries etc.

In the present scheme, no expenses is incurred on land and building as these are rented from an Industrial Estate. Other fixed expenses are given below:

a) Machinery	3,16,800.00
b) Other fixed expenses	20,000.00
c) Preliminary and preoperative expenses	<u>20,000.00</u>
Total fixed capital	3,56,800.00
Rounded off to	3,57,000.00

Details of fixed capital is shown in annexure

2. WORKING CAPITAL This is to provide funds for a definite period for production. In the present case it is calculated for 3 months. This includes investment on raw material, salaries and wages, utilities and other overheads consisting of Repairs and Maintenances on machinery Travelling and Advertisements, Printing and stationery, Postage and Telephone, Rent, Audit fee and legal charges etc. For the rest of the period Capital can be had from the sales of goods produced by the original working capital.

THE WORKING CAPITAL REQUIREMENT FOR 3 MONTHS IS GIVEN BELOW:-

<u>Item</u>	<u>Amount, Rs.</u>
a) Raw Material	75,000.00
b) Salaries and wages	41,000.00
c) Utilities	12,000.00
d) Other overheads	12,500.00
TOTAL (a+b+c+d)	1,40,500.00

Details of working capital components are given in Annexure 2.

SECTION.G. FINANCING PLAN.

Well thoughtout, logically concluded financial planning is a pre-requisite in an industrial venture. For the present scheme the financing plan is given below:-

<u>Item</u>	<u>Amount, Rs.</u>
a) Own Fund	93,000.00
b) Loan from financial Institutions	2,64,000.00
c) Cash Loan from Banks	1,40,900.00
TOTAL	4,97,500.00

For the present scheme an amount of Rs.3,57,000 is required as fixed capital and Rs.1,40,500 as working capital. Normally an entrepreneur cannot meet all the financial requirements needed for an industry from his own pocket. One can get financial assistance from several sources in order that he is not hampered by lack of funds.

SOURCES OF FINANCIAL AIDS

1. State Financial Corporations: They grant loans from Rs.10,000 to Rs.10,00,000 to any single concern. They provide 100% of machinery

cost, 75% of building cost and 40% of working capital at 7.5% interest. Repayment starts only after two years and should be complete within ten years thereafter.

2. Kerala State Small Industries Corporation:

Provides Hire purchase facilities for machinery upto 10 lakhs of rupees on a marginal money deposit of 20% (10% for technically qualified but unemployed). The interest is 7½%. Repayment starts after two years and should be complete within 7 years.

3. National Small Scale Industries Corporation New Delhi:-

Hire purchase facilities are available for both indigenous and imported machineries. Interest is 7½% with a pay back period of 7½ years. The facility can be availed by pledging the machinery.

4. Commercial Banks:

Nationalised banks provide loans for machinery on 25% margin money and 12% interest. Pay back period is 3 years and monthly repayment starts from the third months. For working capital, any amount can be drawn.

Key loan facility:- Eg:- for purchase of raw materials bank will advance money on 25% margin money and 16% interest. The material will be under bank's lock and key. Small amounts can be drawn according to requirement.

Bill Discounting facility:- up to 80% of a marketed consignment is advanced.

5. The Industrial Development Bank of India

With a view to further streamline the availability of credit to Industrial Development the Reserve Bank has a subsidiary under the

name the Industrial Development Bank of India. The Bank is authorised to give all types of financial assistance directly to industries or to other banks and institutions which in turn help the industries. Thus if a bank loan is rediscounted with IDBI, the interest rate may fall from 15% to 10½%.

6. The Unit Trust of India.

The Unit Trust of India aims at the mobilisation of monetary resources of the nation, mainly from the middle income group and to raise capital for nation building activities, mostly as industrial capital.

OWN FUNDS AND BORROWINGS.

In the present scheme 100% of the machinery cost is taken as loan from Kerala Financial Corporation against hypothecation of machinery. The rest of the fixed capital is taken by the entrepreneur. The working capital is acquired by taking loan from banks. Thus own funds amounts to a total of Rs.93,000 and borrowings come to Rs.4,04,500.

SECTION.H. PRICING POLICY

There are mainly three strategies for pricing a product in the domestic market. They are 1) Cost oriented pricing 2) Competition oriented pricing 3) Demand oriented pricings

The selection of a particular pricing policy depends on various considerations. In the present scheme the cost oriented pricing policy is found to be the best alternative. In most cases the supplier will have to supply items according to the specifications given by the customer. In such instances the best alternative is the cost oriented pricing policy. According to this the selling price of the item is

fixed based on the cost of production. An adequate profit margin is taken. In the present case the selling price is fixed to be Rs.285/- 10,000 closures.

SECTION .I. PROFITABILITY

1. Rate of return on own capital

own capital	93,000.00
Net profit	1,09,375.00
∴ Rate of return on own capital	117.7% *****

2. Rate of Return on Capital employed

Total Fixed Capital	3,57,000.00
Working Capital	<u>1,40,500.00</u>
Total Capital employed	4,97,500.00
Net Profit	1,09,375.00
∴ Rate of return on capital employed	22% *****

3. Percentage profit on sales Turn over

Annual Receipts from sales	8,55,000.00
Net Profit	1,09,375.00
% Profit on Sales Turn over.	12.79% *****

BREAK-EVEN ANALYSIS

Break even quantity is that quantity which if produced and sold will give neither a profit nor a loss.

$$B.E. = \frac{F}{P-V}$$

Where F = Annual Fixed Costs.
 P = Price / Ton of Product.
 V = Variable cost / Ton.

Total Sale of Product.	8,55,000.00
Weight.	45 Tons.
∴ Average Price / Ton of Product.	<u>19,000.00</u>

Total variable cost

i) Raw Materials	3,00,000.00
ii) Utilities	48,000.00
iii) Direct Labour	1,31,040.00
iv) Selling Expenses	42,750.00
	<u>5,21,790.00</u>
Rounded off	<u>5,21,800.00</u>

∴ Variable cost / Ton = 11,600.00

Fixed Cost (F)

Total cost of production	6,56,000.00
Distribution expenses	<u>42,750.00</u>
∴ Total Cost.	<u>6,98,750.00</u>
Less variable cost	<u>5,21,800.00</u>
∴ Annual Fixed Cost.	1,77,000.00

$$\begin{aligned} \text{Break even Production, B.E} &= \frac{F}{P - V} \\ &= \frac{1,77,000}{7,400} \text{ Tons.} \\ &= 23.90 \text{ Tons} \\ &\text{*****} \end{aligned}$$

The Total production 45 Tons.

B.E. 23.90 Tons.

Break even production is about 53% of the total production

In terms of the number of closures produced, Total capacity
30 Million numbers.

Break even production. 15.90 Million

SECTION.J. ECONOMIC VIABILITY

1. Interest Commitments:

7.5% Interest on term loan from K.F.C.	19,800.00
16% interest on working capital loan from commercial banks	22,500.00

Total interest commitments	42,300.00

2. Ability to pay Back Borrowed Funds.

The term loan has to be paid back within the prescribed time. Considerable amount on interest can be saved, if the term loan is paid back quickly. Of the total profit approximately 25% is retained and 75% used to pay back term loan. Since part of the money is paid back in the first year, the ability to pay back borrowings will be more, as cash inflows are higher due to decrease in interest.

3. Pay-Back Period

a) Annual Profit	1,09,375.00
b) Depreciation	<u>51,600.00</u>
c) Available Surplus	1,60,975.00
d) <u>Less</u> drawings	<u>40,975.00</u>
e) Amount used for repayment	1,20,000.00
f) Term loan to be paid back	2,64,000.00
g) Pay back period	= 2.2 Years.

SECTION.K. SOCIAL BENEFITS

Small scale enterprises play a vital role in the country's growth and self reliance. This industry along with other small scale industries serve the nation in several different ways. It is a potential source of employment with minimum capital investment. Yield profit to the entrepreneur etc. The main points of significance are

1. Provides more employment opportunities at a lower capital investment
2. Offer a method of ensuring a more equitable distribution of the national income (by breaking monopolies).
3. Facilitates an effective mobilisation of resources, of capital and entrepreneurial skills.
4. Helps to avoid congestion in towns by dispersal of industry.
5. Increases the revenue earnings of the nation through taxes, excise duty etc.
6. Brings personal profits to the entrepreneur.

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ANNEXES

1. DETAILS OF FIXED ASSETS

A. Land and Building		Rented.
B. Machinery	Nos.	Price, Rs.
1) 12" x 30" Mixing Mill with Reduction gear and accessories	1	75,000.00
2) 18" x 18" Hydraulic Press (4 Daylights)	2	1,00,000.00
3) Moulds and accessories		20,000.00
4) Compressor for mould cleaning	1	5,000.00
5) 100 S Boiler with all Accessories	1	40,000.00
6) Weighing Balances		
i) Plat form balance	1	1,500.00
ii) Pan type balance for testing lab	1	1,000.00
iii) Dial type balance	2	5,000.00
7) Testing Equipments		
i) PH meter	1	5,000.00
ii) Hardness Tester	1	1,000.00
iii) Thermostatically controlled air oven	1	2,500.00
iv) Colorimeter	1	3,000.00
v) Miscellaneous items		5,000.00

		2,64,000.00

B/F	2,64,000.00
5% Provision for Price Escalation	13,200.00
Tax @ 7.5%	19,800.00
Transportation @ 2.5%	6,600.00
Erection and Installation @ 5%	<u>13,200.00</u>
TOTAL	<u>3,16,800.00</u> *****

C. OTHER FIXED EXPENSES

Tank and Motors for Water Supply	10,000.00
Tools and Accessories	5,000.00
Office Machinery and equipments	3,000.00
Furniture	<u>2,000.00</u>
TOTAL	<u>20,000.00</u> *****

D. PRELIMINARY AND PRE-OPERATIVE EXPENSES

1. Interest on loan at the rate of 7½% (for 6 months)	10,500.00
2. Travelling Expenses	1,500.00
3. Postage, Telegram, Telephone	1,000.00
4. Printing and Stationery	2,000.00
5. Advertisement	1,000.00
6. Rent and Establishment	2,000.00
7. Other Miscellaneous Expenses	<u>2,000.00</u>
	<u>20,000.00</u>
TOTAL FIXED CAPITAL (B+C+D)	3,56,800.00
Rounded off	<u>3,57,000.00</u> *****

2. WORKING CAPITAL COMPONENTS

(FOR 3 MONTHS)

1. RAW MATERIALS 75,000.00

2. SALARIES AND WAGES 41,000.00

3. UTILITIES 12,000.00

4. OTHER OVERHEADS 12,500.00

TOTAL

1,40,500.00

2.(1)

DETAILS OF WORKING EXPENSES ON
RAW MATERIALS (FOR 3 MONTHS)

MATERIAL	PRICE/KG. RS. PS.	QUANTITY IN KG.	TOTAL COST RS. PS.
PALE CREPE RUBBER	8.00	5,860.00	46,880.00
ZINC OXIDE	16.00	176.00	2,820.00
STEARIC ACID	10.00	59.00	590.00
CALCIUM SILICATE	3.00	1,470.00	4,410.00
FIRST QUALITY CLAY	0.50	2,930.00	1,470.00
DIETHYLENE GLYCOL	12.00	59.00	710.00
PARAFFINIC OIL	18.00	176.00	3,170.00
PARAFFIN WAX	5.00	59.00	300.00
SULPHUR	2.00	88.00	180.00
M B T S	28.40	59.00	1,675.00
T M T	26.85	9.00	245.00
TITANIUM DIOXIDE	12.00	293.00	3,520.00
COLOUR	100.00	12.00	1,200.00
			<u>67,170.00</u>
PROCESS LOSS (10%)			<u>6,717.00</u>
			<u>73,887.00</u>
COST OF PACKING MATERIAL			<u>1,125.00</u>
TOTAL RAW MATERIAL COST FOR 3 MONTHS			75,012.00
ROUNDED OFF	75,000.00		

2.(2) DETAILS OF WORKING EXPENSES ON MAN - POWER
REQUIREMENTS (FOR 3 MONTHS)

CATAGORY	NO. OF PERSONS FOR 2 SHIFTS	MONTHLY RATE OF PAY	TOTAL PER MONTH
MANAGER/TECHNOLOGIST	1	900.00	900.00
TYPIST/ACCOUNTANT	1	400.00	400.00
LAB. TECHNICIAN	1	400.00	400.00
PACKING	1	300.00	300.00
SUPERVISOR (1/SHIFT)	2	450.00	900.00
MILL OPERATORS (1/SHIFT)	2	350.00	700.00
BLANK PREPARATION(2/SHIFT)	4	250.00	1000.00
MOULDING (4/SHIFT)	8	350.00	2800.00
DEFLASHING (4/SHIFT)	8	250.00	2000.00
BOILER ATTENDANTS (1/SHIFT)	2	350.00	700.00
PEON / WATCHMAN (1/SHIFT)	2	200.00	400.00
TOTAL	32		10,500.00
TOTAL FOR 3 MONTHS			31,500.00
TERMINAL WELFARE @ 30%			9,450.00
TOTAL			40,950.00
ROUNDED OFF	41,000.00		

2. (3) DETAILS OF WORKING EXPENSES ON UTILITIES
(FOR 3 MONTHS)

A. ELECTRICITY

<u>ITEM</u>	<u>POWER REQUIRED</u>
1. 2 H.P. MOTOR FOR PUMPING WATER	1.50
2. BOILER	0.80
3. 30 H.P. MOTOR FOR MILL	22.50
4. COMPRESSOR	1.50
5. LAB. EQUIPMENTS? LIGHTING FAN ETC.	2.75
6. TWO 3 H.P. MOTORS FOR PRESS	4.50
TOTAL	33.55

ROUNDED OFF 34 KW

CONSIDERING A LOAD FACTOR OF 0.8, THE POWER REQUIRED IS 27 KW.

• • AVERAGE POWER CONSUMPTION / DAY 450 KWH.
COST OF POWER Rs.0.15/KWH

TOTAL COST OF POWER FOR 3 MONTHS 5,062.50

ROUNDED OFF 5,100.00

B. FUEL

STEAM REQUIREMENT / HOUR 50 KG.
STEAM REQUIREMENT / 3 MONTHS 60,000 KG.
1 LITRE OF FURNANCE OIL CAN GIVE 10 KG. OF STEAM.
FURNANCE OIL REQUIREMENT / 3 MONTHS 6,000 LITRES.
PRICE OF FURNANCE OIL Rs.1.10 / LITRE
TRANSPORTATION COST 0.05 / LITRE
TOTAL COST FOR FUEL FOR 3 MONTHS 6,900.00
TOTAL EXPENSES ON UTILITIES FOR 3 MONTHS

(A + B) 12,000.00

2.(4) OTHER OVERHEADS.
(FOR 3 MONTHS)

SL.NO.	ITEM	EXPENSE RS. PS.
1	Repairs and Maintenance on Machinery @ 5%	4,000.00
2	Travelling and Advertisement	3,000.00
3	Printing and Stationery	1,500.00
4	Postage, Telephone, etc	1,000.00
5	Rent	900.00
6	Audit fee and Legal charges	500.00
7	Miscellaneous	1,600.00
TOTAL		12,500.00

2.(5) DEPRECIATION AND INTEREST
(FOR 3 MONTHS)

1	Depreciation on Machinery @ 15%	11,900.00
2	Depreciation on other Fixed Capital @ 10%	1,000.00
3	Total Depreciation	12,900.00
	Interest on term loan for Machinery @ 7.5%	4,950.00
4.	Interest on Working Capital Loan @ 16%	5,620.00
Total Interest		10,570.00
Rounded off		10,600.00

3. ECONOMICS OF THE PROJECT

COST OF PRODUCTION FOR 3 MONTHS

1. Working Capital	1,40,500.00
2. Depreciation	12,900.00
3. Interest	10,600.00
TOTAL	1,64,000.00 *****

RECEIPTS FOR 3 MONTHS:

Total Income from Sales for 3 Months	2,13,750.00
Less Selling Cost @ 5%	19,700.00
Income from Sales for 3 Months	2,03,050.00 *****

PROFIT FOR 3 MONTHS:

A. Receipts for 3 Months	2,03,050.00
B. Total Expenses for 3 Months	1,64,000.00
Profit (Before Taxation) A - B	39,050.00 *****

4. ANNUAL COST OF PRODUCTION

1. Raw Materials	3,00,000.00
2. Salaries and Wages	1,64,000.00
3. Utilities	48,000.00
4. Other Overheads	50,000.00
5. Depreciation	51,600.00
6. Interests	42,300.00
TOTAL	6,55,900.00

Rounded off	6,56,000.00

5. ANNUAL SALES INCOME AND PROFIT

Income from Sales @ Rs.28.5/1000	
closures for 30 Million closures	8,55,000.00
Less Selling Cost @ 5%	42,750.00
Net Income from Sales	8,12,250.00
Less cost of Production	6,56,000.00
GROSS PROFIT	1,56,250.00

Less Tax incidence Provision @ 30%	46,875.00
NET PROFIT	1,09,375.00

6.

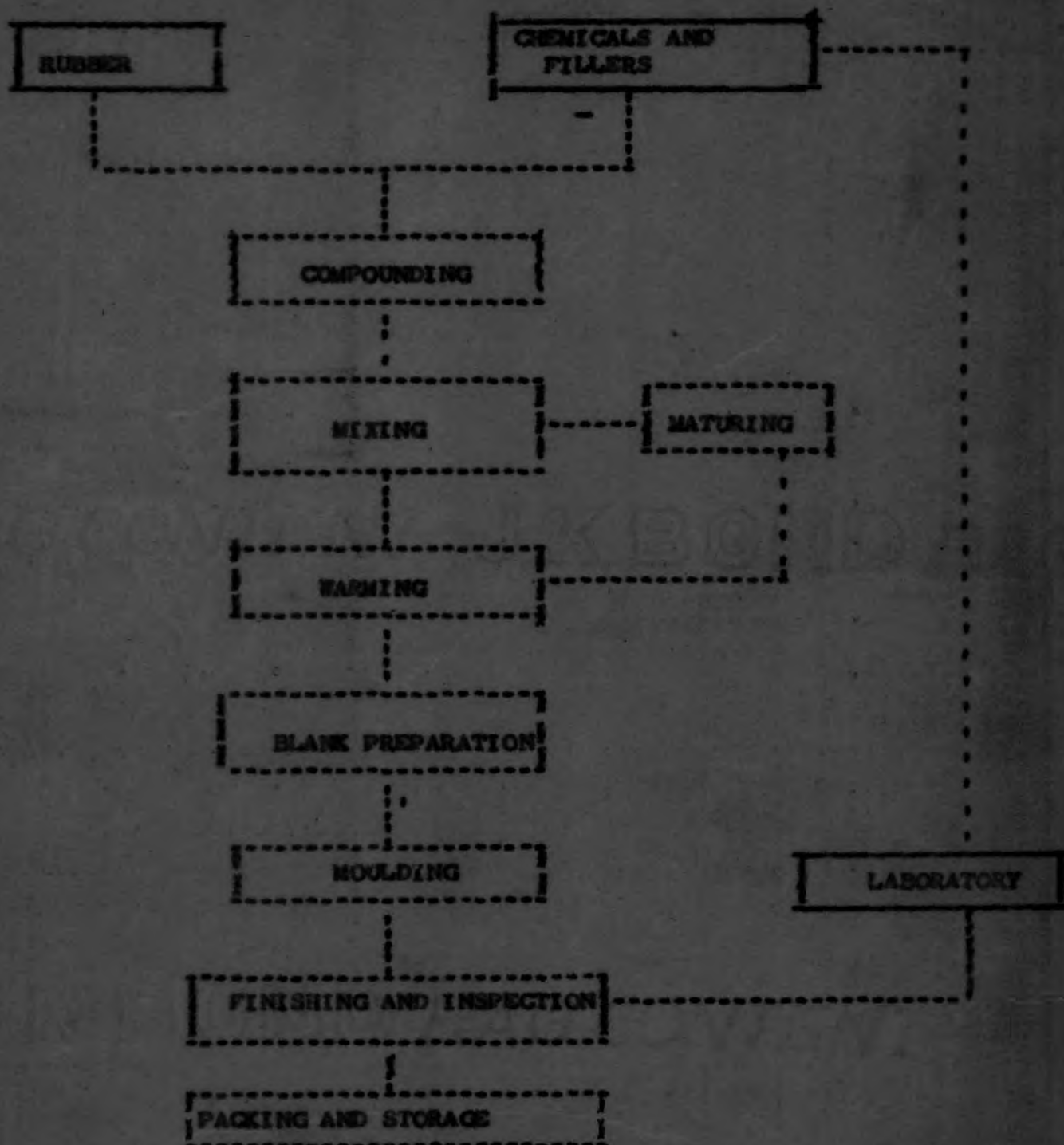
I.S.I. SPECIFICATIONS

.....		
NO.	CHARACTERISTIC	REQUIREMENT

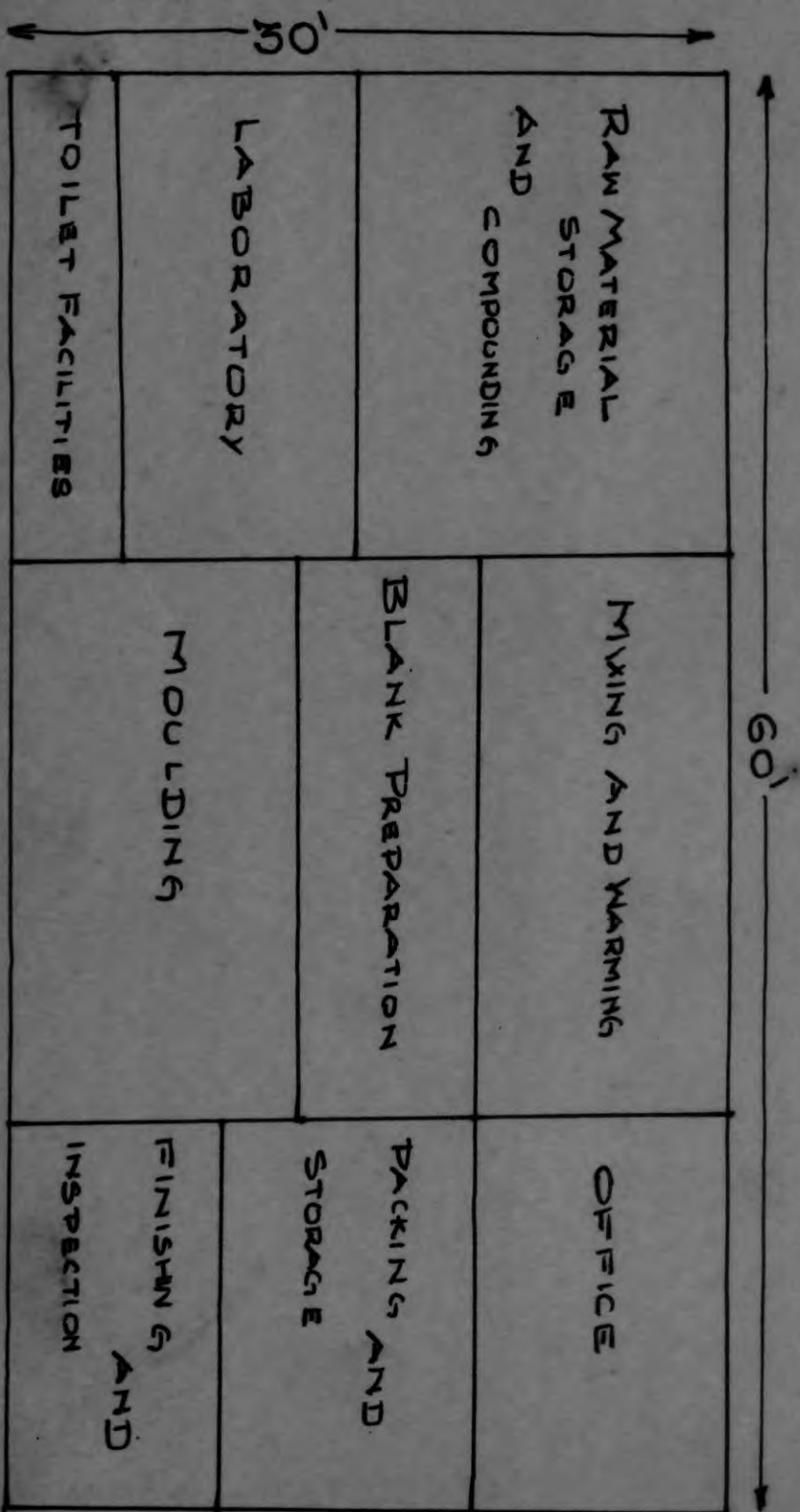
1.	STERILIZATION TEST	Shall not soften, become tacky and there shall not be any visual change.
2.	EXTRACTABLE MATTER	No colour or precipitate shall be formed but faint turbidity may be permitted.
3.	FRAGMENTATION TEST	Maximum fragments permitted per 100 punctures is 40.
4.	SELF SEALABILITY	There shall be no spray of water from any of the closures, No leakage.
5.	ACCELERATED AGEING	Shall not show any sign of tackiness etc.
6.	FREE SULPHUR CONTENT, %	0.2% Maximum.
7.	pH OF AQUEOUS EXTRACT	+ or - 0.5 tolerance on the agreed value
8.	REDUCING SUBSTANCE IN ml.	1.0 Maximum.
9.	% TRANSMISSION OF AQUEOUS EXTRACT AT 620 nm.	95.
10.	HEAVY METALS (AS Pb)	To pass test
11.	HARDNESS	+ or - 5 IRHD tolerance on agreed value
12.	TOTAL ASH CONTENT	+ or - 2% on agreed value.

7.

PROCESS
FLOW DIAGRAM



8. LAYOUT



9.

LIST OF SUPPLIERS OF MACHINERY

- 1) INDIAN EXPELLER WORKS,
A-4, NARODA INDUSTRIAL ESTATE,
NARODA, AHMEDABAD.
- 2) KELACHANDRA FOUNDRY,
CHINGAVANAM, P.O. KOTTAYAM.
- 3) RICHARDSON AND CRUDDAS LTD.,
BYCULLA IRON WORKS, BOMBAY-8.
- 4) SCHAL ENGINEERING WORKS,
AGRA ROAD, BHANDUP, BOMBAY -78.

TESTING EQUIPMENTS

- 1) HIROSHIMA INSTRUMENTS, BOMBAY.
- 2) SYSTRONICS, NARODA, AHMEDABAD.
- 3) INDIAN ENGINEERING COMPANY, WORLI NAKA, P.B. NO. 16551.
BOMBAY-18.

LIST OF RAW MATERIAL SUPPLIERS

PALE CREPE RUBBER- AVAILABLE IN THE LOCAL MARKET.

RUBBER CHEMICALS

- 1) ALKALI AND CHEMICAL CORPORATION OF INDIA LTD., CALCUTTA.
- 2) BAYER (INDIA) LTD., 82, VIR NARIMAN ROAD, BOMBAY -1.
- 3) MINDIA CHEMICALS LTD., WAKEFIELD HOUSE,
11 SPROTT ROAD, BALLARD ESTATE, BOMBAY.
- 4) PARA CHEMICALS,
C/O KERALA PAINTS PVT., LTD., M.G. ROAD, ERNAKULAM.

SULFUR

- 1) ASIATIC CHEMICAL COMPANY,
71, CANNING STREET, CALCUTTA-1.
- 2) SULFUR MILLS, PVT., LTD.,
23, KAILASH DARSHAN, BOMBAY-7.

STEARIC ACID

- 1) GODREJ SOAPS PVT., LTD.,
VIKROLI, BOMBAY-79.

ZINC OXIDE

- 1) ANAND CHEMICALS,
8 HORIMAN CIRCLE, FORT, BOMBAY-1.
- 2) ASHOKA CHEMICAL PRODUCTS,
P-16, KALAKAR STREET, CALCUTTA-7.
- 3) PARA CHEMICALS, ERNAKULAM.

PIGMENTS

- 1) COLOUR-CHEM LTD., FORT HOUSE,
221, DEBABHOY NAVROJI ROAD, BOMBAY-1.

TITANIUM DIOXIDE

- 1) TRAVANCORE TITANIUM PRODUCTS LTD.,
P.B. NO. 64, T V M.
- 2) PARAMOUNT COMMERCIAL CORPORATION,
12-B, FORT CHAMBERS, DEAN LANE,
FORT, BOMBAY-1.

CHINA CLAYS AND CALCIUM SILICATE

- 1) UNION COMMERCIAL AND INDUSTRIAL Co., PVT LTD.,
7 HOMJI STREET, BOMBAY.
- 2) HINDUSTAN CHINA CLAY WORKS,
PAPPINISSERI, CANNANORE, KERALA.

PROCESS OILS AND PARAFFIN WAX

- 1) BURMAH SHELL OIL STORAGE AND DISTRIBUTING COMPANY, OF INDIA LTD.,
BURMAH SHELL HOUSE,
BOMBAY-1.
