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MEDICINE FOR THE RURAL POPULATION IN INDIA

Background Paper

78 6900

MEDICINE FOR THE RURAL POPULATION IN INDIA

by

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PREFACE

I have made an attempt in this presentation to suggest ways and means of providing simple medicaments to the rural population in India. If need be, these suggestions could also be made applicable to rural areas of other developing countries with suitable modifications.

During the process of writing this article, I have drawn upon the experience, knowledge, expertise and time of a large number of friends in the medical profession, colleagues in the industry, and others, and am particularly grateful to Dr. K. M. Parikh, Dr. P. H. Kani, Mr. P. D. Childiyal, Dr. V. S. Talwalkar, Dr. S. N. Iyer, Miss N. S. Gaitonde, Dr. B. K. Mehra, Mr. M. V. Garda, Mrs. B. S. Gandhi, Mr. L. A. Coutinho, Mr. A. H. Negandhi, Mr. V. Punjabi, Mr. M. P. Khadkar, Dr. R. R. Sobti, Pandit Shiv Sharma and Mr. V. S. Dhakras.

I hope that the suggestions made in this presentation will be considered useful by the experts of UNIDO and will be utilised for alleviating the sufferings of millions of people in the rural and developing areas of various countries.

September 1976

C O N T E N T S

CHAPTER - I

INDIGENOUS SYSTEM OF MEDICINE

1.1 Human ailment is as old as human being. Like food, its need for medical aid has been from the very beginning of its existance. In order to cure himself, man tried various methods and materials. Due to the easy availability of a number of plants growing around him, initial trials were conducted on these plants. Through these trials and rationalisation of the results, extended over hundreds and thousands of years, a large amount of information was amassed by various learned-men about the different human ailments and the uses of herbs to cure them. This work was consolidated into books. The science of curing human beings in India with herbs is called 'Ayurveda'. Dhanvantary is considered to be the father of this science and also as the greatest of all great physicians.

1.2 Originally, only crude drugs were used as such or in the decoction form. The individual 'Vaidya' (a physician practicing Ayurveda) used to collect their own requirements of various plant materials and use them in treating their patients. The disadvantage of this system was that they were getting only the regionally available varieties of herbs which differed from place to place. Some of them were not even genuine and therefore there was no means available to them to standardise their preparations for treatment of diseases. The storage conditions of herbs also has a direct impact on the quality of the herbs and its active components. This facility was also not available to the Ayurvedic practitioners in the past. With the advancement of science and technology,

the investigation of various medicinal plants resulted in the isolation of active chemical principles like Quinine, Reserpine, Opium alkaloids, Emetine, etc. The result was that the herbal materials can now be pharmacognostically tested for the right quantity and quality of the active components.

1.3 A number of processing companies have come into existance in various parts of the country in the last five decades who have developed the technical capabilities of handling the herbs, analysing and standardising them. These companies now process the herbs after storage in proper conditions, checking them for their quality and quantity of the active ingredients in a scientific manner. This helps them manufacture preparations of uniform and standard quality which are then sold in the market. This has meant the creation of therapeutic standards for use of various herbs as a mode of medical treatment.

1.4 The various herbal drugs and their formulae for different diseases and indications are properly compiled in different books of Ayurveda. However, various authors, many a times, have given different formulae under the same name. This has caused difficulties in the standardisation of the finished products, as well as the right dosage. The new manufacturers of Ayurvedic drugs in the country have removed these difficulties and have come up with good acceptable compositions of the Ayurvedic formulations. Thus, the same product with the same formulation is available everywhere in the country. These companies have developed pharmacognostical, chemical and physical standards for various herbs and they use these standards during their manufacturing processes. This results

in constant maintenance of potency of these drugs. The packing is also properly designed in order to be able to retain the potency of the drugs so that the physician, when he prescribes them, is quite confident about their effectiveness.

1.5 Ayurvedic drugs are usually very bitter or unpalatable and are to be consumed in large dosage forms and patients do not like to take them. Therefore, these companies have now developed preparations which are more palatable and more acceptable to the patients.

1.6 The belief of the Indian population, especially in the rural areas, in Ayurvedic drugs is enormous. Considering that the major portion of the population lives in 500,000 villages and most of them below poverty line, it is imperative that some Ayurvedic drugs for common ailments should be made available to our fellowmen in the villages.

1.7 Below is given a list of some of the Ayurvedic drugs manufactured in the country and the indications for which they are used:

TABLE - 'A'

Sr.No.	Product	Indications
i)	Sudarshan Churna	For fever, headache, flu, cold, coryza
ii)	Shivakshar Pachan Churna	For stomach troubles such as diarrhoea, vomitting, colic, constipation, dyspepsia, etc.
iii)	Kankayani Gutti	
iv)	Agnitundi Ras	Indigestion, loss of appetite, dyspepsia, colic, weakness and debility, etc.
v)	Chandraprabha Gutti	Urinary anti-septic cystitis, etc.
vi)	Yograj Guggulu	For pain in joints, arthritis, muscular pain, lumbago, etc.

Sr.No.	Product	and uses
vii)	Mahanarayan Tail	For external application for pain on joints
viii)	Manjishtadi Ghrit	For improving blood, skin diseases, ulcers, boils, etc.
ix)	Saindhavadi [illegible]	[illegible] as laxative, constipation, cold, diarrhoea, lymphenitis
x)	Khadiradi Guti	For throat troubles
xi)	Sitopaladi Churna	For stomatitis, foul odour from mouth, pain in cough, hoarseness of voice bronchitis, asthma, etc.
xii)	Triphala Churna	As laxative
xiii)	Isabgol	Demulcent
xiv)	Ashokarishta	For female complaints like menorrhoea, leucorrhoea, etc.
xv)	Godanti	For cold and running nose
xvi)	Tribhuvan Kirti	For cold, fever, headache

3.8 The indigenous types of medicines are generally in the following forms:

i) Powders called 'Churna'

ii) 'Kwath' (decoction) which is a water extract of herbs

iii) 'Gutti' and 'Guggulu' which are generally in tablet forms

3.9 Since the indications are simple, it does not require any help of the physician to be able to identify a drug required by a patient for a particular ailment. It means that if the drugs are easily and cheaply available with proper labelling and instructions for use in the language which is spoken in a particular area of the country, the village folk will be able to utilize them without the assistance of a physician.

1.10 The present day problem is that products dispensed by local physicians are very poor in quality and they charge exorbitant prices for such products. It is therefore suggested that each State of the country should have a Central Ayurvedic Formulating Plant for the standard preparations mentioned above which could be distributed to the villages through local vendors, grocery shops, etc.

1.11 Since each Ayurvedic drug is a combination of several herbs which have to be properly pharmacognostically identified and chemically checked, it is not possible to put up small formulation units in each district place. Only at central places in States can scientific standardization be used in order to manufacture uniform, therapeutically active formulations.

1.12 However, it is worthwhile considering putting up small packaging units for standard preparations in districts, whereas standard products in bulk quantities could be brought from the Central Ayurvedic Formulation Plants in the States. This would mean:

i) availability of therapeutically standard products;

ii) involvement of villagers in the packaging and distribution of these drugs; and

iii) provide job opportunities to the local population.

CHAPTER - II

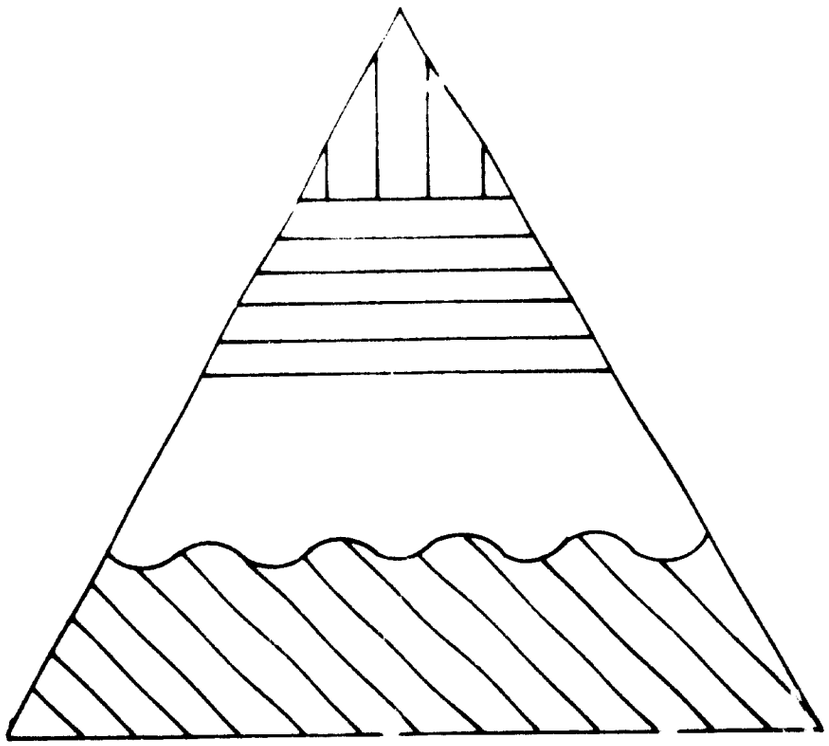
ALLOPATHIC HOME REMEDIES

2.1 Besides Ayurvedic preparations, in the last fifty years chemo-therapy, based on synthetic drugs has made rapid strides in the country and have been able to overcome hitherto uncontrolable diseases. India has made considerable progress in the manufacture and formulation of these new chemo-therapeutically active chemical compounds and has a very well established pharmaceutical industry which caters to the needs of the Indian public for almost all types of diseases. The production of pharmaceuticals in India in 1977-78 is estimated to be around one billion U.S. dollars (8000 million Indian Rupees). The country's requirements as projected both by the industry and by the Government is of the order of 2.38 billion U.S. dollars (19,000 million Indian Rupees) for the year 1982-83. This means a compound growth of approximately 19% over the next five years. This presents a great challenge. But, unfortunately, even out of the present production, most of the drugs manufactured in the country are utilized by 20% of the population living in the urban areas. 80% of the population living in half a million villages of the country hardly have any benefit of the modern, scientifically based drugs. There can be several reasons for this disparity, but the major ones are:

i) non-availability of trained medical or para-medical personnel in the rural areas of the country;

ii) lack of concerted efforts to develop a basic formulary of home remedies which could be manufactured in district places and made available to the rural population to self-medicate themselves at low prices and without any danger of side-effects.

2.2 A number of studies have shown that as much as three-fourth of all health care is self-care which usually involves household remedies. This first line of defence of a person or injuries is of strategic importance for the general well-being of the people. The importance of these home remedies is recognized throughout the world by professional bodies including the World Health Organization. A graphical reproduction of the role played by self-medication is shown below.



2.3 Obviously, no amount of organisational services in terms of number of doctors, dispensaries, hospitals, health centres, medical units and the rest of it would be able to cater to the enormous health programmes required, unless household remedies are made available to the rural population of our country.

2.4 The major characteristics of household remedies are:

i) they have been developed for relief of symptoms and conditions usually minor and self-limiting in nature which are quite easily recognized by consumers without medical supervision,

ii) their proper use must be within the capability of the average consumer with label directions that can be easily understood and followed without professional guidance, and

iii) effectiveness and safety of these products should reach high levels of attainable consistency i.e. safety must carry a greater weight while designing these home remedies.

2.5 In order to identify the important products required to be made available to people in rural areas, several doctors who are working, either through professional bodies like the Indian Medical Association or through social organizations, in the rural areas have been interviewed. Based on the information available through these doctors, and the types of diseases which are very much prevalent in our villages, a formulary of the most important household remedies for the basic requirements of the villages has been developed.

2.5 The following is a list of the household remedies:

TABLE - 'B'

Sr.No.	Products	Package size	Indications & Uses
	TABLETS		
1	Aspirin I.P.	4 tabs.	Headache
2.	Paracetamol I.P.	4 tabs.	Bodyache, cold and fever
3.	Sodium Bicarbonate B.P.	30 tabs.	Stomachache and acidity
4.	Calcium Lactate I.P.	30 tabs.	For lactating mothers & children
5.	Ferrous Sulphate I.P.	30 tabs.	Anemia
6.	Phenolphthalein B.P.	4 tabs.	Purgative
	OINTMENTS		
7.	Iodine with Methyl Salicylate (non-staining) N.F.I.	10 g.	Muscular pain and ache
8.	Salicylic Acid I.P.	10 g.	Fungal infection
9.	Soothing Cream Contains: Euflavin B.P.C. 0.1% Thymol I.P. 0.005% Water miscible ointment base p.s.100%	10 g.	For burns
10.	Methyl Salicylate Compound (Analgesic Balsam) B.P.C. Contains: Methyl Salicylate (50) Cajuput oil (2.5) Cineole (2.5) Menthol (10) Water (4.5) Wool fat (10.5) White bees wax (20)	10 g.	Analgesic balm
11.	Clove Oil I.P.	5 ml.	For toothache

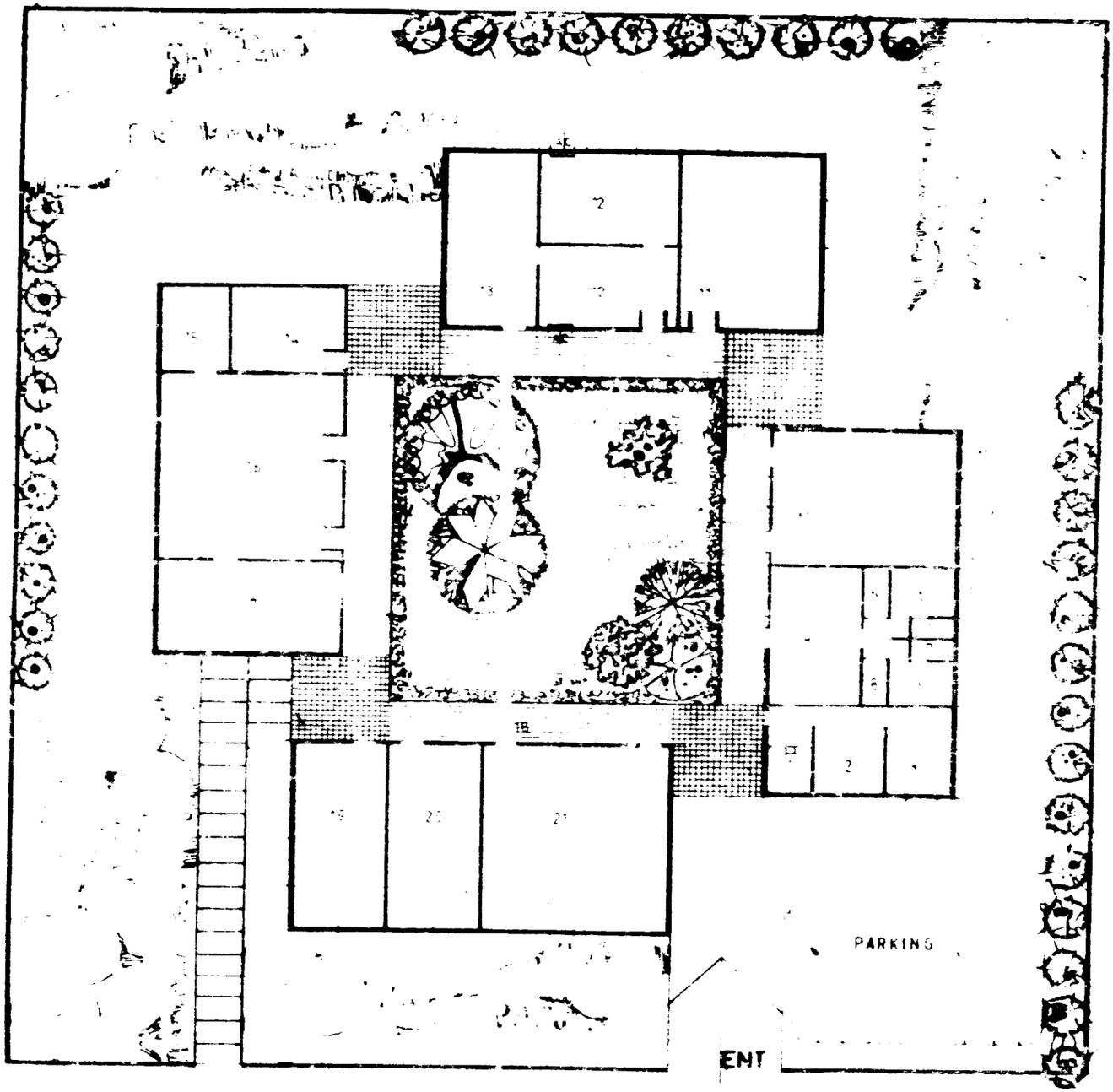
Sr.No.	Product	Package size	Indications & uses
LOTIONS			
12.	Gamma Benzene Hexachloride N.F.I.	50 ml.	For hair lice & scabies
13.	Borax Glycerine Paint N.F.I.	10 ml.	Throat & mouth paint
14.	Compound Benzoin Tincture I.P.	25 ml.	Cuts, bruises & minor wounds
15.	Antifungal Lotion Contains: Resorcinol I.P. 3 g. Salicylic Acid I.P. 3 g. Methylated Spirit to 100 ml.	10 ml.	For ring-worms
16.	Lysol - 50% Cresol V/V in a saponaceous solvent	100 ml.	Antiseptic
LIQUID ORALS			
17.	Sodium Bicarbonate Mixture (Gripe Mixture) N.F.I.	100 ml.	Antigripe carminative mixture
18.	Expectorant Mixture N.F.I.	100 ml.	Cough mixture
19.	Piperazine Citrate Mixture N.F.I.	100 ml.	Anthelmentic (for thread & round worms)
20.	Kaolin Mixture N.F.I.	100 ml.	Diarrhoea
POWDERS			
21.	Electrolyte * Contains: Sodium chloride 3.5 g. Sodium bicarbonate 2.5 g. Potassium chloride 1.5 g. Glucose 10.0 g. (To be dissolved in one litre of clean water)	50 g.	For rehydration
22.	Potassium Permanganate I.P.	10 g.	Anti-infective

* National Symposium on Cholera and Acute Diarrhoeal Diseases, Calcutta - March 1978.

2.7 Most of these formulations are from the various National Formularies or Pharmacopoeias and are also approved by the World Health Organization. This list of formulations could be revised or modified depending upon the requirements of each region.

2.8 Having identified the basic needs, the aim of this paper is to make out a programme to provide a U.S.$0.125 (Indian Rupee one) equivalent of these household remedies per year per person to our people in the villages. The total population of our country at the moment is 634 million and is growing at the rate of 2%, which means that it will be of the order of 700 million in 1982-83. Our aim therefore is to provide 80% of the 700 million people with remedies worth U.S.$0.125 each per annum. This could be done if we organize small Model Manufacturing Units (MMU) for the manufacture of these remedies in our district places. Each such MMU should look after the population in a district or a combination of districts of about two million people. These MMUs should be as near as possible to district or civil hospitals so that certain basic facilities of hospital pharmacy laboratories are available to these units. Besides, district places will have proper transportation system as well as water and electricity required to put up these units. In addition, the benefit of these units in the district places will be that they will have a rural background and will cater to the needs of the people in the rural areas.

2.9 The MMU will consist of a complete pharmaceutical manufacturing facility inclusive of its own Quality Control Laboratory and a distribution set-up. The plan of the MMU has been so designed that this unit can be erected in any part of the country at a minimal cost. A floor plan for the building to house such a model unit is shown on the following page.



1 GUARD PUNCHING
2 OFFICE STAFF
3 CHIEF PHARMACIST
4 LUNCH ROOM
5 STORAGE ROOM
6 JENTS CHANGING ROOM
7 TOILET
8 PANTRY
9 LADIES CHANGING ROOM
10 QUALITY CONTROL LABORATORY
11 GRANULATION
12 TABLETTING ROOM
13 BOTTLE STERILIZING & WASHING
14 EQUIPMENTS & STORAGE
15 STAFF CANTEEN & RECREATION
16 COVERED PARKING AREA
17 GUARD ROOMS
18 STORAGE
19 RAW MATERIAL STORE
20 PACKING

SCHEMETIC LAY-OUT-PLAN OF PROPOSED PHARMACEUTICAL FACTORY FOR RURAL AREAS OF DEVELOPING COUNTRIES

DRAWING REF
DR R N 05

2.10 The Plan takes care of proper ventilation system and provision has also been made for future expansion, as and when the need arises, without much difficulty. This plan has been made taking into consideration -

i) the capacity requirements to fulfil the need of two million people for household remedies of U.S.$0.12 per person per year,

ii) to meet all the requirments of the local Drug Authorities,

iii) taking good manufacturing practices into consideration.

2.11 Raw Materials

All raw materials and packaging materials of standard and pharmacopoeial qualities required for the manufacture of the household remedies identified in the formulary (Table '1') are locally available in sufficient quantities.

2.12 **Packaging**

The packaging should be simple and cheap, but should be able to protect the potency of the drugs. The pack sizes have been so decided as to be sufficient for a particular ailment and to see that there is no wastage. This will also keep the prices of the products low and within the reach of the villager.

2.13 There should be only one pack size for each product in order to make it economic to manufacture and distribute.

2.14 The labels on these packs, besides meeting the requirements of the Drug Authorities and also of the Commodity Packaging Act, should be so designed that the name of the drug is synonym with the ailment and is a direct translation from one regional language to another. In addition, the product should also have a number code which should be the same on the product throughout the country so that this number code could also be used for subsequent purchases. Besides, the label should also have a symbolic representation of the disease or ailment so that even an illitrate person would be able to identify the drug needed. To illustrate, a label for 'Aspirin' is shown on the following page. As will be seen from the label, in Hindi it is called "Medicine for Headache". The number code on the label is the figure '1' which is the number of the product in the formulary (Table 'B'). The symbolic representation of the ailment viz. 'headache' is depicted by the picture of a man holding his hand on his head.

2.15 An illustrative label for 'Aspirin', both in English and Hindi.

2.16 In the following two pages are shown some symbolic representations of a few other products covered by the formulary (Table 'B').

Product No. 4 (Table 'B')

For Lactating Mothers

दूध पिलाती माताओं के लिए

Product No. 12 (Table 'B')

For lice & Scabbies

खुजली और जुँओं की दवा

Product No. 17 (Table 'B')

Gripe water for
digestion of Children

बच्चों के पाचन के लिए
ग्राइप वाटर

Product No. 20 (Table 'B')

For Diarrhoea

दस्त और मरोड के लिए

2.17 The label pattern and packages of the products should be uniform all over the country. Only the language on the labels should change depending upon the State in which they are required. In this way it will be possible to propagate standard preparations throughout the country by both their names in local languages and their number codes along with the symbolic representations which will enable the rural people to identify the products they need. By this scheme, it would, in the initial stages, be able to provide about 500 million people with household remedies worth U.S.$62.5 million (I.Rs. 500 million). The production programme could then be expanded to provide products worth U.S.$0.25; 0.37 or 0.62 (I.Rs.2/-, 3/- or 5/- respectively) equivalent per person per year, depending upon the experiences gained in the first five years of the operation of such units.

2.18 It is proposed that one such MMU should be established on an experimental basis in one district of the country and depending upon the experiences, changes could be made with an ultimate aim of having these MMUs in each and every district of the country.

2.19 Include d Know-how

The technical know-how for the preparations mentioned in the formulary (Table 'D') is widely known and is given in various National Formularies and Pharmacopoeias. However, in order to have a uniform quality for each product, it is proposed that a Central Formulation Laboratory, under control of the Drugs Controller of India, should be created. This Central Formulation Laboratory should provide to all MMUs the details of the manufacturing procedures for each and every product with definite standards and specifications laid down. All MMUs in the States, or as a matter of fact in the entire country, should follow these standard formulae. In the event of any difficulties experienced by any of the MMUs, a technician from the Central Formulation Laboratory could be called in for help. No MMU should be allowed to make any variation at all in the standard formulae without the prior approval from the Central Formulation Laboratory. The Central Formulation Laboratory should train a certain number of technical staff of each and every State Drug Administration so that these technicians could then be deputed to assist the MMUs wherever there is a technical problem.

2.20 Relationship with Hospital Pharmacy in District Civil Hospitals

If sterile areas already exist in district hospitals, then these facilities could be utilized for the manufacture of certain sterile preparations like Sulphacetamide I.P. eye-drops which could be packed under sterile conditions in hospital pharmacies and distributed through the network developed for the household remedies listed in the formulary (Table 'B'). This will provide immediate eye-care and aid to a large number of our village population which suffers considerably because of eye infections.

2.21 Immunologicals

These MMUs which will be having a district and rural background could be provided with a large size refrigerator where the following most important immunologicals required for preventive medicines in the rural areas of the country could be stored and made available to the medical and para-medical profession for immunizing the village population:

i) Cholera vaccine

ii) Typhoid and para-typhoid A & B type vaccines

iii) Smallpox vaccine

iv) Anti-venom serum

v) Oral Polio vaccine

vi) Triple vaccine

2.22 The MMUs could therefore play an important role in the proper storage conditions of these important vaccines to be made available at short notice to the rural population of the country.

2.23 The Quality Control Departments of the MMUs will keep an eye on the expiry dates of these vaccines so that proper material is used before vaccination programme starts. A record of the utilization of the vaccines could also be maintained by the Quality Control Departments of the MMUs.

CHAPTER - III

QUALITY CONTROL

3.1 The quality control functions in a pharmaceutical manufacturing unit comprise of the following:

i) To lay down standards for raw materials, intermediates and finished products.

ii) To test and release raw materials, packaging materials, intermediate forms and finished products.

iii) To prepare appropriate documentation procedures from the receipt of raw and packaging materials, through test and release of such materials, manufacture of the product, warehousing and despatch of the products to distribution centres.

iv) To prepare procedures to guide and implement good manufacturing practices jointly with the production department.

v) To ensure compliance with requirements of the Drugs & Cosmetics Act and the Rules thereunder in case of India, or the appropriate regulations in other countries.

3.2 The requirements and methods to fulfil these above mentioned functions are outlined below:

a) Standards for raw materials, intermediates and finished products

Since most of the products proposed to be manufactured are according to accepted pharmacopoeias or published compendiums, the standards have to be taken down from the same, inclusive of the test procedures.

b) Test and Release of Raw Materials, Intermediate Forms and Finished Products

The testing has to be carried out in a laboratory and the requirements

of fixtures, equipment, etc. are dealt with in a seperate chapter. The equipment indicated is for chemical testing only. Microbiological testing would be required only in the second phase and hence it has not been included in this pr er.

c) Documentation

In order to exercise proper check and control over various operations concerned with manufacturing a pharmaceutical product, the following basic documents must be maintained:

i) Raw materials receipt register
ii) Packaging materials receipt register
iii) Analytical report on each lot of raw material supply
iv) Packaging material inspection report on each lot received
v) Manufacturing or Batch Record Sheet for each product and for every batch of the product which gives complete batch manufacturing history
vi) Analytical report on each product batch
vii) Packaging record for each product batch
viii) Final batch release of each product
ix) Reconciliation of yields against standards
x) Distribution record of each batch of products

The essential particulars to be recorded in these documents or forms can be obtained by a perusal of Schedule 'U' of the Drugs & Cosmetics Rules (India).

d) Good Manufacturing Practices' Procedure

These would have to be prepared jointly by Quality Control and Production departments to cover the following areas:

i) Warehouse - materials receipt and storage

ii) Material weighments and transfer to production

iii) Production area - general checks for each product type, e.g. tablets, oral liquids, etc.

iv) Sanitation and hygiene, including good house-keeping.

e) Compliance with Drugs Control Regulatory requirements

The requirements with respect to the following major aspects, besides a total familiarity with all provisions of the Drugs & Cosmetics Act and Rules (in India) are essential:

i) Manufacturing licence and the conditions therefor

ii) Labelling requirements

iii) Classification of certain drugs in the various schedules of the Drugs & Cosmetics Act and Rules (in India) and the corresponding compliance requirements

iv) Manufacturing areas, documentation etc. requirements as per certain schedules of the Drugs & Cosmetics Act & Rules (in India).

3.3 In order to fulfil these functions effectively, the Head of Quality Control must be independent of the Head of Manufacturing as required by the Drugs & Cosmetics Act and Rules (in India).

CHAPTER - IV

DISTRIBUTION SYSTEM

4.1 Traditional Distribution System

In the past 30 years the pharmaceutical industry in India has developed the traditional ways of distributing drugs e.g. appointment of:

i) Sole Distributors

ii) Whole-salers

iii) Stockists

iv) Preferred Dealers, etc.

4.2 These systems have been used in various forms by various companies to fulfil their marketing needs for distributing their drugs. Since the medicines suggested to be manufactured and distributed in the MMUs are simple household remedies, the above methods of distribution will be only marginally suitable in the rural areas. Therefore, non-traditional methods of distribution will have to be resorted to.

4.3 Non-traditional Distribution System

In the non-traditional system of distribution we will have to follow the avenues which are normally available in the rural areas of the country. To name a few, the following are the most important:

i) Co-operative Societies of various nature

ii) Panchayat offices of villages

iii) Grocery shops - These shops are usually for major purchases

iv) Primary Health Centres

v) Gram Sevaks and Gram Sevikas, a para-medical force that has been created for the rural population by the Ministry of Health. These are groups of young boys and girls who have been specially trained by the Ministry of Health for rendering medical aid in the villages of the country.

vi) The distribution net-work of some of the large consumer products manufacturers like match-boxes, tea, 'bidis', tobacco, etc. in the country.

vii) Chemists and Retailers in the villages or district places.

viii) Physicians and Vaidyas

ix) School teachers

x) Through professional organizations like the Indian Medical Association, the Management Associations and voluntary organizations like the Lions Club and the Rotary Club.

xi) A van could be provided to each MMU for supplying the necessary products to the feeder villages or satellite villages which will in turn become sources of supply of these products to smaller villages.

4.4 In order to be able to choose the right method of distribution, it is suggested that any one of the above methods or a combination of them, which may differ from region to region, could be adopted. Experimental marketing should be done in order to test the best possible methods of distribution in any region.

4.5 Publicity

Adequate publicity should be given to make known these simple household remedies to the rural population and this could best be done by

adopting the following measures:

i) By display of small attractive posters, which should be enlargements of the labels of each product, in village schools, Panchayat offices, nearby bus stations, grocery shops, railway stations, etc.

ii) Wall-painting is the cheapest, simplest and most common way of advertising in rural areas and this is the most widely used system at the moment. Hence, this method of publicity should be utilised extensively for popularizing these simple home remedies.

iii) The villages in the rural areas observe weekly or fortnightly bazaar days and these days could be utilised for advertising, popularizing and distributing these simple home remedies.

CHAPTER V

CAPITAL INVESTMENT AND FINANCIAL PROJECTIONS

5.1 Ownership

The ownership of these MMUs i the districts can be with the State Governments, Co-operative Societies, Philanthropic organisations, Trusts etc.

5.2 Management

In order to make the programme successful, it is absolutely essential that these MMUs are properly managed, technically, financially as well as commercially. If the management is to be provided by the State Governments it would put an enormous strain on the already strained services of the State Governments to provide this kind of expertise. It is suggested that technical and marketing assistance could be taken from existing pharmaceutical companies in the country. Business houses should also be requested to adopt one such unit and provide all the necessary managerial services to these units so that they become economically viable.

5.3 The financial projection for a typical unit and balance sheet for three years has been worked out separately with certain assumptions. It would appear from the financial projection that such units, if managed properly, will be in a position to be economically viable in the third year of working i.e. as soon as they start manufacturing goods worth U.S.$250,000 (2 million Indian Rupees). As the production programme is extended, the units will become financially self-supporting.

5.4 In the following pages the details of investment for an MMU, inclusive of capital equipment, quality control laboratory facilities, personnel and its cost, the earning statement and the balance sheet are given.

5.5 Summary of Investment

	U. S. $	I. Rs.
i) Construction cost	25,000	200,000
ii) Land and development cost	3,125	25,000
iii) Cost of electricity and water supply	6,250	50,000
iv) Cost of air-conditioning and air treatment	6,250	50,000
v) Cost of equipment	34,375	275,000
Total cost of Project	75,000	600,000

5.6 CAPITAL EXPENDITURE

A. PRODUCTION DEPARTMENT

i) Tablet Section	U.S.$	I.Rs.
Planetary Mixer - 50 kg. capacity	2,250	18,000
Multi Mill	1,875	15,000
24 tray Oven	1,250	10,000
16-station Rotary machine	5,000	40,000
Single punch tablet compression machine	1,250	10,000
Weighing balance - 300 kg. capacity	138	1,100
Tablet disintegration test machine	175	1,400
Hardness tester	37	300
Sachet making machine	5,000	40,000
Vacuum system for leak test	250	2,000
Total	17,225	137,800

ii) Liquid Section		
Stainless steel tanks - capacity 400 & 200 litres	1,875	15,000
Agitator (Turbo stirrer)	625	5,000
Filteration unit	750	6,000
pH meter	375	3,000
Hot plates (2 Nos.)	63	500
Bottle gas with burner	63	500
Transferring pump	375	3,000
Deionised water portable unit	437	3,500
Bottle washing unit	187	1,500
Bottle filling machine	1,125	9,000
Pilfer-proof sealing machine	1,000	8,000
Semi-automatic labelling machine	188	1,500
Bottle drying oven	625	5,000
Total	7,688	61,500
Cost of Equipment (i + ii)	24,913	199,300

B. QUALITY CONTROL DEPARTMENT

	U.S.$	I.Rs.
Physical balance	100	800
Analytical balance	437	3,500
Oven - hot air	313	2,500
Vacuum pump	437	3,500
pH meter	375	3,000
Photo electric Colorimeter	900	7,200
Refrigerator	1,125	9,000
Glassware, porcelainware and metalware	1,250	10,000
Miscellaneous	375	3,000.
Total	5,312	42,500
C. Furniture, fixtures, etc.	3,250	26,000
D. Contingencies	900	7,200

TOTAL COST

Equipment - Production Department	24,913	199,300
Equipment - Quality Control Department	5,312	42,500
Furniture, fixtures etc.	3,250	26,000
Contingencies	900	7,200
	34,375	275,000

[illegible]

Department		[illegible]	[illegible] per month U.S.$	Total per month Indian Rs.
Production	- [illegible]	[illegible]	188	1500
	Asst. [illegible]	[illegible]	125	1000
	[illegible]	[illegible]	[illegible]	[illegible]
Packaging	- Semi-skilled	15	562	4500
	Unskilled	[illegible]	50	400
Quality Control	- Chief Chemist	1	125	1000
	Asst. Chemist	1	62	[illegible]
	Laboratory Assistant	1	38	300
Stores	- Store Keeper	1	75	600
	Unskilled	2	50	400
Engineering	- Mechanic - [illegible]	[illegible]	62	[illegible]
	Electrician	[illegible]	50	400
Distribution	- Skilled	2	125	1000
Administration & Accounts	- Supervisor	1	100	800
	Clerks	2	100	800
	Unskilled	1	25	200
	Total	36	1850	14800
Add: other benefits like Provident Fund, State Insurance, Pension scheme, Medical, etc.			278	2220
	Total cost per month		2128	17020
	Total cost per annum		25536	204240

Conversion rate used - U.S.$ 1 = 8 Indian Rupees

5.8 ASSUMPTIONS ON PROJECTIONS

i) Land available free of cost

ii) No additions to Fixed Assets during projected period

iii) Depreciation computed at 10% on cost

iv) Receivables on the basis of one month sales

v) Inventories computed on the following basis:

a) Raw materials - two months consumption

b) Work-in-progress - two months consumption plus 60% overheads

c) Finished goods - one month cost of sales

vi) Accounts payable on the basis of one month cost of materials.

vii) Accrued expenses on the basis of one month expenses

viii) Loans to be of interest free moratorium for an initial period of five years

ix) Inflation rate is estimated at 10%

5.9 PROJECTED EARNING STATEMENT

	First Year		Second Year		Third Year	
	U.S.$	I.Rs.	U.S.$	I.Rs.	U.S.$	I.Rs.
Sales	112,500	900,000	175,000	1,400,000	250,000	2,000,000
Raw Materials	52,3[illegible]	423,000	99,250	794,000	137,5[illegible]	1,100,000
Packing Materials	9,000	72,000	15,750	126,000	25,000	200,000
Labour & Overheads	31,250	250,000	36,250	290,000	40,000	320,000
Depreciation	7,500	60,000	7,500	60,000	7,500	60,000
	100,625	805,000	148,750	1,190,000	210,000	1,680,000
Gross Profit	11,875	95,000	26,250	210,000	40,000	320,000
Less: Expenses -						
Selling & Distribution	17,500	140,000	26,250	210,000	32,500	260,000
General Administration	7,500	60,000	8,125	65,000	8,750	70,000
Total	25,000	200,000	34,375	275,000	41,250	330,000
Operating Profit/(Loss)	(13,125)	(105,000)	(8,125)	(65,000)	(1,250)	(10,000)

Conversion rate used - U.S. $ 1 = 8 Indian Rupees

5.10 PROJECTED BALANCE SHEET

	First Year		Second Year		Third Year	
	U.S. $	I.Rs.	U.S. $	I.Rs.	U.S. $	I.Rs.
Fixed Assets	75,000	600,000	75,000	600,000	75,000	600,000
Less - Depreciation	7,500	60,000	15,000	120,000	22,500	180,000
A. Net Assets	67,500	540,000	60,000	480,000	52,500	420,000
Current Assets						
Receivables	9,375	75,000	14,500	116,000	20,875	167,000
Inventories	32,875	263,000	51,750	414,000	76,375	611,000
Cash & Bank etc.	6,250	50,000	7,500	60,000	9,375	75,000
	48,500	388,000	73,750	590,000	106,625	853,000
Less:Current Liabilities:						
Accounts Payable	5,000	40,000	8,750	70,000	13,750	110,000
Accrued Expenses	4,750	38,000	5,875	47,000	6,875	55,000
	9,750	78,000	14,625	117,000	20,625	165,000
B. Net Current Assets	38,750	310,000	59,125	473,000	86,000	688,000
Total (A + B)	106,250	850,000	119,125	953,000	138,500	1,108,000
Represented by:						
Loans	81,875	655,000	102,875	823,000	123,500	988,000
Capital	37,500	300,000	37,500	300,000	37,500	300,000
Retained Earning/(Loss)	(13,125)	(105,000)	(21,250)	(170,000)	(22,500)	(180,000)
Total	106,250	850,000	119,125	953,000	138,500	1,108,000

Conversion rate used - U.S.$ 1 = 8 Indian Rupees

CHAPTER - VI

SOCIO-ECONOMIC BENEFITS

The socio-economic benefits that will be derived out of the proposed programme will be:

i) The provision of these simple, harmless, home remedies will save a large number of manhours which are normally wasted because of minor ailments and suffering that our rural population undergoes due to non-availability of simple medicaments. According to our estimate, eight man-days are lost per person per year in rural India because of minor ailments. This will work out to an yearly loss of six million man-years taking 50% of the rural population as working on farms.

ii) If the simple medicaments are provided at the right time, mortality rate among children will fall considerably.

iii) There will be local employment. The MCUs will provide opportunities for young village boys and girls who have been to schools to be gainfully employed. It will also provide additional source of income for grocers and vendors in the village areas who will be selling most of these harmless home remedies.

iv) The rural population will have a direct involvement in the family welfare programme of the country.

v) Because of the possibilities of getting these simple medicaments in their own villages, the pressure on the Primary Health Centres of the Government will be less, whereby the doctors could concentrate on larger areas.

vi) The industrial worker in the urban areas is medically covered by a scheme called the Employees' State Insurance Scheme (E.S.I.S.) wherein an employer contributes financially sufficient amounts towards the maintenance of the health programme. However, there is no such benefit available to the rural population which is mainly engaged in agriculture. The scheme suggested, which is expected to become economically viable in the third year, even if it runs into minor losses initially, will provide some medical relief to our village population which has hitherto been denied this facility.

vii) Healthy life is a more fulfilling life.

CHAPTER - VII

PRESENT POSITION OF THE DRUG INDUSTRY IN INDIA

7.1 As mentioned earlier, the drug industry in the country is highly developed and almost all pharmaceutical preparations, including some of the bulk drugs are manufactured and distributed. The production of pharmaceuticals in 1977-78 is estimated to be around U.S.$ 1 billion (8000 million Indian Rupees) and the projected requirement of the government for 1982-83 is of the order of U.S.$ 2.38 billion (19,000 million Indian Rupees). The following chart shows that the aim is to almost double the per capita drug consumption as a percent of per capita income:

TABLE - 'C'			U. S. $
	1977-78 (estimated)	1982-83 (projected)	Growth Rate 1977-82
Population	634 million	697 million	2%
Per capita income	175	200	[illegible]
Drug Production	1 billion	2.38 billion	19%
Per capita drug consumption	1.6	3.4	17
Per capita drug consumption as % of per capita income	0.90%	1.69%	13%

7.2 In order to achieve the above, the major objective of the industry will be to:

i) Increase the present coverage of the 20% of the population by modern medicines to 30%. This will comprise of 22.5% of urban and 7.5% of the rural population.

ii) Make medicines available at world competitive prices.

iii) Keep the import content of the medicines manufactured in the country below 5%.

iv) Increase exports.

7.3 The following chart gives an idea of the demand projection by anatomical groups:

TABLE - 'D'

U.S. $ in million

Group	1977-78	%	1982-83	%	Growth Rate 1972-77	Growth Rate 1977-78
Alimentary tract & metabolism	307.5	(30.7)	675.0	(28.4)	17.4	17.0
Anti-infective	237.5	(23.7)	612.5	(25.8)	18.2	21.0
Respiratory	93.8	(9.4)	212.5	(9.0)	19.8	18.0
Central nervous system	62.5	(6.2)	131.3	(5.5)	17.6	15.0
Blood & blood forming	60.0	(6.0)	156.3	(6.6)	15.0	21.0
Dermatologicals	53.8	(5.4)	125.0	(5.3)	24.8	18.4
Antiparasitics	40.0	(4.0)	127.5	(5.4)	24.1	26.0
Musculo-skeletal	39.0	(3.5)	80.0	(3.4)	19.3	18.0
Genito-urinary	30.0	(3.0)	60.0	(2.5)	15.0	15.0
Cardio-vascular	27.5	(2.8)	65.0	(2.7)	17.2	18.6
Systemic hormones	23.7	(2.4)	55.0	(2.3)	22.3	18.0
Sensory organs	21.2	(2.1)	52.5	(2.2)	19.6	20.0
Others	7.5	(0.8	22.4	(0.9)	16.4	24.6
Total	1000.0	(100)	2375.0	(100)	18.3	19.0

7.4 The chart below shows the demand of bulk drugs in the country:

TABLE - 'E'

U.S. $ in million

A. BULK DRUG REQUIREMENT	1977-78	1982-83	Growth Rate 1977-82 (%)
Domestic production	218.8	562.5	21
Imports *	93.7	187.5	15
Total	312.5	750.0	19

	1977-78	1982-83	Growth Rate 1977-83 (%)
B. FORMULATION PRODUCTION	1000.0	2376.0	19

The ratio of bulk drugs to formulations is 3.2 in 1977-78 and is likely to remain the same in 1982-83.

7.5 The present investment in the pharmaceutical industry is over U.S.$750 million (6000 million Indian Rupees), and in order to meet the requirements, both for bulk drugs as well as formulations for 1982-83, the estimated investment has to rise to as much as U.S.$1874 million (15,000 million Indian Rupees). Both the industry and the Government are seized of the problem and if the industry's performance in the past is any indication, it is hoped that these targets will be achieved.

7.6 Bulk Drugs

Since the production of bulk drugs in the country has to increase to U.S.$562 million (4,500 million Indian Rupees) per year, considerable amount of technology has to be acquired from abroad and also developed from within to meet the bulk drug requirements. Government has to favourably consider the import of appropriate technologies into the country, especially for products which involve high technology.

7.7 It is also very important that if the requirements of bulk drugs in the country are to be met, suitable technologies have to be developed or purchased for a large number of important intermediates which go toward making the important basic drugs. A panel of technologists and research workers, working under the Chairmanship of this author, has identified these intermediates, their quantities required, the final

products and the quantities that could be manufactured out of them. The list is given below:

7.8 TABLE - 'F'

Sr.No.	Drug Intermediates	Quantity (Tonnes)	Basic Drugs	1982-83 Quantity (Tonnes)
1.	Acetoin	60	Sulphamoxole	120
2.	Trimethoxy-benzaldehyde	) 60	Trimethoprim	50
3.	Guanidine hydrochloride *	)		
4.	Metol	30	Diloxanide furoate	20.5
5.	4,7-Dichloroquinoline	)400	Chloroquin phosphate	500
6.	Novaldiamine	)350	or sulphate	
7.	4-Methyl-5-ethoxazole	) 40	Vitamin B6	70
8.	cis-Butenediol	) 50		
9.	Trimethyl hydroquinone	) 10	Vitamin E	10
10.	Isophytol	) 10		
11.	Dimethylaminopropyl chloride hydrochloride	10	Chlorpromazine hydrochloride and others	24
12.	2,4-Dichlorobenzoic acid	16	Fursemide	10
13.	Nitrofuraldehyde diacetate	) 80	Nitrofurazone	80
14.	Semicarbazide hydrochloride	) 20	Furazolidone	
15.	Amino-oxazolidone sulphate	) 30	Nitrofurantoin	
16.	Amino-hydantoin sulphate	) 30		
17.	8-Hydroxyquinoline	300	Derivatives of 8-Hydroxy-quinoline	600
18.	2-Methyl-imidazole	650	Metronidazole	500
19.	1S-APA	)150	Ampicilin	100
20.	d-Phenyl glycine	)100		
21.	Isoxamine	100	Sulphamethoxazole	200
22.	DL-Amino butanol	)225	Ethambutol	100
23.	D-Tartaric acid	)300		
24.	4:7-Dichloro-quinoline	140	Amodiaquin	200

Sr.No.	Drug Intermediates	Quantity (Tonnes)	Basic Drugs	1982-83 Quantity (Tonnes)
25.	M-chloro aniline disulphonamide	6	Hydrochlorothiazide	6
26.	Isobutyl benzene	20	Ibuprofen	20
27.	2-Amino-pyrimidine *	200	Sulphadiazine	400
28.	Guanidine nitrate * or hydrochloride	100	Sulphaguanidine	
29.	para-Aminophenol from Nitrobenzene	1000	Paracetamol	1100

* Since 120 tonnes of Guanidine is required for 2-Amino-pyrimidine, the total requirement of Guanidine in this list for the three drugs amounts to 230 tonnes.

7.9 Research & Development

From the above it is very clear that considerable research and development efforts will have to be made within the country to meet the targetted requirements of both bulk drugs and formulations for the health care and family welfare of the country's population. National laboratories and private laboratories are doing their best to develop such technologies. It is expected that they will make a great contribution to the basic drug manufacturing programme in the coming years. However, in order to stimulate the research and development effort in the country, certain incentives should be provided, viz:

i) Research and development of various identified intermediates should be judiciously distributed amongst two or three research and development laboratories, taking into consideration the capability and the interest of the particular research and development unit. This should prevent unhealthy competition and avoid repetitious work.

ii) All research laboratories which are recognized by the Department of Science & Technology should be permitted to a weighted deduction of 175% of their expenses on research and development in their Income Tax returns. The research units which undertake to take up the allotted research and development work in developing the know-how for the manufacture of the identified intermediates should be given automatic recognition by the Department of Science and Technology.

iii) Once the desired know-how for a particular intermediate/ basic drug has been developed and viable production of the same is established for at least a period of two years, all imports of these intermediates/basic drugs should be stopped thereafter.

7.10 In the meantime, till our own technologies are available, the import of foreign technologies should be permitted for bulk drugs as well as intermediates. The ratio in foreign exchange saving in the first five years should be at least 1:15.

SUMMARY

In Chapter I, an attempt has been made to suggest how indigenous Ayurvedic medicines could be therapeutically improved and distributed to the rural population of India.

In the following Chapter II, the concept of a Model Manufacturing Unit to manufacture simple allopathic home remedies has been outlined. A floor drawing of the proposed plan of an MMU has also been included. Suggestions have been made to use certain labelling system so as to make it easy for the illiterate millions to buy appropriate drugs for minor ailments without the assistance of medical or para-medical professionals.

Quality control of the products to be manufactured in the MMUs have been discussed in Chapter III.

The distribution system of the products proposed for manufacture in the MMUs is suggested in Chapter IV.

The requirements of plant and machinery, personnel and financial projection of the working of an MMU has been presented in Chapter V.

In Chapter VI, some of the socio-economic benefits that could be derived by the implementation of the proposed manufacturing programme of simple home remedies have been described.

The present position of the drug industry in India and its future challanges are highlighted in Chapter VII of this presentation.

G L O S S A R Y

Ayurveda	:	Indian indigenous system of medicine
Bidis	:	Locally manufactured cigarettes in which the tobacco is wrapped in special leaves. These are commonly smoked by village folk.
Churna	:	Powder form of Ayurvedic drugs.
Gram Sevaks	:	Young boys who have para-medical training and serve in villages.
Gram Sevikas	:	Young girls who have para-medical training and serve in villages.
Gutti or Guggulu	:	Ayurvedic drugs in tablet form.
Panchayat	:	A body of elected representatives of a village which looks after the general community welfare.
Quath	:	Water decoction of herbs.
Tail	:	Oily decoction of herbs.
Vaidya	:	A physician practicing Ayurveda.

A B B R E V I A T I O N S

B.P.	:	British Pharmacopoeia
B.P.C.	:	British Pharmaceutical Codex
I.P.	:	Indian Pharmacopoeia
MMU	:	Model Manufacturing Unit
N.F.I.	:	National formulary of India
Tabs.	:	Tablets

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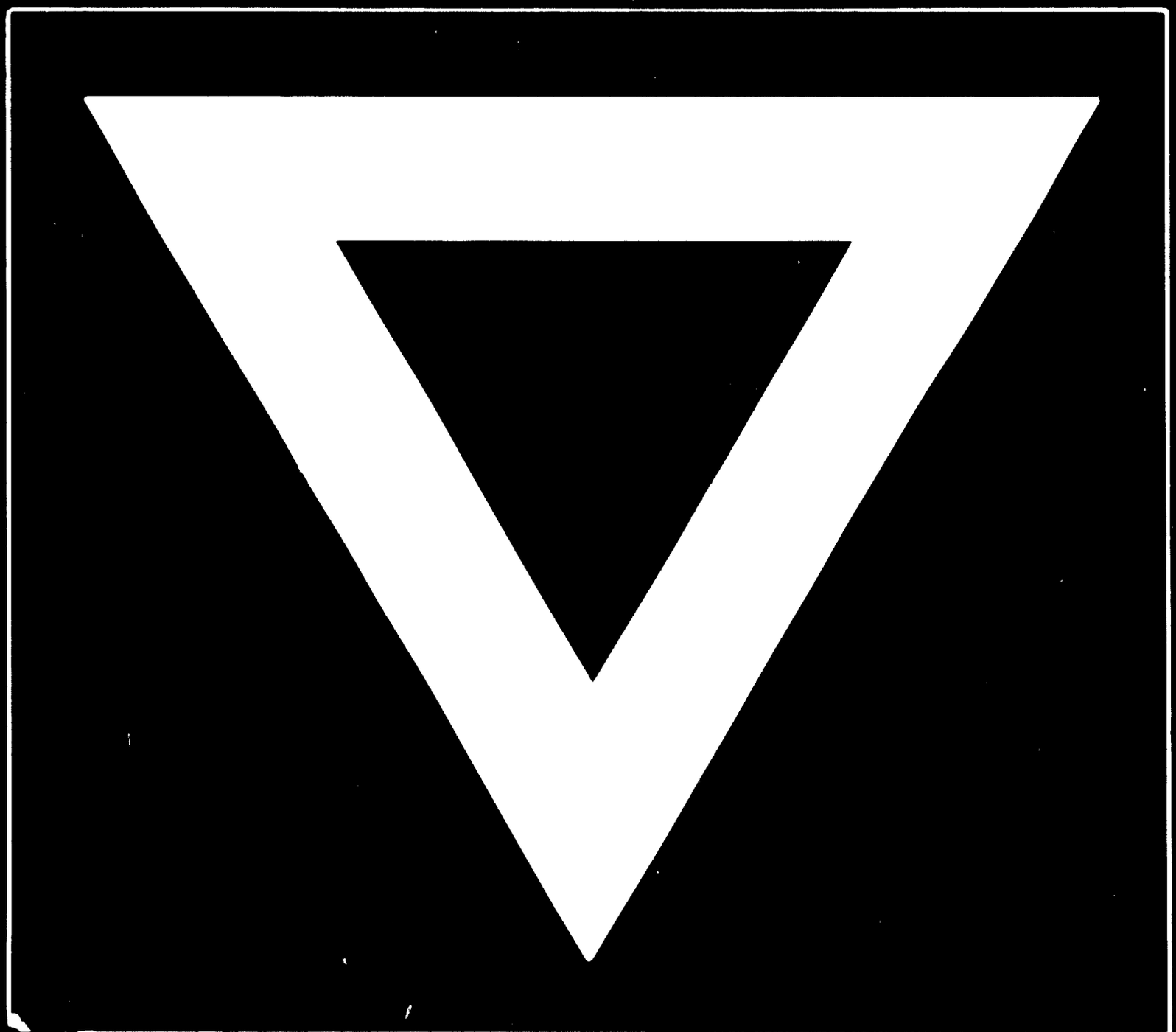

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