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PHARMACEUTICAL INDUSTRY IN INDIA 1/

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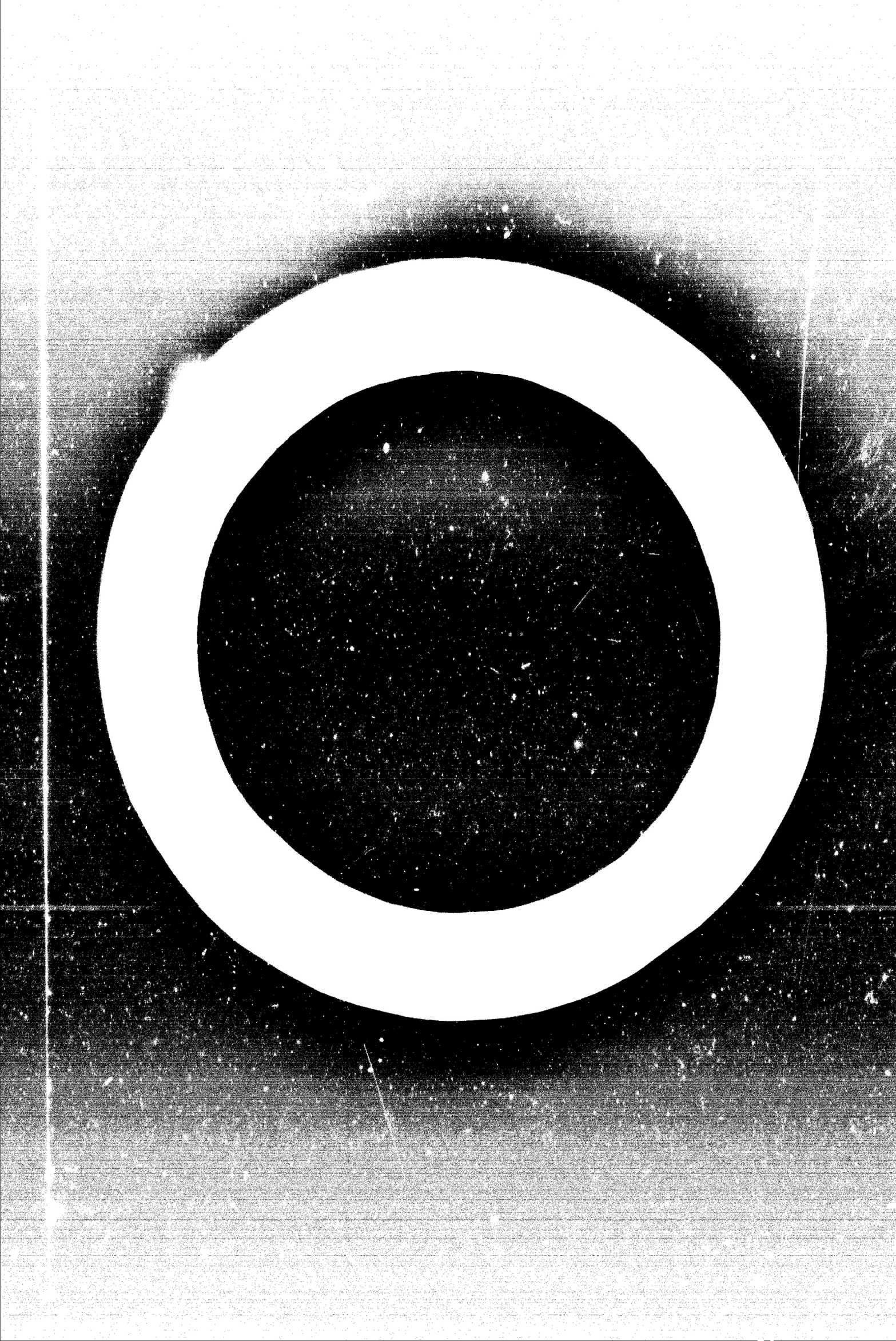


In 1968 thepharmaceutical industry in India can be said to have completed two decades of organised existence. It was in 1948 that the industry started its career with a definite plan of growth within the larger framework of the country's overall industrialisation. The cumulative impact as a manufacturing industry of consequence began to be felt from 1958 onwards when a large number of factories progressed from blue print to production. It would be relevant at this stage to evaluate the direction the industry has taken in terms of the nation's economy and national health.

National economy.

As an industry, the pharmaceutical sector falls entirely in the category of a chemical-based industry. However, 20 years ago, the organic chemicals industry had not reached a stage of development when it could feed the pharmaceutical sector with many of its requirements. The opposite was the case in Europe and the United States, where the pharmaceutical industry came into being after the chemical industry had acquired a base from where it could meet the needs of drug manufacturing units.

The pharmaceutical industry therefore, undertook to manufacture its own requirements of many of the substances, thus adding to the dimensions of the chemical industry in particular, and accelerating the pace of industrialisation in general. Progressively the organic chemicals industry is orienting its production to meet the requirements of the pharmaceutical sector. This is helping the old pharmaceutical manufacturing units to enlarge their manufacture and new ones to enter the industry with basic manufacturing programmes.

Today the pharmaceutical industry has grown to be the largest in terms of value among the chemical based industries, with estimated production value of nearly Rs.2000 million. The percentage of pharmaceutical production to total chemical production in terms of value is roughly

30 per cent (Rs.2000 million in a total value of Rs.7000 million). Comparative figures for some of the highly industrialised countries are: Japan - 23 per cent ($ 1175 million out of Rs.5159 million for chemicals); the United Kingdom - 10 per cent ($ 600 million out of $ 5990 million for chemicals) and West Germany - 15% ($ 1050 million out of Rs.6985 million).

Capital structure: The current capital investment in the industry is estimated at Rs. 1500 million; as against Rs.240 million in 1952 and Rs.560 million in 1962. By the end of the Fourth Plan in 1974, the capital structure is expected to be of the order of Rs.2000 million. The growth rate of capital in the ten years from 1956 to 1967 has been three-fold.

Production: In 1947 the production was of the value of Rs.100 million. In 1968 the gross output was Rs.2000 million, a twenty-fold increase, an outstanding achievement for any sector in Indian industry.

In any assessment of production an important consideration is whether the industry has developed along the lines of self-sustaining growth. The indigenous manufacture of raw materials is a key phase in the planned development of a self-sustaining industry. Basic manufacture, therefore, was accorded first priority in the initial development of the industry, and today the industry is self-sufficient to a large extent in its raw material requirements.

Fifty-five units are engaged in the basic manufacture of a wide range of products that go to feed the formulation plants of their own units as also of other manufacturers in the organised and small-scale sector. The value of basic manufacture is estimated at Rs.250 million at present. This output generates a diverse formulation production of finished goods of approx. of the value of Rs.1250 million.

The value of basic drug production will increase by another Rs.50 million by 1970, by which time, the newly sanctioned manufacturing programmes will have been implemented. The Fourth Plan target for basic drugs is Rs.500 million, to be reached by 1973-74. When that output is reached the industry will be self-sufficient for most of its requirements of raw materials, save an import of a few items whose manufacture would be uneconomical in relation to the demand.

The general production covers a wide range of items which include antibiotics; sulpha drugs; anti-leprotic drugs; hormones; analgesics; antipyretics, vitamins; tranquillisers, anti-histamines; phytochemicals and various other pharmaceutical chemicals.

The technology employed in production and quality control is of the level obtaining in the industrialised countries in Europe, in the United Kingdom and the U.S. This was made possible by the Government of India's policy of allowing international collaboration where such assistance would confer long-term benefits to Indian industry. The benefits of such a policy have been two-fold; the latest plant and equipment, and the foreign exchange to buy it, and the latest know-how in production have become available to the country without having to start from scratch and the benefits of modern drugs which have been proved efficacious have come available to our people.

Employment: The organised sector alone gives employment to over 60,000 people. Of these about 10% are technically trained. Another feature of international collaboration with Indian industry has been that technicians and administrators receive advanced training abroad. On their return, these personnel pass on the benefits to their colleagures. In the pharmaceutical industry about 100 persons of various skills are sent abroad every year to study the latest know-how in product

development, manufacturing, quality control and administration.

Science & Technology: As yet diffused, but slowly crystallising as a major force are the enlarging dimensions of science pushed forward by a research-based industry that must remain scientific even in its day-to-day operations. Thousands of young men and women are learning new disciplines keeping pace with the rapid strides of scientific development around the globe, and, in the aggregate, constituting the spearhead of a technological society.

Of the several contributory factors to the emerging 'temper of science' a substantial share must be accorded to the Government's policy of harnessing international know-how to the needs of the country as a means of accelerating the pace of industrialisation. Collaboration was encouraged in all the fields of industrial endeavour - scientific, technological, financial and managerial. A fundamental of this policy was that units established with such collaboration should evolve programmes that would finally lead to indigenous self-sufficiency in materials and men. The pharmaceutical industry made maximum use of this incentive and today stands poised to compare equally with its counterparts in the industrialised countries.

National Health: The development of an industrial base, with its own research and product development centres, quality control checks, and effective distribution apparatus, has brought modern medicine in adequate quantities to our physicians and hospitals. The availability of medicine is the bedrock of any national health programme. The industry has grown concurrently with the country's health plans and helped it to keep its pace of development.

Collaboration tie-ups have made it possible for the industry to introduce new drugs discovered anywhere in the world. Clinical

trials, an essential stage in the development of a new drug, have now the advantage of obtaining testing facilities all over the world. The feedback of clinical information on new and old drugs from all parts of the world are communicated to the medical profession in India for guidance in their practice. Health is an international problem. The pharmaceutical industry, international in character and motivation, has widened the horizons of National health.

However, while the progress made by the industry is quite commendable, it has so far succeeded in touching only the fringe of the health problem of the country. Even today more than 80% of the population get little or no medical attention. They depend on traditional cures, mostly from herbs, recommended by the village 'doctor' or passed on as a 'family secret'. As education and industrialisation increasingly invades the periphery of our rural world, an awareness of scientific medication is beginning to spread. As the ramified health plans consolidate in village centres, this awareness will only be accelerated. In the initial stages the demand may be only for common items like anti-bacterials and prophylactics. As purchasing power increases, so will be the demand for sophisticated drugs.

Structure of the Industry.

After independence in 1947, the Government launched a programme of planned industrialisation of the country. Until then, like all other industries, the pharmaceutical industry, too, represented an assorted accumulation of enterprises, sporadic in origin and thriving at various stages of incoherent development. In 1948, a survey was made of the country's industrial potential in every sector, and a programme of development projected. The development programme was phased in five-year plans which had, for their objectives, specific goals in different fields, to be reached in a sequence of progressive self-sufficiency.

The pharmaceutical industry was included within the scope of this regulated development. In 1953, the Union Ministry of Commerce and Industry set up a Pharmaceutical Enquiry Committee to recommend the lines on which the industry could be developed as an integrated industry. At the same time, the Government placed the industry in a classification that allowed both the Government and private enterprises to set up manufacturing units. The policy for the first phase of development was manufacture of drugs from the basic stages.

To ensure that the industry would achieve the required pattern of growth, it was placed within the purview of the Industries (Dev. & Regulation) Act, and put under the guidance of the Directorate-General of Tech. Development (DGTD).

The primary function of this Directorate General is to bring about inter alia an integrated development of all allied industries like the chemical and other chemical based industries, and the chemical plant equipment industry. This measure has enabled the concurrent growth of the connected industries on a preplanned pattern.

To broad-base planning a Development Council, with membership representing the different interests of the industry, the trade and the consumer, was set up. The council which is reconstituted every two years, advises Govt. on matters relating to manufacture and distribution. It meets every quarter and assesses the requirements of the industry in relation to its growth outlined in the five-year plans, and projects a development programme for the subsequent plans. For the Fourth Plan, the Council departed from the past practice of setting up specific targets for different essential items of manufacture, and outlined "indicative" figures on the basis of estimated potential.

In planning or sanctioning new manufacturing units, or expansion in existing unit, the DGTD takes into consideration the needs of the country in terms of the requirements of the type of product sought to be manufactures. Over production, or the manufacture of products that have no urgency or special ...

clinical demand, are discouraged. By this principle of selectivity and priority in the matter of manufacturing capacities and product proliferation, the DGTD ensures the consolidation of an industrial complex that is both viable and rational.

The 125 manufacturers borne on the list of the DGTD, known generally as the organized sector, constitute the core of the Industry. To be eligible to this list a firm must have minimum investment in plant equipment of Rs.7.5 lakhs (750,000 Rs.) In the small-scale sector the number of manufacturers is estimated to be 2300. These units are engaged mostly in formulation and are controlled by the State Government. The organized sector is responsible for over 80% of the total drug production in the country.

Basic Manufacture:

Appendix gives the overall picture of progress in the manufacture of basic drugs, indicating the capacities licensed, the actual production achieved so far, stages from which manufacture is being undertaken and the indicative figure for each of the items for the Fourth Plan period.

Antibiotics :

PENICILLIN: Soon after technology was established in the advanced countries for the large-scale manufacture of antibiotics, the Government of India, with financial and technical assistance from UNICEF & WHO, set up a plant for the basic manufacture of antibiotics at Pimpri, near Poona. The initial production at this plant run by

M/s Hindustan Antibiotic Ltd., was 9 MMU of Penicillin per annum. Production was gradually increased by carrying out improvements in the manufacturing processes and by additions to the equipment. In 1957-58 the production rose to 21 MMU, to 40 MMU in 1960-61, and now the capacity exceeds to 80 MMU per annum.

The Private Sector entered the field with the Unit at Baroda, having an initial capacity of 10 MMU per annum. The present capacity of this unit is of the order of 80 MMU. A second unit in the private sector was established in Calcutta with a capacity of 20 MMU per annum. Both these units have with improvement in technology and with the installation of balancing equipment enlarged their capacities further. Meanwhile, the Government floated another undertaking for the basic manufacture of pharmaceuticals, the Indian Drugs and pharmaceuticals Ltd., (I.D.P.L.) This undertaking has established an antibiotic plant at Rishikesh with a capacity of 140 MMU of penicillin per annum. The combined output of these plants is adequate to meet the country's requirements of this antibiotic, with scope for a surplus for export. Simultaneously, production has been envisaged of semi-synthetic penicillins which are replacing injectables, and have proved remarkably effective in the treatment of deep-seated infections.

Streptomycin & Dihydrostreptomycin:

These antibiotics are of special value in combatting TB. Hindustan Antibiotics, in technical collaboration with a U.S. firm set up a plant at an initial cost

of Rs.21.8 million. The original capacity of 45 tonnes of streptomycin and dihydrostreptomycin annually, has been increased to 80-90 tonnes. The outlay for this expansion was met from the firm's own resources and amounted to Rs.5.5 million.

The Rishikesh plant of IDPL has a capacity of 85 tonnes. A unit in the private sector also produces these antibiotics with a capacity of 40 tonnes per annum. (Expanding further to 85 t/p.a. When full production is reached the requirements of the country for this drug will be fully met.

TETRACYCLINES:

These are wide spectrum antibiotics very effective in the treatment of bacterial infections and some viral diseases. It has special significanc in the campaigg against Trachoma, which particularly afflicts children and cause blindness, Basic manufacture of Tetracycline is being done at the following places: a private sector unit at Chandigarh with a capacity of 10 tonnes per annum; a private sector unit at Bulsar with a capacity of 10 tonnes per annum; a private sector unit at Baroda with a capacity of 3 tonnes per annum and Hindustan Antibiotics with a capacity of 1.5 tonnes per annum.

The Rishikesh Antibiotic plant of IDPL have also set up a capacity of 120 tonnes per annum for this group of antibiotics.

The possibility of using tetracycline in the production of animal feed supplements is being explored. As an over-production of tetracycline in

terms of medical requirements is likely to occur when the Rishikesh unit reaches full capacity, diversion of its use also as animal feed supplements will result in an improvement in milk, meat and poultry products.

CHLORAMPHENICOL: An antibiotic used extensively in the treatment of Typhoid and other enteric diseases as also whooping cough, two units, one with a capacity of 30 tonnes per annum and another with 20 tonnes per annum, have been esablished in Bombay. A third unit with a capacity of 18 tonnes is being set up in Calcutta.

OTHER ANTIBIOTICS: A capacity of 300 kg for Amphotericin, an antifungal antibiotic, has been established at Baroda. This antibiotic is already being exported from India. A capacity of 1 tonne per annum has been established at Pimpri for Hamycin and Dermostatin, antifungal antibiotics developed by Hindustan Antibiotics. Production of these antibiotics has also been leased to firms abroad. The IDPL unit in Rishikesh is also establishing a capacity of 10 tonnes of Nystatin. New capacities for Erythromycin, Kanamycin and Neomycin, etc. are being established in Gujarat.

SYNTHETIC DRUGS.

A wide range of synthetic drugs are being produced in large quantities, Important among these are sulpha drugs, anti-TB drugs, anti-leprotic drugs, analgesics, anaesthetics and anti-malarials.

SULPHA DRUGS:

Units in the private sector have established an aggregate capacity of about 500 tonnes. IDPL have established a capacity of 510 tonnes for sulpha drugs at their synthetic drug plant at Hyderabad. The capacities cover sulphanilamide, sulphadiezene, sulphadimidine, sulphaguanidine, sulphaphenazole, sulphapyridine, sulphasomidine and sulphacetamide.

ANTI TB DRUGS

The production of PAS and its salts - used in the treatment of tuberculosis - reached 260 tonnes in 1968. four units in the private sector have an aggregate installed capacity of 400 tonnes per annum. Similarly, at another unit manufacturing anti-TB drugs, INH is produced in sizable quantities. The Synthetic Drugs Plant of the IDPL with a capacity of 20-40 tonnes per annum has been installed, which is also supplying one of the intermediate hydrazine hydrate for its manufacture. In a private sector unit, also situated at Hyderabad, the starting material Gamma Picoline (as also other Picolines and Pyridine) are being produced to meet the requirement of INH manufacturers and for other drugs.

ANTI-LEPROTIC DRUGS:

One unit in Bombay is in production with an annual capacity of 11 tonnes for sulphones; 3 units in West Bengal with an aggregate capacity of 7.5 tonnes per annum are also in production.

ANALGESICS:

Two units in Bombay and one in West Bengal, all in the private sector have a total installed capacity of 740 tonnes per annum for analgesics like Aspirin. A production level of 600 tonnes per annum has been achieved during 1968. The production of other analgesics such as metamizol, amidopyrine, phenacetin and paracetamol have commenced, and are meeting the requirements of the country.

ANAESTHETICS:

One unit in Bombay has a capacity of 50 tons for procaine hydrochloride. A unit in Baroda manufactures Lignocaine, another local anaesthetic, whose production has already exceeded the full installed/licensed capacity of 500 kg. Ether and chloroform are being produced in adequate quantities and ether is also being exported.

ANTI-MALARIALS:

Amodiaquin, a synthetic antimalarial and chloroquin, a synthetic anti-malarial and amoebicide, are being produced with a combined installed capacity of 45 tonnes per annum. Production of Pyrimethamine is also planned.

VITAMINS:

Synthetic Vit. 'A' is being produced from the basic stage from lemon grass oil by two factories in Bombay with a total capacity of 25-30 MMU. The starting material, lemon grass oil, is indigenously available.
Beta-ionine, an intermediate produced in the manufacture of Vitamin A, is now being exported to the tune of

Rs.1.5 million per annum. A greater scope for the export of this product is envisaged. Production of Vitamin 'A' reached 30 MMU in 1968.

Two units, in Maharashtra and Gujarat, have been established for the production of 76 Kg. of Vitamin B12. The Maharashtra unit employs the direct fermentation process. Production reached 75 kg in 1968.

For Vitamin 'C', a capacity for 120 tonnes in the private sector has been established, and is in full production. Hindustan Antibiotics are planning another capacity of 125 tonnes per annum. Expansion of both the units have also been taken up.

Other Vitamins whose production has been established in the country are Nicotinic Acid and amide to the extent of 60 tonnes per annum in Bombay. In Hyderabad, an additional capacity of 25 tonnes per annum has been planned and the production of the starting material Beta Picoline has already commenced. In the IDPL synthetic drugs plant, an annual capacity of 20 tonnes of nicotinamide has been established. Other Vitamins that are being produced / planned at this plant are Vitamin B1, (30 tonnes per annum); Vitamin B2 (5 tonnes per annum) and Folic Acid (1000 kg. per annum).

SYNTHETIC HORMONES:

A total capacity of 3100 kgs. has been established for synthetic hormones like prednisone, prednisolone, cortisone, hydrocortisone, methyltestosterone, progesterone. Production of hormones is based on Diosgenin obtained from

Dioscorea, which is grown in the Kashmir and Kulu Valleys. Steroid intermediates produced from diosgenin are already being exported in significant quantities.

GLANDULAR PRODUCTS.

A capacity of 1500 MU of insulin has been established. The actual production was 870 MU in 1968. Large quantities of liver extracts and similar preparations are also being made in the country.

DRUGS OF VEGETABLE ORIGIN.

A wide variety of flora and fauna grow in the country because of the varying types of climates and soils. The recorded botanical wealth consists of more than 2000 types of medicinal and essential oil bearing plants. Several of these plants have been in use for centuries for their medicinal properties.

Most of these plants grow wild in the country. Now that they are being increasingly used as starting material for many of the products for manufacturing units, in furtherance of their self-sufficiency programmes, are establishing scientific methods of cultivation and collection.

Sceintific cultivation of dioscorea, for the production of synthetic hormones; and podophyllum for the extraction of its active principles, have been organised over large areas in the Kulu and Kashmir valleys. Otherplants like Belladonna, Digitalis, Pyrethrum and Mentha arvensis are also being cultivated extensively for the extraction of their active principles and for export. Experimental cultivation of solanum in the plains another plant used in the syntheses or normones has given promissing results.

QUININE: Cinchona is cultivated over large areas totalling about 20,000 acres in Darjeeling (W.Bengal), the Nilgiris and Anamalais, in Madras. The factories attached to these plantations have a total production capacity of 61 tonnes per annum of quinine. Efforts are being made to increase the production of quainine salts to the maximum possible extent for meeting the growing demand from the foreign markets. Although the use of quinine as an antimalarial drug has gone down it is used increasingly for the production of quinidine and as a bitter for aerated waters and in alcoholic beverages.

STRYCHNINE & BRUCINE: Large quantities of Nux vomica seeds grow in the forests of Orissa, Andhra Pradesh, Madras and other States. The Nux vomica alkaloids, Strychnine and Brucine are now extracted in three factories, one each in Calcutta, Hyderabad and Amritsar, with a total capacity of 36 tonnes per annum. Another unit has also been established in Cochina. The entire output of these factories is exported.

EMETINE: Plantations have been established in Darjeeling, West Bengal , to grow Ipecac to the extent of 30,000 kgs. of dry roots and are largely meeting the requirements for the production of Emetine. Emetine is being extracted at two factoreis - one in Calcutta and the other in Bombay, with a total annual capacity of 590 kgs.

DIGITALIS GLYCOSIDES: Two units for the extraction of Digoxin from locally grown digitalis leaves have been set up in Bombay. The scientific cultivation of Digitalis to obtain a single high constituent of the active principle,

Digoxin, and the application of modern extraction technology have made possible the indigenous manufactre of this cardiac drug.

OTHER PLANT PRODUCTS: A multi-purpose plant is being set up to extract the active principles of senna, belladonna, podophyllum, etc. The total active principles of some of these plant products are already being extracted in this country and the new unit envisages, in addition, isolation of the active constituents.

VACCINES AND SERA:

India has had an excellent record in the development and production of prophylactic vaccines for use in the prevention of cholera, typhoid and plague. All these are being exported and efforts continue to meet the increasing demand specially for items needed in mass immunization programmes. Other prophylactics produced in the country are the triple antigen for immunising children against diphteria, pertussis and tetanus; and antitoxins and sera for tetanus, gas-gangrene, diphteria, etc. All these are produced both by Public Health Laboratories and in private sector manufacturing units.

Other pharmaceutical Chemicals.

In addition, the pharmaceutical industry produces a number of other items such as calcium gluconate and other calcium salts, ferrous gluconate, ferrous fumarate and other ferrous salts, nikethamide, Glycerophosphates, chloral hydrate, saccharine, etc.

Antihistamines like Meclozine, and Buclizine, etc., Tranquillisers like Meprobamate and chloropromazine, anti-

filarials, Diethyl carbamazine citrate and oral anti-diabetics like Tolbutamide, chlorpropamide are the other items produced in the country. Export of some of these items like calcium gluconate has commenced.

Surgical sutures and Dressings:

A capacity of 7.2 million feet of plain, chromic and needled sutures, starting from locally available sheep intestines has been established. Production of silk sutures (for which an export potential exists) has also been established. Modern methods of sterlisation using radiation technique is being set up as an experimental measure and will soon be expanded for commercial use.

Sources of raw materials:

The organic chemical industry in the private sector now manufactures an increasing variety of items, specially suited to the pharmaceutical industry. The petrochemical industry makes available starting materials for synthetic drugs like benzene, phenol, ethyleneoxide, pthalic anhydride, monochloro and dichloro acetic acid, etc. The downstream units of the petrochemical industry, now under construction, will produce more and more of the starting materials and intermediates of the drugs, dyes, plastics and allied industries.

A pooling of the demands of these chemical-based industries has made possible the planned production of the required starting materials and intermediates.

As the pharmaceutical industry is a section of the chemical industry, integrated development of all the chemical-based industries is vital in any plan for the development of new sources of materials. For example, the manufacture of drugs is interrelated with the manufacture of chemicals, solvents, nutrient media, machinery, etc. As all these industries are being handled by the Directorate General of Technical Development, it has been possible to make an integrated approach to the development of all the connected industries.

Some items like nutrient media, precursors and chemical solvents are now being produced in India almost to the full extent of their requirements in the manufacture of antibiotics. Nutrients like lactose and lard oil have been completely replaced by indigenously available sucrose and corn oil. Soyabean meal has been replaced by groundnut and cotton seed meal. Soyabean protein is absolutely essential as in the production of Streptomycin this is being obtained by making protein concentrates of soyabean that is now being grown in the country and used sometimes in combination with cottonseed protein. Imported anti-foam compounds and suractants have now been substituted by those which are locally produced.

In the field of solvents butanol, butylacetate, isopropyl alcohol, acetone, methanol, the chloromethanes and chloro ethanes have all become indigenous.

The development of the chemical industry in the advanced countries underwent 3 distinct technological phases.

The first phase was the conversion of crude minerals into chemical products for use in other industries. The second stage was the development of chemicals extracted from natural products like coal, wood and other similar materials. The third and current phase is the cracking of mineral oils or gases leading to the production of a vast number of organic chemicals hitherto produced from coal and other natural sources as well as other chemical building blocks like ethylene, propylene and butylene, and synthetic organic chemicals with complicated molecular structure. These stages of development covered a period of 100 years in the advanced countries, but where our country is concerned, these have had to be abridged. We therefore find the three phases overlapping in India.

In all these industries, as far as our country is concerned, the last 10 years have witnessed much greater evolution than all the previous years put together.

With regard to basic inorganic chemicals, which fall in the first stage, the greatest impact has been on the production of nitrogenous fertilisers. The large number of petroleum refineries that have been established in the country will further augment the production of fertilizers.

The second stage of development, the production of chemicals from natural sources, has also made considerable progress, which could have been higher but for the intermittant running of the by-product plants in the steel industry in the past few years.

The third stage, the age of petrochemicals has got off to a good start. This class of industry is tied not only to raw materials for its functioning, but also to an assured offtake of the multiple production for its economic viability. For this reason it is essential that integrated complexes of this kind are meticulously planned, choosing appropri te technology, ensuring Co-ordinated implementation of the different components, achieving optimum exploitation of raw materials and services, and phasing production in a manner that matches the offtake pattern. Three integrated petrochemical com lexes are now in operation. With the phenomenal increase in the supply of raw materials to the organic chemical-based industries, made possible by the petrochemicals complexes, the pharmaceutical industry finds itself on a firmer base for an equally phenomenal rise in production.

PHARMACEUTICAL PROCESSING :

The journey of a drug from an idea in a research laboratory until it reaches the hands of a patient as a result of a doctor's prescription is not only long and arduous but an exacting science. It is estimated that out of a possible 3000 - 4000/compounds tested in a research laboratory, only 1 may hold promise of being effective in clinical practice. The selected compound then passes through several rigourous tests, like Toxicological investigations which are designed to ensure that a drug does not exert any detrimental

effect on the human systeme either when it is undergoing clinical trials or later after it has been introduced into therapy. Thereafter a dosage form is arrived at. The dosage form is then tested by clinicians for a particular group of indications. These clinical trials are conducted by selected physicians by a system of controlled studies in hospitals all over the world. On the basis of this clinical evaluation the firm introduces the drug to doctors for use in their daily practice. This is where pharmaceutical processing comes in.

Each pharmaceutical firm has built up its own tradition of quality and purity in pharmaceutical processing. This quality and purity the pharmaceutical firm seeks to guarantee through its brand name which links the product to the manufacturer. Since a drug is a matter of life and death, the firm spares neither trouble nor expense in developing the chemical entity it has discovered into an elegant and safe pharmaceutical preparation.

The areas in which the firm stakes its own reputation as regards quality of its drugs are: Purity, stability, precision in dosage, freedom from side effects, pleasant taste and ease of administration. This process involves no less than 24 stages of formulation research and application.

Manufacturers in the organised sector are equipped to accomplish the entire gamut of modern pharmaceutical formulation. The drugs marketed by them conform to

international standards. Some of the important stages in Pharmaceutical Processing involved are: stability, consistency in dosage in the sense that the active principle retains its potency over a given period of time. Any contaminant may cause deterioration of the drug on storage, and also undesirable toxic effects which necessitates mantenance of high purity of the product and compatability with coating agents, preservatives, other excepients, etc. used in their formulation.

Particle size and absorption:

The rate of absorption of a drug which in turn depends on particle size is of paramount importance in giving the desired therapeutic effects. Depending on the particle size of the active ingredient in any formulation the choice of finished product has to be made for treatment of any condition and cannot be based merely on the active ingredients, it contains.

Vehicle or base: The active principle has often to be presented in a convenient form for the patient's use. It may have to be dissolved or suspended in a vehicle which will mask the bitter taste or an unpleasant odour, or will ensure quick dispersion facilitating absorption. The vehicle should also ensure that the drug is released at the correct time and rate so that there is neither a delay in the release(and hence in action), nor too rapid a release and hence a high peak concentration in the blood and rapid elimination from the body.

Compatability: An active ingredient has to be often mixed with many additional substances for purposes of masking a bitter taste, or ensuring a better absorption or a smoother manufacturing process and stability on storage. These may be excepients, disintegrants, coating agents, solvents, preservatives, emulsifying agents etc. Care has to be taken that these additives are compatible with the active ingredient and do not remove its therapeutic effect or render it toxic by changin the chemical composition.

Sustained release Dosage forms: In this type of presentation 2 or 3 different sets of coated granules are made from the same drug or 2 - 3 drugs, each type of granule having a different disintegration time. These mixed granules are then put in the same capsule. The therapeutic advantage for this presentation is the avoidance of unnecessarily high peal concentration of drugs in the blood and the maintenance of optimum blood concentrations over a long period, 24 hours or the spaced release of different drugs after the administration of a single capsule.

Disintegration: A tablet or a capsule has to be rapidly disintegrated at the right place to be of optimum use. The disintegration time is of paramount importance and can make a product extremely useful or inactive.

Enteric Coating: Sometimes, it is necessary to prevent the destruction of a drug by the gastric acidity or to prevent its disintegration in the stomach. In such cases the drug is enteric coated so that the gastric enzymes do not act upon the drug. Enteric coating is a very critical process and unless care is taken, tablets may be passed out without being dissolved.

Viscocity: is a physical phenomenon which in certain types of medication also has a direct bearing on rate of absorption and action. It is of special significance in the formulation of liquids and viscosity is, therefore, always carefully controlled by reputable manufacturers of liquid specialities.

Melting point: A good example is the manufacture of suppositories. Care has to be taken that products like these will liquify within the minimum time. This raises the question of controlling the melting point during storage in unfavourable climatic conditions. Extensive formulation research is done here to ensure that a brand product fulfils all the necessary conditions.

Other considerations are: flavour, packaging and storage. Pharmaceutical processing is a precise science and a rigid discipline. For manufacturers in the organised sector this has become a tradition and a way of life. These are the norms by which the industry in India has come to equal its counterparts in the advanced countries.

Quality Control:

Quality control is an essential adjunct to both basic manufacture and pharmaceutical processing. A responsible manufacturer develops and uses a number of control procedures to ensure the safety and efficacy of his products. Quality control operates not only at the final stage but at every stage right from the testing of starting materials till the finished product comes out in packed form. The quality of raw materials, semifinished and finished bulk materials is of great importance and has to be repeatedly checked. Glassware used for bottles, vials and ampoules have to be the right variety. Packaging material has to be light and strong. Labels should be precise and informative meeting the requirements of drug laws.

The most important control is of the product itself. Everything about it must be checked. The qualities of

components, all the physical characteristics, sterility, freedom from pyrogen, disintegration time, all these must be within the stipulated limits in every batch. Only then can a doctor prescribe a drug with the confidence that his patient will get the best.

Pharmacopoieas and similar official compilations prescribe standards for the various criteria described above. But these are only the minimum requirements. Very often the standards of a responsible manufacturer are much higher and more stringent than those of the pharmacopoieas. These higher standards are often necessary to ensure the physiological availability of the active component to the patient.

The systems procedures and criteria observed by Indian manufacturers in quality control are identical to those adopted by pharmaceutical firms in industrialised countries.

EXPORTS:

The major segments in which the industry has found an export market are: basic drugs and drug intermediates, active principles of plant products and also finished formulations. O the Rs.30.5 million earned from exports in 1967-68, the share of each to the total was 18% basic drugs and intermediates, 26% plant products; 56% finished formulations.

Efforts are being made to boost exports in all these areas though the industry stands at a disadvantage in relation to world prices. The factors that are against the industry's attempts to arrive at competitive international prices are: Economies of scale have yet to reach required proportions, the limiting factors being: (a) low average purchasing level within the country (b) Distribution of manufacturing capacities in different regions; (c) unfavourable conditions for a distribution of export revenue loss over the domestic consumption (d) newly independent countries, in various stages of development who are progressively installing formulation and manufacturing units and are trying to protect them by imposing import restrictions in their countries.

T he pharmaceutical industry is one of the 58 priority industries and also one of the ~~10~~ 10 industries listed under the heading 'Industries for Export Obligations' in the Import Trade Control Schedule. As a result of this classific tion, according to the Governments' import-export policy for 1968-69, the industry has an obligation

to export a minimum of 5% of its 'book-value of production', to be entitled to its full requirements under the need-based policy. Book value production has been officially definied as ex-factory cost. Only the units borne on the list of the DGTD(organised sector) come under this export scheme.

For an achievment of the magnitude of exports of Rs.80-90 million required, the industry however desires more flexibility in pricing and other manufacturing and marketing operations than permitted hitheto by Government.

All the same, both the Industry and Gove-rnment are making coordinated efferts to achieve this objective. Promotion of, export of finished products in the neighbouring countries, supply of drug intermediates to the more developed countries, specially to the collaborating firms, repalcing export of crude drugs with the isolated active principles are some of the measure the Industry has under-taken. The Government in turn reimburses the exporting firms with the imported components, gives draw backs on import duties paid on the imported components and any indirect excise duties etc. paid on raw materials by a suitable cash subsidy.

Research

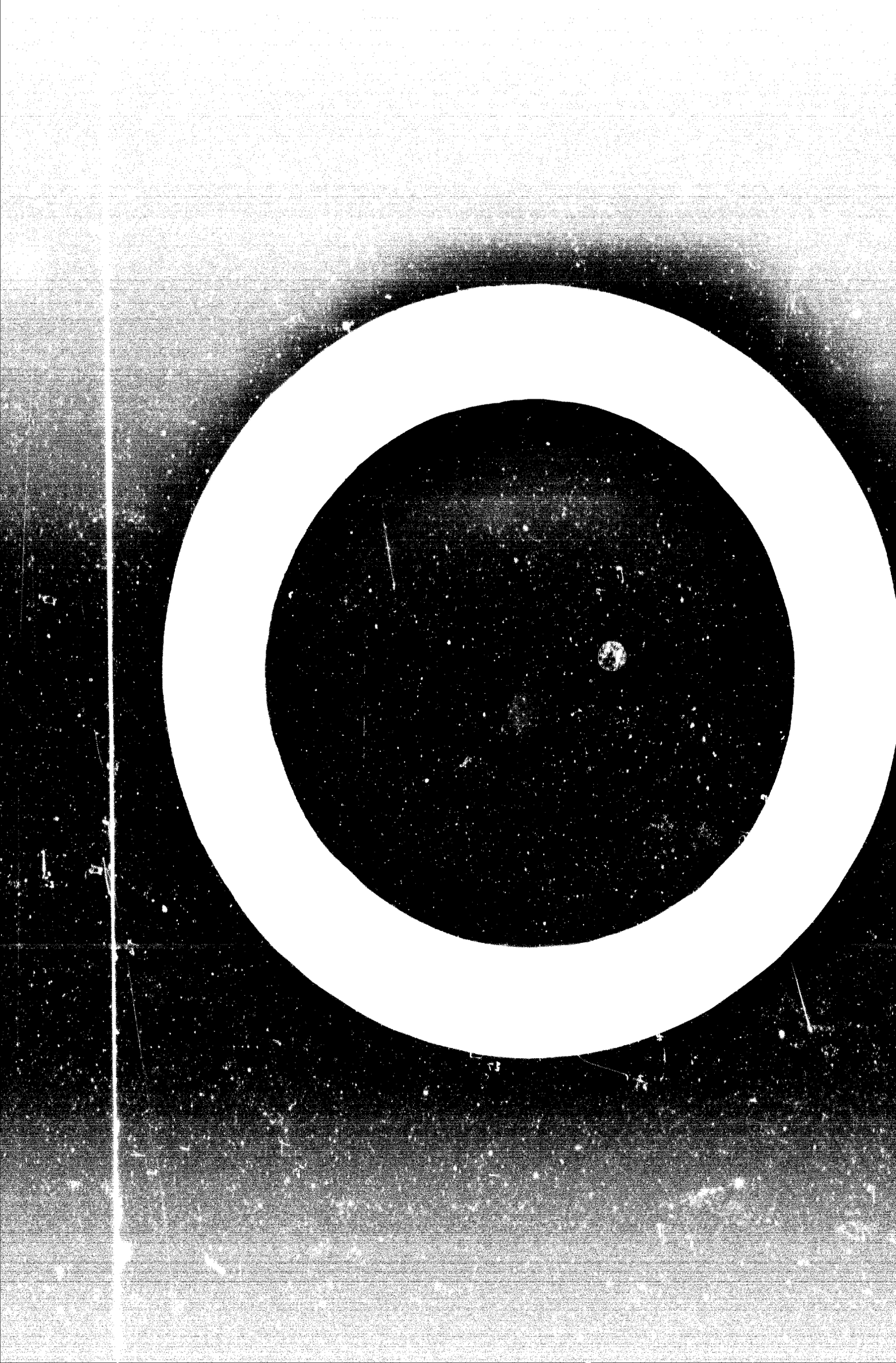
Research is the fountainhead of the pharmaceutical industry. At the apex is the search for new drugs as cures for the as yet incurable diseases and more effective and less toxic ones even for those which have remedies. The time/and research cost for the development of new drugs involved are progressively rising. The number of new drugs being introduced is also showing a decline. This is because of the high level of development already achieved in many fields which makes it difficult to find improved drugs as also the exacting tests that they have to undergo before they can be approved. The search for new drugs has made a beginning in this country and will progress in tune with economic realities. A few research centres opened by the industry are devoting their efforts to this task. Many firms, in their expansion projects, have kept room for this phase of development and some have also identified their areas of specialisation. To avoid duplication of scientific endeavour and wasteful expenditure these proposed laboratories will form a link in the international chain of research units of the respective firms.

Down the pyramid are other forms of research: formulation research to improve the dosage forms of existing drugs, improve the manufacturing processes to give higher yields and reducing manufacturing costs. Considerable work in this direction is being undertaken by the major manufacturing units.

The present economic climate in the country has thrown up a new field of research: Development Research - formulating new drugs to suit the health problems peculiar to India with ingredients indigenously available; and replacing or reducing the imported ingredients in existing drugs. This type and extent of research, therefore, is essentially linked with economic necessities. Besides development research, manufacturing units in India are doing extensive work in formulation research to accord with the climatic and health patterns in the country.

The Future.

These are the contours of a growth industry, inter-weaving with the economic patterns of the country's industrial fabric. A singular advantage for the industry has been the regulation of its growth from infancy in conformity with national priorities and ressurces. This phased development has created an infrastructure that can meet the challenges of changing technologies and remain competitive in world markets.



Sl. No.	I T E M	Unit	Capacity licensed/ approved as on 1.4.68	Capacity installed as on 1.4.68	PRODUCTION 1966	PRODUCTION 1967	PRODUCTION 1968	LIFT 1966-67	LIFT 1967-68 (Upto Dec.)	Current Demand	Targets fixed by the Dev. Council for 1973-74	Addl. licensed capacity required
1	2	3	4	5	6	7	8	9	10	11	12	13
I.	ANTIBIOTICS:											
1.	Penicillin	MMU	264	167	134.62	122.30	18.97	72.45	40.95	175	250	Nil
2.	Streptomycin	Tonnes	215	140	104.39	126.32	43.75	7.69	56.84	200	300	85
3.	Tetracyclines	"	144.5	26	18.97	18.05	6.82	35.72	16.46	45	150	5.5
4.	Chloramphenicol	"	72.4	41	28.88	24.73	26.43	64.71	27.94	55	100	28
5.	Newer Antibiotics (Neomycin, Bacitracin Erythromycin, Nystatin Polymyxin, Hamycin, Kanemycin, Grisofulvin).	"	14.0	Nil	Nil	Nil	10.17	9.38	N.A.	-	30	16
II.	SULPHAS:											
6.	Sulpha Drugs	Tonnes	1000	536	214.13	198.81	1275	1242	738.5	1300	1800	800
III.	ANTI T.B. DRUGS:											
7.	P.A.S., Salts &Esters	"	460	402	324.43	261.00	93.60	192.49	60.99	450	750	290
8.	I.N.H.	"	186.4	71.6	59.53	39.74	21.92	28.84	5.20	75	250	64
9.	Thiacetazone	"	61	15	8.68	9.90	N.A.	N.A.	N.A.	15	100	-
IV.	ANTI-DYSENTERY DRUGS:	"										
10.	Halogenated Oxyquinoline		84.1	84.1	89.72	82.58	-	-	-	90	150	66
11.	Emetine &Dihydroemetine	Kgs.	590	590	363.4	353.6	2.48	36	34	350	600	10
(V)	ANTI-LEPROSY DRUGS:											
12.	D.D.S.	Tonnes	18.3	18.3	4.27	3.02	1.10	1.00	8.52	12	80	62
VI.	ANTI-DIABETICS											
13.	Insulin	MU	1500	1500	458.40	659.71	519	38.35	24	800	1000	Nil
14.	Tolbutamide	Tonnes	43	43	21.94	12.87	1.21	0.57	1.16	25	105	58
15.	Chlorpropamide	"	3.2	3.2	9.49	6.00	1.71	0.18	0.60	8		
16.	Phenformin	"	1.0	1.0	28.40Kgs.	50 Kgs	0.30	0.40	0.38	-		
VII	ANTI-MALARIALS:											
17.	Amodiaquin, Chloroquin & Pyrimethamine.	"	63	39	17.69	13.19	15.50	18.86	13.49	40	120	57
VIII.	ANTI-FILARIALS:											
18.	Diethylcarbamazine	Tonnes	56	26	9.07	12.59	0.0	0.29	0.29	15	50	Nil
IX.	ANAESTHETICS											
19.	Ether(anaesthetic)	"	350	350	88.30	91(estd)	N.A.	N.A.	N.A.	100	400	-
20.	Ethyl Chloride	"	144	144	39.40	52.94	N.A.	NA.	N.A.	50	150	-
21.	Procaine Hcl.	"	102	90	3.66	36.29	1.30	25.11	36.60	75	100	-
22.	Xylocaine	Kgs.	500	500	640.9	992.50	N.A.	N.A.	N.A.	1000	5000	4500
X.	ANALGESICS & ANTIPYRETICS:											
23.	Aspirin	Tonnes	560	740	442.2	581.8	1.64	0.05	Nil	600	1000	260
24.	Sodium Salicylate	"	405	379	274.27	191	-------- Nil -------			200	800	400
25.	Phenacetin	"	132	112	4.32	16.18	245.18	229.21	303.44	350	260	60
26.	Paracetamol	"	71	30	0.11	10.2	N.A.	N.A.	N.A.			
27.	Analgin	"	10	10	Nil	Nil	42.70	60.90	63.41	100	200	190
28.	Phenylbutazone and other anti-rheumatics.	"	20	10	9.75	11(estd)	21.12	24.58	N.A.	40	75	55
XI.	ANTHELMINTICS:											
29.	Piperazine&derivatives	"	51.35	Nil	Nil (Basic)	Nil	5.47	0.20	0.25	-	50	Nil
30.	Bephonium Hydroxynaphthoate and other enthelmintics.	"	5	5	4.91	-	N.A.	N.A.	N.A.	5	10	5

1	2	3	4	5	6	7	8	9	10	11	12	13
XII.	ANTACIDS:											
31.	Magnesium Trisilicate	Tonnes	Demands are being met from indigenous production.				N.A.	N.A.	N.A.	-	100	Nil
32.	Aluminium Hydroxide	"					N.A.	N.A.	N.A.	90	100	Nil
33.	Magnesium Hydroxide	"									50	Nil
34.	Magnesium Carbonate	")									150	Nil
XIII.	BARBITURATES:											
35.	Phenobarbitone	"	10	Nil	Nil	Nil)	17	28.25	N.A.	35	50	40
36.	Other Barbiturates (Amylobarbitone, Pentobarbitone)	"	-	Nil	Nil	Nil)						
XIV.	STEROIDS:											
37.	Prednisone & Prednisolone	Kgs.)					2.5	0.8	7)			
38.	Dexamethasone	")	2723	6720	1203	847.1	6.17	15.82	10.32	1200	3000	Nil
39.	Cortisone & Hydrocortisone	")	(All synthetic hormones)	(Including intermediates)			4.2	29.4	34.44			
40.	Triamcinolone	")					27.0	25.91	28.60			
XV.	ALKALOIDS OF VEGETABLE ORIGIN:											
41.	Atropine	Kgs.	(Capacity to be fixed on the basis of performance).		Nil	20(estd)	-	-	-	-	50	-
42.	Caffeine	Tonnes	22	22	16.9	15.22	69.23	29.89	17.88	40	100	78
43.	Digitalis Glycosides	Kgs.	(Capacity not fixed).	26.0	1.63 (Digo in only).	4.77 (Digoxin)	3.97 3.4	30.17 8.16	6.00 4.02	15 10 as Digoxin.	100	Nil
44.	Ergot alkaloids.	"			-	-	12.98	14.58	6.53	10	50	50
45.	Morphine alkaloids	"	2000	2000	3281	3025.4	-	-	-	3000	3000	Nil
46.	Codein, Noscapine and other anti-tussives.	"	(--- Demands being met from indigenous production---)							-	Double the present consumption.	Nil
47.	Reserpine	"	14	12	Nil	Nil	N.A.	N.A.	N.A.	-	50	36
48.	Scopolamine	"	(Capacity to be fixed on the basis of performance).		-	-	N.A.	N.A.	N.A.	-	50	-
49.	Strychnine	Tonnes	36	36	22.31	17.84	-	-	-	Mainly for export.	(May be stepped up as per demand).	Nil
XVI.	ENZYMES:											
50.	Papain	Tonnes	19.2	Nil	Nil	Nil	-	7.39	9.05 (upto Feb.)	12	20	20
51.	Pancreatin	"	72	Nil	Nil	Nil	-	13.75	10.36 (upto Feb.)	15	36	Nil
52.	Trypsin	"	(-- ---------- Small industry sector ----------)								10	Nil
53.	Diastase	"	28 (approved)	Nil	Nil	Nil	-	3.6	3.77 (upto Feb.)	5	15	Nil
XVII.	HORMONES:											
54.	Adrenaline	Kgs.	48	48	12.48	N.A.	15.33	13.51	6.61	25	20	Nil
55.	Pituitary (Posterior lobe extract).	"	Nil	Nil	Nil	Nil	85.36	159	108.69	150	50	50
56.	Other Hormones (Methyl Testosterone, Progesterone & Androne).	"	(Information given under Corticosteroids).				250	116	61	100	250	Nil
XVIII.	MUSCLE RELAXANTS:											
57.	Gallamine Triethiodide	"	Nil	Nil	Nil	Nil	NA.	N.A.	N.A.	-	20	-
58.	Tubocurarine	"	Capacity to be fixed.	Nil	Nil	Nil	N.A.	N.A.	N.A.	-	30	-
59.	Suxamethonium Chloride	"	5	Nil	Nil	Nil	N.A.	NA.	N.A.	-	20	15
XIX.	PLASMA SUBSTITUTES:											
60.	Dextran Injection	litres	270,000	259,200	79143	74000 (estd.)	Nil	113Kgs.	189Kgs.	-	1 Million	0.7Million.
XX.	VITAMINS:											
61.	Vitamin A	MU	25	25	20.44	25.05	Nil	Nil	100MU	30	50	-
62.	Vitamin B 1	Tonnes	30	Nil	Nil	Nil	46.22	31.92	23.77	40	75	45
63.	Vitamin B 2	"	5	Nil	Nil	Nil	7.55	10.92	7.04	10	10	5
64.	Vitamin B 6	"	1	1	0.692	Nil	3.00	9.29	8.26	12	15	14

1.	2	3	4	5	6	7	8	9	10	11	12	13
65.	Vitamin B-12	Kgs.	76.2	56.2	54.59	60(estd.)	1.12	1.16	25.62	100	100	25
66.	Folic Acid	Tonnes	1	Nil	Nil	Nil	1.42	2.66	1.77	*	5	4
67	Nicotinic Acid/Amide	"	134	77	49.95	45(estd.)	88 Kg.	147 Kg.	7 Kg.	60	250	115
68.	Vitamin C	"	245	120	132	75.40	42.70	287.25	166.41	200	500	250
69.	Vitamin D	"	1	115Kgs.	Nil	4.25 Kg.	6.325	3.207	6.4	25Kg.	1	Nil
							(------ Million M.Us ----)					
70.	Vitamin E	"	Nil	Nil	Nil	Nil	1.63	3.65	2.79	4	4	4
71.	Vitamin K	Kgs.	150	150	779	-	170	1186	255	1000	1300	1150
72.	Pentothenate & Panthenol	Tonnes	Nil	Nil	Nil	Nil	9.76	12.95	9.62	15	12	12
XXI.	OTHER MISCELLANEOUS DRUGS:											
73.	Amphetamine & its allyl derivatives.	Kgs.	200	200	-	-	N.A.	N.A.	N.A.	-	200	Nil
74.	Antihistamines	Tonnes	5.95	5.95	2.36	2.90	8.81	8.82	N.A.	12	40	35
75.	Bismuth Salts.	"	103	100	-	-	Nil	6 Kg.	15 Kg.	-	-	-
76.	Calcium Gluconate	"	247.7	247.7	129.19	123.77	16.49	23.12	42.05)	300	300	52
77.	Calcium Lactobionate	"					0.1	Nil	Nil)			
78.	Calcium Lactate	"	12	12	-	4.9	42.0	20.00	38.38	60	200	188
79.	Glyceryl, Trinitrate, Erithrityl, Tetra-nitrate P.E.T.N.	Kgs.									100	-
80.	Ephedrine	Tonnes	19.8	1.8	140.5Kg.	375 Kg.	10.97	16.29	10.18	20	30	10
81.	Hydrochlorthiazide	"	13	10	444 Kg.	222 Kg.	25 Kg.	20Kg.	55 Kg.	500 Kg.	50	37
82.	Polythiazide	"	Nil	Nil	Nil	Nil	19 Kg.	20Kg.	Nil	25Kgs.	10 [60]	10 [47]
83.	Methaquolone Hcl.	"	-	-	369.75Kg.	1000 Kg. (estd.)	N.A.	N.A.	N.A.	-	10	-
84.	Nikethamide	"	7.1	7.1	6.68	4.55	Nil	Nil	Nil	7	20	13
85.	Nitrofurans(Nitrofurantein Furazolidone Nitrofurazone)	"	20 (Letter of intent).	Nil	Nil	Nil	N.A.	NA.	N.A.	-	20	Nil
86.	Rehidine	Kgs.	1.23	Nil	Nil	Nil	435	748	289	500	1000	Nil
87.	Tranquilizers Chlor-promazine Meprobamate etc.)	Tonnes	(Information to be collected)				-	7.72	9.24	N.A.	10	40
88.	Sera	MU					17342	6855	N.A.	-	-	-
89.	Vaccines	Litres					Nil	Nil	Nil			
90.	Polio Vaccines	Mio.Doses	Nil	Nil	Nil	Nil	N.A.	N.A.	NA.A	-	20	20

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