Departmental Manual

DCA 113

DR. MCR HUMAN RESOURCE DEVELOPMENT INSTITUTE OF ANDHRA PRADESH HYDERABAD

DRUGS CONTROL ADMINISTRATION

DR.MCR HRD INSTITUTE Of Andhra Pradesh

Dear Reader,

As part of its endeavour to provide a SMART (Simple, Moral, Accountable, Responsible and Transparent) administration, the State Government of Andhra Pradesh has launched a major Human Resource Development and Training initiative aimed at developing a large human resource base of well informed and responsive functionaries and officials.

The successful and effective implementation of any initiative or programme in government is largely the result of the involvement and efforts put in by its functionaries at all levels. Obviously, the most fruitful way in which to bring this about is to make individual functionaries aware of their role functions and responsibilities. To achieve this, the Human Resource Development Institute of AP, as the apex training institution of the State Government responsible for the overall implementation and co ordination of the state training initiative, has proposed to bring out departmentwise Manuals in two parts, namely

1. Departmental Manual
2. Functionary Manual

The Departmental Manual would indicate the role, responsibilities and functions of the department. The Functionary Manual will detail , as the nomenclature indicates, the functions and responsibilities of the functionaries within the department, at all levels. While doing so, the evolving role of governmental functionaries in being effective managers of change in a welfare state has been delineated. The Departmental Manual also details the department's organisational chart, the rules, regulations, legislations and enactments which govern its functioning and direct its activities and the various interdepartmental interactions it has to perform. The Manual also facilitates a definition of the Department's role in serving the general public as customer

while drawing up a vision for its future development in the coming decades in line with the Vision 2020 of the state.

The present volumes developed by the Drugs Control Admnistration are in two parts. As is evident, these publications are the outcome of thorough study and analysis of the department's role, functions and procedures. They are intended to serve as useful aids to each and every employee of the department in the effective discharge of his functions. It may be noted, however, that these manuals do not replace the codes and orders on the subject but are, at best, meant to guide and assist the functionaries in the effective discharge of their duties.

Any suggestions for the improvement, of these Manuals may be sent directly to the Director General, Dr. MCR HRD Institute of Andhra Pradesh, Road No. 25, Jubilee Hills, Hyderabad -500 003, for consideration and incorporation in subsequent updations and revisions of the Manuals.

PVRK PRASAD IAS
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Dr. MCR Human Resource Development
Institute of Andhra Pradesh
&
Ex-officio Spl. Chief Secretary to Government (HRD)

INTRODUCTION

In the begining of the 20th century Drug Industry was practically non-existent in India and drugs were being imported from abroad. The first world war changed the situation and not only were finished and cheap drugs imported in increasing volume, but also the need for production of drugs indigenously was also voiced from all sides. With the clamour for swadeshi goods manufacturing concerns, both Indian and foreign, sprang up to produce pharmaceuticals at cheaper rates to compete with imported products. Naturally some of these were of inferior quality and harmful for public health. The Government was, therefore, called upon to take notice of the situation and consider the matter of introducing legislation to control the manufacture, distribution and sale of drugs and medicines.

The common laws of the country deal with general offences of every-day life and do not deal with the minimum requirements that should be complied with for supply of drugs of standard quality.

Drug has a special significance in human life. There may not be any need of a drug for a healthy person in normal life. But in illness, accidents, epidemics and natural disasters drugs are urgently required to combat the disease and it is there that drug fights DEATH. DRUG is therefore the greatest weapon of mankind to fight DISEASE and DEATH. It is at this very point of death that the specific drug of highest quality and purity has to win the battle for life. There, one cannot compromise for anything less. Hence DRUG CONTROL. Through scientific research of centuries, to-day's drugs are very powerful as well as aggressive to all infections and these include complicated chemical compounds. Antibiotics, Biological con-centrates, Blood products, and Medical devices.

The main objective of Drugs Control is to ensure that the drugs that are made available to the people, who use them for prevention, mitigation or treatment of diseases, are of the required standards of quality, purity and strength are packed in containers giving all necessary information about the drug and its manufacturer. The philosophy of Drugs Control is that unless quality control discipline embracing ancillary requirements are im-posed by law at all stages of import, manufacture, storage, sale and dsitribution, the people cannot be assured of the quality and safety of the drugs used by them. Hence the need to regulate import, manufacture and sale of drugs.

CONTENTS

Chapter - I

Origin of the Department

1. ORIGIN OF THE DEPARTMENT

a) The genesis of Drug Control in India could be traced back to the preindependence era. The need for legislation on drugs arose due to our dependence on imported drugs. During the first world war, there was a mushroom growth of pharmaceutical industry in European countries and the Indian market was used by these countries and foreign traders settled in India to dump substandard and adulterated drugs manufactured by them. More so, some very commonly used drugs even for simple ailments were also imported for some medicinal preparations which were manufactured indigenously and there was no standardization of these preparations and drugs were indiscriminately used.

b) In 1927 a Resolution was adopted by the Council of States recommending to the Governor General in Council to urge all Provincial Governments to take immediate steps to control the indiscriminate use of drugs and to bring in legislation for the standardization of the preparations and for the sale of such drugs.

c) In August 1930, in response to public opinion against defective drugs and in pursuance of the Resolution of 1927, the Government of India appointed a Committee known as the Drugs Enquiry Committee with Col. R.N. Chopra as its Chairman to enquire into the extent to which drugs of impure quality or defective strength were being imported, manufactured or sold in India and to recommend steps for controlling such import, manufacture and sale, in public interest. This Committee also known as the Chopra Committee, recommended among, others, to make a Central Legislation to control drugs. As a result of this Committee's report, the Government of India passed the Drugs Act in 1940 to regulate

the import, manufacture, distribution and sale of drugs. The Drugs Act received the assent of the Governor General on April 1940. The Drugs Rules were framed in 1945 to give effect to the provisions of the Act. The Drugs Act. 1940 and the Drugs Rules, 1945 came into operation in all the Part A and Part C States from, Is' April 1947. In part B States it-came into operation subsequently. The area of Andhra State was Listed in part States under the composite state of Madras and the Drugs Act 1940 and Drugs Rules 1945 so far as they relate to Andhra State were published in the Gazette dated 18 th February 1947. The Drugs Act 1940 and Drugs Rules 1945 were not implemented in Telangana area prior to formation of AP State and the same was notified in the Andhra Pradesh Gazette dated 6 th August 1959.

d) Drug Control is- both a public health and a social welfare measure enforced by the Central and State Governments by ensuring compliance of the provisions of the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945. The application of the Act was through the Central Government for imports, registration of new drugs, licensing of certain categories of drugs and banning of harmful and/or irrational drugs, and through the State Governments for regulating the manufacture, distribution and sale of drugs in the respective states.

e) When the Drugs Act was enacted in 1940, cosmetics were not included under this statute. Reports started appearing in the press that due to the absence of control measures, unscrupulous manufacturers were making attractive cosmetics like lipsticks with harmful textile colours, creams and powders with toxic raw materials. Hospitals started reporting cases of obstinate skin disorders due to use of these harmful cosmetics. Hence in the year 1962, cosmetics were brought under the purview of The Drugs Act and the title The Drugs Act (as it was known upto that time) was amended and changed to **"The Drugs & Cosmetics Act'.**

f) In the state of Andhra Pradesh, Drugs Control Department

began its operations in 1952 with four Drugs Inspectors forming an insignificant part of the Directorate of Medical and Health Services for implementation of Drugs Act 1940 and Drug Rules 1945 in Andhra area of the State and subsequently with four more Drugs Inspectors appointed for implementation of the above statute in Telangana area after the formation of separate Andhra Pradesh State. The Food control administration was also functioning under the Directorate of Medical and Health Services along with Drugs control Department. On the recommendations of the Government of India, the State Government, after review of the implementation of Prevention of Food Adulteration Act and The Drugs and Cosmetics, Act 1940 and Rules made thereunder, separated the Food and Drugs Administration from the Directorate of Medical and Health Services and a separate Food and Drugs Control Department was created on 9-11-1976. Subsequently in the year 1981 State Government separated the work relating to Drugs Control Administration from Food and Drugs Administration and a separate Directorate, for Drugs Control Administration was created under the administrative control of a Director.

g) With an increasing awareness to follow Quality control Discipline and comply with the internationally accepted norms of Good Manufacturing Practices, Drug manufacturers in India, by and large, tend to comply with these requirements of the drug Control. Such self-imposed discipline has helped in building up the image of the drug manufacturers of the country in foreign market, as a result the volume of drugs exported every year is ascending.

h) Drugs Control today is thus the result of Government's effort as well as the manufacturers commitment to manufacture and market quality drugs.

Chapter - II

Evolution of the Department

2.EVOLUTION OF THE DEPARTMENT

In 1930, in pursuance of a resolution passed in the Council of States the Government appointed the Drug Enquiry Committee under the Chairmanship of Col.R.N.Chopra to inquire into the extent to which drugs of impure quality or defective strength were being imported, manufacture or sold in India, and to recommend steps for controlling such import, manufacture and sale in the public interest. As a result of the report of this Committee, the Central Government passed the Drug Act, 1940 to regulate the manufacture, distribution, import and sale of Drugs. Drugs Rules were framed in 1945 to serve the purpose of this Act. By the enforcement of this Act and Rules, the State Governments have been given the responsibility of controlling the manufacture of Drugs and Pharmaceuticals and their sale. The Drugs Act is enforced in the State as per G.O.Ms.NO. 1182, Health and Local Administration (Health), dated: 21-5-1959.

The Drugs Act, 1940 was amended in 1962 to bring Cosmetics within its purview to control the import manufacture and sale of Cosmetics with a view to ensuring that the Cosmetics marketed in the country are safe for use. The Drugs Act, 1940 is retitled as "The Drugs and Cosmetics Act, 1940" and the Rules are retitled as "The Drugs and Cosmetics Rules, 1945."

The Government of India has passed a legislation the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and the relevant Rules 1955 to control the advertisements of Drugs in certain cases to prohibit the Advertisements for certain purpose of remedies alleged to possess magic qualities and to provide for matters connected therewith. This Act and Rules are enforced by this Department in the State of Andhra Pradesh vide G.O.Ms.No.2515, Health, dated: 16-9-1963.

In exercise of the powers conferred by (Sub-Class xi) of clause (a) of Section 2 of the Essential Commodities Act, 1955 (10 of 1955) , the Central Government declared Drugs to be essential commodity for the pur-

pose of the Essential Commodities Act, 1955. Following the emergency in October, 1962, the Union Ministry of Health was anxious to ensure that unscrupulous manufacturers and dealers do not take advantage of the situation and raise the prices of drugs. In order to protect consumers from being over charged by such unscrupulous dealers, the Government have passed different orders under the Defence of India Rules/under the Essential Commodities Act, 1955 as enlisted below.

1. Drugs Prices (Display and Control) Order, 1962.
2. Drugs Prices (Display and Control) Order,1967.
3. Drugs (Prices Control) Order, 1979.
4. Drugs (Prices Control) Order, 1987.
5. Drugs (Prices Control) Order, 1995.

These orders are implemented in the State of Andhra Pradesh by Drugs Control Administration under the authority of Notifications issued by Government, from time to time, the latest being G.O.Ms.No.233 H.M&FWDept., dt.3-4-1990 read with G.O.Ms.No.238 HM&FW Dept., dt.24-4-1993.

The statutory control over Narcotic Drugs was exercised in India through a number of Central and State enactments. The principles Central Act, namely, the Opium Act, 1857, the Opium Act, 1878 and the Dangerous Drugs Act, 1930 were enacted for a long time with the passage of time and the developments in the field of illicit drug traffic and Drug abuse at National and International level, the Government of India had postulated an Act namely, the Narcotic Drugs and Psychotropic Substances Act, 1985 to Consolidated and Amend the Law relating to Narcotic Drugs, to make stringast provision for the control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances, to provide for the forfeiture of property derived from, or used in, illicit traffic in Narcotic Drugs and Psychotropic Substances, to implement the provisions of the International Convention on Narcotic Drugs and Psychotropic Substances and for matters connected therewith. Government of Andhra Pradesh had published "Andhra Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1986" and authorised this Department to implement the provisions of this Rules partly

vide G.O.Ms.No.186 Revenue (E) Dept., dated: 14-2-1986.

a) Drugs Control Department in Andhra Pradesh has its beginning in 1952 with the appointment of four Drugs Inspectors in the erstwhile Andhra State in the Directorate of Medical and Health Services. The Drugs Act 1940 and The Drug Rulers 1945 were implemented in Andhra area only and after the formation of separate Andhra Pradesh State in the year 1956 four more Drugs Inspectors were appointed with ancillary staff for implementation of Drugs Act 1940 and Drug Rules 1945 in Telangana area also. In the year 1963 two posts of senior Drugs Inspectors were further created who were subsequently redesignated as Assistant Drugs Controllers.

b) The Government of India, Ministry of Health meanwhile has amended the Drugs and magic Remedies (objectional Advertisements) Act 1954 where in the duties of search and seizure under this Act were entrusted to officers holding Gazetted status only and on review of the status of drugs Inspector of various states. It was observed that in some States the Drugs Inspectors were Gazetted and in other States they were Non Gazetted. The Central Council of Health at its meeting held on 5 th to 7 th November 1963 adopted a resolution recommending that the Drugs Inspectors of all States should be of gazetted rank and in view of this State Government conferred Gazetted status to the Drugs Inspectors and sanctioned 20 posts of Drugs Inspectors with effect from 17-12-1966.

c) In 1966, the three member Committee of Government of India headed by S.K. Borkar, the then Drugs Control (India) gave their report after study of the set up of various State Drug Control Administrations, staffing pattern and Drug Testing facilities recommending expansion of Drug Control Administrations in the States for more stringent enforcement of Drugs and Cosmetics Act and Rules made thereunder. Basing on the above report, the State government sanctioned one post of Deputy Drugs Controller, one post of Assist-

ant Drugs Controller and two posts of Drugs Inspectors with supporting staff on 2-2-1970.

d) Basing on the above Committee's report and also on the report submitted by another Committee headed by Smt. Purabi Mukhopadhyay the State Government at the instance of Government of India and basing on the proposals of the Director of Medical and Health Services sanctioned, permission to establish the first State Drugs Testing Laboratory and also sanctioned one Senior Scientific Officer (to be notified as Government Analyst under Drugs and Cosmetics Rules), two Junior Scientific Officers, two; Senior Scientific Assistants, two Junior Scientific Assistants and supporting Laboratory staff and Ministerial staff on 23-.11-1970.

e) The Government created a vigilance cell headed by an Additional Director Vigilance and Enforcement of the rank of a Deputy Inspector General of Police with supporting staff on 28-6-1974 for effective enforcement of Prevention of Food Adulteration Act 1954 and Drugs & Cosmetics Act 1940 to work under the direction and control of the Director of Public Health Family Planning and Drugs Control.

f) The functioning of Food and Drugs Administration in the State was reviewed by the Government from time to time. As the implementation of Prevention of Food Adulteration Act 1954 and Drugs & Cosmetics Act 1940 suffered from several handicaps, the administrative setup was strengthened by appointing a whole time officer as Drugs Controller and Food Health Authority and separated Food & Drugs Administration from the control of the Directorate of Medical and Health Services. The Food and Drugs Control was formed on 9-11-1976. Sri M.V. Thomas, I.P.S., D.I.G. of Police was appointed as the first ad of the Department of Food and Drugs Control Department of Andhra Pradesh.

g) In the year 1980 the Government sanctioned a post of Joint Drugs Controller, a Junior Scientific Officer, and an Administrative Officer with supporting staff to strengthen the Department further,

h) In 1981 the Government separated the Drugs Control Administration from the Food and Drugs Control Department and a separate Directorate called The Directorate, Drugs Control Administration was established for more effective enforcement of Drug Laws in the State. Sri:C. Gopala Krishna Murthy, Deputy Drugs Controller, a technically qualified person who was first, appointed as Drugs Inspector under section 21 of Drugs & Cosmetics Act, was appointed the first Director of Drugs Control Administration in the State. During this time the main Administrative wing of the independent department was located in a portion of the building of the institute of Preventive Medicine in Narayanaguda and Drugs Control Laboratory was in rented private building in Musheerabad at Hyderabad.

i) In the year 1982, Government created the post of Deputy Drugs Controller at Head Quarters to assist the Director in enforcement of Drug Laws and further created two regional offices headed by Assistant Drugs Controllers, one at Vijayawada for entire coastal Andhra region and anothe at Warangal for Telangana region. The licensing procedure of sale concerns was decentralized for the first time and the Assistant Drugs Controllers of Regional Offices were notified as licensing authorities of Sales concerns. Additionally three more posts of Drugs Inspectors were created with supporting staff in regional offices.

j) In 1984, Government created three more Regional Offices at Cuddapah, Rajahmundry and Hyderabad with three more Regional Assistant Drugs Controllers. 10 posts of Drugs Inspectors were also created with supporting staff for better enforcement. In the Drugs Control Laboratory, an additional post of Junior Scientific officer was also created.

k) In the year 1985, one post of Deputy Drugs Controller was upgraded to Joint Drugs Controller in the enforcement wing and in the Laboratory wing a post of Senior Scientific Officer with ancillary staff to supervise several sections of the Lab were sanctioned.

l) In the year 1986, the Government after examining the growth of

Pharmaceutical Industry and Trade in and around Vijayawada Region, sanctioned a Regional Drug Testing Laboratory at Vijayawada to increase the facility of testing drug samples by creating one post of junior Scientific Officer and supporting staff.

m) The Government allotted around two acres of land in the vicinity of T.B. Hospital, Erragadda, Hyderabad with a budgetary sanction of 21.37 lakhs for construction of building complex. The Administrative wing and Laboratory wing of the department was occupied in the new building complex at Vengalarao Nagar named as " Drugs Control Bhavan" in February 1988.

n) In the year 1989, at the head quarters Drugs control Laboratory one more post of a Junior scientific Officer with supporting staff was created. A post Asst. Director (Non Technical) was also created in the Administrative wing to look after the work of accounts and stores.

o) In the year 1991, 10 more posts of Drugs Inspectors and supporting staff were created for effective implementation of Drug Laws.

p) Training of enforcement officers: The Inspectors and other officers of the enforcement wing are imparted training to update their knowledge and skills on matters touching various enactment's implemented by them. Annexure-1 shows different types of training imparted to these officers.

q) During 1991 Government allotted a site in the campus of University of Health Sciences, Vijayawada for construction of a building for housing the Regional drug Testing Laboratory, Vijayawada and Regional Office of Asst. Director, Vijayawada. The construction of the Building with a budget of Rs. 27.89 lakhs was completed in August 1994 and since then the Regional testing lab, Regional Office of Assistant Director, Vijayawada and Office of the Drugs Inspector, Vijayawada are functioning in this building. The Regional testing lab at Vijayawada is able to analyse 800 Drug samples per annum.

r) In 1995 Government of India sanctioned an amount of Rs. 36.87 lakhs for construction of a separate building for Drug Testing Lab at Hyderabad under Central Assistance Scheme. The Drug Testing Lab in Hyderabad started functioning in the new premises in August 1997. An amount of Rs. 2.13 lakhs was also spent on the purchase of lab equipment.

s) The department of Drugs Control Administration is having two Drugs Control Laboratories one at Hyderabad and the other at Vijayawada. The Drug Control Laboratory at Hyderabad is able to undertake the analysis of many categories of Drugs whereas 'the Drugs Control Laboratory at Vijayawada is undertaking Chemical analysis only. The details of facilities available for test/analysis of drugs and cosmetics in Drugs Control Laboratories at Hyderabad and Vijayawada in A.P. State and other Government laboratories in the country which undertake test/analysis of special categories of Drugs are given in Annexure-1.

The Drugs Control Laboratory at Hyderabad is functioning with a joint Director (Laboratory), Two Senior Scientific Officers and five Junior Scientific Officers . Two Senior Scientific Officers and notified as Government Analysts. The Drugs control Laboratory at Vijayawada is headed by a Junior Scientific Officer who is also notified as Government Analyst.

The samples lifted and sent for analysis by the Drugs Inspectors in the State of Andhra Pradesh include samples lifted from Government Hospital/ Institutions, Private Hospitals, Manufacturing Units. Wholesale and Retail Chemists and also from unlicensed dealers. The samples also comprise of Drugs for veterinary use and cosmetics.

The following testing facilities are available in the Drugs Control Laboratory at Hyderabad.

1. Micro Biology Division.. This Division is undertaking the testing of all parenteral preparations for Sterility, Microbiological assays of

Vitamins Microbiologicals assays of antibiotics and also the R.W.C. in the disinfectant fluids.

2. Pharmacology Division: This division undertakes the testing of the parenteral preparations for pyrogens and also toxicity test for antibiotics.

3. Pharmaceutical Chemistry Division: This division is equipped to take up the physical, chemical and instrumental methods of analysis of Drugs and Cosmetics.

Analysts working in the Drugs Control Laboratory are imparted training to update their knowledge and skills in the recent trends and methods of test / analysis, Facilities available for training analysts are given in Annexure - III

t) In September 1996 the Goverment posted a separate Administrative head for the Department with an All India Service Officer of the rank of and Inspector General of Police. Sri K. Jagannadha rao, I.P.S., I.G. was appointed as head of the Department. Sri K. Krishna Moorthy. I.P.S., I.G. took over as head of the department in February 1999. The Director, Drugs Control Administration is the licensing and controlling authority under Drugs and Cosmetics Act and rules made thereunder for manufacturing units and also for manufacture and distribution of Narcotic Drugs under A.P. Narcotic Drugs and Psychotropic substances Act and A.P. Narcotic Drugs and Pshychotropic Substances Rules.

Chapter - III

Present role

3. PRESENT ROLE

Andhra Pradesh State occupies a very prominent place in the pharmaceutical map of India with currently 1946 licensed manufacturing units which include 242 bulk drug units, 562 formulation units, 113 blood banks, 183 cosmetics licenses, 776 loan licenses, 63 re - packing units and 7 approved laboratories. The total number of licensed sale premises existing in the State is 31, 442 (figures upto 12/98). The Drugs Control Administration' in Andhra Pradesh which made a small beginning with 4 Drugs, Inspectors in 1952 in the Office of Directorate Of Medical and Health Services has undergone major changes in its organisational setup keeping in view the growth of pharmaceutical Industry and Trade in the State. Today the Drugs Control Administration is a separate department under the Ministry of Medical and Health and family welfare in the Government of Andhra Pradesh headed by a full time inspector General, Drugs & Copyright as its Administrative head and a Director exercising the powers of licensing and Controlling Authority with separate enforcement wing and laboratory wing.

The aim of the department is to control the quality of drugs manufactured and sold in the state, to control the menace of movement of spurious and substandard drugs in the State and to ensure that the drugs are manufactured and sold under and in accordance with the conditions of licenses issued and they are sold at reasonable prices fixed by Government and further also to ensure unwary public are not misled by objectionable advertisements in respect of use of drugs for certain ailments, diseases and disorders.

This Department has necessary machinery in preventing the substandard or spurious drugs entering the market and has got necessary procedures prescribed under various enactments related to drugs for assuring the availability of quality drugs in abundant quantities at affordable prices (in respect of scheduled formulations under Drugs (Prices Control) Order, 1995).

The aims and objectives of this Department are brought home by periodical inspections of manufacturing units engaged in the manufacture of drugs/Cosmetics, inspection of Sales outlets, inspection of Medical Stores attached to Government Institutions/ Hospitals, collecting samples of drugs or cosmetics for Test or analysis, scrutinising the claims of medicines for unethical claims, to scrutinise the formulations for their prescribed prices and to control the misuse of drugs and formulations.

The Drugs Control Administration in the State is implementing the following Central Legislations throughout the State.

1. THE DRUGS AND COSMETICS ACT, 1940 AND RULES MADE THEREUNDER:

An Act to regulate imports, manufacture, distribution and sale of Drugs and Cosmetics in the country. The main object of the Act is to prevent substandard in Drugs and Cosmetics. To ensure the quality of drugs manufactured and sold in the State, drug samples are taken from manufacturing units and sales outlets and their quality is assessed after conducting test/analysis in the laboratories of the Drugs Control Administration.

2. DRUGS (PRICES CONTROL) ORDER, 1995 MADE BY THE GOVERNMENT OF INDIA UNDER SECTION 3 OF THE ESSENTIAL COMMODITIES ACT 1955 (10 OF 1955):

In this order prices of 76 Bulk drugs and their formulations are fixed by the Government of India (National Pharmaceutical Pricing Authority under the Ministry of Chemicals and Fertilizers, Government of India) so as to make these drugs available to the public at affordable prices. The enforcement wing of the Drugs Control Administration implements the provisions of the Drugs (Price Control) Order in respect of the current prices of Bulk drugs and their formulations as fixed by the National Pharmaceutical Pricing Authority. The Drugs Control Administration also assists the National Pharmaceu-

tical Pricing Authority in realisation of the excess prices charged by the errant manufacturers besides taking legal action against the erring manufacturers and dealers.

3. THE DRUGS AND MAGIC REMEDIES (OBJECTION ABLE ADVERTISMENTS) ACT , 1954 & RULES MADE THEREUNDER:

The above Act is an important piece of legislation, enacted with a view to prevent objectionable and misleading advertisement sin order to discourage self medication and self treatment and control the advertisement of drugs in certain cases, to prohibit the advertisements for certain purpose of remedies alleged to possess magic qualities and to provide for matters connected therewith The enforcement wing of Drugs Control Administration scrutinises the labels, advertisement sand other material for possible misleading and objectionable advertisements and the violators are prosecuted in the Courts of law.

4. THE ANDHRA PRADESH NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES RULES 1986 (LICENSING PART)

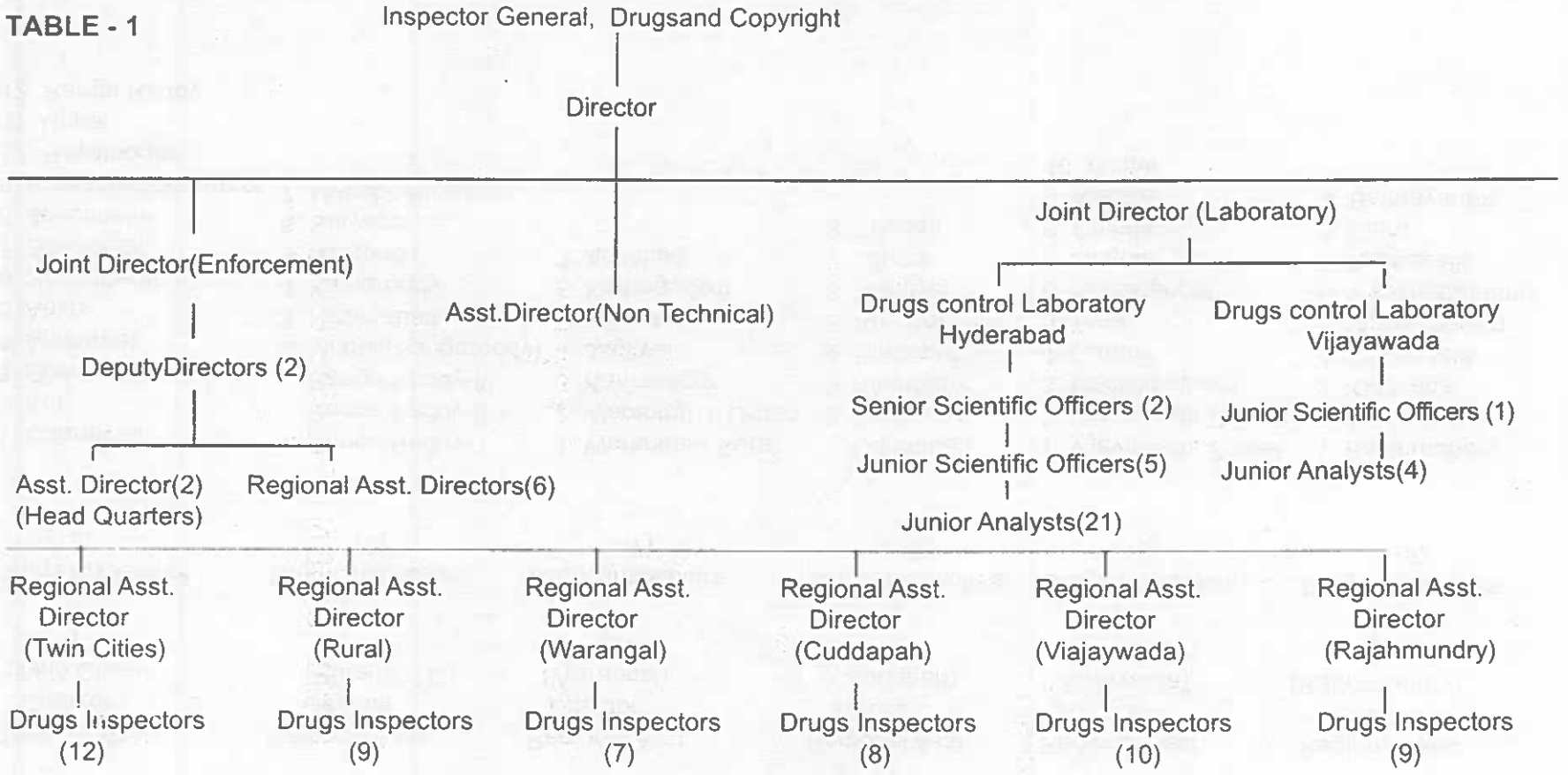
Under Andhra Pradesh Narcotic Drugs and Psychotropic Substances Act and Andhra pradesh State rules made thereunder, the manufacture, sale and transport of certain notified drugs and psychotropic substances used as drugs are regulated under a license issued by Drugs Control Administration.

Chapter - IV

Organisational Structure

ORGANISATIONAL STRUCTURE OF DRUGS CONTROL ADMINISTRATION DEPARTMENT HEIRARCHY, VARIOUS CATEGORIES OF POSTS AND NO. OF SANCTIONED POSTS.

TABLE - 1



Note : The officers of the Drugs Inspector located are shown inTable-2

TABLE-2

Regional Asst. Director (Twin Cities)	Regional Asst. Director (Rural)(OTC)	Regional Asst. Director (Warangal)	Regional Asst. Director (Cuddapah)	Regional Asst. Director (Viajaywada)	Regional Asst. Director (Rajahmundry)
Drugs Inspectors (12)	Drugs Inspectors (9)	Drugs Inspectors (7)	Drugs Inspectors (8)	Drugs Inspectors (10)	Drugs Inspectors (9)
1. Charminar	1. Ranga Reddy- I	1. Warangal-I Rural	1. Cuddapah	1. Vijayawada Zone-I	1. Rajahmundry
2. Koti	Ranga Reddy-II	2. Warangal -II Urban	2. Proddutur	2. Vijayawada Zone-II	2. Amalapuram
3. Gowliguda	Ranga Reddy-III	3. Karimnagar	3. Anantapur	3. Machilipatnam	3. Kakinada
4. Ameerpet	2. Medak(Sangareddy)	4. Jagityal	4. Hindupur	4. Guntur	4. Srikakulam
5. Abids	3. Nizamabad	5. Khammam	5. Kurnool	5. Tenali	5. Vizianagaram
6. Secunderabad	4. Kamareddy	6. Kothagudem	6. Nandyal	6. Narsaraopet	6. Visakhapatnam
7. Balanagar	5. Nalgonda	7. Adilabad	7. Chittor	7. Ongole	7. Anakapalli
8. Jeedimetla	6. Suryapet		8. Tirupati	8. Chirala	8. Eluru
9. Ramachandrapuram	7. Mahaboobnagar			9. Nellore	9. Bhimavaram
10. Hayatnagar				10. Gudur	
11. Uppal					
12. Ranga Reddy					

TABLE - 3

LOCATION OF REGIONAL OFFICES

REGION- I	:	HYDERABAD
		1. Twin Cities of Hyderabad and Secunderabad.
REGION - II	:	HYDERABAD (OTHER THAN TWIN CITIES)
		1. Ranga Reddy district 2. Medak District 3. Nizamabad District 4. Nalgonda District 5. Mahaboobnagar District
REGION -III		WARANGAL
		1. Warangal District 2. Karimnagar District 3. Khammam District 4. Adilabad District
REGION - IV		CUDDAPAH
		1. Chittoor District 2. Cuddapah District 3. Kurnool District 4. Anantapur District
REGION - V		VIJAYAWADA
		1. Krishna District 2. Guntur District 3. Prakasam District 4. Nellore District
REGION - VI		RAJAHMUNDRY
		1. Srikakulam District 2. Vizianagaram District 3. Visakhapatnam District 4. East Godavari District 5. West Godavari District

TABLE - 4

CADRE STRENGTH OF DURGS CONTROL ADMINISTRATION

Sl. No.	Name of the Post	Head Quarters	Region	Total
1.	Director	1	--	1
2.	Joint Director	2	--	2
3.	Deputy Director	2	--	2
4.	Assistant Director	3	5	8
5.	Senior Scientific Officer	2	--	2
6.	Junior Scientific Officer	5	1	6
7.	Assistant Director (N.T)	2	--	2
8.	Drugs Inspector	12	43	55
9.	Superintendent	10	4	14
10.	Personnel Assistant	1	--	1
11.	Senior Assistant	13	5	18
12.	Junior Analyst	21	4	25
13.	Junior Assistant	25	10	35
14.	Typist	9	5	14
15.	Junior Assts.-cum Typist	8	47	55
16.	U.D. Steno	2	--	2
17.	L.D.Steno	4	--	4
18.	Record Assistant	1	--	1
19.	Lab Technician	4	--	4
20.	Lab Attendant	8	2	10
21.	Sweeper	1	1	2
22.	Driver	4	4	8
23.	Motor Cycle Messenger	1	--	1
24.	Electrician	1	--	1
25.	Scavenger	1	--	1
26.	Assistant Librarian	1	--	1
27.	Night Watchman	2	3	5
28.	Xerox Operator	1	--	1
29.	Animal Keeper	2	--	2
30.	Mali	2	--	2
31.	Attender (jamedars-2)	34	52	86
TOTAL		186	186	372

Chapter - V

Role of each category

5. ROLE OF EACH CATEGORY

I. INSPECTOR GENERAL, DRUGS AND COPYRIGHT:

He is the Head of the Department and Administrative Incharge for overall "Administration. His powers may be classified into two parts namely.

i) Administrative ii) Finance

ADMINISTRATIVE :

He is the Head of the Department, appointing Authority, Transferring Authority and Disciplinary Authority.

FINANCIAL POWER:

He exercises financial powers of the Head of the Department in terms of Article 6 of Chapter-II of Financial Code Vol.I. He is also the Controlling authority for budget expenditure and revenue of the Department.

2. DIRECTOR:

To look after the Technical matters in implementation of various statutes enforced by the department. He is also notified as the licensing Authority in respect of Drugs/Cosmetics Manufacturing Units and also notified as controlling authority for enforcement officers.

3. JOINT DIRECTOR (ENFORCEMENT):

To assist the Inspector General and Director in respect of all matters relating to technical and administration entrusted-

4. JOINT DIRECTOR (LABORATORY)

To assist the Inspector General and Director in all matters relating to analysis of Drugs & Cosmetics in drug testing laboratories and their functioning at Hyderabad and Vijayawada.

5. DEPUTY DIRECTORS:,

To assist the Inspector General, Director and Joint Director enforcement in all matters relating to technical and administration entrusted to them.

6. SENIOR SCIENTIFIC OFFICERS:

Discharge the statutory functions of the Government Analyst under Rule 45 & 46 of Drugs and Cosmetics Rules, 1945 and supervise the work of the Junior Scientific Officers and Junior Analysts.. i

7. ASSISTANT DIRECTORS:

To assist the Inspector General, Director, Joint Director, and Deputy Directors in respect of all matters relating to enforcement and administration entrusted to them.

8. ASSISTANT DIRECTORS (N.T.) :

To look Planning and Budget, Establishment, Accounts and discharge the duties of Drawing and disbursing Officer and Stores and all matters assigned by the Inspector General.

9. JUNIOR SCIENTIFIC OFFICERS :

To Supervise the work of junior Analysts in their respective Units and analysis of samples of drugs & cosmetics and assist the senior scientific officer and the Joint Director (Laboratory).

10. JUNIOR ANALYSTS :

To undertake the Analysis of drugs and cosmetics and submit the

reports to the Junior Scientific Officer after analysis.

11. REGIONAL ASSISTANT DIRECTORS :

He is the Head of the Region. He is the Co - ordinator between the Inspector General, Drugs and Copyright , Director JD(E), D.D. and also the Drugs Inspectors in his region. He is the immediate and direct supervising officer of the Drugs Inspectors working in the Region. His powers are classified into 3 parts .

a) **Statutory**

b) **Administrative**

c) **Financial**

a) Statutory:

He is the Licensing Authority under Drugs and Cosmetics Act, 1940 and Rules made thereunder in respect of Sales Licenses in the respective Region.

b) Administration:

His Administrative powers are in respect of all matters of appointment, disciplinary, transfers and posting of certain categories employees in the Region.

c) Financial:

His financial powers are about sanction of T.A. Bills of Drugs Inspectors and Ministerial Staff etc., and also Drawing and Disbursing Officer in respect of his Office and also other Financial powers as delegated from time to time.

12. DRUGS INSPECTORS:

He is of Gazetted rank and the Head of his Office in the Department. He Is the Field enforcement officer. His powers are also classified into three parts:

a) **Statutory**

b) Administrative

c) Financial

a) Statutory

He has to perform the statutory functions and duties under the following enactment's in the area assigned to him.

i) Drugs and Cosmetics Act 1940 and rules made thereunder.

ii) Drugs and Magic Remedies (Objectionable Advertisements) Act. 1954

iii) Drugs (Prices Control) Order 1995

iv) Narcotic Drugs and Psychotropic Substances Act 1995 and Rules made there under

b) Administrative.

His administrative powers are in respect of Appointment, Disciplinary and sanction of leaves in respect of Last grade services in his Office.

c) Financial:

He, is the head of Drugs Inspector's Office and Drawing and Disbursing Officer in respect of all the claims due to the employees working in his Office.

Chapter - VI

Major Enactments, Rules and Regulations which govern each of the Functionaries

6.MAJOR ENACTMENTS, RULES AND REGULATIONS WHICH GOVERN EACH OF THE FUNCTIONARIES

A. INSPECTOR GENERAL DRUGS AND COPY RIGHT

Administrative Functions:

1. Fundamental Rules
2. C.C.A. Rules
3. Conduct Rules.
4. State and Subordinate Service Rules
5. Organisation of Local Cadre Rules
6. Service Commission Rules
7. Principles of Administrative Law
8. District Office Manual

Financial Functions:

1. A.P. Financial Code
2. A.P. Treasury Code
3. A.P. Accounts Code
4. A.P. Budget Manual
5. A.P. Pension Code
6. A.P.G.P.F. Rules
7. A.P.G.T.S. Rules
8. Indian Accounts and Audit Manual

9. A.P. Manual of Special Pay and Allowances.

B. DIRECTOR

Statutory Duties -Acts and Rules

1. The Drugs and Cosmetics Act, 1940
2. The Drugs and Cosmetics Rules, 1945 -Under Rules 49A, 50 and 50A of the Drugs and Cosmetics. Rules, 1945, the Director is notified as Licensing. Authority and Controlling Authority under the Drugs and Cosmetics Act, 1940.
3. The Drugs and Magic Remedies (Objectionable Advertisements) Act., 1954 -Under Section 8 of the Act, the Director is authorized to exercise the powers vested under the Act.
4. The Drugs and Magic Remedies (Objectionable Advertisements) Rules 1955.
5. The Drugs (Price Control) Order 1995 made by Central Government under Essential. Commodities Act, 1955.
6. The Narcotic Drugs and Psychotropic substances Act, 1985.
7. The A.P. Narcotic Drugs and Psychotropic Substances Rules, 1986 - Under the Rules, The Director, Drugs Control Administration is notified as Licencing and Controlling authority Under the Act and Rules.

C. JOINT DIRECTOR (ENFORCEMENT):

To assist the Inspector General and Director in all matters pertaining to enforcement of above statutes and in administrative matters entrusted to him from time to time.

D. JOINT DIRECTOR (LABORATORIES)

To assist the Inspector General and Director in all matters pertaining to the functions of Drugs Control Laboratories in the state.

E. DEPUTY DIRECTORS

To assist the Inspector General, Director and Joint Director (Enforcement) in all matters pertaining to the enforcement and administrative matters entrusted to them from time to time.

F. ASSISTANT DIRECTOR

Licencing Authority for sales concerns under rule 59 (1) of Drugs & Cosmetics Rules 1945 and other enactments listed under administrative and financial functionaries.

To assist the Inspector General in all matters pertaining to General Administration including financial matters.

H. DRUGS INSPECTORS

a) Statutory:

* Drugs & Cosmetics Act 1940 and rules made there under 1945 -Exercise the provisions of the Act by invoking the powers vested in them under section 22 of the Act and perform duties as per rule 51 & 52 of Drugs and Cosmetics Rules 1945.
* Drugs (Prices Control) Order 1995 -Exercise the provisions of the orders by invoking the powers vested under para 23 of the said order.
* Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 and rules there under -Exercise the provisions of the Act by invoking the powers vested in them under section 8 of the Act.
* Andhra Pradesh Narcotic Drugs and Psychotropic Substances Rules 1986 Under rule 2 (f), they are recognised

as inspectors to discharge the duties under the Act and rules-

b) Administrative & Financial Duties to the Extent of Functioning of the office of Drugs' Inspector:

I. SENIOR SCIENTIFIC OFFICERS/GOVT. ANALYSTS:

Senior Scientific Officers perform duties as Government analysts under the provisions of Drugs & Cosmetics Act and rules made there under in respect of test/analysis of Drugs and Cosmetics under rule 45 of Drugs and Cosmetics rules 1945.

J. JUNIOR SCIENTIFIC OFFICERS/GOVT. ANALYSTS :

To assists the Government Analysts in test / analysis of Drugs & Cosmetics and further to supervise the work of junior analyst and to perform the duties of Government analysts under rule 45 on their notification as Government analysts.

Chapter - VII

Areas of Inter Face

7. AREAS OF INTERFACE

I. GENERAL PUBLIC :

1. Consumer forums
2. Trade Associations
   a) All India Organisation of Chemists & Druggists
   b) District Chemist & Druggist Associations of various Districts,
   c) Manufacturers Associations:
      i) All India Drugs Manufacturers Association.
      ii) Bulk Drugs Manufacturers Association.
      iii) Organisation of Pharmaceutical Manufacturers, A.P.
3. Professional Associations
   a) Indian Pharmaceutical Association,. A.P. State branch
   b) Indian Medical Council, A.P. State branch
   c) A.P. State Pharmacy Council, Hyderabad.

II. CENTRAL GOVERNMENT DEPARTMENTS:

a) Central Drugs Standard Control Organisation,, New Delhi.

b) Central Drugs Standard Control Organisation, Zonal Office, Chennai.

c) Central Drugs Standard Control Organisation, Sub-Zonal Office, Hyderabad.

d) National Pharmaceutical Pricing Authority, Dept. of Chemicals & Petro chemicals New Delhi.

e) Central Government Health Scheme Medical Stores Depot.

f) Narcotic Drugs Commission, Chennai.

g) Insurance Medical Services, Medical Stores and Blood Banks in ESI Hospitals Institutions under ESI Schemes.

III. DRUGS CONTROL DEPARTMENTS IN ALL THE STATES IN INDIA

IV. OTHER DEPARTMENTS:.

a) Police Department:

To help in special investigations and at times to execute warrants of arrest on the accused in the Criminal Cases filed by the department officers under trial in various courts.

b) District Collectorates in all the Districts.,

c) Medical Education Departments medical stores and blood banks in government hospitals attached to teaching institutions.

d) Medical and Health services departments medical stores in the District Medical and Health Offices in the district.

e) Vaidya Vidhan Prarishad medical stores, blood banks in district head quarters, area hospitals and district co-ordinator hospital services medical stores.

f) Institute of Preventive Medicine and State Food Health Authority: Blood banks vaccine production centers under the department.

g) AIDS Control Department : To coordinate the functioning of Blood Banks.

h) Family welfare department: To initiate follow up action on the inspections of medical stores under the department.

i) Animal Husbandry Department: To initiate follow up action on the inspections of Medical Stores in Veterinary Hospitals, Dispensaries, Vaccine Production Centres etc.

j) Dr. MCR Human Resource Development Institute, Hyderabad.

k) State Excise Department.

l) Training Establishment in Andhra Pradesh State and in other parts of the country.

Chapter - VIII

Vision

8.VISION

The Government of Andhra Pradesh has released the draft Vision - 2020 document setting the aims and aspirations whose basic thrust is to make development in the State in all fronts totally sustainable. This is envisaged by building capabilities, focussing on high potential centers and transforming governance with the intention to provide its people tremendous opportunities to achieve prosperity and well being and enjoy a high quality of life.

A.P.'s Pharma sector is well known internationally for its skills in chemical synthesis and process engineering and its speed in market. By 2020, it is envisaged a large part of India's Pharmaceutical activity like manufacturing of bulk drugs, intermediates and formulations as well as Research and Development of New Drugs will be based in Andhra Pradesh. The state can capitalize on these strengths acting quickly in the window of opportunity provided by regulatory change to build a strong globally Competitive potential major pharmaceutical center in Indian Pharmaceutical Industry.

The mission of the Drug Control Administration (DCA) is to protect the public health of the Nation as it may be impaired by drugs, biological products, cosmetics, medical devices, and additives.

Health is a fundamental human right. In a welfare State it is the responsibility of the Government of ensure that the drugs available to the consumers are of standard quality conforming to established specification regarding identity, strength and purity and also that they are safe and efficacious. The mission of the Drugs Control Administration is to assure the supply of quality drugs is adequate quantities at affordable prices to the consumers. The Drugs Control Administration has necessary machinery in preventing the sub-standard or spurious drugs entering the market.

This mission of the Drugs Control Administration is achieved by implementing various enactments related to drugs in the State. This Department which made its beginning with 4 Drugs Inspectors in the year 1952, is strengthened from time to time and as a result, this Department is pres-

ently functioning with 55 Drugs inspectors to control the manufacture and sale or distribution of drugs and cosmetics in the State. The Drugs inspectors during their routine inspections collect samples of drugs or cosmetics for the purpose of Test or analysis from manufacturing units, sales outlets, Government institutions and Hospitals etc., and submit the same to the Drugs Control Laboratories where they are tested or analysed for their quality, strength and purity, the Drugs Control Department has a drug testing Laboratory at Hyderabad which made its beginning prior to 1970 with 3 Analysts is presently strengthened with 32 Analysts who undertake the test or analysis of drugs. Another important event in the Drugs Control Administration of Andhra Pradesh is the establishment of a Drug Testing Laboratory at regional level in Vijayawada in the year 1986. It is worth noting that Andhra Pradesh is the only State to start Drugs Control Laboratory at regional level. On an average these 2 Laboratories together are equipped to analyse about 3,000 Drug Samples per annum. While the Drugs Control Laboratory at Vijayawada can undertake the analysis of drugs or Cosmetics not requiring Biological or Microbiological methods, the Drugs Control Laboratory at Hyderabad can undertake the Test or analysis of all drugs except vaccines, Sera, Blood products and mechanical contraceptives.

The continuous endeavour of this Department has been to ensure the availability of drugs of standard quality at reasonable prices to the needy. In recent times the advances in science and technology have been too rapid and revolutionary, paving the way for longevity of life span and betteringthe quality of life. As the longevity and quality of life is proportional to the availability of remedial measures, there has been constant improvement in the field of presently available drugs and invention of newer molecules in therapeutic front. In this ever changing scenario, the Drugs Control Administration has to be read by in dealing with these developments.

Andhra Pradesh is occupying a prestigious position in the manufacture of Bulk drugs and related formulations in the international Pharmaceutical market. Drugs Control Administration is the organisation issuing Licences for the manufacture and sale of drugs in our State..

VISION :

The advent of computers and information technology has pushed

convention to back seat and speed and accuracy have been the order of the day.

On manufacturing front, the Drugs Control Administration shall have competence to assess the applicability, viability and safety of the technologies that are going to be used in the manufacture of new drug molecules viz., Synthetic, biological and immunological and also the newer types of dosage delivery systems.

PLAN OF ACTION

The enforcement personnel of Drugs Control administration will update their knowledge with regard to pharmaceutical technology, to be able to interact, guide, motivate the control the manufacturing sector.

TRAINING:

As training is a continuous process for bettering the knowledge and skills, the object of efficient and effective enforcement personnel will be achieved if periodical training is imparted to the enforcement staff of Drugs Control Administration with the help of indigenous and foreign organisations/ institutions, to improve and update the competence and skills of enforcement officers. Short-term academic training programmes will also be organised. These measures will equip- the enforcement wing of Drugs Control Administration in rendering their duties more objectively especially in the back drop of W.H.O./G.M.P. CERTIFICATION sought by many of the manufacturers in our State.

REINFORCEMENT OF ENFORCEMENT BASE:

The strength of the enforcement personnel has to be increased manifold from the present strength so as to ensure that the officer incharge of a particular area can effectively inspect the licensed premises in his area not only, not less, than twice in a year as ordained in the Act but also more often to effectively identify and

prevent the manufacture, sale and the movement of spurious Not of Standard Quality drugs in view of the rapid growth in pharmaceutical sector in the State.

Net working with a budget outlay of Rs.20.55 lakhs under World bank Assistance Scheme and the proposals sent are under consideration.

MODERNISATION OF TESTING FACILITIES:

With the increase in the number of manufacturers sales premises, there will be a manifold increase in the sampling of drugs. To cope up with this increase, the existing facilities in the Drugs Control Administration Laboratories have to be updated and also more number of laboratories will have to be established with latest equipment so that more number of samples can be analysed without delay. For strengthening the existing testing facilities in Drugs Control Laboratories proposals for budgetary sanction of Rs. 162.00 Lakhs for purchase of sophisticated equipment to analyse newer drug delivery systems and further budgetary sanction of Rs.107..00 Lakhs sought for construction of Additional Block in Drug testing Laboratories at Hyderabad and Vijayawada are under consideration of the Government of India under Central Assistance Scheme through the -World Bank funding.

BUDGETARY ALLOTMENT

The Drugs and Cosmetics Act stipulates that fair prices have to be tendered whenever drug samples are taken for analysis. With vast increase in new drug molecules and dosage forms, the cost on sampling has become high and the present budgetary allotments for this purpose, are inadequate. Hence, separate budgetary provision for this purpose exclusively will. have to be made, for effective and purposeful sampling.,

To augment the strength field Enforcement Officers,: under the Central Assistance Scheme through World Bank funding, proposals are under consideration for sanctioning 31 posts of Drugs In-

spectors at an estimated budget of Rs.27.00 Lakhs. In addition, sanction of higher level supervisory officers in the cadre of Joint Director(1), Deputy Directors (6), Assistant Directors (15), Deputy Director, NonTechnical (1), to have effective and meaningful supervision has also been proposed under the 1th Finance Commission seeking a budgetary sanction of Rs. 1.78 Crores. These proposals of additional enforcement staff and supervisory officers would help the administration perform better.

As effective supervision and transportation facilities are essential for timely detection and containment of crime, enforcement staff shall be provided with faster transportation facilities and adequate number of supervisory officers.

Communication Network:. Timely and accurate information is vital in any organisation,. more so for an enforcing agency like Drugs Control Administration. Computerisation and its related networking can be effectively used in preparing and updating the data-base and communication of information within the department and with other external parallel. functioning agencies. This is a very important step for prevention of drug related offences and for processing of manufacturing sales applications. It is envisaged to provide computer facility and communication . As quality improvement is a continuous process ad crime is as old as humanity, no fixed time - frame may possible be fixed for the realisation of this vision. The cut delays in processing of the manufacturing applications. The low incidence of the movement of the spurious/Not of standard Quality drugs are some of the factors for measuring the achievements in the realisation of this vision.

ANNEXURE - I

TRAINING PROGRAMMES FOR DRUGS INSPECTORS AND OTHER OFFICERS IN ENFORCEMENT WING

On appointment as *a* Drugs Inspector, a candidate is trained at Drugs Control Administration, Hyderabad for a period of not less than 30 days. The induction training programme includes both theoretical and practical aspects. The candidate is trained under various enactment viz., Drugs and Cosmetics Act, 1940 and Rules made thereunder, Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 and Rules'thereunder and Drugs (Price Control) Order, 1995.

The candidate is attached to the local Drugs Inspectors for inspections of Medical Shops - both retail and whole sale, manufacturing units, blood banks, etc. He is also trained on the procedures of Sampling of drugs for Test 1 Analysis, Seizure of drugs and documents etc., He is also trained on the procedures of Sampling of drugs for test/analysis, seizure of drugs and documents etc. He is also trained on the procedures of Court proceedings, preparing complaints to be filed in the Court etc.

The following are the facilities for imparting further training to enforcement officers:

1. THE CENTRAL DRUGS STANDARD CONTROL ORGANISATION :

CDSCO organises orientation training programmes to all the Drugs and other cadres of the officers of enforcement wing deputed by; the State Goverment.

The main object of this training programme is to keep the officers abreast with the latest developments in manufacturing and Quality

control Techniques for effective enforcement of the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. This programme runs for 30 days.

The Training programme is organized by the Deputy Drugs Controller (India), under CDSCO Training Scheme, Stationed at Bombay.

2. THE CENTRAL DRUGS STANDARD CONTROL ORGNAISATION :

CDSCO, organises another training programme on, all India basis, a short term training course (5 days) on Inspection of "Blood Banks Blood Products" at Mumbai/Chennai/Bangalore , Nellore etc., for Drugs Control Administrations in the Country. Deputy Drugs Controller (India), Drugs Inspectors Training Scheme, C.G.H.S. Dispensary Building, 1" Floor, C.G.S. Colony, Kane Na gar, Antop Hill, Munibai - 400 032.

3. Central Research Institute, Kasauli, Himachal Pradesh :

Organises a training programme for the Drugs Inspectors and other senior Officers of the Drugs Control Administration in the Country on the Inspection and Quality Control measures applicable to Vaccine & Sera. The programme is generally of 15 days duration.

4. World Health Organisation :

W.H.O. also organises training programme on various subjects related to Drugs. This programme is as designed by W.H.O. through its zonal Office at Delhi. The selection is on all India basis as per the norms of Central Government /World Health organisation.

5. Dr. M.C.R. Human Resources Development : Institute e of Andhra Pradesh at Hyderabad is imparting exclusive training programmes on Administrative, Financial and various other discipline at levels of functionaries.

ANNEXURE-II

FACILITIES AVAILABLE FOR TEST / ANALYSIS OF DRUGS/ COSMETICS

UNDER DRUGS AND COSMETICS ACT. 1940 AND RULES MADE THEREUNDER

" **DRUGS** INSPECTORS ",appointed under section 21 of the Drugs and Cosmetics Act, 1940 collect samples of Drugs/Cosmetics various sources and submit to various Laboratories for Test/Analsis. Various Laboratories available in the country are as detailed below:

In Andhra Pradesh:

1. *Drugs Control Laboratory, Hyderabad..*

   This laboratory undertakes the test/analysis of all drugs except Vaccine, Sera for human use, mechanical contraceptives, viz., Condomes, Oral Polio Vaccines, Veterinary Sera & Vaccines, Veterinary Diagnostic Antigens Etc.

2. Drugs Control Laboratory, Vijayawada:

   This lab undertakes the Test/Analysis of all Drugs/Cosmetics which do not involve Biological or Micro-biological tests.

Laboratories At Other Places:

1. Central Drug Laboratory, Calcutta:

   Central Drugs Laboratory , Calcutta is the National Statutory Lab of the Government of India for Quality Control of Drugs and Cosmetics. This Laboratory is an appellate authority in matters of disputes relating to quality of drugs.

   Drugs Inspectors can directly submit the samples of drugs/cosmetics to Central Drugs ' Laboratory for Test/ Analysis if necessary facilities are not available in the State Drugs Control Laboratories. The Certificates of Test/ Analysis issued by the Central Drugs Laboratory are final as per the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder .

Hon'ble Courts also forward samples of Drugs/Cosmetics. To Central Drugs Laboratory for Test/ Analysis at the request either of the accused or at the request of the complainant.

Address: Central Drugs Laboratory, No.3, Kyd Street, Calcutta -16.

2. **The Central Research Institute, Kasauli, Himachal Pradesh:**

The Central Research Institute, Kasauli undertakes the Test/ Analysis of the following drugs:

1. Sera
2. Solution of Serum Proteins intended for injection.
3. Vaccines.
4. Toxins
5. Antigens
6. Anti-toxins
7. Sterlized surgical ligature and sterilized surgical suture.
8. Bacteriophages.

3. **Pasteur Institute Of India, Coonoor AND**

4. **Enterovirus Research Centre:**

(Indian Council of Medical Research), Haffkine, Institute Compound, Parel, Mumbai -400 012, under take the Test / Analysis "Oracle Polio Vaccine".

5. **Indian Veterinary Research Institute, Izzatnagar / Mukteswar under takes the Test/ Analysis of the following Drugs:**

1. Anti-sera for veterinary use.
2. Vaccines for Veterinary use.
3. Toxoids for Veterinary use.
4. Diagnostic Antigens for Veterinary use.

6. **Laboratory of the Serologist and Chemical Examiner to the Government of India, Calcutta:**

undertake the Test/Analysis of "VDRL Antigens".

7. **Department of Biomedical Engg. Indian Institute of Technology, New Delhi:**

undertakes the Test Analysis of "Intra Uterine Devices" and "Falopian Rings".

8. ***Central Indian Pharmacopoeal Laboratory, Ghaziabad:***

undertakes the Test Analysis "Condomes".

Note : The Director of the Laboratories mentioned at Sl.No.2 to 8 are vested with the powers similar to powers vested with the Director, Central Drugs Laboratory Calcutta under Drugs'& Cosmetics Act.

ANNEXURE-III

TRAINING PROGRAMMES ORGANISED FOR JUNIOR ANALYST WORKING IN THE DRUGS CONTROL LABORATORIES OF THE STATE

Junior Analyst of the Drug Control Laboratories in Andhra Pradesh State on their first appointment are imparted induction training programme for one month in Drugs Control Laboratory, Hyderabad.

Other training facilities for Junior Analyst are given below:

1 Microbiological Method of Analysis of Drugs at Central Drugs Laboratory, Calcutta-.

2. Pharmacological and Toxicological Testing of Drugs at Central Drugs Laboratory, Calcutta.

3. Instrumental Methods of Analysis of Drugs at Central Drugs Laboratory, Calcutta.

4. Advanced Chromotography and Spectrophotometric e' Methods of Analysis of Drugs at Central Drugs Laboratory Calcutta.

5. Bacterial Endotoxins 'at C.I.P.L. Ghaziabad.

6. Contraceptive Medical devices and Non-Contraceptive Medical devices at C.I.P.L,Ghaziabad.

ANNEXURE IV(A)

STATEMENT SHOWING THE STATISTICAL REPORT OF THE DRUG CONTROL, ADMINISTRATION UPDATED UPTO 31.03.99

Sl.	Particulars	1995-96	1996-97	1997-98	1998-99
I.	Total No. of Manufacturing Licences Existing in the State	1942	1591	1800	1993
	a) Bulk Drugs	292	223	231	244
	b) Formulation	654	477	531	570
	c) Blood Banks	45	81	99	116
	d) Cosmetics	180	180	182	184
	e) Loan Licences	701	561	687	811
	f) Repacking Licences	65	62	63	64
	g) Miscellaneous (Approved Labs)	5	6	7	4
II.	Number of Manufacturing Licence Suspended	12	2	2	Nil
III.	Number of Manufacturing Licences Cancelled	241	43	25	29
IV.	Number of Sales Licences Existing in the State	25347	26536	29329	32205
V.	Number of Sales Licences Suspended	608	925	2574	2121
VI.	Number of Sales Licences Cancelled	372	584	706	606
VII.	'No. of Samples Analysed	1877	3041	3041	4088
VIII.	No. of Samples found not of Standard Quality	144	193	215	191
	a) Within Andhra Pradesh	63	146	144	127
	b) Outside Andhra Pradesh	81	47	71	64
IX.	No.of Stop Production Orders issued	41	38	196	137
X.	No. of Show Cause Notices issued	84	106	63	37
XI.	No. of Cases referred to other states	44	54	62	64

ANNEXURE IV(B)

STATEMENT SHOWING THE LIST OF PROSECUTIONS AND OTHER PARTICULARS PERTAINING TO ALL REGIONS AS ON 31.03.99

Sl.No.	Particulars	Upto 1995	1996	1997	1998	1999	Total
I.	**NOT OF STANDARD QUALITY**						
1)	Prosecution Ordered	56	14	45	44	3	162
2)	Charged& Pending Trails	27	10	31	28	3	99
3)	Convictions	18	1	1	--	-	20
4)	Acquitted	11	3	3	3	-	18
5)	Pending (Under Investigation)	-	-	11	14	-	25
II.	**SPURIOUS**						
1)	Prosecution Ordered	64	6	29	10	-	109
2)	Charged & Pending Trails	40	4	23	8	-	75
3)	Convictions	3	-	-	-	-	3
4)	Acquitted	9	1	-		-	10
5)	Pending (Under Investigation)	2	1	6	2	-	11
III.	**D.P.C.O.**						
1)	Prosecution Ordered	4	41	5	1		51
2)	Charged & Pending Trails	1	-	-	-	-	
3)	Convictions	2	1	-	-	-	3
4)	Acquitted	1	-	-	-	-	1
5)	Pending(Under Investi ation)	-	40	5	1	-	46
IV.	**D.M.R (O.A.)**						
1)	Prosecution Ordered	6	3	5	5	-	19
2)	Charged & Pending Trails	2	1	-	4	-	7
3)	Convictions	4	2	-	1	-	7
4)	Acquitted	-	-	-	-	-	
5)	Pending (Under Investigation)	-	-	-	-	-	-
V.	**SEIZURES**						
1)	Prosecution Ordered	87	41	28	24	3	183
2)	Charged & Pending Trails	30	26	18	22	2	98
3)	Convictions	41	6	5	2	-	54
4)	Acquitted	15	3	-	-	-	18
5)	Pending (Under Investigation)	1	6	5	-	1	13
VI.	**BLOOD BANKS**						
1)	Prosecution Ordered	-	1	2	1	-	4
2)	Charged & Pending Trails	-	-	2	1	-	3
3)	Convictions	-	1	-	-	--	1
4)	Acquitted	-	-	-	-	-	-
5)	Pending (Under Investigation)	-	-	-	-	-	-

ANNEXURE - V(A)

REGISTERS TO BE MAINTAINED AT OFFICES OF THE INSPECTOR GENERAL, DRUGS AND COPYRIGHT, REGIONAL ASSISTANT DIRECTOR, DRUGS INSPECTOR, DRUGS CONTROL ADMINISTRATION

1. Inward Register.
2. Outward Redgister.
3. Distribution Register.
4. Attendance Register.
5. Casual Leave Register
6. Increment Watch Register.
7. Service Registers availability Register.
8. Movement Register.
9. Turn duty Register
10. Trunk Call Register
11. Establishment Register (Temporary/ Permanent).
12. L.P.C. Register (Inward/Outward).
13. Treasury, Reconcilliation Register.
14. Budget Control Register.
15. Contingent Bill Register.
16. Vehicle Log Book.
17. Register of Unserviceable items of Vehicles.
18. Vehicle accident Register.
19. Personal Registers.
20. Local Delivery Register.
21. Postal Dispatch Register.
22. Register post despatch Register,
23. Fair copy Register.

24. Stamps account/Service postage Register.
25. Pay Bill Register.
26. Establishment Acquittance Register.
27. Cash Book.
28. U.D. Pay Register.
29. T.A. Bill Register.
30. G.P.F. Register.
31. Tour Advance Register.
32. Festival advance Register.
33. Marriage Advance'Register.
34. Office Expenses Register.
35. Record issue Register.
36. Library Register.
37. Library issue Register.
38. Furniture Receipt/issue Register.
39. Stationery Receipt/Issue Register
40. Copy applications Register.
41. Revenue Receipts issue Register.
42. LAQ/LSQ Register.
43. Prosecution cases Register.
44. Not of Standard Quality Reports Register.
45. Drugs seizures Register.
46. D.P.C.O. cases Register.
47. D.M.R.O. cases Register.
48. All statistics.
49. Periodical Register (Out-going/Incoming).
50. H.B.A. Register.
51. Motor Cycle Advance Register.

ANNEXURE -V(B)

REPORT TO BE SENT TO GOVERNMENT FOR REVIEW BY THE CHIEF MINISTER

PROFORMA - I

STATEMENT SHOWING THE NUMBER OF INSPECTIONS CARRIED OUT

Sl. No.	Month & Year	Inspections carried out		Target fixed	Target achieved	Remarks
		Manufacturing	Sales			
1	2	3	4	5	6	7
						Action taken on the contraventions found is in proforma - II

PROFORMA - II

STATEMENT SHOWING THE NUMBER OF MANUFACTURING AND SALES LICENCES SUSPENDED / CANCELLED FOR VARIOUS REASONS

Sl.No.	Month and	Manufacturing		Sales	
		Suspended	Cancelled	Suspended	Cancelled
1	2	3	4	5	6

PROFORMA - III

STATEMENT SHOWING THE NUMBER OF SAMPLES RECEIVED AND ANALYSED IN DRUGS CONTROL LABORATORIES

Sl. No.	Month & Year	Samples pending at the end the previous months		Samples received during the month		Target fixed to each junior analyst		Achievement/ smaples analysed		Samples found not of standard quality	
1	2	3		4		5		6		7	
		Hyd	Vij	Hyd	Vij	Hyd	Vij	Hyd	Vij	Hyd	Vij

PROFORMA - IV

STATEMENT SHOWING THE ACTION TAKEN ON NOT OF STANDARD QUALITY REPORTS OF GOVERNMENT ANALYSTS OF THE DRUGS CONTROL LABORATORIES IN THE STATE AND OTHER STATES

Sl No.	Month & Year	N.S.Q. Reports Received		Stop production orders issued	Show cause notice issued	Referred to other states where the companies are situated	Remarks
		Reports of Government analysts of the state	Reports referred from other State Drugs contolllers				
1	2	3	4	5	6	7	8

PROFORMA -V

STATEMENT SHOWING THE NUMBER OF PROSECUTIONS LAUNCHED AND DETAILS FO JUDGEMENTS DELIVERED UPTO END OF THE MONTH

Sl No.	Month & Year	Number of cases pending at the end of the previous month	Prosecu-tions launched during the month	Judge-ments delivered	Convic-tions	Acquittal	No. of cases pending at the end of the month
1	2	3	4	5	6	7	8

PROFORMA - VI

STATEMENT SHOWING THE NUMBER OF MANUFACTURING AND SALES UNITS EXISTING IN THE STATE UPTO THE END OF THE MONTH

Total No. of Manufacturing concerns existing in the State.

a) No. of Basic Drugs Units.
b) No. of Formulation Units
c) No. of Blood Banks.
d) No. of Cosmetics Licences.
e) No. of Repacking units.
f) No. of Loan Licences.
g) Miscellanious (Approved Labs)

Total No. of Licences issued :

a) No. of Basic Drugs Units.
b) No. of Formulation Units
c) No. of Blood Banks.
d) No. of Cosmetics Licences.
e) No. of Repacking units.
f) No. of Loan Licences.
g) Miscellanious (Approved Labs)

No. of sales unit existing in the state as on ----------

Report sent to the Government for Review. **ANNEXURE - V (C)**

FILE DISPOSAL DRIVE - WEEKLY DISPOSAL STATISTICS
INPUT FORMAT FOR HEADS OF DEPARTMENT - REPORT FOR THE WEEK ENDED- 199

Secrettariat Department Code : **Name of the H.O.D. :**

Head of the Department Code : **Total No. of sections in the H.O.D.:**

PENDING FILES AT THE BEGINNING OF THE WEEK					FILES RECEIVED DURING THE WEEK					Files Disposed During The week	Pendency of files at the end of the week
Public Importance	Court Cases	Service Matters	Others	Total	Pub.Imp.	Court Cases	Service Matters	Others	Total		
A B C	A B C	A B C	A B C		A	A	A	A			

a. Files pending for less than three months.
b. Files pending for more than three months but less than one year.
c. Files pending for more than one year.

Note : 1. Week end implies Saturdays of the week. In case of a Holiday the Day before Holiday has to be taken as weekend.
2. Files have to be classified as cases of Public Importance, Court Cases, Service matters and other Files other than Court Cases Service Matters, Cases of Public Importance have to be grouped under other.

Certificate

The information now furnished covers ---------- sections out of ---------- sections in the head of the department.

Signature :

Designation :

ANNEXURE V (D)

ANNUAL PERFORMANCE STATEMENTS OF THE DEPARTMENT SUBMITTED TO THE STATE GOVERNMENT FOR PRESENTATION IN LEGISLATIVE ASSEMBLY IN THE FOLLOWING FORMATS

FORMAT - I

Sl. No.	Particulars	Previous year	Current year
1.	Total No. of samples analysed		
1.	No. of samples found not of standard quality. a) Within the state (samples of the units located in A.P.) b) Outside the state (samples of the units located outside the state)		
2.	Percentage of drugs found to be not of standard quality		
3.	Hospital samples analysed. a. Hospital Samples analysed and found not of standard not of standard quality b. Percentage of Hospital samples found not of standard quality. c. Withing the State (sample of the units located in the state. d. Outside the state (Samples of the Units outside the state.		

FORMAT - II

Sl. No.	Particulars	Previous year	Current year
1.	Total No. of Licenses suspended. a) Sales Licenses. b) Manufacturing Licenses.		
2.	Total No. of Licenes Cancelled. a) Sales Licenes b) Manufacturing Licences.		
3.	Stop production orders issued to manufacturing Concerns in respect of drugs declared as not of standard quality.		
4.	Show cause notice issued in respect of drugs declared as not of standard quality		
5.	No. of cases referred to concerned state drugs controllers in respect of drugs declared as not of standard quality for necessary action.		
6.	No. of seizures conducted		
7.	No. of prosecutions launched.		
8.	No. of prosecutions convicted.		
9.	No. of Prosecutions acquitted.		
10.	No. of prosecutions pending trial in courts		

FORMAT - III

PART I

Total No. of Drug Inspectors	No.of Samples taken	Total no.of cases pending in various courts	No.of cases decided by the courts up to the end of February of the year	
			In favour of Prosecution	Against the Prosecution
Sanctioned Vacant				

PART - II

Total No. of Junior analysts	Total No.of Samples analysed	Total no. of samples foundnot of standard	No. of cases action taken
Sanctioned Vacant			

ANNEXURE -V(E)

PROFORMA FOR PROSECUTION PARTICULARS IN RESPECT OF ALL REGIONAL OFFICES IN REVIEW MEETINGS OF INSPECTOR GENERAL

Year	VJA	RJY	CUD	WGL	TC	OTC	TOTAL
I. NOT OF STANDARD QUALITY :							
Prosecution ordered							
Charged and Pending Trail							
Convictions							
Acquittals							
Pending (U.I)							
II. SPURIOUS :							
Prosecution ordered							
Charged and Pending Trail							
Convictions							
Acquittals							
Pending (U.I)							
III. D.P.C.O :							
Prosecutions ordered							
Charged and Pending Trail							
Convictions							
Acquittals							
Pending (U.I)							
IV. D.M.R. (O.A.)							
Prosecution ordered							
Charged and Pending Trail							
Convictions							
Acquittals							
Pending (U.I)							
V. SEIZURES :							
Prosecution ordered							
Charged and Pending Trail							
Convictions							
Acquittals							
Pending (U.I)							
VI. BLOOD BNAK							
Prosecutions ordered							
Charged and Pending Trail							
Convictions							
Acquittals							
Pending (U.I)							

ANNEXURE -V(F)

PROFORMA FOR PERFORMANCE REPOR OF THE DRUGS INSPECTORS FOR THE MONTH OF

Sl. No.	Name of the Office	No. of Inspections		Violations		Samples lifed						Total		Seizures conducted		Com-plaints received		Investiga-tion		Remarks of the head of the Dept.
						Hospital		Trade		Mfg.										
		Pre Mon	Cur Mon	Pre Mon	Cur Mon	Pre Mon	Cur Mon	Pre Mon	Cur Mon	Pre Mon	Cur Mon	Pre Mon	Cur Mon	Pre Mon	Cur Mon	Pre Mon	Cur Mon	Pre Mon	Cur Mon	
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21

ANNEXURE -V(G)

PROFORMA OF NOT OF STANDARD QUALITY DRUGS FOR REVIEW COMMITTEE MEETING ON

Sl. No.	Name of the drug, B. No. D/M, D/E	Name of the Manufacturer	Report No. Opinion and date of govt. analyst and reasons for failure	Name of the Drugs Inspector and area who has picked up the sample for analysis	Previous No.s and Reports of the firm and action taken on them	Decision of the R.C.on action to be taken	Action taken	Final action taken	Remarks
1	2	3	4	5	6	7	8	9	10

ANNEXURE -V(H)

PROFORMA OF NOT OF STANDARD QUALITY DRUGS COMMUNICATED TO OTHER DEPARTMENTS.

Sl. No.	Name of the drug, B. No. D/M, D/E	Name of Manufac-turer	Report No. Opinion and date of govt. analyst and reasons for failure	Name of the Drugs Inspector and area who has picked up the sample for analysis	Stage of the file	Decision of the R.C. on action to be taken.
1	2	3	4	5	6	7

ANNEXURE - V (I)

CHECK LIST FOR APPLICATIONS FOR GRANT OF LICENCES IN FORM - 25 AND 28 OF DRUGS AND COMSMETICS AND RULES MADE THERE UNDER

Documents to Be Submitted By the Applicant (All In Triplicate Set)

1. Covering letter
2. Challan for the required amount under the Head of Account 0210 - Medical and Public Health, o6 - Public Health. 104- Fee, Fines etc.
3. Statutory Forms :

Form	Fees Rs.
24	500.00
27	1,000.00
24 F (Schedule X)	1,000.00
24 A (Schedule X)	200.00
27 A (Schedule X)	600.00
24B(Schedule X)	100.00
31 (Schedule X)	500.00
31 A (Sehedule X)	500.00
	15.00
30 Test Licence	
Labs :	
27C (Blood Bank)	1,000.00
36 (Laboratory	1,000.00
27B Manufacture of	

Drugs specified	
In Sch. C, C & X	1,000.00

4. Plan and Layout of the Premises showing the installation of Machinery and equipment (Peferably Blue Print)

5. Attested copies fo documents relating to the ownership / Rent/ Lease/ Allotment of the Site Building.

6. Declaration of the Proprietary/ Partners Directors etc.

6A. Atlested copies of Partnership Deed / Memorandum of the Articles.

6A . Affidavit - Attested Notary regarding responsibility.

7. Detailed list fo Anlytical Equipment -= with Purchase Bills.

8. Detailed list fo Manufacturing equipment wiht purchase Bill.

9. Attested copies of qualificatio Certificates, experience Certificates, Bio - Dat and declarations fo Technical Staff in the prescribed Profoma with attested Photos.

10. Attested copy of S.S.I Registration Certificat

11. Permission from the Municipality / Municipal Corporation / Panchayat Authorities for construction / Starting the Unit.

12. Permission from the Health Authorities for starting the Unit

13. Permission from the Inspector of Factories.

14. Permission from the Inspector of Boile rs (if applicable)

15. Documents and other Particulars to show the compliance fo Good Manufacturing Practices as laid down in Schedule 'M' and 4 of Drugs and Cosmetics Rules (Proforma records).

Documents Required In Case Of Application For Drug Formulations Manufacture

1. Consolidated list of formulations with packing particulars.

2. Specimen Labels.
3. Labels of similar products.
4. Method of anlaysis for the finished products and also for the ingredients which are not specified in any Pharmacopoeias of any official compendia of Drugs Standards.
5. Method of Manufacture.

Documents Required In Case Of Application For Bulk Drugs

1. Permission from A.P. Pollution Control Board.
2. Permission from the Municipal Corporation of Hyderabad for transfer of treated effluents into the central storage in case of Units situated in and around of Twin Cities.
3. Brief Manufacturing Procedure and flow chart for the durgs applied for, and Analytical procedure.
4. Note on the nature of effluents, its treatment and disposal.
5. Details of Raw Materials, its requirement co - efficient and Testing Procedures.
6. Packing Particulars.

ANNEXURE - V(J)

CHECK LIST FOR RENEWAL OF DRUGS MANUFACTURING LICENCES IN FORM 25 - A

And 28 -A Under Drugs & Cosmetics Act And Rules Made There Under

1. Challan for required amount under correct Head of Account.

	Rs.
For Fresh Licence in Form - 24 & 27 :	1250.00
For Fresh & Loan Licence in Form - 24A & 27 A	800.00
For Renewal in Form 24 :	450.00
For Renewal in Form 27 :	800.00
For Renewal of Loan Licence in Form 24 A	200.00
For Renewal of Loan Licence in Form 27 A	500.00

2. Proscribed application forms duly filled.
3. Original Drugs manufacturing Licences with original list of approved products with additional products approved.
4. Consolidated list of approved products with packing details.
5. Set of printed labels of all approved products.
6. Production partirulars of last Licensing period (Year wise)..
7. Declaration- to the affect that there is no change either in constitution or premises or in the Technical Staff (Wherever applicable).
8. Samples of products lifted by Drugs Inspector for analysis in any and its detailed.'
9. List of manufacturing equipment with additions.
10. List of analytical equipment deletions if any,
11. Declaration of Technical staff in prescribed Proforma.

12. Plan and Layout of the existing building with any alterations and modifications.

13. Documentation and other particulars to show the compliance of G.M.P. as per Schedule 'M'.

14. Information on Proforma for Government in case of Bulk Drugs.

15. Affidavit regarding responsibility attested by the Notary.

16. Details of Partners/Directors/Proprietor with their residential addresses, are etc.

17. Copy of **S.S.I.** Registration Certificate.

ANNEXURE - V(K)

CHECK LIST FOR OBTAINING A RETAIL LICENSE IN FORM 20, 21 UNDER DURGS AND COSMETICS ACT AND RULES THERE UNDER

1. COVERING LETTER
2. Application in form - 19, 4 copies
3. S.B.H. Challan for Rs. 80/- for with xerox copy.
4. Declaration by the Proprietor or Partner 1 + 1
5. Specimen Signatures of Proprietor / Partner 1 +1
6. building Owner's Declaration 1 + 1 Attested by Gazetted Officer 1 + 1.
7. Rental Agreement duly attested by Public Notary 1+1.
8. A.P.S.E.B. or M.C.H. Tax Receipt 1+1.
9. Refrigerator purchase bill 1 + 1 or letter with details of Refrigerator.
10. Declaration by the Oualified person 1+1
11. Special Declaration by Registered Pharmacist on Rs. 1 0/- bond paper 1 + 1.
12. Original Registered Pharmacy Certificate.
13. Specimen Signature of Qualified Person 1+1.
14. Xerox copies of Registered Pharmacist Certificate 4 with Photos affixed and attested by a Gazetted Officer.
15. Plan of the Shop 1+1 (Minimum size 10 sq. mtrs..)
16. Partnership Deed attested by Gazetted Officer 1+1.
17. National Savings Certificate Xerox copies Rs. 1,000/-.

ANNEXURE - V(L)

CHECK LIST FOR OBTAINING WHOLE SALE LICENSES IN FORM 20B, 21B

UNDER DRUGS AND COSMETICS ACT AND RULES THERE UNDER

1. COVERING LETTER
2. Application in form - 19, 4 copies
3. S.B.H. Challan for Rs. 80/- for with xerox copy.
4. Declaration by the Proprietor or Partner 1 + 1
5. Specimen Signatures of Proprietor / Partner 1 +1
6. Rental Agreement duly attested by Public Notary.
7. Building Owner's Declaration attested by Gazetted Officer 1+1.
8. M.C.H. or A.P.S.E.B. Tax Receipt 1+1.
9. Partner Deed 1+1.
10. Specimen Signature of competent Pers on 1+1.
11. Competent person - Experience Certificate (minimum 4 years) and one year in case of a graduate.
12. Competent person qualification certificate copies with photo attested by the Gazetted Officer.
13. Plan of the shop 1+1 (Minimum size 10 sq. mtrs.).
14. Declaration by the competent person 1 + 1.
15. Refrigerator details.
16. National Savings Certificate Xerox copy for Rs. 5,000/-

यदैव विद्यया करोति श्रध्दयोपनिषदा
तदैव वीर्यवत्तरं भवति

Duty performed
with Knowledge, Faith and Devotion,
becomes really effective

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