Functionary Manual

DCA 113

Dr. MCR Human Resource Development Institute of Andhra Pradesh Hyderabad

Drugs Control Administration

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

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

INTRODUCTION

The Drugs Control Administration at the time of inception in the year 1952 was .functioning in the Directorate of medical Services. The first basic level functionaries sanctioned to this Department were four Drugs Inspectors for implementation of the Drugs and Cosmetics Act, 1940 and Rules made thereunder (formerly called as The Drugs Act, 1940 and The Drugs Rules, 1945) in the erstwhile Andhra State for implementation in Andhra area only. After the formation of separate Andhra Pradesh State in the year 1956 four more Drugs Inspectors were appointed and implementation of this Statute was extended to Telangana Area also.

Subsequently, Drugs Control Administration was also entrusted with the enforcement of Prevention of Food Adulteration Act and the Head of the Department was designated as Drugs Controller and Food Health Authority. In the year 1981 the Department of Drugs Control Administration was accorded independent status with a separate Directorate headed by a Director functioning under the Ministry of Medical and Health, Government of Andhra Pradesh.

The main objective of Drugs Control Administration 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 and are packed in containers giving all necessary information about the drug and its manufacturer, Drugs Control Administration regulates the manufacture, sale and distribution of drugs in the State.

Drugs Control Administration in the State of Andhra Pradesh is implementing the following Central legislation throughout the state.

1. The Drugs and Cosmetics Act, 1940 and Rules made thereunder .

2. Drugs (Prices Control) Order, 1995.

3. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules made thereunder .

4. The Andhra Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1986 (Licensing Part).

The organisational set up of various functionaries in Drugs Control Administration are broadly classified into two wings.

I. Enforcement Wing 2. Laboratory Wing

Enforcement Wing performs the functions of enforcement of the above legalisation in the State and Laboratory Wing performs the Test/Analysis of various Drugs/Cosmetics samples sent for analysis and issues the Certificate of Test/Analysis. The Inspector General, Drugs and Copyright is the overall Head of the Department for General Administration and under him Enforcement Wing and Laboratory Wing functionaries perform their distinct functions enlisted in this functionary Manual in detail.

No functionary' manual is prepared in this Department till to date and this manual now brought out is an initial effort in this direction incorporating the consolidated information covering all the areas revolving around each functionary in the Department on the lines of suggestion given by Dr.M.C.R. Human Resources Development Institute of Andhra Pradesh in pursuance of the directions of Government of Andhra Pradesh.

K KRISHNA MOORTHY IPS

Inspector General, Drugs & Copyright

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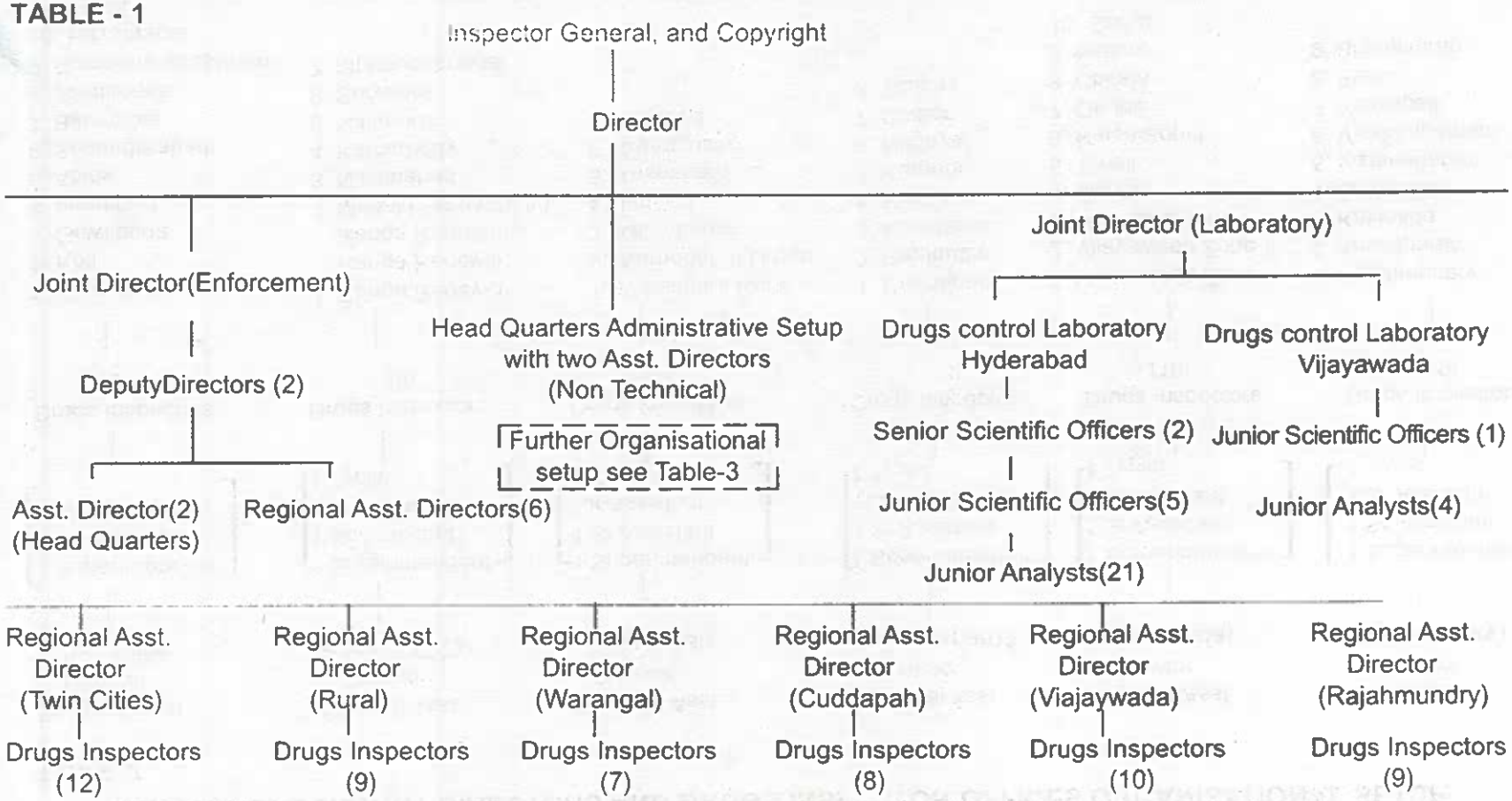
Organisational Structure of Drugs Control Administration

ORGANISATIONAL STRUCTURE OF DRUGS CONTROL ADMINISTRATION

TABLE - 1



Note : The Offices of the Regional Assistant Directors, and Drugs Inspectors organisational setup is shown in Table-2

REGIONAL ASSISTANT DIRECTORS AND DRUGS INSPECTOR OFFICES ORGANISATIONAL SETUP.

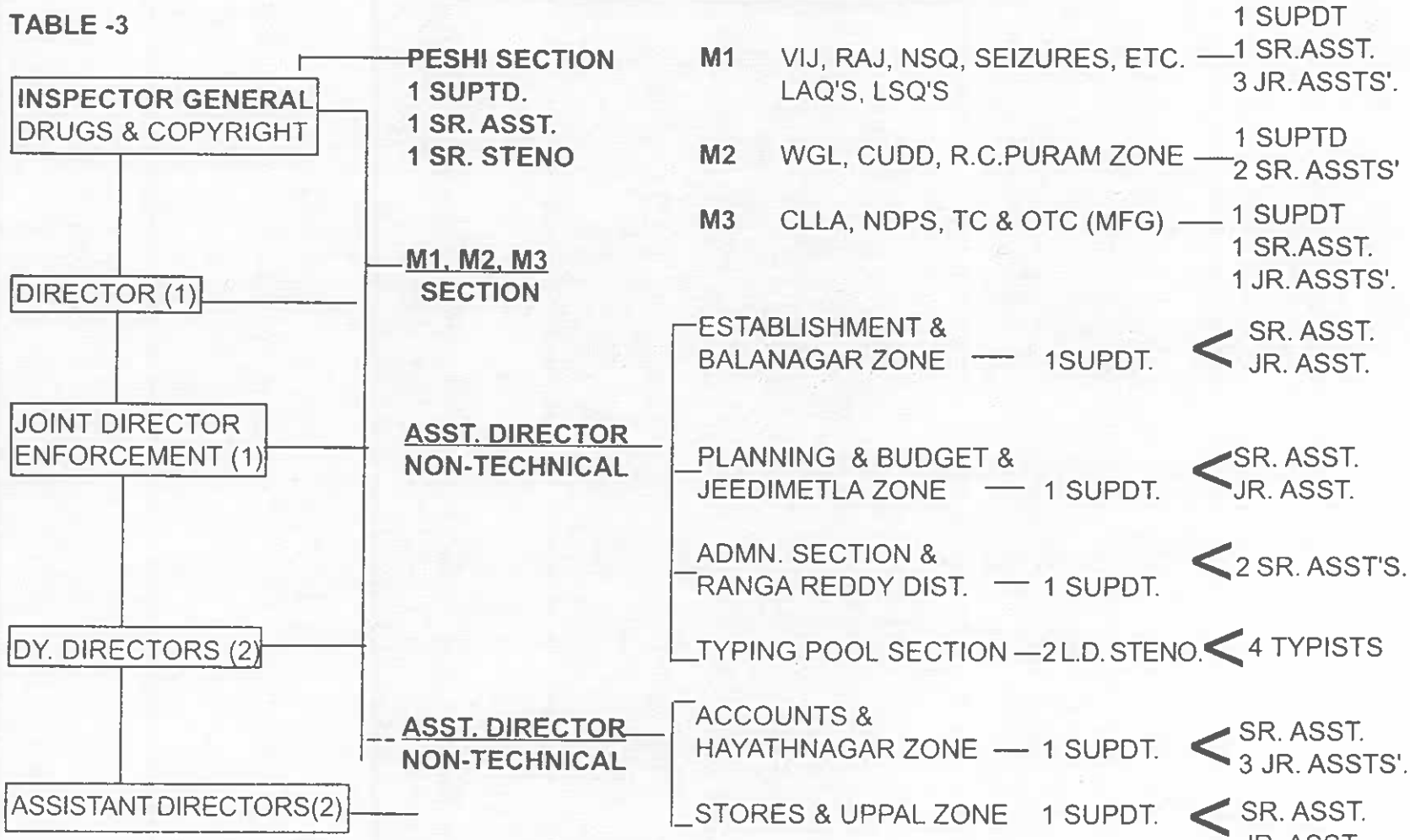
TABLE-2

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

Note : Each Office of the Drugs Inspector is having a junior Assistant / Typist and an Attender. In addition is some of the offices of Drugs Inspectors a post of watch man is also existing.

HEAD QUARTERS ADMINISTRATIVE SETUP

TABLE -3



Chapter - II

Functionaries in Drugs Control Administration

FUNCTIONARIES IN DRUGS CONTROL ADMINISTRATION

INSPECTOR GENERAL, DRUGS AND COPYRIGHT

ORIGIN OF THE POST REASONS FOR CREATION AND ROLE PLAYED BY THE FUNCTIONARY :

The Department of Drugs Control, Administration was originally functioning under the Directorate of Medical Services. The Director of Medical Services was the Drugs Controller and Licensing Authority under the Drugs and Cosmetics Act, 19401 and Drugs and Cosmetics Rules, 1945 till 1976.

In the year 1976, the Government posted Sri M.V. Thomas, I.P.S.. deputy, Inspector General of Police as Additional Director, Vigilance and Enforcement in Medical Department. The Government felt that there should be an independent and separate Department for Food and Drugs for effective functioning and enforcement of Drugs and Cosmetics Act and Prevention of Food Adulteration Act in the State. So, the Drugs Control Organisation and Food Control Organisation was separated from the Directorate of Medical and Health Services. Sri M.V. Thomas, I.P.S.. was appointed as Head of the Department. Subsequently the Govermnent separated the work relating to enforcement of prevention of Food Adulteration Act and Food Laboratory, from this Department in October, 1981 and kept this under the administrative control of the Director, Institute of Preventive Medicine, so as to facilitate the Drugs Control Department to concentrate on the effective enforcement of the Drugs and Cosmetics Act and other related enactments. From June 1981 to August 1996, the department was headed by Sri C. Gopala Krishna Murthy, a technically qualified Director.

The Government in G.O.Rt.No.4673, General Administration (SSC) Department.' dated 26-08-1996 created an ex-cadre post of Inspector General, Drugs and Copy right in the Office of the Director General and Inspector General of Police. A.P., Hyderabad and posted Sri K.Jagannadha Rao, I.P.S., as Inspector General, Drugs and Copyright to look after the general administration in the Department of Drugs Control Administration with effect from 28-08-1996. Subsequently, Sri. K.Krishna Moorthy. I.P.S.. was posted as the Inspector ' General, Drugs and, Copyright' transferring Sri K.Jagannadha Rao, I.P.S.. in the. month of February, 1999. The Inspector General, Drugs and Copyright, is the Head of the Department of Drugs Control Administration since 28-08-1996.

POSITION AND SPAN OF INTERACTION WITHIN THE DEPARTMENT:

The Inspector General, is the Head of the Department looking after the overall administration and enforcement of Drugs and Cosmetics Act, 1940 and Rules made thereunder and also related enactments. In order to achieve this objective he takes the assistance of the Director, Joint Directors (Enforcement and Laboratory), Deputy Directors and Assistant Directors, Assistant Directors (Non-Technical) and also the Regional Assistant Directors of the six Regions in the State. He interacts with the Drugs Inspectors also periodically to achieve this objective

He conducts meetings of Regional Assistant Directors every month to review and assess performance of the Regional Assistant Directors and also the Drugs Inspectors who are the field officers at the grass root level and evolves strategies for bringing about improvements in their performance.

FUNCTIONS DISCHARGED BY THE FUNCTIONARY:

He is the head of the Department. The powers of the Inspector General, , are classified into field functions and desk functions:

1. Field Functions:

a) Inspection of subordinate offices i.e., Regional Offices of Assistant Directors. Drugs Control Laboratories and offices of Drugs Inspectors periodically.

b) Attends the meetings of Public Accounts Committee, Legislative Assurance Committee, Departmental Clearance Committee, Departmental Review Committee, Drugs Consultative Committee, Project and Programme Approval Committee, Departmental Promotion Committee, etc.

2. Desk Functions:

a) He is the head of the Department to ensure proper functioning and performance of the Director, Joint Directors, Deputy Directors, Senior Scientific, Ofricers, Assistant Directors, Assistant Directors (Non-Technical), Junior Scientific Officers and Drugs Inspectors.

b) He is the Administrative head supervising overall administration of Drugs Control Administration.

c) Appoints initial Gazetted Officers viz., Asst. Directors (Non-Technical), Junior Scientific Officers and Drugs Inspectors, Appoints all Non-Gazetted staff and Class-IV.employees at Headquarters.

d) Transfers and Postings of Junior Scientific Officers and Drug Inspectors are done by him.

e) Sanctions casual leaves and Earned Leaves to the Gazetted Officers and Earned leaves to the Non-Gazetted Officers at Headquarters. He also sanctions Casual leave and Earned leaves to the Regional Asst. Directors and Earned leaves to the Drugs Inspectors.

f) Sanctions increments to all the Gazetted Officers in the Department.

g) Sanctioning Authority in respect of Pensions to all Gazetted Officers, Non Gazetted Officers and Class IV Employees at Headquarters and all Senior Assistants and Superintendents working in the Regional Offices.

h) Reviews the performance of the Regional Assistant Directors once every month in the monthly meetings.

i) He is the Disciplinary Authority and Appellate Authority under A.P. Civil Services (CCA) Rules in respect of first Gazetted..Officers (Assistant Director (N.T.), Junior Scientific officers, Drugs Inspectors, Non-Gazetted Officers and Class-IV employees at Headquarters, Senior Assistants and Superintendents working at Regional. Offices.

j) Looks after the Administrative matters relating to Establishment, Stores and Accounts.

k) He nominates the Vigilance Officers, Press and Public Relations Officer and enquiry officers in Departmental enquiries.

l) He initiates the AnnuaL Confidential Reports in respect of r he Director. He countersigns the Annual Confidential Reports of Joint Directors, Deputy Directors, Assistant Directors, Senior Scientific Officers, Assistant Directors (Non-Technical), Junior Scientific Officers,' Drugs Inspectors, Superintendents and Junior Analysts.

m) He exercises financial powers of the Head of the Department in terms of Article-6 of Chapter-II of Financial Code Vol-I.

n) He is the Budget Controlling Authority of the Department. Preparation of Budget and Estimates, Revenue and Expenditure, scrutiny of Revenue and Expenditure statements, preparation of Number statements and all related financial matters are approved by him.

o) Sanctions loans to the Employees such as House Building Advance, Motor Cycle Advances, Marriage Advances. G.P.F. Loans, reimbursement of Medical expenses to the Employees.

p) To formulate the Plan Schemes.

q) Approves Purchase of Machinery and equipment and Materials and Supplies.

OPERATIONAL JURISDICTION OF THE FUNCTIONARY..

He is the Head of the Department. He is independent in his decisions both in the Administrative and financial matters. He is responsible for proper

and effective functioning of the Department. His decisions are binding on all the Officers of the Department. He is the, appellate Authority of every decision taken by his subordinates. He has jurisdiction over the entire State of Andhra Pradesh.

ENACTMENTS, RULES AND REGULATIONS FOR DISCHARGE OF ABOVE FUNCTIONS:

The functionary is governed by the following enactments in the discharge of his functions.

Administrative:

a) Andhra Pradesh Fundamental Rules.

b) Andhra Pradesh State and Subordinate Service Rules.

c) Andhra Pradesh Ministerial Service Rules.

d) District Office Manual.

e) Andhra Pradesh Conduct Rules.

f) Andhra Pradesh Civil Services (Classification, Control, Appeal) Rules. Andhra Pradesh Service Commission Rules.

Financial..

a) Andhra Pradesh Financial Code Vol. 1 & II.

b) Andhra Pradesh Treasury Code Vol-1 &, 11

c) Andhra Pradesh Account Code Vol. I

d) Andhra Pradesh Budget manual

e) Andhra Pradesh Manual of Special Pay and Allowances.

h) Andhra Pradesh Pension Code

i) Andhra Pradesh General Provident Fund Rules

j) Andhra Pradesh Group Insurance Scheme Rules.

k) Indian Accounts and Audit Manual.

CRITICAL PROVISIONS OF THE ENACTMENTS:

The Inspector General, takes all necessary steps for correct and proper

implementation of the Rules and Regulations related to the Department for effective functioning and enforcement of the Acts and Rules in the State.

INTRA-DEPARTMENTAL AND INTER DEPARTMENTAL APPROACH IN CASE OF ANY HELP:

The Inspector General, is overall head of the department of Drugs Control .Administration. Where any help is required intra-departmentally he approaches the Police Department or other Departments for getting assistance. Where inter departmental help is required he coordinates the work inter-departmentally.

ADMINISTRATIVE ACCOUNTABILITY AND REMEDIAL ACTION IN CASE OF OMISSIONS AND COMMISSIONS:

The Inspector General, is the Disciplinary Authority under Andhra Pradesh Civil Services (CCA) Rules, 1991. He is the Competent Authority to initiate Departmental action against any Subordinate Officers in the department for misconduct or misbehaviour or any violation of Rules.

He is the Appellate authority for any decisions of subordinate officers. He can take appropriate necessary action for any remedial measure as per the procedure laid down under the above Rules.

QUANTIFICATION OF WORK OUTPUT AND ASSESSMENT OF HIS PERFORMANCE:

The Government has fixed certain parameters for evaluation of performance of Heads of Departments, and the monthly evaluation report contains the following parameters,:

a) implementation of the policies.

b) Performance in projects and programmes.

c) Disposal of files.

d) Disposal of references from Chief Minister's Office.

c) Implementation of Chief Minister's announcements,

f) Computerisation of the Departments.

g) Disposal of Courts cases.

h) Periodic action on matters referred by Vigilance and Enforcement and Anti Corruption Bureau.

i) Media sensitiveness and responses to reports.

j) Regular inspections.

k) Surprise inspections, findings follow-up action.

l) Human Resources Developments Programmes.

m) Office Environment.

n) Administrative Reforms.

o) Corrective Action on Audit Reports.

p) Follow-up action of Comptroller and Auditor General Reports.

In addition the following parmeters are specific to the Department of Drugs Control Administration:

a) Number of inspections of manufacturing and Sales concerns carried out.

b) Number of violations detected.

c) Number of samples of drugs picked for analysis.

d) Number of samples received and analysed in Drugs Control Laboratories of the State.

AREAS OF PERIODICAL REPORTING AND REPORTING FORMATS:

The following periodicals are to be submitted to the Govermnent of India and Govermnent of Andhra Pradesh.

a) Resume on Drugs Control Administration to be submitted to the Government of India.

b) Monthly report on enforcement of Drugs and Cosmetics Act and Rules made thereunder has to be submitted to the Government of Andhra Pradesh.

c) Annual Administration Report.

d) On Jamnabhoomi Programme.

i) Report on Clean and Green.

ii) Report on File disposal.

e) Expenditure on Plan Schemes.

f) Annual Self appraisal Report.

LIST OF REGISTERS TO BE MAINTAINED BY THE FUNCTIONARY:

The list of Registers maintained in the office of Inspector General, Drugs and Copyright are shown in Amexure-I

FORMS OF CORRESPONDENCE OR DOCUMENTATION:

The following forms are used for communication of information from the Head of the Department

a) State Administration Report.

b) Resume on Drugs Control Administration to be sent to the Government of India in connection with the Drugs Consultative Committee meetings.

c) Annual Self Appraisal Report to the Government.

d) Service Satisfactory Certificates in respect of all the Gazetted Officers in the Department.

AREAS OF INTERFACE WITH PUBLIC AND OTHER DEPARTMENTS.

The Inspector General, Drugs and Copyright attends meetings convened by Indian Pharmaceutical Association, A.P. Chemists & Druggists Association and Indian Drug Manufacturers Association.

A) General Public:

i) Consumer Forums.

B) Trade Associations:

i) All India organisation of Chemists & Druggists.

ii) Dist. Chemists & Druggists Association of various Districts.

iii) Manufacturers' Association:

All India Drugs Manufacturers Association.

Bulk Drug Manufacturers Association.

Oganisation of Pharmaceutical Manufacturers of A.P.

C) Professional Associations:

i) Indian Pharmaceutical Association of A.P. State Branch.

ii) India Medical Council of A.P. State Branch.

iii) A.P. State Pharmacy Council, Hyderabad.

D) Central Government Departments:

i) Central Drugs Standard Control Organisation, New Delhi.

ii) Central Drugs Standard Control Organisation, Zonal-Office. Chennai.-

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

iv) National Pharmaceutical Pricing Authority, Dept. of Chemicals & Petrochemicals, New Delhi.

v) Central Govermnent Health Scheme Medical Stores Department.

vi) Narcotic Drugs Commission, Chennai.

vii) Insurance Medical Services, Medical Stores and Blood Banks in E.S.I. Hospitals/Institutions under E.S.I. Schemes.

E) Drugs Control Departments In All Tire States In India

F) Other Departments:

i) Police Department

To help in special investigations and to execute warrants of arrest on the accused in the Cases filed by the departmental officers in-various courts.

ii) District Collectorates in all the Districts.

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

iv) Medical and Health services departments Medical stores in the District Medical and Health Offices in the District.

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

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

vii) AIDS Control Department : To co-ordinate the functioning of Blood Banks.

viii) Family welfare department: To initiate follow up action on the inspections of medical stores by this department.

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

x) Dr. MCR Human Resource Development Institute. Hyderabad.

xi) State Excise Department.

xii) Training Establishments in Andhra Pradesh State and in other parts of the country.

Chapter - III

Enforcement Wing

ENFORCEMENT WING

DIRECTOR

ORIGIN OF THE POST, REASONS FOR CREATION AND ROLE PLAYED E THE FUNCTIONARY:

The Drugs Control Department was functioning under the Direct rate of Medical Services. The Director of Medical Services was also th Drugs Controller and Licensing Authority under the Drugs and Cosmetics Ac 1940 and Drugs and Cosmetics Rules, 1945 upto 1976.

To enforce the Drugs and Cosmetics Act and Prevention of Food Adu teration Act more effectively Government posted a separate Director for Publ Health, Family Planning, Food and Drugs Control. The Goverrunent create a-Vigilance Cell and posted an Officer of the rank of a Deputy Inspector Ger eral of Police to work under the Director of Public Health, Family Planning an Drugs Control vide G.O.Ms.No.587 Health, dated 28-06-1974.

Subsequently, the Government felt that there should be an independ ent Department for effective enforcement of the Drugs and Cosmetics Act an Prevention of Food Adulteration Act. Keeping this in view, Food and Drug Control Department was on 09-11-1976 vide G.O.Ms.No.1078, M&H, dated 09-11-1976. Sri M.V.Thomas, I.P.S., was appointed as the Head of the Depart ment. Again, the Government separated the work relating to Enforcement o Prevention of Food Adulteration Act and Food Laboratory from this Depart ment during October, 1981 to facilitate the Drugs Control Department to con centrate on effective enforcement of Drugs and Cosmetics Act and Rules made thereunder. Sri C. Gopala Krishna Murthy, Joint Drugs Controller, a techni cally qualified person who was first appointed as Drugs Inspector under Sec tion 21 of The Drugs and Cosmetics Act was appointed the first Director of independent Drugs Control Administration in the State. Now the Director looks after the technical matters and declared as Licensing Authority and Controlling

Authority under the Drugs and Cosmetics Rules in respect of Drugs Manufacturing concerns. The Inspector General, Drugs and Copyright is the Head of the Department.

POSITION AND SPAN OF INTERACTION WITHIN THE DEPARTMENT:

The post of the Director is filled by the Government by promotion from the panel of Joint Directors. The Director interacts with the Joint Directors, Deputy Directors, Assistant Directors, Drugs Inspectors and also with the officers of Drugs Control Laboratories. The Director interacts with all the subordinate Officers, Inspector General and with the public.

FUNCTIONS DISCHARGED BY THE FUNCTIONARY

The Director is appointed under Sub-rule (1) of Rule 69, rule 90 read with sub-rule (1) of rule 138 of the Drugs and Cosmetics Rules, 1945 as Licensing Authority for the purpose of Part-VII and Part-XIV of the said rules and also the approving authority for the purpose of Part-XV-A of the said Rules for the entire State of Andhra Pradesh and also appointed as Controlling Authority under sub rule (3) of rule-50 of the Drugs and Cosmetics Rules, 1945 for the purpose of sub-rule (2) of rule-50 of the said rules.

The following functions discharged by the Director:

Statutory Functions:

1) Grant/Renewal of Drug Licences and Cosmetics Licences to the Manufacturing Units in the State.
2) Grant/Renewal of Narcotic Drugs and Psychotropic substances Licences in the State.
3) Investigation on complaints relating to the Drugs and Cosmetics Act and the Rules made thereunder.
4) Issue of Show Cause Notices to the Drugs/Cosmetics Manufacturing Units in the State.
5) Cancellations/Suspensions in respect of Drugs Manufacturing Units and Cosmetics manufacturing units in the State.
6) Forwarding of applications to the Drugs Controller General (In-

dia), (Central Licensing Approving Authority) New Delhi for grant/ renewal of Licences to the Blood Banks, Sera and Vaccine Manufacturing Units. Large Volume Parenteral Manufacturing Units in the State.

7) Issue of Certificate of World Health Organisation G.M.P. Standards to the Drugs Manufacturing Units.

8) Issue of Transport Permits of Narcotic Drugs under N.D.P.S. Rules, 1986.

9) Action to be taken on the Not of Standard Quality Reports received from the Government Analysts/State/Outside State.

Desk Functions :

To initiate Annual Confidential Reports of the Joint Directors.

Field Functions:

1. Supervise the functioning of the Drugs Testing Laboratories at Hyderabad and Vijayawada.
2. Attend the meetings like Drugs Consultative Committee, Drugs Advisory Committee.
3. Inspections of Regional Offices of Asst. Directors, Offices of the Drugs Inspectors, and Drugs Control Laboratories.

OPERATIONAL JURISDICTION OF THE FUNCTIONARY:

The jurisdiction of the Director comprises the entire State of Andhra Pradesh

ENACTMENTS, RULES AND REGULATIONS FOR DISCHARGE OF ABOVE FUNCTIONS:

The Director is appointed as Licensing Authority in respect of Manufacturing concerns and also Controlling Authority under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. He is also the Licensing Authority under Andhra Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1986. The functions of the Director are statutory in nature.

The functions of the Director are governed under the following enactments also:

a) Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

b) Drugs (Prices Control) Order, 1995.

c) Andhra Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1986 (Partly).

CRITICAL PROVISIONS OF THE ENACTMENTS:

The Director is notified as Licensing Authority for the Manufacturing concerns of Drugs and Cosmetics in the State. Under the provisions of Drugs and Cosmetic Rules 1945 Director is also notified as controlling authority under the above said rules.

INTRA-DEPARTMENTAL AND INTER DEPARTMENTAL APPROACH IN CASE OF ANY HELP:

Since Inspector General, Drugs and Copyright is the Head of the Department of Drugs Control Administration, Director may seek necessary assistance and guidance from him both for Intra-departmental matters and Inter-departmental matters.

ADMINISTRATIVE ACCOUNTABILITY AND REMEDIAL ACTION IN CASE OF OMISSIONS OR COMMISSIONS

The Director is accountable to the Inspector General, and the Government for his acts of omission and commission. The Director can either by himself or through the Inspector General can initiate remedial action.

QUANTIFICATION OF WORK OUTPUT AND ASSESSMENT OF HIS/HER PERFORMANCE:

The Director is the Convenor of Review Committee Meeting in respect of the Reports of Not of Standard Quality/spurious drugs and violations under Drugs (Prices Control) Order, 1995 and Drugs and Magic Remedies (Objectionable Advertisement) Act. The Review Committee Meeting is conducted twice in a week by the Director. The Director has to submit the report on the

Review Committee Meetings to the Inspector General for review periodically.

AREAS OF PERIODICAL REPORTING AND REPORTING FORMATS:

a) Annual Self appraisal report.

b) Tour programme.

c) Inspection Reports on Offices of The Drugs Inspectors, Regional Asst. Directors and Drugs Control laboratories.

d) Annual Confidential Reports of the Joint Directors.

LIST OF REGISTERS TO BE MAINTAINED BY THE FUNCTIONARY:

This functionary does not maintain separate registers.

FORMS OF CORRESPONDENCE OR DOCUMENTATION:

1) Non-Conviction Certificate.

2) Performance Certificate of the Manufacturing Units.

3) Good Manufacturing Practices Certificate.

4) World Health Organisation Good Manufacturing Practices Certificate.

5) Transport Permits for Narcotic Drugs under Narcotic Drugs and Psychotropic Substances Rules 1986.

6) Market Standing Certificate.

The formats the above certificates/statutory forms are enlisted in Annexure-II

AREAS OF INTERFACE WITH PUBLIC AND OTHER DEPARTMENTS

The Director attends meetings convened by Indian Pharmaceutical Association, A.P. Chemists & Druggists Association and Indian Drug Manufacturers Association.

General Public:

i) Consumer Forums.

Trade Associations:

i) All India Organisation of Chemists & Druggists.

ii) Dist. Chemists & Druggists Association of various Districts.

iii) Manufacturers' Association:

All India Drugs Manufacturers Association.

Bulk Drug Manufacturers Association.

Oganisation of Pharmaceutical Manufacturers of A.P.

Professional Associations :

i) Indian pharmaceutical Association of A.P. State Branch.

ii) Indian Medical Council of A.P. State Branch.

iii) Andhra Pradesh State Pharmacy Council, Hyderabad.

Central Government Departments:

i) Central Drugs Standard control Organisation, New Delhi.

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

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

iv) National Pharmaceutical Pricing Authority, Dept. of Chemicals & Petrochemicals. New Delhi.

v) Central Government Health Scheme Medical Stores Department.

vi) Narcotic Drugs Commission, Chennai.

vii) Insurance Medical Services, Medical Stores and Blood Banks in E.S.I. Hospitals/Institutions under E.S.I. Schemes.

Drugs Control Departments In All The States in India

Other Departments

i) Police Department :

To seek help in special investigations and to execute warrants of arrest of accused persons in Cases filed by the departmental officers in various courts.

ii) District Collectorates in all the Districts in Andhra Pradesh.

iii) Medical Education Department Medical stores and blood banks in govermnent hospitals attached to teaching institutions.

iv) Medical and Health services department Medical stores in the District Medical and Health Offices in the district.

v) Vaidya Vidhan, Prarishad Medical stores, Blood banks in district head quarters, area hospitals and district co-ordinator hospitals services medical stores.

vi) Institute of Preventive Medicine and State Food health authority, Blood bank, Vaccine production centers under its control

vii) AIDS Control Department: To co-ordinate the functioning of Blood Banks.

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

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

x) Dr. MCR Human Resource Develpment Institute, Hyderabad.

xi) State Excise Department.

xii) Training Establishments in Andhra Pradesh State and in other parts of the country

JOINT DIRECTOR (ENFORCEMENT)

ORIGIN OF THE POST, REASONS FOR CREATION AND ROLE PLAYED BY THE FUNCTIONARY:

During the year 1980, when the Department was functioning as Food and Drugs Administration, Government sanctioned a post of Joint Drugs Controller with supporting staff vide G.O.Ms. No. 767, dated 7-9-80 in order to strengthen the Supervisory officers set up at the Directorate. Joint Director

(Enforcement) assists the Inspector General, Drugs and Copyright and the Director, in respect of all matters pertaining to administrative and statutory functions entrusted to him.

POSITION AND SPAN OF INTERACTION WITHIN THE DEPARTMENT:

Joint Director (Enforcement) is the senior most Officer in the Enforcement Wing next to the Director in the Department and he interacts with the Inspector General, who is the head of the Department, Director, Deputy Directors, Asst. Directors and Drugs Inspectors.

FUNCTIONS DISCHARGED BY THE FUNCTIONARY :

The functions discharged by the above functionary are as follows :

Statutory functions :

1. Since the Joint Director (Enforcement) is the Officer appointed under section 21 of Drugs and Cosmetics Act, he assists the Director on all matters arising out of the implementation of the Drugs and Cosmetics Act, 1940 and Rules made thereunder, Drugs (Prices Control) order, 1995, Drugs and Magic Remedies (Objectionable Advertisements) Act,1954.

   and Rules thereunder and Andhra Pradesh Narcotic Drug and Psychotropic Substances Rules, 1986.

Desk functions:

1. He processes the applications received in respect of Grant / renewal of manufacturing Licences, issue of World Health organisation/Good Manufacturing Practices Certificates ' etc., received from Assistant Directors and forward the same to the Director with remarks.
2. He may call for any further information needed for statutory compliance from the Assistant Directors and the Drugs Inspectors.
3. He also processes all the files leading to suspension cancellation of Manufacturing Licences and issue of prosecution orders for violations.

4. He performs all such other functions and duties as are being entrusted by the Inspector General, Drugs Control Administration from time to time

5. He initiates Annual confidential reports of the Deputy Directors and forwards the Annual Confidential Reports initiated by his subordinate officers.

Field Functions

1. He undertakes investigations of complaints and inspects the subordinate offices of Deputy Directors, Regional Assistant Directors and Drugs Inspectors on specific directions of Inspector General.

The above functionary does not have any financial functions to perform independently

OPERATIONAL JURISDICTION OF THE FUNCTIONARY:

The Joint Director (Enforcement) is subordinate to the Inspector General and Director. He is not authorised to take independent decisions and his operational jurisdiction is the entire State of Andhra Pradesh, subject to the over all control of the Inspector General.

ENACTMENTS, RULES AND REGULATIONS REQUIRED TO BE FOLLOWED IN DISCHARGE OF ABOVE FUNCTIONS:

Since he continues to be an Officer appointed under Section 21 of Drugs and Cosmetics Act, 1940, he has the power to discharge the statutory duties as envisaged under Drugs and Cosmetics Act, 1940 and Rules made thereunder and related enactments as and when required under the instructions of the Inspector General, who is the Head of the Department.

CRITICAL PROVISIONS OF THE ENACTMENTS:

The critical provisions of various enactments listed in the functionaries of the Director, Deputy Directors, Assistant Directors and Drugs Inspectors are also the critical provisions of this functionary in as much as they relate to the activities of Licensing of Manufacturing Units, taking departmental action on erring manufacturers and issuing prosecution orders for offences.

INTRA DEPARTMENTAL AND INTER DEPARTMENTAL APPROACH IN CASE OF ANY HELP:

This functionary seeks the help of superior officers in the Head Office namely the Inspector General, who is the Head of the Department and the Director as and when required within the Department. He has no Direct intra-departmental contact, but when he authorised by the Head of the Department for any specific assignment, he may interact with that department.

ADMINISTRATIVE ACCOUNTABILITY AND REMEDIAL ACTION IN CASE OF OMISSIONS OR COMMISSIONS:

He is accountable to the Inspector General, Drugs and Copyright and the Director on all technical and administrative matters entrusted to him.

QU ANTIFICATION OF WORK OUTPUT AND ASSESSMENT OF HIS /HER PERFORMANCE:

The quantification of work of this functionary is based on the disposal of various tasks entrusted to him. The work Pertaining to the inspection of Deputy Directors work, offices of Assistant Directors and Drugs Inspectors performed by the Joint Director (Enforcement) is reviewed and assessed by the Inspector General periodically.

AREAS OF PERIODICAL REPORTING AND REPORT ING FORMATS :

1 Monthly Tour Diary

2. Annual confidential reports initiated by the Joint Director (Enforcement)

3. Annual Self Appraisal Report

4. Inspection Report on Subordinate Offices.

The proforma of Annual Self Appraisal Report and Annual confidential Report are detailed Annexure-III

LIST OF REGISTERS TO BE MAINTAINED BY THE FUNCTIONARY:

Since the Joint Director (Enforcement) does not have an independent office and is an integral part of the Office of the Inspector General, Drugs Con-

trol Administration, no separate registers are maintained by him.

FORMS OF CORRESPONDENCE OR DOCUMENTATION :

Same as listed for the Director, Drugs Control Administration.

AREAS OF INTERFACE WITH PUBLIC AND OTHER DEPARTMENTS:

The Joint Director (Enforcement) does not have his own office. He works in the office of the Inspector General, Drugs and Copyright at the Headquarters and hence the possible areas of interface with public and other departments are as listed for Inspector General, and Director, Drugs Control Administration.

DEPUTY DIRECTOR

ORIGIN OF THE POST, REASONS FOR CREATION:

The post of Deputy Director first designated as Deputy Drugs Controller was sanctioned by the State Govermnent vide G.O.Ms.No.174 Health, dated 02-02-1970 basing on a report of the three Member Committee constituted in 1966 headed by Sri S.K.Borkar, the then drugs Controller (India) who after a study of the set ups of various State Drugs Control Administrations had suggested the expansion of the Administration set up and staffing pattern. Subsequently, in the year 1982, State Government created One more post of Deputy Director (Deputy Drugs Controller) at Headquarters vide G.O.Ms.No.306 M&H, dated 29-03-1982 to assist the Director in effective supervision over subordinate Officers and in enforcement of Drugs Laws.

ROLE PLAYED BY THE FUNCTIONARY:

The Deputy Director assists the Inspector General, Director and Joint Director (Enforcement) in all administrative and technical matters entrusted from time to time.

POSITION AND SPAN OF INTERACTION WITHIN THE DEPARTMENT:

Deputy Director is the middle level officer in the hierarchy of the Enforcement Wing of this Department. He interacts with the Assistant Directors

and other Supervisory Officers at Headquarters as and when re uired in the implementation of various enactments enforced by this Department besides attending to periodical review meetings of Assistant Directors held by the Inspector General.

THE FUNCTIONS DISCHARGED BY THE FUNCTIONARY

The functions discharged by this functionary are as follows :

Statutory Functions:

1. Since the Deputy Directors are Officers appointed under Section 21 of Drugs and Cosmetics Act, they assist the Director and Joint Director (Enforcement) on all matters arising out of the implementation of the Drugs and Cosmetics Act, 1940 and Rules made thereunder, Drugs (Prices Control) Order, 1995, Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules thereunder and Andhra Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1986.
2. They process the applications received in respect of Grant renewal of manufacturing Licenses, issue of World Health Organisation/Good Manufacturing Practices Certificates etc., received from Assistant Directors and forward the same to the Director with their remarks.
3. They also call for any further information needed for statutory compliance from the Assistant Directors and the Drugs Inspectors.
4. They also process all the files leading to suspension/cancellation of Manufacturing Licenses and issue of prosecution orders for violations.
5. They will assist the Director and Joint Directors in over all administration relating to technical matters.
6. They issue the certificates in respect of the manufacturing units like Nonconviction, Performance, General G.M.P. certificates in the areas allotted by the Inspector General (Drugs and Copyright).

Desk Functions :

1. They assist the Inspector General in all administrative matters - entrusted to them from time to time.
2. They perform all such other functions and duties as are being entrusted by the Inspector General, from time to time.
3. They initiate Annual confidential report of the Assistant Directors and forward the Annual confidential reports initiated by the Sub-ordinate Officers.

Field Functions:

1. They undertake investigations of complaints and inspections of subordinate offices of Regional Assistant Directors and Drugs Inspectors on specific directions of Inspector General.

   These functionaries do not have any financial functions to perform independently

OPERATIONAL JURISDICTION OF THE FUNCTIONARY:

The operational jurisdiction spreads over the entire State of Andhra Pradesh...He will supervise the work of Assistant Directors and Drugs Inspectors as and when required. He does not take any independent decision, but assists the Director, Joint Director, (Enforcement) and Inspector Gencral in taking decisions. He processes all manufacturing files of the areas assigne.

ENACMENTS, RULES AND REGULATIONS REQUIRED TO BE FOLLOWED IN DISCHARGE OF ABOVE FUNCTIONS:

The Deputy Directors are required to follow the below mentioned statutory enactments and Rules in the discharge of their functions.

a) The Drugs and Cosmetics Act, 1940.
b) The Drugs and Cosmetics Rules, 1945.
c) The Drugs (Prices Control) Order, 1995.
d) The Drugs and Magic Remedies (Objectionable Advertisements), Act, 1954 and the rules made thereunder.

e) The Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955.

f) The Andhra Pradesh Narcotic Drugs and Psychotropic Substances, Rules, 1986 (Partly).

CRITICAL PROVISIONS OF THE ENACTMENTS:

The critical provisions of various enactments listed in the functionaries of the Director, Assistant Directors and Drugs Inspectors are also the critical provisions to this functionary in as much as they relate to the activities of Licensing of Manufacturing Units, taking departmental action on erring manufacturers and issuing prosecution orders.

INTRA DEPARTMENTAL AND INTER DEPARTMENTAL APPROACH IN CASE OF ANY HELP:

This functionary seeks the help of the superior officers in the head office namely the Inspector General, who is the head of the Department and the Director, Joint Director (enforcement) as and when required for interaction within the department. He has no direct intra departmental contact but when he is authorised by the Head of the Department for any specific assignment, he may interact with other departments.

ADMINISTRATIVE ACCOUNTABILITY AND R EMEDIAL ACTION IN CASE OF OMISSIONS OR COMMISSIONS:

The Deputy Director is accountable to Inspector General and Director and Joint Director (Enforcement) in all matters related to administration and Enforcement entrusted from time to time. In cases of omission.or commission he can seek necessary assistance and guidance from the superior officers.

QUANTIFICATION OF WORK OUTPUT AND ASSESSMENT OF HIS/HER PERFORMANCE:

The quantification of work of this functionary is based on the disposal of various tasks entrusted to him. The work pertaining to the inspection of Offices of Assistant Directors and Drugs Inspectors performed by the Deputy Director is reviewed and assessed by the Inspector General periodically.

AREAS OF PERIODICAL REPORTING AND REPORTING FORMATS:

a) Tour Dairy

b) Annual Confidential Report initiated by the Deputy Director.

c) Annual self appraisal report

d) Inspection Reports on subordinate Offices.

The proforma of Annual Self Appraisal Report and Annual Confidential Report are enlisted in Annexure-II

LIST OF REGISTERS TO BE MAINTAINED BY THE FUNCTIONARY:

Since the Deputy Director does not have an independent Office and is an integral part of the Office of the Inspector General, no separate registers are maintained by him.

FORMS OF CORRESPONDENCE OR DOCUMENTATION:

Same as listed for the functionary of Director.

AREAS OF INTERFACE WITH PUBLIC AND OTHER DEPARTMENTS:

Deputy Director does not have his own office. He works in the Office of the Inspector General, at the Headquarters and hence the possible areas of interface with public and other departments are as listed for the Inspector General and the Director Drugs Control Administration.

ASSISTANT DIRECTOR

ORIGIN OF THE POST, REASONS FOR CREATION AND ROLE PLAYED BY THE FUNCTIONARY:

During the year 1963, two posts of Senior Drugs Inspectors were created at Headquarters in Hyderabad vide G.O.Ms.No.1935 Health, dated 28-06-1963 for supervision of the work of Drugs Inspectors in the State. Subsequently, these posts were redesignated as 'Assistant Drugs controllers'. One more post of 'Assistant Drugs Controller' was created during the year 1970 vide G.O.Ms.No. 174 Health, dated 02-02-1970 for supervision of the work of the Drugs Inspectors and to assist the Deputy Drugs Controller who

was declared as Licensing Authority in respect of Sales concerns for the entire State and also to assist the and Drugs Controller for effective implementation of Drugs and Cosmetics Act, 1940 and Cosmetics Rules 1945.

Subsequently, the Government decentralised the Licensing system inrespect of Sales concerns and created two Posts of Regional Assistant Drugs Controllers during the year 1982 vide G.O.Ms.No.306 M&H, dated 29-03-1982 one at Vijayawada and the other at Wa rangal and also notified them as Licensing Authority for Sales concerns. The Government further created 3 more posts of Regional Assistant Drugs Controllers during the year 1984 G.O.Ms.No.304 M&H, dated 31-03-1984 locating the Regional Offices at Cuddapah, Rajahrnundry and vide G.O.Ms.No. 860 M&H, dated 29-12-1984, at Hyderabad (Other than Twin Cities O.T.C.).Now there are six Regional Offices in the State. Each Regional Office is headed by an Assistant Director (changed Designation in 1991) who is functioning as 'Licensing Authority' for 'Sales Concerns' for the respective regions.

All the above posts of Assistant Drug Controllers were subsequently redesignated by the Government as "Assistant Directors" in the year 1991 vide G.O.Ms.No.255 HM&FW(L2) Dept., dated 26-03-1991.

POSITION AND SPAN OF INTERACTION WITHIN THE DEPARTMENT:

The post of Assistant Director is filled by promotion from the approved panel of Drugs Inspectors. He is the head of the Regional Office discharging the duties of 'the Licensing Authority in respect of Sales concerns in the respective region and immediate supervisory Officer over the Drugs inspectors. He interacts with his subordinate Officers within his jurisdiction once in a month to review their work and performance in matters connected to enforcement of different enactments and matters connected to General Administration and Office matters. He will also attend the meetings convened by the Inspector General, Drugs and Copyright. He initiates the Annual Confidential Reports of the Drugs Inspectors.

The Assistant Directors posted at the Head Quarters in the office of the Inspector General perform administrative, technical and field functions as entrusted by the Inspector General from time to time and assist the Deputy

Directors, Joint Director (Enforcement), the Director and the Inspector General.

FUNCTIONS -DISCHARGED BY THE FUNCTIONARY:

He is the head of the Reigional Office. His functions are classified into three parts:

1) Statutory Functions.
2) Desk Functions
3) Field Functions.

Statutory Functions:

1 The Assistant Director is notified as Licensing Authority in respect of Sales concerns under Rule 59 of the Drugs and Cosmetics Rules, 1945 in the region. He, therefore, discharges the duties as Licensing Authority to receive applications through the area Drugs Inspectors to grant/renew the Licences or to reject them if found not suitable. He also takes necessary departmental action on the erring sales outlets as Licensing Authority, by way of suspending or cancelling the Licences

2) He issues show cause notices, suspension orders. Warnings and cancellation of Licenses of Sales concerns for contravention noticed /reported.

Desk Functions :

1) He is the appointing authority for Junior Assistant, Junior Assistants -cum- Typists, Drivers within the region and also Attenders and Watchman in his Office.
2) He is the disciplinary authority in respect of Jumiot Assistants, junior Assistant - cum - Typists, drivers in his region and attenders / Watchman in his office.
3) He is the authority for regularisation and declaration of the probations of the above employees,
4) Sanctions all kinds of leave to the employees in his office (Sen-

ior Assistant,' junior Assistants, Junior Assistant-cum-Typists, Driver, Attenders and Watchman).

5) He sanctions casual leave to the Drugs Inspectors.

6) He transfers the junior Assistants, Junior Assistant-cum-Typist and Attenders within the District and within in the Region .

7) He reviews the performance of the, work of Drugs Inspectors in the Region once a month.

8) He motivates, guides, supervises and co-ordinates the work of the Drugs Inspectors in the region.

9) He submits the performance report on the Drugs Inspectors and all other reports on statutory work sought by the Inspector General.

10) He initiates Annual Confidential Reports of the Drugs Inspector in the region and Office Superitendents of Regional Office in duplicate and forwards them to the Inspector General.

11) He reviews the individual performance of the Drugs Inspectors in his region.

12) He follows up further action on prosecution cases.

13) He maintains service registers of the staff working in his office and keeps them upto date.

14) He submits report on implementation of official language (Telugu).

15) He is the Drawing and Disbursing Officer and Controlling Officer for pay and allowance, T.A., and Contingencies in respect of his offices.

16) He submits D.O.R. Statements to the Inspector General in respect of his office.

17) He submits budget Estimates and Revised Estimates and Number Statements to the Inspector General in respect of his office.

18) He Accords sanction of Rs.2001 as Permanent Advance.

19) He is the Counter signing authority of the T.A. Bills in respect of Drugs inspectors and also the Non-Gazetted Staff of the Regional Office of the Region.

20) He sanctions increments to the Non-Gazetted Staff in his Office.

Field Functions:

1) He investigates complaints, inspects the subordinate offices of Drugs Inspectors, conducts Joint raids on manufacturing and sales outlets and submits his report to the Inspector General.

THE OPERATIONAL JURISDICTION OF THE FUNCTIONARY:

Assistant Director is notified as Licensing Authority in respect of Sales concerns in the Region. He is competent to exercise his statutory powers within his jurisdiction in respect of Sales concerns. He has to recommend the cases of violations to prosecute the offenders in the Court of Law and seek permission from the Inspector General.

ENACTMENTS, RULES AND REGULATIONS THAT ARE REQUIRED TO BE FOLLOWED IN THE DISCHARGE OF ABOVE FUNCTIONS:

The Assistant Director is appointed as Licensing Authority in respect of Sales concerns under Rule 59 of the Drugs and Cosmetic Rules, 1945 in the Region. As such, he is the'statutory authority under Drugs and Cosmetic Act, 1940 and Rules made thereunder. The following are the other related enactments and Rules in addition to the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetic Rules, 1945, which are required to be followed in discharge of the functions.

a) Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

b) Drugs (Prices Control) Order, 1995.

c) Andhra Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1986 (Partly).

d) Criminal Procedure Code of India 1973.

e) Indian Evidence Act.

CRITICAL PROVISIONS OF THE ENACTMENTS:

As the Assistant Director is notified as Licensing Authority under Rule 59 of the Drugs and Cosmetics Rules, 1945, he exercises his powers while (i) Granting/Renewing the Licenses of Sales outlets (ii) Rejecting the application for Grant/Renewal of Licenses of Sales outlets (iii) Taking De artmental Action like suspension or cancellation of the Licenses for any violations of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.

In addition all the critical provisions of the enactments listed for the Drugs Inspectors are equally the critical positions for this functionary also.

INTRA DEPARTMENTAL AND INTER DEPARTMENTAL APPROACH IN CASE OF ANY HELP:

The Assistant Director continues to be an officer appointed under Section 21 of the Drugs and Cosmetics Act, 1940 and hence he is also deemed to be a public servant within the meaning of Section 21 of the Indian Penal Code. He may approach the local Police Officers in case of emergency. He may also seek the guidance or instructions from his superior Officers including Inspector General as and when required.

ADMINISTRATIVE ACCOUNTABILITY AND REMEDIAL ACTION IN CASE OF OMISSIONS OR COMMISSIONS:

The Assistant Director is accountable to the Inspector General, who is the Head of the Department for his acts of omission and commission. Regarding remedial action for acts of commission or omission in investigation of cases of violations, the Assistant Director can initiate corrective actions by ordering reinvestigations by another Officer/or reinvestigate cases himself and initiate reports for taking Departmental actions against erring Officers. Regarding remedial actions in other matters he has to address the Head of the Department. The Assistant Director is the Competent Authority under A.P. Civil Services (CCA) Rules, 1991 in respect of the Junior Assistants, Junior Assistant-cum-Typists, Typists, Drivers, Attenders and Watchman, to initiate and take departmental action.

QUANTIFICATION OF WORK OUTPUT AND ASSESSMENT OF HIS PERFORMANCE:

a) No. of inspectioris conducted.

b) No.of raids conducted.

c) No. of Manufacturing Units inspected.

d) No. of days toured.

e) No. of Licenses (Sales concerns) suspended.

f) No. of Licenses cancelled.

g) Disposal of cases.

The Inspector General will review the above work as per the targets Fixed in the monthly meetings at Headquarters and assesses the performance of the Assistant Directors.

AREAS OF PERIODICAL REPORTING AND REPORTING FORMATS:

a) Consolidated Monthly performance report of the Drug Inspectors working in his Region.

b) Monthly Inrformance report of the Assistant Director.

c) Official Language (Telugu) - Implementation

d) Expenditure Statement.

e) D.O.R. Statements.

f) Tour Dairy.

g) Annual Confidential Re rts of the Drugs Inspectors working in his region.

h) Number Statements (Due on 1 "August).

i) Budget Estimates and Revised Estimates (Due on 1" October).

j) Annual Self Appraisal Report.

The formats of consolidated monthly performance report of the Drug Inspectors' working in the region, monthly performance report, annual self appraisal report, annual confidential report are enlisted in Annexure-II

LIST OF REGISTERS TO BE MAINTAINED BY THE FUN IONARY:

List of Register maintained in the Office of the Assistant Director are given in the Annexure-II

FORMS OF CORRESPONDENCE OR DOCUMENTATION:

Application for grant or renewal of Licenses ('for all types of' Sales Outlets are received through the Drugs Inspector and the statutory formats of the forms of correspondence are detailed in Annexure-II

AREAS OF INTERFACE WITH PUBLIC AND OTHER DEPARTMENTS

A) General Public:

i) Consumer Forums.

B) Trade Associations:

i) All India Organisation of Chemists & Druggists.

ii) Dist. Chemists & Druggists Association of various Districts.

iii) Manufacturers' Association:

All India Drugs Manufacturers Association.

Bulk Drug Manufacturers Association.

Oganisation of Pharmaceutical Manufacturers of A.P.

C) Professional Associations:

i) Indian Pharmaceutical Association of A.P. State Branch.

ii) Indian Medical Council of A.P. State Branch.

iii) Andhra Pradesh State Pharmacy Council, Hyderabad.

D) Central Government Departments :

i) Central Drugs Standard Control Organisation, New Delhi.

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

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

iv) National Pharmaceutical Pricing Authority, Dept. of Chemicals & Petrochemicals, New Delhi.

v) Central Government Health Scheme Medical Stores Department.

vi) Narcotic Drugs Commission, Chennai.\

vii) Insurance Medical Services. Medical Stores and Blood Banks in E.S.I. Hospitals/Institutions under E.S.I. Schemes.

E) Drugs Conirol Departments In All The States In India

F) Other Departments..

i) Police Department: To help In special investigations and to execute warrants of arrest on the accused in Cases filed by the departmental officers in various courts.

ii) District Collectorates in all the Districts

iii) Medical Education Department Medical stores and blood banks in government hospitals attached to teaching institutions.

iv) Medical and Health services department Medical stores in the District Medical and Health Offices in the district.

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

vi) Institute of Preventive Medicine and State Food Health Authority Blood banks, vaccine production centers under its control.

vii) AIDS Control Department : To co-ordinate the functioning of Blood Banks.

viii) Family Welfare department : To initiate follow up action on the inspections of medical stores.

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

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

xi) State Excise Department.

xii) Training Establishments in Andhra Pradesh State and in other parts of the country.

DRUGS INSPECTOR

ORIGIN OF THE POST:

The post of Drugs Inspector was created by the State Government in the Drugs Control Department in the year 1952. Four posts of Drugs Inspectors were initially sanctioned in the composite State of Madras Government to function under the Directorate of Medical Services for implementation of the provisions of Drugs Act 1940 and the Drug Rules, 1945 relating to Andhra area only. After the formation of Andhra Pradesh State, four more posts of Drugs Inspectors were sanctioned in the year 1959 with ancillary staff for implementation in Telengana area also. These posts which were nonGazetted at the time of creation were given the Gazetted status in the year 1966 after the amendment of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 by the Central Government requiring the powers of search and seizure to be vested only to Gazetted rank Officers. Further in the year 1966, 20 more posts of Drugs Inspectors were sanctioned. From time to time new posts of Drugs Inspectors were sanctioned in the State to meet the requirements of Enforcement functionaries at the field level. 'Today the Drugs Control Administration has 55 Drugs Inspectors working in various regions of" the State.

The 55 posts of Drugs Inspectors sanctioned in various G.O.s are indicated hereunder

1. G.O.Ms.No. 4129 Health, dated 06-12-1950 - 4 Posts (Non Gazetted)
2. G.O.Ms.No. 2340 Health, dated 26-10-1959 - 4 Posts (Non Gazetted)
3. G.O.Ms.No. 1939 Health, dated 28-06-1963 - 12 Posts (Non Gazetted)
4. G.O.Ms.No. 2744 Health, dated 17-12-1966 - 20 Gazetted posts

of Drugs Inspectors sanctioned after surrender of 20 Non Gazetted posts.

5. G.O.Ms.No. 174 Health, dated 02-02-1970 - 2 Posts
6. G.O.Ms.No. 59 Health, dated 16-06-1971 - 1 Post
7. G.O.Ms.No. 1268 M&H, dated 26-12-1978 - 3 Posts
8. G.O.Ms.No. 306 M&H, dated 29-03-1982 - 4 Posts
9. G.O.Ms.No. 304 M&H, dated 31-03-1984 - 7 Posts
10. G.O.Ms.No. 860 M&H, dated 29-12-1984 - 1 Post
11. G.O.Ms .No. 443 M&H,, dated 14-08-1985 - 6 Posts
12. G.O.Ms.No. 302 HM&FW, dated 03-06-1990 - 1 Post
13. G.O.Ms.No. 78 HM&FW, dated 31-01-1991 - 10 Posts

REASONS FOR CREATION:

Under the Drugs and Cosmetics Act, 1940 enacted by the Central Government this Department in Andhra Pradesh State enforces the provisions of Chapter-IV of the above Act for Allopathic drugs through the Drugs and Cosmetics Rules, 1945 to regulate the manufacture. sale and distribution of drugs in the State. Under Section 21 of the Drugs and Cosmetics Act, the State Government is empowered to appoint Drugs Inspectors to enforce the provisions of the above Act and thereby the Drugs Inspectors are conferred certain of were by virtue of Section 22 of the said Act.

ROLE PLAYED BY THE FUNCTIONARY:

The Drugs Inspector is the field level enforcement Officer enforcing the provisions ofthe following statutes.

1. wwThe Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945.
2. Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.
3. Drugs (Prices Control) Order, 1995 issued by the Government of

India under Section 3 of the Essential commodities Act 1955 (10 of 1955).

4. Andhra Pradesh Narcotic Drugs and Psychotropic Substances Rules 1986 (Partly).

POSITION AND SPAN OF INTERACTION WITHIN THE DEPARTMENT:

The Drugs Inspector interacts with the Assistant Director of the Regional office and other superior Officers at Headquarters as and when required in the implementation of Drugs and Cosmetics Act, 1940 and the Rules made thereunder, besides attending periodical monthly review meetings conducted by the Assistant Director of the Region. The Drugs Inspector also takes part in all the programmes organised by the District Collector as per the directives of the State Government.

FUNCTIONS DISCHARGED BY THE FUNCTIONARY:

The functions discharged by the Drugs Inspector are classified into three parts.

Statutory Functions..

1. Appointed as Drugs Inspector under Section 21 of the Drugs and Cosmetics Act, 1940 to enforce the provisions of Chapter IV of the above Act and the Drugs and Cosmetics Rules, 1945 in respect of Allopathic drugs and Cosmetics in the areas assigned. The notifications conferring the State-wide jurisdiction under the above Act of all the drugs Inspectors in the State are listed in Annexure.

2. Authorised to enforce the provisions of Drugs (Prices Control) Order, 1995 under para 21 and also under Section I2 AA of Essential Commodities Act, 1955 vide Notification of the Statement Government listed in Annexure.

3. Authorised to enforce the provisions of Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 under Section-8.

4. Authorised to enforce the provisions of A.P. narcotic Drugs and Psychotropic Substances Rules, 1986(Partly) by virtue of appoint-

ment under Section 21 of Drugs and Cosmetics Act, 1940.

Desk Functions :

1. He is the Head of his office in the Gazetted rank.
2. He is the appointing authority in respect of Office Attender in his office.
3. He is the disciplinary authority under A.P. Civil Services (CCA) Rules, 1991 in respect of Office Attender in his office.
4. He has to submit his performance report to the Regional Assistant Director periodically.

Field Functions :

1. He has to attend the monthly review meeting conducted by the Regional Assistant Director concerned.
2. He is the field enforcement officer for detection and investigation of offences under various Statutes enforced by the department.
3. He has to investigate into complaints made to him or received from his superior officers.
4. He has to attend to courts of law during trials of criminal cases filed under various Statutes enforced by the department.
5. He has to submit the periodicals to the Headquarters in matters relating to Janmabhoomi Programmes, file disposals, implementation of official language (Telugu) in his office.
6. He is the Head of the Office of Drugs Inspector and Drawing and Disbursing Officer for the Staff working in his Office and is also having limited financial powers as listed in the Annexure - II(2) of Volume -2 of Functionary Manual.
7. To submit Budget Estimates and Expenditure Statement to the Headquarters in respect of his office.

OPERATIONAL JURISDICTION OF THE FUNCTIONARY:

The operational jurisdiction of the Drugs Inspector is limited to the area

assigned to him eventhough the Notification empowers him for the entire. State of Andhra Pradesh. He will conduct inspections of Manufacturing Units, Sales concerns Government Hopsitals/Institutions Medical Stores in the area assigned to him. He will discharge the duties of the Drugs Inspector as per the provisions under Drugs and Cosmetics Act, 1940 and Rules made thereunder and related enactments. He is an independent statutory functionary Authority in taking decisions as er the different Statutes en forced by the Department.

1. To perform the statutory functions and duties under the above enactments in the area assigned to the, Drugs Inspector subject to the instructions of the Controlling Authority (Director) from time to time on any general or specific issues that are arising from time to time.
2. Inspection of Licensed Sales and Manufacturing premises not less than twice a year within the area assigned to him.
3. Inspection of complaints in writing which may be made to him.
4. To institute prosecution against the violators under the above said provisions of the Act and Rules made thereunder.
5. To inspect not less than 25 units (both Manufacturing and Sales concerns) per month.
6. To lift 6 Drug samples per month for Test or analysis from Manufacturing and Sales concerns and Government institutions.
7. To maintain record of all inspections made and action taken by him in the performance of his duties including the lifting of samples and seizure of stocks and to submit the copies of such records to the Inspector General, Drugs & Copyright and Director, Drugs Control Administration.

ENACTMENTS, RULES AND REGULATIONS FOR DISCHARGE OF ABOVE FUNCTIONS:

The Drugs Inspector is required to follow the following Enactiments and Rules in the discharge of Statutory, Administrative and Financial Functions.

1. **Statutory Functions:**

a) The Drugs and Cosmetics Act, 1940.

b) The Drugs and Cosmetics Rules, 1945.

c) The Drugs (Prices Control) Order, 1995.

d) The Drugs and Magic Remedies Advertisements) Act, 1954.

e) The Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955.

f) The Andhra Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1986 (Partly).

Desk Functions:

1. Andhra Pradesh Fundamental Rules.
2. Andhra Pradesh Civil Services (CCA), Rules.
3. Andhra Pradesh -Civil -Services Conduct Rules.
4. Andbra Pradesh State andSubordinate Rules.
5. Andhra Pradesh Last Grade Service s Rules.
6. District Office Manual.

Financial :

1. Andhra Pradesh Financial Code.
2. Andhra Pradesh Treasury Code.
3. Andhra Pradesh Accounts Code.
4. Andhra Pradesh Budget Mannual.
5. Andhra Pradesh Pension Code.
6. Andhra Pradesh General Provident Fund Rules.
7. Andhra Pradesh G.T.S. Rules.
8. Andhra Pradesh Manual of Special Pay and Allowances.

CRITICAL PROVISIONS OF THE ENACTMENTS..

1. The Drugs And Cosmetics Act, 1940 And Rules Made Thereunder:

Chapter -IV and V of the Drugs and Cosmetics Act and Part V, Part-VI, Part-VII, Part-VIII, Part-IX, Part-X, Part-XB, Part-XII, Part-XIV, Part-XV and Part-XV(a) of the Drugs and Cosmetics Rules, 1945 are the critical provisions that are relevant for the effective discharge of the duties of the Drugs Inspectors.

Of these, Sections 16 to 19, 21, 22, 23, 25, 27, 28, 32 of Chapter IV of the Act and Section '34 under Chapter-V of the Act are very important and frequently used Sections. The main functions of the Drugs Inspector being the ascertainment of the quality of the drugs that are available in the State, he acts as per the provisions under Section 22 following the procedure as laid down under Section 23. These are the very important provisions under the Act for the effective discharge of the duties of the Drugs Inspector along with the provisions of Rule 65 under Drugs and Cosmetics Rules.

The important sections of the Enactment are the following :

a) Under Sec,22 of the Act the Drugs Inspector is vested with powers to inspect Drugs/Cosmetics manufacturing and Sales premises, take samples of the same for analysis, search any person/place/ vehicle and seize the drugs/cosmetics and records for violations. He is also vested with the power to issue an order directing a person not to dispose a Drug/Cosmetic in his possession for a fixed period of time.

b) The Drugs Inspector is the only person authorised under Section 32 of the Act to launch prosecutions in the Courts of Law.

c) The Drugs Inspector has to perform his duties as per Rule 51 of Drugs and Cosmetics Rules, 1945.

d) The Drugs Inspector inspects Drug/Cosmetic manufacturing premises to verify the compliance of the conditions of License granted/renewed as stipulated in Rules 71, 71A, 71B, 74, 74A, 74B, 76, 78, 78A, Schedule 'M' and Schedule 'U' and Drugs and Cosmetics Rules 1945.

e) The Drugs Inspector inspects Sales Premises to verify the compliance of the conditions stated in the Licenses and also as stated in Rule 65 of Drugs and Cosmetics Rules, 1945.

f) The Drugs Inspector takes samples of Drugs/Cosmetics for the purpose of Test or analysis as per the procedure laid down under Section 23 of the Act. Intimation to a person from whom sample of Drug or Cosmetic is taken is given in Form- 1 7 and the procedure of despatch of sealed portion of sample to Government Analyst is as per Rule 57.

9) The disposal of remaining portions of samples taken for test or analysis and intimation of seizure of Drugs/Cosmetics or Documents to the Courts of Law for safe custody is as per Section 23 of the Act.

h) The Drugs Inspector takes further action on the reports of the Government Analyst as per Section 25 of the Act.

II. Drugs (Prices Control) Order, 1995:

The critical paras under this order are para 7, para 9, para 12, para 18 and para 19. The powers of entry, search and seizure are given in Para 21 and the procedure adopted is as per Section 100 of Criminal Procedure Code. 1973.

III. Drugs And Magic Remedies (Objectionable Advertisements) Act, 1954 And Rules, 1955.

Under this Act the critical sections are Section 3, Section 4, Section 7 and Section 8. The operation method is given in Section 8 and the procedure adopted is as per Section 98 of Criminal Procedure Code 1973.

iv. The Andhra Pradesh Narcotic Drugs And Psychotropic Substances Rules, 1986

Chapter V of the said Rules are the Critical Provisions more frequently used by Drugs Inspectors and Regional Assistant Directors.

V. Criminal Procedure Code, 1973:

a) The Drugs Inspector while conducting the search and seizure is to follow the procedure as per Section 94 and 1 00 of the Criminal Procedure Code.

b) During trial of cases filed in Courts Drugs Inspector is to follow the procedures listed in Section 244 to 247 of Criminal Procedure Code.

c) Limitation on taking cognisance of certain offences as per Section 467 to 473 are to be referred.

d) For effecting arrest of offenders the provisions of Section 42, 43, 44 have to be referred.

VI. The Indian Evidence Act 1872:

a) For proving confessions of accused or any other person Section 27, 28, 29, 30 are to be referred.

b) For proving statements of persons who can or cannot be called as witnesses and that of third persons/experts are guided by Section 32 and Section 34 to Section 47 of the Indian Evidence Act.

c) In respect of proof of facts by oral and documentary evidence. Section 56 to Section 78 are to be referred.

d) On burden of proof Section 101 to Section 108 are important provisions.

e) On examination of witnesses - Section 135 to Section 164 are critical provisions.

INTRA DEPARTMENTAL AND INTER DEPARTMENTAL APPROACH IN CASE OF ANY HELP

Intra-Departmental.

1. The Drugs Inspector can approach the Assistant Director of the respective Regional Office for immediate guidance and assistance in the discharge of his official duties. Further, he can also seek guidance and assistance from the Deputy Directors/ Joint Director (Enforcement) and Director at the Headquarters.
2. The Drugs Inspector can also seek assistance and guidance from

the Inspector General, Drugs and Copyright, Drugs Control Administration for assistance and guidance within the Department and from outside the Department.

Inter Departmental..

1. **Police:** To seek assistance of the Police from the police Station having the jurisdiction over the are in which action is to be taken when trouble is anticipated to conduct a search or seizure and also to execute summons and warrants of arrest issued by the Courts of Law.
2. **Revenue Department:** To obtain assistance of the Revenue Department Officers like Mandal Revenue OfficersNillage administrative Officers while conducting searches and seizures of residential premises.
3. **Municipal Corporation And Municipalities:** To collect information on the ownership of the building premises where violations under Drug, Laws are suspected/detected.
4. **Commercial Taxes Department:** to collect information on the Constitution particulars and Turnover particulars/Sales Tax returns submitted by the Manufacturers and Traders.

ADMINISTRATIVE ACCOUNTABILITY AND REMEDIAL ACTION IN CASE OF OMISSIONS OR COMMISSIONS:

The Drugs Inspector is accountable to the Regional Assistant Director concerned and all the superior officers-and Govermnent in respect of all the matters related to enforcement of Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 and related enactments for any omissions relating to matters of investigations and other statutory functions, the Drugs Inspector can seek the guidance and assistance of the Regional Assistant Director/other superior Officers of the Departm ent and rectify the same.

QUANTIFICATION OF WORK OUTPUT AND ASSESSMENT OF HIS PERFORMANCE:

The Drugs Inspector should submit a monthly report to the respective

Regional Assistant Director on all matters pertaining to his duties and functions. The following information has to be furnished to the Regional Assistant Directors concerned. (The Proforma is at Annexure).

1) He should undertake not less than 25 detailed inspections and not less than 10 routine inspections of Sales concerns per month. Inspection of One Manufacturing concern is treated as equivalent to three detailed inspections of sales concerns for the purpose of targets because the inspection of Manufacturing concerns involves more time and closer scrutiny.

2. He should report not less than 5 cases of violations in Sale premises per month.

3. He should sample for the purpose of Test/Analysis not less than Drugs/Cosmetic samples per month. Three from manufacturing/ Sales concerns and Two from Government Hospitals/Institutions and one Veterinary drug sample from a Government Veterinary Dispensary /Insti tuti on.

4. No. of cases filed in the Courts after receipt of the prosecutions ordersfrom the Head Office.

5. No. of seizures conducted and action taken thereof.

6. No. of violations detected and reported under different enactments ie. Drugs and Cosmetics Act, Drugs Magic Remedies (Objectionable Advertisements) Act, 1954 and Drugs (Prices Control) Order, 1995.

AREAS OF PERIODICAL REPORTING AND REPORTING FORMATS:

a) Tour dairy.

b) Monthly performance report.

c) Monthly expenditure and Challan receipts Statements.

d) Annual self appraisal report

e) Budget Estimates of his Office.

f) D.O.R. monthly Statement.

The above information furnished by the Drugs Inspector will be helpful in evaluating his performance by the Assistant Director and thereby the Head of the Department. The formats of monthly performance report, annual self appraisal report are detailed in Annexure-II(10) of Volume-2 of Functionary Manual.

LIST OF REGISTERS TO BE MAINTAINED BY THE FUNCTIONARY:

The list of registers maintained in the office of the Drugs Inpsector are listed in Annexure-II

FORMS OF CORRESPONDENCE OR DOCUMENTATION:

a) Proforma for inspection of Manufacturing Units IV. Fluids and Vaccines and Sera.

b) Proforma of Inspection of Manufacturing and Sales concerns as per Form-35 of Drugs and Cosmetics Act.

c) Proforma for inspection of Blood banks.

d) Form-15 Proforma under Drug and Cosmetics Rules.

e) Form-16 Proforma under Drugs and Cosmetics Rules.

f) Form-17 and 17 A under Drugs and Cosmetics Rules.

g) Application for grant/renewal of Licence to Manufacture drugs in Form-24 and 27.

h) Application for grant/renewal of Licence for Sale/Distribution of drugs in Form-19.

i) Application for issue of Test Licences in Form-30.

j) Application for issue of Licence to operate a Blood Bank in Form-27-C.

The statutory formats of correspondence/documentation above listed are given in Annexure-II

AREAS OF INTERFACE WITH PUBLIC AND OTHER DEP ARTMENTS:

A) General Public:

i) Consumer Forums.

B) Trade Associations:

i) All India Organisation of Chemists & Druggists.

ii) Dist. Chemists & Druggists Association of various Districts.

iii) Manufacturers' Association:

All India Drugs Manufacturers Association.

Bulk Drug Manufacturers Association.

Oganisation of Pharmaceutical Manufacturers of A.P.

C) Professional Associations:

i) Indian Pharmaceutical Association of A.P.State Branch.

ii) India Medical Council of A.P .State Branch.

iii) A.P. State Pharmacy Council, Hyderabad.

D) Central Government Departments:

i) Central Drugs Standard Control Organisation, New Delhi.

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

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

iv) National Pharmaceutical Pricing Authority, Dept. of Chemicals & Petrochemicals, New Delhi.

v) Central Government Health Scheme Medical Stores Department.

vi) Narcotic Drugs Commission, Chennai.

vii) Insurance Medical Services, Medical Stores and Blood Banks in E.S.I. Hospitals/Institutions under E.S.I. Schemes.

E) Drugs Control Departments In All the States In India

F) Other Departments:

i) Police Department :

To help in special investigations and to execute warrants of arrest

on the accused in the Cases filed by the departmental officers in various courts.

ii) District Collectorates in all the Districts.

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

iv) Medical and Health services departments Inspections of medical stores in the District Medical and Health Offices in the District.

v) Vaidya Vidhan Prarishad Medical stores, Blood banks in district head quarters, Area hospitals and District co-ordinator hospital services medical stores -Inspection of Blood Banks and Medical Stores under their control.

vi) Institute of Preventive Medicine and State Food Health Authority Inspection of Blood banks, vaccine production centers under its control.

vii) AIDS Control Department: To inspect the Blood Banks jointly along with the officers of the Department.

viii) Family welfare Department: Inspections of medical stores and picking of samples of Drugs for analysis.

ix) Animal Husbandry Department: Inspections of Medical Stores in Veterinary Hospitals, Dispensaries, Vaccine Production Centres etc.

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

xi) State Excise Department.

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

xiii) Labour and employment Department (Dist. Employment Exchange).

xiii) District Treasury and Accounts Department.

xix) Nationalised Banks.

Chapter - IV

Laboratory Wing

LABORATORY WING

JOINT DIRECTOR (LABORA TORY)

ORIGIN OF THE POST, REASONS FOR CREATION AND ROLE PLA YED BY THE FUNCTIONARY:

The post of Joint Director (Laboratory) was created vide G.O.Ms.No.195 M&H (L2) Department, dated 25-03-1985 by earmarking one of the existing Joint Directors in the Department. Long experience in the Test/ Analysis of Drugs and Cosmetics and administration of Laboratory activities are considered as the basic requisites to the incumbent of this category of post. Taking into consideration of the above, the post is created for the said purpose. The above functionary supervises the functioning of Drugs Control Laboratories in the State. There are two Drug Control Laboratories in the State, one at Headquarters, and the other at the premises of Regional Office, Vijayawada.

POSITION AND SP AN OF INTERACTION WITHIN THE DEP ARTMENT:

This functionary is the Senior Most Officer in the Drugs Control Laboratory Wing next to the Director in the Department and he interacts with the Inspector General, who is the Head of the Department and the Director, Senior Scientific Officers. .Junior Scientific Officers and with all other subordinate staff of the Laboratory .

FUNCTIONS DISCHARGED BY THE FUNCTIONARY :

The functions of Joint Director (Laboratory) are as follows :

Desk Function :

1. To effectively supervise the functioning of all the Drugs Testing Laboratories in the Drugs Control Administration, Andhra Pradesh.
2. To perform all such other functions and duties in respect of Drug Testing Laboratories in the State entrusted by the Inspector Gen-

eral Drugs and Copyright and / or the Director from time to time.

3. To process all the files relating to issue of Developmental and functional activities of Drugs Testing Laboratories in the State.
4. To organise training programmes to the Junior Analysts, Joint Scientific officers and Senior Scientific officers as and when required.
5. All the consumables required for the day to day functioning of Drugs Control Laboratories like, Reagents, Apparatus, proper working conditions of various instruments, availability of animals etc., are to be coordinated by this functionary and bring it to the notice of Director and Inspector General well in advance for taking necessary action.
6. He initiates Annual Confidential Reports of Senior Scientific Officers and forwards the Annual confidential reports initiated by his subordinate officers.

Field Function :

He inspects the Drugs Control Laboratories at Hyderabad and Vijayawada and submits his report to the Inspector General who is the Head of the Department through Director Drugs Control Administration.

OPERATIONAL JURISDICTION OF THE FUNCTIONARY:

The Joint Director (Laboratory) is an Officer for supervising the work of all the Government Drugs Control Laboratories in the State. He cannot take any independent decisions as he is subordinate to the Inspector General and the Director. He submits the performance report of the Laboratory to the Inspector General periodically.

ENACTMENTS, RULES AND REGULATIONS FOR DISCHARGE OF ABOVE FUNCTIONS:

The Joint Director (Laboratory) is to follow the statutory provisions listed under the category of Government Analyst while assessing the compliance of the said provisions

CRITICAL PROVISIONS OF THE ENACTMENTS:

All the provisions of the Drugs and Cosmetics Act 1940 and rules made

there under which are listed as critical to the government analyst are also equally the critical provisions to this functionary.

INTRA DEPARTMENT AL AND INTER DEP ARTMENT AL APPROACH IN CASE OF ANY HELP:

This functionary seeks the help of superior officers in the Head Office namely the Inspector General, who is the Head of the Department and the Director as and when required within the Department. He has no direct intra-departmental contact, but when he is authorised by the Head of the Department for any specific assignment, he may interact "with that department.

ADMINISTRATIVE ACCOUNTABILITY AND REMEDIAL ACTION IN CASE OF OMISSIONS OR COMMISSIONS:

He is accountable to the Inspector General, who is the Head of the department and to the Director in all matters pertaining to the statutory and administrative aspects of the Drugs Control Laboratories in the State. Any commission or omission can be attended by him to the extent rectifiable and he can approach his superiors, namely the Inspector General, who is the head of the Department or the Director for remedial action.

QUANTIFICATION OF WORK OUTPUT AND ASSESSMENT OF HIS PERFORMANCE :

The Joint Director (Laboratory) shall ensure that the functioning of Drugs Control Laboratories is smooth and result-oriented. The quantification of his work and performance output is based on the sum total of subordinate functionaries performance in the Drugs Control Laboratories. His work assessment is done by the Director and the Inspector General, Who is the head of the Department.

AREAS OF PERIODICAL REPORTING AND REPORTING FORMATS:

He submits his monthly performance reports of the Drugs Control Laboratories to the 'Head of the Department. He also submits his Annual self appraisal reports to the Head of the Department. No separate formats of periodical reporting are prescribed.

The formats of Annual Self Appraisal Report, Annual Confidential Report

are enlisted in Annexure-II

LIST OF REGISTERS TO BE MAINTAINED BY THE FUNCTIONARY:

The Registers and records maintained in the Drugs Control Laboratories are given in Annexure-II

FORMS OF CORRESPONDENCE OR DOCUMENTATION:

This functionary does not correspond independently, since he is not the Head of the Office. Any correspondence has to be made through the Inspector General.

AREAS OF INTERFACE WITH PUBLIC AND OTHEIR DEPARTMENTS:

This functionary does not have direct interface with the public or other Departments.

SENIOR SCIENTIFIC OFFICER (GOVERNMENT ANALYST)

ORIGIN OF THE POST:

The post was created in the year 1970 vide G.O.Ms.No. 2151 Health, dated 23-11-1970 when the first State Drugs Testing Laboratory was sanctioned by the State Government with one sanctioned post. In order to discharge the statutory duties under Drugs and Cosmetics Act and Rules made thereunder to receive the samples of Drugs and Cosmetics taken for the purpose of Test/analysis and issue of Certificate, the Senior Scientific Officer was notified as Government Analyst under Section 20 of Drugs and Cosmetics Act. Subsequently, in the year 1985 vide G.O.Ms.No. 43 HM&H, dated 14-08-1985 another post of Senior Scientific Officer with ancillary staff was sanctioned.

REASONS FOR CREATION:

The post of Senior Scientific Officer, was created to supervise the functioning of Drugs Control Laboratory and to perform the statutory duties of Government Analyst.

ROLE PLA YED BY THE FUNCTIONARY:

Senior Scientific Officer performs the role of Government Analyst as per Rule 45 & 46 of Drugs and Cosmetics Rules, 1945.

POSITION AND SPAN OF INTERACTION WITHIN THE DEPARTMENT:

He is subordinate to Joint Director (Laboratory) and interacts with Junior Scientific Officers of the Testing section of the Laboratory under his control and also interacts with Joint Director (Laboratory), Director and Inspector General who is the Head of the Department.

FUNCTIONS DISCHARGED BY THE FUNCTIONARY:

The Senior Scientific Officers notified as Government Analyst under section 20 of Drugs & Cosmetics Act performs the following functions.

Statutory Functions:

The following are the duties enlisted for the Government Analyst as per Rules 45 and 46 of Drugs and Cosmetics Rules, 1945.

Rule 45:

1. The Government Analyst shall cause to be analysed or tested such samples of (Drugs and Cosmetics) as may be sent to him by Inspectors or other persons under the provisions of Chapter-IV of the Act and shall furnish reports of the results of Test or Analysis in accordance with these Rules.
2. A Government Analyst shall from time to time forward to the Government reports giving the results of Analytical work and research with a view to their publication at the discretion of Government.

Rule 46 :

On receipt of a package from an Inspector containing a sample for Test or Analysis, the Government Analyst shall compare the seals on the packet (or on portion of sample or container) with the specimen impression received separately and shall note the condition of the seals on the packet or on portion of sample or container). After the Test or Analysis has been completed, he shall forthwith supply to the Inspector a report in triplicate in Form 13 of the result of

the Test or Analysis, together with full protocols of the Test or Analysis applied.

Desk Functions:

a) Overall supervision on the functioning of the Sections of the Laboratory under his control and general administration on their day to day functioning.

b) Preparation of Annual Indents for procurement of Chemicals, Glassware, equipment and other Laboratory materials pertaining to his Section.

c) Submission of requirement of reference standards from Central Drugs Laboratory and other authorised agencies to Joint Director (Laboratory) who in turn shall submit the same to the Director/Inspector General for orders.

d) Procurement of Analytical procedures for Patent and Proprietary medicines as and when required through Joint Director (Lab).

e) Correspondence with Drugs Inspectors and other Officers with reference to his Sections.

f) Maintenance of statistical data of Sections supervised by him in the Laboratory.

g) Initiates Annual Confidential Reports in respect of Junior Scientific Officers and forwards Annual confidential report initiated by Junior Scicntitic Officers..

OPERATIONAL JURISDICTION OF THE FUNCTIONARY

The Government Analyst is notified for the entire State of Andhra Pradesh. However, he discharges his duties as Government Analyst in respect of the Section of the Laboratory assigned to him by the Head of the Department. As Government Analyst, he is authorised to give Expert opinion independently in the prescribed Form (form 13) as per Drugs and Cosmetics Rules, 1945 on the result of Test/Analysis of Drugs/Cosmetics.

ENACTMENTS, RULES & REGULATIONS FOR DISCHARGE OF ABOVE FUNCTIONS:

The enactment governing this functionary is Section 20 of the Drugs and Cosmetics Act, 1940 read with Rules 45 and 46 of Drugs and Cosmetics Rules, 1945.

CRITICAL PROVISIONS OF THE ENACTMENTS:

The critical provisions governing this functionary are Rule 45 and 46 of Drugs and Cosmetics Rules, 1945. The operational procedures are as detailed under statutory functions supra.

INTRA DEPARTMENTAL AND INTER DEPARTMENTAL APPROACH IN CASE OF ANY HELP:

In case of any help needed this functionary can approach Joint Director (Laboratory), Director and the Inspector General who is the Head of the Department and also the Drugs Inspector concerned in matters related to Test/Analysis of Drugs & Cosmetics.

ADMINISTRATIVE ACCOUNTABILITY AND REMEDIAL ACTION IN CASE OF OMISSIONS OR COMMISSIONS

This functionary is accountable to Joint Director (Laboratory), Director and Inspector General, who is the Head of the Department. He is also accountable to the Drugs Inspector to issue the certificate of Test/Analysis. Further, he is also accountable for the work carried out by his subordinate staff under his control.

QUANTIFICATION OF WORK OUTPUT AND ASSESSMENT OF HIS/HER PERFORMANCE:

The work performance turned out by Senior Scientific Officer as Government Analyst is quantified by taking into consideration the sum total of the samples received and analysed by the Junior Scientific Officers under his control. The assessment of his performance is done by the Inspector General, who is the Head of Department in review meetings conducted by him at regular intervals.

AREAS OF PERIODICAL REPORTING AND REPORTING FORMATS:

This functionary submits the details of the monthly Statement of samples of Drugs/Cosmetic received, tested/analysed, and pending analysis in the proforma at Annexure- II

LIST OUT REGISTERS TO BE MAINTAINED BY THE FUNCTIONARY:

The Registers maintained in the Sections of the Laboratory under the control of Government Analyst are the following and the formats are listed at Annexure-II

1. Register of Receipt of Samples for Analysis.
2. Register of Result of Analyst of Drugs/Cosmetics.

FORMS OF CORRESPONDENCE OR DOCUMENTATION:

He receives the samples of Drugs/Cosmetics along with the correspondence in statutory Form 18 with covering letter from the Drugs Inspector and issues the Certificate of Test/Analysis in the statutory Form 13 whose formats are reproduced at Annexure-II

AREAS OF INTERFACE WITH PUBLIC AND OTHER DEPARTMENTS:

This functionary does not have any direct interface with the public However, he interacts through proper channel with the Central Drugs Laboratory, Calcutta for procurement of reference standards and special procedures of TestlAnalysis as and when required.

JUNIOR SCIENTIFIC OFFICER

ORIGIN OF THE POST :

The post of Junior Scientific Officer was created in the Drugs Control Laboratory (formerly called as Drugs Testing Laboratory) in the year 1970 vide G.O.Ms.No.2151 Health, dated 23.11.70 with 2 posts sanctioned along with Senior Scientific Officer and other ancillary staff. Subsequently three more posts of Junior Scientific Officers were sanctioned in the Headquarters Drugs Testing Laboratory vide G.O.Ms.No.1290 M&H, dated 30.8.80, G.O.Ms.No.304 M&H dated 31.3.84,G.O.Ms.No.829 M&H dt. 8.12.86 respectively. In the year

1986 after the sanction of separate Regional Drugs Testing Laboratory at Vijayawada another post of Junior Scientific Officer was sanctioned vide G.O.Ms.No.230 HM & FW dated 27.3.89 and this Junior Scientific Officer was notified as Government Analyst for discharging statutory functions.

REASONS FOR CREATION:

The Drugs Control Laboratory consists of various Sections covering Microbiology, Pharmacology, Pharmaceutical Chemistry divisions. In order to supervise the functioning of different Units in the respective divisions of the Laboratory and to assist the Senior Scientific Officers notified as Government Analysts in all matters pertaining to Test/Analysts of Drug/Cosmetic samples, the post of Junior Scientific Officer was created.

ROLE PLAYED BY THE FUNCTIONARY:

This functionary supervises the work turned out in the Units of the respective Divisions of the Drugs Control Laboratory assigned to him from time to time. He also undertakes the analysis of Drugs/Cosmetics in addition to Junior Analysts independently.

The Junior Scientific Officer at Regional Drugs Testing Laboratory, Vijayawada also performs the functions of Government Analyst as per the notification of the Government under Section 20 of Drugs and Cosmetics Act.

POSITION AND SPAN OF INTERACTION WITHIN THE DEPARTMENT:

They are subordinate to Senior Scientific Officer and interacts with the Junior Analysts working under their control and with Senior Scientific Officer under whose supervision they work and also with Joint Director (Laboratory).

FUNCTIONS DISCHARGED BY THE FUNCTIONARY

The functions of Junior Scientific Officers are broadly classified as follows:

Desk Functions

a) To receive the samples from coding cell.

b) To maintain sample register in the Format prescribed.

c) To distribute the samples to the Junior Analysts working in the unit

d) To pay special attention in case of the samples found Not of Standard Quality.

e) To scrutinise the records of samples carried out by Junior Analysts and after confirmation only to submit the report to the Senior Scientific Officer (Government Analyst) and to conduct random analysis of such samples. He will pay special attention to critical points of analysis and also consult concerned Senior Scientific Officer and take guidance.

f) In addition to the above, as per the targets fixed, Junior Scientific Officers should analyse not less than (5) samples per month independently.

g) To forward all kinds of leave applications of the staff working in the Laboratory to the sanctioning authority, through Senior Scientific Officer .

h) He is the initiating officer to write Annual Confidential Reports in respect of Junior Analysts working in the Unit.

i) To prepare indents of chemicals, glassware etc., required for analysis well in advance and to submit through the Senior Scientific Officer.

j) To prepare requisitions for supply of special items like rare chemicals and ancillary equipment etc.

k) To maintain inventory of equipment, Glassware, Furniture etc., in the Unit assigned.

l) To organise training programme, to the fresh recruits of Junior Analysts before assigning duties.

m) To take responsibility to develop/procure new techniques and mcthods of Test orAnalysis for regular and new molecules that have to be adopted for their analysis and to gain latest techniques in day to day changing methodology. The Junior Scientific Officer can approach the Senior Scientific Officer or the Director to procure necessary technical information.

Statutory Functions :

In respect of Junior Scientific Officer at Regional Drugs Testing Laboratory at Vijayawada notified as Government Analyst, he performs the statutory functions of Rule 45 and 46 of Drugs and Cosmetics Rules as follows:

Rule 45:

1. The Government Analyst shall cause to be analysed or tested such samples of (Drugs and Cosmetics) as may be sent to him by Inspectors or other persons under the provisions of Chapter IV of the Act and shall furnish reports of the results of Test or Analysis in accordance with these Rules.
2. A Government Analyst shall from time to time forward to the Government reports giving the results of Analytical work and rcscarch with a view to their publication at the discretion of Government.

Rule 46 :

On receipt of a package from an Inspector containing a sample for Test or Analysis, the Government Analyst shall compare the seals on the packet (or on portion of sample or container) with the specimen impression received separately and shall note the condition of the seals on the (packet or on portion of sample or container). After the Test or Analysis has been completed he shall forthwith supply to the Inspector a report in triplicate in Form 13 of the result of (the Test or Analysis, together with full protocols of the Test or Analysis applied.

OPERATIONAL JURISDICTION OF THE FUNCTIONARY:

The Junior Scientific Officer in addition to undertaking analysis of Drug/ Cosmetic samples by themselves also supervise the functioning or respective Units of the Laboratory assigned to them from time to time by the Head of the Department. The Junior Scientific Officer and Regional Drug Testing Laboratory, Vijayawada discharges the duties of Government Analyst under Rule 45 and 46 of Drugs and Cosmetics Rules 1945 independently since he is notified as Government Analyst in respect of drugs not requiring Biological and Microbiological methods of analysis. He also has State-wide jurisdiction since he

is notified as Government Analyst.

ENACTMENTS, RULES AND REGULATIONS FOR DISCHARGE OF ABOVE FUNCTIONS:

While the Junior Scientific Officer at Drugs Control Laboratory, Hyderabad do not have statutory powers, they assist the Senior Scientific Officers/Government Analysts in the matters of Test / Analysis of drugs/Cosmetics. However, the Junior Scientific Officer at Regional Drug Testing Laboratory, Vijayawada notified as Government Analyst is governed by Rule 45 and 46 of Drugs and Cosmetics Rules, 1945 as described for Senior Scientific Officers.

CRITICAL PROVISIONS OF THE ENACTMENTS:

The Junior Scientific Officers at Headquarters Drugs Control laboratory are not governed by any critical provisions of statutory enactments. However, their work duties form part of the critical provision of Drugs and Cosmetics rules mentioned for Senior Scientific Officer /Government Analysts. In respect of Junior scientific Officer at Regional Drug Testing Laboratory, Vijayawada, the critical provision are as enumerated under the critical provisions of Senior Scientific Officer.

INTRA DEPARTMENTAL AND INTER DEPARTMENT AL APPROACH IN CASE OF ANY HELP:

The Junior Scientific Officer can seek help and guidance from the Senior Scientific Officers and other superior Officers of the Department in all matters related to him.

ADMINISTRATIVE ACCOUNTABILITY AND REMEDIAL ACTION IN CASE OF OMISSIONS OR COMMISSIONS;

The Junior Scientific Officer is accountable to Senior Scientific Officer and the Head of the Department for their acts of omission and commission. Regarding remedial action for acts of commission or omission in the Test/ Analysis of drugs/Cosmetics, the Junior Scientific Officer can himself undertake re-testing of the drug/cosmctic or under . the supervision of Senior Scientific Officer. In respect of testing of drugs/cosmetics by Junior Analysts, any act of commission or omission can be corrected by ordering retest/analysis by

another Junior Analyst or by himself and initiate reports for taking departmental action against erring officers. Regarding remedial action in other matters he has to address the Head of the Department through proper channel.

QUANTIFICATION OF WORK OUTPUT AND ASSESSMENT OFHIS/ HER PERFORMANCE:

The quantification of work output expected from the functionary is to see that he independently tests/analysis a minimum of 5 samples of drug/cosmetic per month and also to ensure that Junior Analysts working under him also complete test/analysis of required No. of samples assigned to them every month. Basing on the work turned out and also on his abilities to operate the functioning of his Unit smoothly and effectively, maintaining the records properly, his performance will be assessed. Any incorrect.report of analysis generated from his Unit reflects on the assessment of his performance.

AREAS OF PERIODICAL REPORTING AND REPORTING FORMATS :

This functionary reports periodically (every month) the samples of drugs/ cosmetics received in the month from the coding cell, samples analysed by Junior Analysts under his control and also by him independently in the prescribed format mentioned at Annexure-II

LIST OF REGISTERS TO BE MAINTAINED BY THE FUNCTIONARY:

The Registers maintained by the Junior Scientific Officers are:

a) Register of Samples received from coding cell.

b) Register of Receipt of Samples for Analysis.

c) Register of Result of Analysis of Drugs/Cosmetics.

d) Junior Scientific officer at Regional Drug Testing Laboratory Vijayawada is to maintain all the Registers maintained by Senior Scientific Officers/Government Analysts.

The proforma of registers maintained by the Junior Scientific Officers are listed in Annexure-II

FORMS OF CORRESPONDENCE OR DOCUMENTATION:

No form of correspondence is entertained directly by Junior Scientific

Officers working in Headquarters. However, the Junior Scientific officer working at Regional Drug Testing Laboratory at Vijayawada receives the samples along with statutory correspondence as Government Analyst. ,

AREAS OF INTERFACE WITH PUBLIC AND OTHER DEPARTMENTS:

The Junior Scientific officers do not have any direct contact with the public or other Departments.

JUNIOR ANALYST

ORIGIN OF THE POST:

The creation of this post originated when two posts of Junior Analysts (formerly known as Senior Scientific Assistant) were sanctioned in the year 1970 vide G.O.Ms.No. 2151 Health, dated 23-11-1970 along with Senior Scientific Officer, 2 Junior Scientific Officers, when the first State Drug Testing Laboratory, was sanctioned by the State Government. Subsequently, in order to strengthen the Drug Control laboratories at Hyderabad and Vijayawada and to increase the testing facilities 23 more posts of Junior Analysts were sanctioned in the following G.O Ms..Nos.

I. G.O.Ms.No. 562 M&H, dated 09-06-1976 -4 posts

2. G.O.Ms.No. 1229 M&H, dated 25-08-1980 -4 posts

3. G.O.Ms.No. 304 M&H, dated 31-03-1984 -8 posts

4. G.O.Ms.No. 770 M&H, dated 04-11-1986 -2 posts

5. G.O.Ms.No. 619 HM&FW, dated 31-03-1988- 2 posts

6. G.O.Ms.No.230 HM&FW, dated 27-03-1989- 3 posts

REASONS FOR CREATION:

The post of junior Analyst is created for fulfilling the requirement of undertaking " complete test/analysis of a drug/cosmetic as per standards prescribed. Junior Analyst forms the basic functionary of the Drugs Control Laboratories.

ROLE PLAYED BY THE FUNCTIONARY:

The Junior Analyst undertakes test/analysis of a drug or cosmetic as per

the standards prescribed under the supervision of Junior Scientific Officers and Senior Scientific Officers. Junior Analyst is subordinate to Junior Scientific Officer and is of non-Gazetted status. He interacts with the Junior Scientific Officers and other superior Officers of the Department. He also interacts with other Junior Analysts, Laboratory Junior Assistants, Laboratory Technicians and Laboratory Attendants.

POSITION AND SPAN OF INTERACTION WITHIN THE DEP ARTMENT:

Junior Analyst is subordinate to Junior Scientific Officer and is of non-Gazetted status. He interacts with the Junior Scientific Officers and other superior Officers of the Department. He also interacts with other Junior Analysts, Laboratory junior Assistants, Laboratory Technicians and Laboratory Attendants.

FUNCTIONS DISCHARGED BY THE FUNCTIONARY:

The Junior Analyst performs the following Desk Functions only:

a) To receive the samples for test analysis of drugs and Cosmetics from the concerned Unit Junior Scientific Officer and maintain a record of these samples in a Register .

b) To analyse not less than 20 samples per month as per the targets fixed.

c) To conduct the Test/Analysis of the allotted samples according to the standards prescribed under Drugs and Cosmetics Act, 1940 and Rules made thereunder, to maintain complete observation record and also to submit analytical report to the Junior Scientific Officer of the Unit.

d) To prepare, standardise and maintain standard volumetric solutions for various drug samples independently.

e) To prepare reference standards of Drugs on par with the standards procured from Central Drug Laboratory and other authorised agencies, and to maintain record thereof.

f) He is responsible for maintenance of the sophisticated instruments like H.P.L.C., U.V. Spectrophotometer, Auto Titrator etc.

g) He is responsible for periodical calibration of instruments like U V. Spectrophotometer, H.P.L.C., P.H. Meter, Balances etc.

h) He is responsible to indent the required chemicals etc. well in advance through the Junior Scientific officer concerned for carrying out the Test/Analysis of drug samples.

i) He is responsible to maintain hygenic conditions in the areas like Microbiology, Pharmacology, Chemical Units etc.

j) To co-ordinate with fellow Analysts in maintainig Good laboratory Practices.

The above functionary does not have any field or statutory functions:

OPERATION JURISDICTION OF THE FUNCTIONARY:

The operational jurisdiction of this functionary is limited to the samples of drugs/cosmetic given to him for analysis. He cannot take any independent decision. He has to submit the result of analysis along with written observations to the Junior Scientific Officer for taking further action.

ENACTMENTS, RULES AND REGULATIONS FOR DISCHARGE OF ABOVE FUNCTIONS:

This functionary is a subordinate to Junior Scientific Officer and carries on the analytical work as allotted by Junior Scientific Officer strictly as per the standard books of Pharmacoepia like I.P ., B.P ., U .S.P ., B.P. Vet, E.P. International Pharmacoepia etc. and Scientific Journals.

CRITLCAL PROVISIONS OF THE ENACTMENTS:

As this functionary does not have statutory responsibilities, the methods and procedures followed in analysis of drugs form the critical provisions of this functionary.

INTRA DEPARTMENT AL AND INTER DEPARTMENT AL APPROACH IN CASE OF ANY HELP:

In case of any help, he can seek the assistance and guidance from his Junior Scientific Officer, Senior Scientific Officer and other superior Officers.

ADMINISTRATIVE ACCOUNT ABILITY AND REMEDIAL ACTION IN CASE OF OMISSIONS OR COMMISSIONS:

This functionary is accountable to Junior Scientific Officer in all matters pertaining to Analysis of Drugs and Cosmetics assigned to him. Any omission or commission can be rectified by his own initiation by conducting Retesting of the samples or at the directions of Junior Scientific Officer and Senior Scientific Officer.

QUANTIFICATION OF WORK OUTPUT AND ASSESSMENT OF HIS/HER PERFORMANCE :

The work of Junior Analyst is quantified against the targets fixed for him lor analysis of drugs/cosmetics. The targets fixed for this functionary are enumerated in the listing of the functions to be discharged at para 3.

AREAS OF PERIODICAL REPORTING AND REPORTING FORMATS:

The Junior Analyst will report to the Junior Scientific Officer the work carried out by him every day or on completion of analysis of a drug or Cosmetic whichever is earlier.

LIST OF REGISTERS TO BE MAINTAINED BY THE FUNCTIONARY:

The Registers and records to be maintained by this functionary are as follows :

1) Rough note book.
2) Observation Record of findings.
3) Work sheet.

FORMS OF CORRESPONDENCE OR DOCUMENTATION:

This functionary does not have any independent correspondence. However, he submits the worksheet containing the details of observations and result of analysis to the junior Scientific Officer.

AREAS OF INTERFACE WITH PUBLIC AND OTHER DEPARTMENTS:

This functionary does not have any public interface. He interacts with his fellow Junior Analysts and the Junior Scientific Officer and Senior Scientific Ofiicer in all matters pertaining to his functions.

Annexures

OFFICE OF THE INSPECTOR GENERAL, DRUGS AND COPYRIGHT DRUGS CONTROL ADMINISTRA TION : : VENGALRAO NAGAR HYDERABAD-38

Rc. No. 10/Peshi/96 Dated: 18-10-1996

Sub: Drugs Control Administration -Maintenance of Personal Files - Initiation of Annual Confidential Reports -Certain instructions -Issued - Regarding.

****

On perusal of the maintenance of Personal Files and procedure being following in the initiation of Annual Confidential Reports, the following instructions are issued in respect of initiating Annual Confidential Reports etc.

1. The Regional Assistant Director will be Reporting Officers (Initiating Officers for Annual Confidential Reports) on Drugs Inspectors working under their and they will initiate the Annual Confidential Reports on them.

2. The Deputy Director in-charge of the respective areas will be Reporting Officers (Initiating Officers for Annual Confidential Reports) on Regional Assistant Directors working under them

3. The Joint Director concerned to subjects / territories will be Reporting Officers (Initiating Officers for Annual Confidential Reports) for Deputy Directors working under them.

4. Director will be the Reporting Officer (Initiating Officers for Annual Confidential Reports) for Joint Directors in the Drugs Control Administration.

5. The Junior Scientific Officers concerned will. be the Reporting Officer (Initiating Officers for Annual Confidential Reports) for Junior Analysts working in their unit,

6. The Senior Scientific Officer will be the Reporting Officer (Initiating Officer for Annual Confidential Reports) for Junior Scientific Officers working under them.

7. The Joint Director In-charge Laboratory will be Reporting Officer (Initi-

ating Officer for Annual Confidential Reports) for Senior Scientific Officers in the Drugs Control Laboratory. These orders will come into force with immediate effect.

Please acknowledge receipt of this memo.

INSPECTOR GENERAL, DRUGS & COPYRIGHT
DRUGS CONTROL ADMINISTRATION

OFFICE OF THE INSPECTOR GENERAL, DRUGS AND COPYRIGHT DRUGS CONTROL ADMINISTRATION :: VENGALRAO NAGAR :: HYDERABAD -38.

Rc. No.27 /Peshi/97 Dated: 25-02-l997

Sub: Drugs Control Administration -Review of the performance of the Drugs.Inspectors at the Directorate during the monthly meeting of the Regional Assistant Directors -Certain clarifications and instructions -Issued.

During the review of the performance of the Drugs Inspectors in the monthly meetings of the Regional Assistant Directors, it is observed that the Drugs Inspectors do not seem to have a clear understanding as to how to report the number of violations detected in a month.

They are informed that the number of violations detected in a month means the number of firms in which the Drugs Inspector has detected violations. In other words, the number of violations detected during the inspection of a particular firm, irrespective of the number of violations detected in that firm should be counted as one case of violations only. Every Drugs Inspector should report not less than (10) such cases of violations per month.*

As informed earlier, every Drugs Inspector should make not less than (25) detailed inspections and not less than (10) routine inspections per month. They are informed that a detailed inspection of a manufacturing concern will be treated as equivalent to (3) detailed inspections of sales concerns for the purpose of targets. .

As regards the Drugs Inspectors who are also looking after the work of coding they should make not less than (15) detailed Inspections and not less than (10) routine inspections per month this reduced target is fixed for them taking into consideration, the additional work entrusted to them in coding cell.

The Regional Assistant Directors are instructed that while coming to the Monthly meetings, they should bring the list of files relating to any subject pending with the Directorate so that such files can be discussed in the meeting itself and disposed off without any further delay.

These orders will come into force with immediate effect.

INSPECTOR GENERAL
DRUGS AND COPYRIGHT
DRUGS CONTROL ADMINISTRATION

* The no. of violation of 10 are reduced to 5 on the instruction of Inspector General from the month of September, 1998.

OFFICE OF THE INSPECTOR GENERAL, DRUGS AND COPYRIGHT :: DRUGS CONTROL ADMINISTRATION :: VENGALRAO NAGAR :: HYDERABAD - 38

Rc. No. 13/Peshi/96 Dated: 30-04-1997

Sub: Drugs Control Administration -Inspection of subordinate Offices and Manufacturing concerns and Government Hospitals -Certain instruction - Issued.

******

The Regional Assistant Director working in Drugs Control Administration were instructed to inspect not less than 3 Manufacturing concerns and also conduct not less than 3 joint raids every month in their respective areas. They were also instructed to inspect not less than 2 offices of drugs inspectors every month.

They are informed that the inspection reports of the 2 offices of Drugs Inspectors as asked for in the reference cited are not received every month.

Hence, they are instructed to submit their inspection reports from November, 1996 onwards. If they have not inspected and conducted raids etc., they should submit a Nil report giving reasons for not complying with the instructions.

Their reports should reach the undersigned on or before 07-05-1997 positively.

Receipt of the memo should be acknowledged.

INSPECTOR GENERAL
DRUGS AND COPYRIGHT
DRUGS CONTROL ADMINISTRATION

To

All the Regional Assistant Directors in the State.

Copy to : Joint Director & Director, FAC, Drugs Control Admn, Hyderabad.

Copy to : Joint Director (K), Drugs Control Admn, Hyderabad.

Copy to : Deputy Director, Drugs Control Admn., Hyderabad.

Copy to : Stock File / Spare.

Annexure -I

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

1. Inward Register .
2. Outward Register.
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 Despatch Register .
22. Regester 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.
3 I. 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. CopyApplications 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 .

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

Office of the Inspector General,
Drugs and Copyright,
Drugs Control Administration,
Vengal Rao Nagar, Hyderabad

L.Dis.No. /M3A/199 Dated: —1999.

G.M.P. CERTIFICATE

This is to certify that M/s.

is a Licencee holding Drug Manufacturing Licences in Form-25 and 28 bearing No. Dated: for the manufacture of Drugs approved by this Department.

2) The firm by and large are following GOOD MANUFACTURING PRACTICES to the extent possible as stipulated under the provisions of Schedule "M" of Drugs and Cosmetics Rules, 1945.

3) This Certificate is issued as requested by the firm for the limited purpose of submitting the same to in connection with Tender purposes only.

4) This Certificate is valid for a period of one year only from the date of issue.

DIRECTOR,
DRUGS CONTROL ADMINISTRATION

To

GOVERNMENT OFANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

Office of the Inspector General,
Drugs and Copyright,
Drugs Control Administration,
Vengal Rao Nagar,
Hyderabad

L.D is.No . /M3A/99 Dated :

FREE SALE CERTIFICATE

This is to certify that M/s.
are holding Drug Manufacturing licence in form-25 and 28 bearing no..... dated: ..... granted and issued by the Drugs Control Administration, Andhra Pradesh, Hyderabad under the provisions of Drugs and Cosmetics Act, 1940 and rules made thereunder. Under the said licence the firm is permitted to manufacture the following products with I.P. Standard to be freely sold in India and B.P./USP standard for export orders.

NAME OF THE PRODUCT

This certificate is issued for the limited purpose of registration of the said products in domestic and export as mentioned above.

DIRECTOR
DRUGS CONTROL ADMINISTRATION

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

Office of the Inspector General,
Drugs and Copyright,
Drugs Control Administration,
Vengal Rao Nagar, Hyderabad

L.Dis.No. /98 Dated :

MANUFACTURING & MARKETING CERTIFICATE

This is to certify that M/s.

are holding valid manufacturing licence bearing no. ..... dated: .....issued by this Department and they are manufacturing the following products since the last three years.

It is further certified that the following products are also being marketed for the last three years. ,

The products are as follows:

S.No.	Name of the product	Pharmacopoeial Specification	Strength

This certificate is issued for the limited purpose submitting it to tender purpose.

DIRECTOR,

DRUGS CONTROL ADMINISTRATION

To

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

Office of the Inspector General,
Drugs and Copyright,
Drugs Control Administration,
Vengal Rao Nagar, Hyderabad

L.Dis.No. / 99 Dated :

NON-CONVICTION CERTIFICATE

This is to certify that M/s. _____ concern holding Drug Manufacturing Licence in Form-25 and 28 bearing no. _____ dated _____ valid upto ._____This firm has not been convicted under the Drugs and Cosmetics Act, 1940 and Rules made thereunder .

This certificate is given as requested by the firm and for the limited purpose of submitting the same to the in connection with the above firm participating in Tenders only.

This certificate is valid for one year only from the date of issue.

DIRECTOR,
DRUGS CONTROL ADMINISTRATION

To

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

Office of the Inspector General
Drugs and Copyright,
Drugs Control Administration,
Vengal Rao Nagar, Hyderabad

L.Dis.No. Dated :

CERTIFICATE OF PHARMACEUTICALS PRODUCTS

Manufacturer	:	M/s.
When applicable	:	
Placing the product on the market	:	As detailed below
It is certified that :		
These products which has been	:	Since they are permitted
authorised to be placed on the market for use in the country	:	to manufacture for Export
Drugs Licence No.	:	
The products which have not been	:	Since they are permitted
authorised to be placed on the	:	to manufacture the products for
market for use in this country	:	export purpose
for the following reasons.		

It is also certified that (a) the manufacturing plant in which the products are produced is subject to inspection at suitable intervals.

The unit M/s. _____ was jointly inspected by Sri _____ Controller (India), Central Drugs Standard Control Organisation and Sri _____ Drugs Inspector, of this office.

(b) The manufacturer conforms to requirement for Good Manufac-

turing Practices in the manufacture and quality control (As recommended by the World Health Organisation) in respect of products (Bulk Drugs) to be sold or distributed within the country or origin (or to be exported).

DIRECTOR
DRUGS CONTROL ADMINISTRA TION

To

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

Office of the Inspector General,
Drugs and Copyright,
Drugs Control Administration,
Vengal Rao Nagar, Hyderabad

L.Dis.No. Dated :

PERFORMANCE CERTIFICATE

This is to certify that M/s..... are issued Drug Licence bearing No._____ dated: _____ in Form-25 and 28 valid upto for the manufacture of the drugs approved by this Department.

The performance of the firm in the manufacture of drugs approved to them is found to be satisfactory for the last (3) years i.e.

This certificate is given as requested by the firm and for the limited purpose to submit the same to
in connection with the Rate Contract Tender only.

This certificate is valid for a period of one year only from the date of issue.

DIRECTOR

DRUGS CONTROL ADMINISTRATION

To

FORM-NDPS-4

(See Rule 94)

FORMAT OF AUTHORISATION FOR THE INTER-PROVISIONAL IMPORT OF MANUFACTURED DRUGS INTO THE STATE OF ANDHRA PRADESH

Mr. _____ its Messrs. , are Hereby authorised to import the undermentioned drugs from Mr. _____ its Messrs.

Exact description of the work	Total quantity of the drug to be imported	Percentage of the drug contents.	REMARKS

This authorisation must be used within two months from the date of its issue.

This authorisation shall be delivered on arrival of drugs at their destination to _____ the bulk of the consignment shall not be broken in transit.

Dated the LICENSING AUTHORITY

* Name and full address of the Importer-

+ Name and full address of the Exporter.

Designation of the officer to whom the pass is to be delivered.

Note: This authorisation is issued in Triplicate. Part-I is to remain in the office of issue, Part-II is to be forwarded to the Authority of the place of export and Part-III is to be handed over to Importer to accompany the consignment.

FORM-NDPS-5

(See Rule 95)

FORMAT OF AUTHORISATION FOR THE INTER-PROVISIONAL EXPORT OF MANUFACTURED DRUGS FROM THE STATE OF ANDHRA PRADESH

Mr.* _____ is
Messrs. are

Hereby authorised to export the under mentioned drugs to

Mr. ** _____ is
Messrs. are

by ***._____

in **** _____

Exact description of the Drugs	Total quantity of the drug to be imported	Percentage of the drug contents.	REMARKS

This authorisation will remain in force upto the evening of _____ 19

The bulk of the consignment shall not be broken in transit.

Dated LICENSING AUTHORITY

* Name and full address of the Importer-

** Name and full address of the Exporter.

* * * Route and mode of conveyance.

**** Number and description of packages.

NOTE: This authorisation is issued in Quadriplicate. Part-I is to remain in office of issue, Part-II to be handed over to consignor to accompany the consignment, Part-III is to be ' forwarded to the authority at the place of import and Part-IV is to be issued in case of despatch of drugs by parcel post and handed over to the consignor for production at the post office of despatch.

FORM-NDPS 6

(See Rule 96)

FORMAT OF AUTHORISATION FOR THE TRANSPORT OF MANUF ACTURED DRUG WITHIN THE STATE OF ANDHRA PRADESH,

Mr. _____

hereby authorised to transport to

From M/s._____

The under mentioned drugs

Exact description of the work	Total quantity of the drug to be imported	Percentage of the drug contents.	REMARKS

This authorisation must be used within two months from the date of its issue.

Dated LICENSING AUTHORITY

* Name of the persons or firm authorised.

Locality and District of destination of consignment.

Name and full address of the firm supplying the drug.

Note: This authorisation is issued in Triplicate counter foil copy to remain attached to book, Duplicate copy to remain attached to book, Triplicate copy to be handed over to the applicant to accompany the consignment.

FORM 15

[See Rules 54 and 145-C]

Order under section 22(1)(c) of the Drugs and Cosmetics Act, 1940 Requiring a person not to dispose of stock in his possession

Whereas I have reason to believe that the stocks of drugs/cosmetics in your ' possession, detailed below contravene the provisions of section 18 of the Drugs and Cosmetics Act, 1940.

Now, therefore, I hereby require you under clause (c) of sub-section (1) of section 22 of the said Act, not to dispose of the said stock for a period of ..... days from the date of this order .

Date ..... Inspector

Details of stock drugs/cosmetics

Date..... Inspector

FORM 16

[See Rules 55 and 145-B] ,

To

Reccipt for stock of drugs or cosmetics or for record, register, Document or material object seized under section 229(1)(c) Or (cc) of the Drugs and cosmetics Act, 1940

The stock of drugs or cosmetics or records, registers, documents or material objects detailed below has/have this day been seized by me under the provisions of clause or clause (cc) of sub-section (1) of section 22 of the Drugs and Cosmetics Act, 1940 (23 of 1940) from the premises of .....Situated at .....

Date ..... Inspector ..... Details of drugs, cosmetics, records, registers, documents or material Objects seized.

Date ..... Inspector .....

FORM 17

[Sèe Rules 56 and 145-A]

Intimation to person from whom sample is taken

To

.....

.....

.....

I have this day taken from the premises of ..... of situated at..... samples of the drugs/cosmetics specified below for the purpose of test or analysis.

Date ..... Inspector .....

Details of samples taken

Date ..... Inspector .....

FORM 17-A

[See Rules 56A and 145AA]

Receipt for samples of Drugs or Cosmetics taken where Fair Price Tendered thereof under sub-section (1) of section 23 of the Drugs Cosmetics Act, 1940 is refused

To

.....

.....

.....

Whereas I, this ..... day of ..... 19 Have taken, from the premises of ..... Situated at .: ..... .samples drugs/cosmetics as specified below:-

Details of samples .....

And whereas I had offered to pay you rupees ..... as the fair price of the samples of drugs/cosmetics taken;

And whereas, you have refused to accept the fair price tendered thereof;

Now, therefore, I give you this receipt as the fair price tendered for the samples of the drugs/cosmetics taken by me.

Date. ....

Inspector ..

FORM 18

[See Rule 57]

Memorandum to Government Analyst

Serial No. of Memorandum .....

From:

To.

The Government Analyst.

The portion of sample/container described below is sent herewith for test or analysis under the provisions of clause (i) of sub-section (4) of section 23 of the Drugs and Cosmetics Act, 1940.

The portion of sample/container has been marked by me with the following mark.

Details of portion of sample or container with name of drug cosmetic which it purports to contain.

.Date ..... Inspector .....

FROM 13

[See Rule 46]

Certificate of test or analysis by Government Analyst under Section 25(1) of the Drugs and Cosmetics Act, 1940

1. Name of Inspector from whom received .....

2. Serial No. and date of Inspector's memorandum .....

3. Number of samples. .....

4. Date of receipt. .....

5. Names of drugs purporting to be contained in the samples.....

6. Conditions of seals on the package or on portion of sample or container. .....

7. Result of test or analysis with protocols of test or analysis applied. .....

In the opinion of the undersigned the sample referred to above is of standard quality as defined in the Drugs and Cosmetics Act. 1940 and Rules thereunder / is not of standard -quality as defined in the Drugs and Cosmetics Act. 1940 and Rules thereunder for the reasons given below: .

Date ..... Government Analyst.....

FORM 19

[See Rule 59(2)]

Application for grant or renewal of a license to sell, stock, exhibit or offer for sale or distribution of drugs other than those specified in Schedule X

1. I/We ..... hereby apply for license for license to sell by wholesale/retail drugs specified in Schedules C and C(I) excluding those specified in Schedule X and/or drugs other than those specified in Schedule C, C(1) and X to the Drugs and Cosmetics Rules, 1945 and also to operate a pharmacy on the premises situated at. .....

2. The sale and dispensing of drugs will be made under he personal supervision of a qualified person, namely:

(Name) .... (Qualification).

(Name)..... ..... (Qualification).

3. Categories of drugs to be sold.

4. Particulars for special storage accommodation.

5. A fee of rupees ..... has been creditcd to Government under the head of account , ...

Date ..... Signature .....

FORM 19-A

[See Rule 59(2)]

Appllication for grant or renewal of a restricted license to sell, stock, ' exhibit [or offer for] sale, or distribute drugs by retail by dealers who do not engage the services of a qualified person

1. I/We ..... of ..... hereby apply for a license to sell by retail (i) Drugs other than those specified in ScheduleC, C(I) and X on the premises situated at ..... or (ii) Drugs specified in Schedule C(I) on the Qremises situated at / Drugs specified in Schedule C(I) as vendor in the area .....

2. Sales shall be restricted to such drugs as can be sold without the supervision or

a qualified person under the Drugs and Cosmetics Rules.

3. Names or classes of drugs proposed to be sold .....

4. Particulars of the storage accommodation for the storage of Schedule C(I) drugs on the premises referred to above. ,

5. The drugs for sale will be purchase from the following dealers and

such other dealers as may be endorsed on the license by the Licensing Authority from time to time,

Name of the dealer..... Signature .....

FORM 20

[See Rule 61(1)

License to sell, stock, exhibit or offer for sale or distribute drugs by retail other than those specified in Schedule, C, C(I) and X

1. ..... is hereby licensed to sell, stock, exhibit or offer for sale or distribute by retail drugs other than those specified in Schedule C C(1) and X of the Drugs and Cosmetics Rules, 1945, and to operate a pharmacy on the premises situated at ..... Subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the rules thereunder .

2. The license shall in force from ..... to .....
.....

3. Name(s) of qualified person(s) in charge.....

4. Categories of drugs ....

Date..... License No. ..... Licensing Authority

Conditions of licence -see statutory form

FORM 20-A

[See Rule 61(1)]

Restricted licence to sell, stock, exhibit or offer for sale or distribute drugs by retail other than those specified in Schedules C, C(I) and X for dealers who do not engage the services of a qualified person

1. ..... is hereby licensed to sell, stock or exhibit or offerfor sale or distribute on premises situated at ..... the following drugs being drugs other than those specified in Schedules C, C(I)

and X of the Drugs and Cosmetics Rules, 1945 subject to the condition specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

2. The license shall be in force from..... to .....

3. The licensee can deal only in such drugs as can be sold without the supervision of a "qualified person" under the Drugs and Cosmetics Rules, 1945.

4. The licensee shall buy drugs only from the following dealers and such other

dealers as may be endorsed on the license by Licensing Authority from time to time.

Name of the dealer..... License No.....

Date ..... Licensing Authority

Conditions of licence -see statutory form

20-B

[See Rule 61(1)

License to sell, stock, exhibit or offer for sale or distribute by wholesale Drugs other than those specified in Schedules C, C(I) and X

1. ..... is hereby licensed to sell, stock, exhibit or offer for sale or distribute by wholesale drugs other than those specified in Schedules C, C(1) and on the premises situated at ..... subject to the conditions specified -below and to the provisions of the Drugs and Cosmetics Act, 1940, and the Rules thereunder.

2. The license shall be in force from ..... to.....

3. The sale shall be made under the personal supervision of a competent person.....

(Name of the competent person .....

4. Categories of drugs .....

Date ..... License No.....

LicensingAuthority

Conditions of licence -see statutory form

FORM 21-A

[See Rule 61(2)]

Restricted license to sell, stock, exhibit or offer for sale or distribute - by retail drugs specified in Schedule C(I) excluding those specified in Schedule X for dealers who do not engage the services of a qualified person

1. ..... is hereby licensed to sell, stock, exhibit or offer for sale or distribute by retail on the premises situated at..... the following drugs being drugs specified in Schedule C (1) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945, subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder .

2. The license shall be in force from..... to.....

3. Particulars of Schedule C(1) excluding those specified in Schedule X drugs to be sold

4. The licensee shall buy drugs only from the following dealers and such other dealers as may be endorsed on the licence by the Licensing authority from time to time.

Name(s) of the dealer(s)

Date ..... Licence No. .....

Licensing Authority .....

Conditions of licence -see statutory form

FORM 21-B

[See Rule 61(2)]

License to sell, stock, exhibit or offer for sale or distribute by wholesale drugs specified in Schedules C and C (1) excluding those specified in Schedule X

1. ..... is hereby licensed to sell, stock, exhibit or offer for sale or distribute by wholesale on the premises situated at ..... the following categories of drugs specified in Schedules C and C(1) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

Categories of drugs

2. The license shall be in force from..... to .....

2-A. The sale shall be made under the personal supervision of a competent person. (Name of the competent person.

3. This license is subject to the conditions stated below and to the provisions of the Drugs and Cosmetics Act, 1940, and the Rules thereunder .

Date ..... License No .....

Licensing Authority

Conditions of licence -see statutory form

FORM 21-C

[See Rule 63-A]

Certificate of renewal of licence to sell, stock, exhibitor offer for sale or distribute drug

Number of license and date of issue .....

I. Certified that license No..... in Forms 20, 20-A, 20-B, 20-F, 20-G, 21, 21-A or 21-B granted on the ..... to ..... for sale of following drugs at the premises situated at..... has been renewed for a period from..... to .....

2.Categories or particulars of drugs .....

3. Name(s) of qualified persons(s) in charge .....

Date:..... Licensing Authority

Conditions of licence -see statutory form

FORM 24

[See Rule 69]

Application for the grant or renewal of a license to manufacture for sale or for distribution of drugs other than those specified in Schedule C, C(I) and X Specified in Schedule C, C(I) and X

1. I/We ..... of ..... hereby apply for the grant/renewal ofa license to manufacture on the premises situated at ..... the following drugs being drugs other than those specified in Schedules C, C(I) and X to the Drugs and Cosmetics Rules, 1945.

2. Names of drugs categorised according to Schedule M.

....

3. Names, qualifications and experience of technical staff employe<;I for manufacture and testing.

4. A fee of rupees. has been credited to Government under the head ofaccount Date Signature Note: The application should be accompanied by a plan of the premises.

FORM 25

[See Rule 70]

License to manufacture for sale or for distribution of drugs other than those specified in Schedule C, C(I) and X

Number of License and date of issue.....

I. ..... is hereby licensed to manufacture the fol-

lowing categories of drugs being drugs other than those specified in Schedules C, C(I) and X to the Drugs and Cosmetics Rules, 1945 on the premises situated at..... Under the direction and supervision of the following competent technical staff:

(a) Competent technical staff(Names) .....

(b) Names of drugs (each item to be separately specified).....

2. The license authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manfuactured under the license. subject to the conditions applicable to license for sale.

3. The License shall be in force from..... to.....

4. The license is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date ..... Signature .....

Designation .....

Conditions of licence -see statutory form

FORM 26

[See Rules 73 and 83]

Certificate of renewal of licence to manufacture for sale of drugs other than those specified in Schedule C, C (1) and X

1. Certificate that licence No..... granted on the to ..... for the manufacture of the following categories of drugs being * drugs other than those specified in Schedules C. C(1) and X drugs specified in Schedules C and C(1) excluding those specified in Schedule X to the Drugs and Costmetics Rules. 1945. at the premises situated at ..... has been renewed from..... to .....

2. Name(s) of competent technical staff .....

3. Names of the Drugs (each item to be separately specified) .....

Date..... Signature.....

Designation .....

Conditions of licence -see statutory form

FORM 26-A

[See Rules 73-A and 83-A]

Certificate of renewal of loan licence to manufacture for sale of drugs other than those specified in Schedule X

1. Certified that a loan licence No. ..... granted on the ..... to ..... for the manufacture of *drugs other than those specified in Schedules C, C(I) and X ..... the undermentioned drugs being drugs specified in Schedules C and C(1) excluding those specified in Schedule X, to the Drugs and Cosmetics Rules, 1945, at the premises situated at ..... Clo ..... has been renewed from ..... to .....

2. Names of the drugs (each substance to be separately specified).

3. Names of the competent technical staff .....

Date ..... Signature.....

Designation.....

Conditions of licence -see statutory form,

FORM 25-B

[See Rule 70]

Licence to repack for sale or distribution of drugs being drugs Other than those specified in Schedules C and C(I) Excluding those specified in Schedule X

Number of licence and date of issue .....

1. ..... of ..... is hereby granted a licence to repack the following drugs for sale or distribution on the premises situated at ..... Under the supervision of the following competent staff:

a) Names of drugs to be repacked .....

b) Names of competent staff .....

2. The licence shall be in force from ..... to .....

3. The licence authorises the sale by way of wholesale dealing by the licensee and storage for sale by the licence of the drugs repakced under the licence subject to conditions applicable to licences for sale.

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date ..... Signature .....

Designation .....

Conditions of licence - see statutory form

FORM 26-B

[See Rule 73-B]

Certificate of renewal of licence to repack for sale or distribution of drugs being drugs other than those specified in Schedules C and C(I) excluding those specified in Schedule X

1. Certified that licence No. ..... granted on the..... to..... for the repacking of the following drugs at the premises situated at..... has been renewed from..... to .....

Names of drugs to be repacked .....

2. Names of competent staff .....

Date ..... Signature .....

Designation.....

Conditions of licence -see statutory form

FORM 27

Application for grant or renewal of a licence to manufacture for sale or for distribution of drugs specified in Schedules C and C(I) excluding those specified in Part XB and Schedule X

1. I/We ..... hereby apply for the grant / renewal ofa licence to manufacture on the premises situated at ..... the undermentioned drugs, being drugs specified in Schedules C and C(I) excluding those specified in Part XB and .X to the Drugs and Cosmetics Ruloes, 1945.

Names of drugs. .....

(each item to be separately specified).....

2. The names, qualifications and experience of the expert staff re-

sponsible for the manufacture and testing of the above -mentioned drugs :

(a) Name(s) of staff responsible for test.....

(b) Name(s)of staff responsible for manufacture .....

3. The premises and plant are ready for inspection

will be ready for Inspection on

4. A fee of rupees..... and an Inspection fee of rupees ..... has been credited to Government under the head of account.....

Date ..... Signature.....

Designation .....

FORM27A

[See Rule 75-A]

Application for grant or renewal of a loan licence to manufacture for the sale or for distribution of drugs specified in Schedules C and C(1) excluding those specified in Part XB and Schedule X

1. I/We ..... of ..... hereby apply for the grant/ renewal of loan licence to manufacture on the premises situated at ..... C/o..... the undermentioned drugs, being drugs specified in Schedules C and C(I) excluding those specified in Part XB and Schedule X to the Drugs and Cosmetics Rules, 1945.

Names of drugs (each substance to be separately specified).....

2. The names, qualification and experience of the expert staff actually connected with the manufacture and testing of the specified products in th manufacturing premises :

(a) Name(s) of expert staff responsible for manufacture .....

(b) Name(s) of the expert staff responsible for testing .....

3. I/We enclose :

(a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is inteneded to be utilised by me / us.

(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their expert staff, equipment and premises for manufacture of each item required by me / us and that they will analyse every batch of finished products and maintain the registers of raw materials, finished products and reports of analysis separately on this behalf.

(c) Specimens of labels, cartons of the products proposed to be manufactured.

4. A fee of rupees. has been credited to Government under the head of account.....

Date ..... Signature .....

FORM 27-8

Application for grant or renewal of a licence to manufacture for sale- or for distribution of drugs specified in Schedules C, C(I) and X

1. I/We ..... of ..... hereby apply for the grant / renewal of a licence to manufacture on the premises situated at ..... the undermentioned drugs, specified in Schedules C, C(1) and X to the Drugs and Cosmetics Rules, 1945.

2. Names of drugs. .....

3. The names qualifications and experience of the expert staff responsible for the manufacture and testing of the above-mentioned drugs.

(a) Name(s)of staff responsible for test.....

(b) Name(s) of staff responsible for manufacture .....

4. The premises and plant are ready for inspection / will be ready for inspection on. .....

5. A fee of rupees ..... and an inspection fee of rupees ..... has been credited to the Government under the head of account .....

Date: ..... Signature.....

The application shall be accompanied by a plan of the premises.

FORM 27-C

[See Rules 122-F]

A pplication forgrant or renwal of licence for the O peration of Blood Bank, processing of Whole Human Blood for Components and / or manufacture of blood products

I. I/We ..... of ..... hereby apply for the grant / renewal of licence to operate a Blood Bank, processing of Whole Human blood for components and / or manufacture of blood products.

Names of the Human Blood Components intended to be processed shall be specified.

2. The names, qualifications and experience of expert staff :

(a) Name(s) of Medical Officer.

(b) Name(s) of Registered Nurse.

(c) Name(s) of Blood Bank Technician. ,

3. The premises and plan are ready for inspection /will be ready for inspection on .....

4. A fee of rupees ..... and an inspection fee of

rupees ..... has been credited to the Government under the head of account.....

Date ..... Signature.....

Designation.....

FORM 27-D

[See Rule 75]

Application for grant or renewal of a licence to manufacture for sale or for distribution of Large Volume Parenterals / Sera and Vaccines excluding those specified in Schedule X

1. I/We ..... of ..... hereby apply for the grant / renewal of a licence to manufacture for sale or distribution on the piemises situated at ..... the under mentioned Large Volume Parenterals / Sera and Vaccines, specified in Schedules C and C(I) to the Drugs and Cosmetics Rules, 1945.

2. Name(s) of drug (s).....

(each item to be separately specified)

3. The name(s), qualifications and experience of the competent technical staff responsible for the manufacture of the above-mentioned drugs.

(a) Name(s) of staff responsible for testing .....

(b) Name(s) of staff responsible for manufacture .....

4. The premises and plant are ready for inspection / will be ready for inspection on. .....

5. A fee of rupees ..... and an inspection fee of Rupees ..... has been credited to the Government under the Head of Account .....

Date ..... SIgnature .....

Designation .....

FORM 28

[See Rule 76]

Licence to manufacture for sale or for distribution of drugs specified In 'Schedules C and C(I) excluding those specified in Schedule X

Number of licence and date of issue .....

1. ..... is hereby licenced to manufacture at the premises situated at ..... the following drugs, being drugs specified in Schedules C and C(I) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

Names of drugs .....

2. Names of competent technical staff .....

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licences for sale.

4. The licence shall be in force from to .....

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

.Date of issue..... Signature.....

Deslgnatlon .....

Conditions of licence -see statutory form

FORM 30

[See Rule 90]

Application for licence to manufacture drugs for Purposes of examination, test or analysis

I ..... of ..... by occupa-

tion..... hereby apply for a licence to manufacture the drugs specified below for purposes of examination, test or analysis at ..... and I undertake to comply with the conditions applicable to the licence.

Names of drugs

Date : ..... Signature .....

FORM 29

[See Rule 89]

Licence to manufacture drugs for purposesof examination, test or analysis

I ..... of ..... is hereby licensed to manufacture the drugs specified below for purposes of examination. test or analysis at. .....

2. The licence is subject to the conditions prescribed in Part VIII of the drugs and Cosmetics Rules, 1945.

3. The licence shall be in force for one year from the date specified below:.

Names of drugs

Date ..... Licensing Authority .....

Conditions of licence -see statutory form

FORM 31

[See Rule 139]

Application for grant or renewal of a licence to manufacture Cosmetics for sale or for distribution

1. I/We ..... of ..... hereby

apply for the grant / renewal of a licence to manufacture on the premises situated at ..... the following cosmetics.

2. Names of cosmetics .....

3. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises .....

4. I/We enclose :

(a) A true copy of a letter from me / us to the manufacturing concern whose manufacturing capacity is intended to be utilised by me / us.

(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their expert staff, equipment and premises for the manufacture of each item required by me / us and that they will analyse every batch of and mainain the registers of raw materials, finished products and report of analysis separately in this behalf.

Specimens oflabels, cartons of the products proposed to be manufactured.

5. A fee of rupees ..... has been credited to Government under the head of account .....

Date..... Signature .....

FORM 32

[See Rule 140]

Licence to manufacture cosmetics for sale or for distribution

Number of licence and date of issue .....

I, ... is hereby licensed to manufacture on the premises situated at ..... the following cosmetics under the supervision of the following technical staff :

(a) Names of cosmetics

(b) Names of the technical staff

2. The licence shall remain in force from..... to..... (both days inclusive).

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Drugs and Cosmetics Rules, 1945.

Date ..... Signature .....

Designation.....

Conditions of licence -see statutory form

FORM 32-A

[See Rule 139-8]

Loan licence to manufacture cosmetics for sale or for distribution

1. Number of licence and date of issue .

2. ..... of ..... is hereby granted a loan licence to manufacture the following cosmetics on the premises situated at..... C/o ..... under the direction and personal supervision of the following technical staff :

(a) Namesofthetechnical staff .....

(b) Names of cosmetics .....

3. The licence shall remain in force from..... to.....

4. The licence is subject to the conditions stated below and to such other conditions as are specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date ..... Signature .....

Designation.....

Conditions of licence -see statutory form

FORM 35

[See Rules 65,67-0,74, 74-A, 74-B, 78, 78-A, 85-H, 142, 142-A, 158 and 158-A]

FORM IN WHICH THE INSPECTION BOOK SHALL BE MAINT AINED

A. The cover of the Inspection Book shall contain the following particulars, namely:

1. The name and address of the Licensee .....

2. Licence number and the date upto which the licence is valid.....

B. (1) The pages of the Inspection Book shall be serially numbered and dulystamped by the Licensing Authority. The pages, other than the first and the last pages, shall have the following particulars :

Name and designation of the Inspector who inspects the premises of the Licensee .....

Date of Inspection .....

Observations of the Inspector .....

Signature of the Inspector

(ii) the first and last pages of the Inspection Book shall be enclosed by the Licensing Authority with the following words, namely:

Inspection Book maintained by M/s. ..... situated at ....for licence number..... in Form..... under Drugs and Cosmetics Rules

SEAL AND SIGNA TURE OF THE LICENSING AUTHORITY.

STATEMENT SHOWING THE D.P.C.O. CASES FOR THE PERIOD DURING

S I No.	Name of the Drug B.No. D/M & D/E	Name of the firm and address	Lr. No. and date of RAD/D.I.	Decision taken in R.C. Meeting required by	Remarks
1	2	3	4	5	6

PROFORMA - I

Month and year :

1. STATEMENT SHOWING THE ACTION TAKEN OF NOT OF STANDARD QUALITY DRUGS

Sl. No.	Name of the Drug and Batch No.	Name of the Manufacturer and address	Report No. date and reasons for Not of Stand-ard Quality	Sample picked upby	Action taken including recalls of the drug	Final action taken
1	2	3	4	5	6	7

PROFORMA - II

II. PROSECUTION REGISTER (NOT STANDARD QUALITY/SPURIOUS)

Sl. No.	Name of the Drug and Batch No.	Name of the Manufacturer and address	P.O. issued to D.I RC.No. and date	Date on which Charge sheet filed	Judgement delivered on date	Convicted / Acquitted	Whether preferred appeal
1	2	3	4	5	6	7	8

PROFORMA - III

II. PROSECUTION REGISTER (SEIZURES)

Sl. No.	Details of the seizure includ-ing value	Name of the accused	P.O. issued to D.I RC.No. and date	Date on which Charge sheet filed	Judgement delivered on date	Convicted / Acquitted	Whether preferred appeal
1	2	3	4	5	6	7	8

WATCH REGISTER OF RENEWALS OF MANUFACTURING LICENCES

Sl. No.	Name of the firm	Forms Drug Licence No. & date	Validity of the Licence	Periods of renewal
1	2	3	4	5

STATEMENT SHOWING THE PARTICULARS FO ALLOTMENT IN LIFTING OF NARCOTIC DRUGS FOR THE PERIOD

Allotted to the A.P. State DCA Hyderabad	PETHIDINE in kgs	MORPHINE in Kgs	CODEINE IN Kgs	MEDICINAL OPIUM in Kgs.	DEXTROPROPOXYPHENE HCL IN Kgs
Realloted to the firms by Drugs Control Admn. Andhra Pradesh					

Sl.	Name of the firm	Alloted	Lifted	Bal.	Alloted	Lifted	Bal.	Alloted	Lifted	Bal.	Alloted	Lifted	Bal	Alloted	Lifted	Bal

Govt. of Andhra Pradesh

STORES SECTION

OFFICE OF THE INSPECTOR GENERAL, DRUGS & COPYRIGHT,

DRUGS CONTROL ADMINISTRATION HYDERABAD

STOCK REGISTER OF CHEMICALS, CLASS WARE AND EQUIPMENTS ETC.

Name of the A rticle

Date	Particulars of transaction	Quantity received	Issued	Balance	Remarks
1	2	3	4	5	6

BUDGET CONTROL REGISTER
STORES SECTION

Sl. No.	Name of the Firm	Bill No.	Date	Amount	Balance	Signature of the Stores Officer
1	2	3	4	5	6	7

ఆంధ్రప్రదేశ్ ప్రభుత్వం ఔషధ నియంత్రణ ప్రయోగ శాల

ఔషధ నియంత్రణ పరిపాలన శాఖ, హైదరాబాద్

ఔషధముల విశ్లేషణ తెలియజేయు పట్టిక పుస్తకం నమూనా

నివేదిక సంఖ్య	ప్రయోగశాల సంఖ్య	ఔషధం పేరు బ్యాచ్ సంఖ్యయు	తయారు చేయువారి పేరు	వర్గం	ఔషధం ఏ సంస్థ నుండి తీసినది	ఔషధ తనిఖీ అధికారి పేరు	ఫలితం	తేది	విశేషాంశములు
1	2	3	4	5	6	7	8	9	10

ఆంధ్రప్రదేశ్ ప్రభుత్వం ఔషధ నియంత్రణ ప్రయోగ శాల

ఔషధ నియంత్రణ పరిపాలన శాఖ, హైదరాబాద్

ఔషధముల విశ్లేషణ నిమిత్తము ముట్టిన ఔజిళ్ళరు నమూనా

ప్రయోగ శాల సంఖ్య	షారం 18 ఏ నమూనా నిర్దేశ సంఖ్య, తనిఖీదారు పేరు, స్థలం	ఔషధం పేరు బ్యాచ్ సంఖ్య	తయారు చేయువారి పేరు	ఔషధం అందిన తేది	వర్గం	ఔషధం ఏ సంస్థ నుండి తీసినది	ఔషధపు పరిమాణం	ఔషధపు వాడుక గడువు ముగియు తేది	విశ్లేషణ ఫలితము		అభిప్రాయం
1	2	3	4	5	6	7	8	9	10	11	12

FORMAT OF CONSOLIDATED MONTHLY STATEMENT OF PERFORMANC EOF DRUGS CONTROL LABORATORY SUBMITTED BY SENIOR SCIENTIFIC OFFICER /GOVT. ANALYST

MONTHLY STATEMENT FOR THE MONTH OF ------ 1999

1. No. of Samples pending at the end of previous month
2. No. of samples received during the month
3. Total No. of samples at the end of the current month
4. Total No. of samples analysed during the month
5. Total No. of samples pending at the end of the month

SENIOR SCIENTIFIC OFFICER
AND GOVERNMENT ANALYST
DRUGS CONTROL DEPARTMENT
HYDERABAD

FORMT OF CONSOLIDATED STATEMET OF PERFORMANCE FOR THE LAST THREE MONTHS

COMPARATIVE STATEMENT OF THE SAMPLES ANALYSED RE-PORTS DURING THE LAST THREE MONTHS

	Month 1	Month 2	Month 3
1. No. of samples analysed			
2. No. of smaples found to be Standard Quality			
3. No. of Samples found to be Not of standard Quality			

SENIOR SCIENTIFIC OFFICER
AND GOVERNMENT ANALYST
DRUGS CONTROL DEPARTMENT
HYDERABAD

MONTHLY STATEMENT OF SAMPLES ANALYSED OF DRUGS/ COSMETICS MANUFACTURED WITHIN THE STATE AND OUTSIDE THE STATE

Samples Analysed under	No. of samples declared Standard Quality		No. of samples declared Not of Standard Quality	
	Units located in A.P. State	Units located outside A.P.	Units located in A.P. State	Units located outside A.P.
ACT SAMPLES				
1. Manufacturing Units				
2. Wholesale Trade				
3. Retail Trade				
4. Vet. Trade Samples				
HOSPITAL SAMPLES				
1. State Govt. Hospitals				
a) A.P.V.V.P.				
b) D.M & H.O. & PHCs				
c) Teaching Hospitals/ Stores				
3. Central Govt. Hospls.				
a) Govt. Medical Stores Dept.				
b) CGHS Dispensaries				
c) Public Sector Hosp.				
d) ESI Hospital/Stores				
4. Non- statutory Samples				

SENIOR SCIENTIFIC OFFICER
AND GOVERNMENT ANALYST

MONTHLY STATEMENT FOR THE MONTH OF 99

1. No. of samples analysed
2. No. of sampels found Standard Quality
3. No. of samples found to be Not of Standard Quality

FORMAT OF PERFORMANCE REPORT OF JUNIOR SCIENTIFIC OFFICER / JUNIOR ANALYST IN DRUGS CONTROL LABORATORY

DAILY PERFOMACE REPORT CONSOLIDATED FOR THE MONTH OF

Name of the Junior Scientific Officer /Junior Analyst

Sl No.	Date of Analysis	Nature of Analysis	Number of Ingredients	Remarks
1	2	3	4	5

INDIVIDUAL MONTTHLY STATEMENT OF ANALYSIS REPORT OF JUNIOR SCIENTIFIC OFFICER /JUNIOT ANALYST

Name of the month :
Name of the JSO /Junior Analyst :

Sl. No.	No. of Samples pending on the last day of previous month	No. of Samples alloted for the month	No. of Samples analysed durign the month	No. of samples pending at the end of the month	No. of days attended to analysis work during the month	Remarks
1	2	3	4	5	6	7

Date : Signature of the JSO/ Junior Analyst

MONTHLY PERIODICAL REPORT OF PERFORMANC EOF JUNIOR SCIENTIFIC OFFICER IN DRUGS CONTROL LABORATORY

Periodical report for the month of

UNIT

1. No. of samples pending at the end of previous month.
2. No. of samples received during the month
3. Total No. of Samples as on
4. Total No. of sampels analysed during the month
5. Total No.of sampels pending as on

S.No.	Name of the JSO /Jr. Analyst	No. of samples analysed
1.		
2.		
3.		
4.		
5.		

Note :

UNIT OFFICER

MONTHLY DETAILED STATEMENT PARTICULARS OF NOT OF STANDARD QUALITY DECLARED DRUGS

Sl. No.	Code no. Place of Drugs Inspector	Name of the product	Name of the Manu-facturer	Mfg. Date	Exp. Date.	Source	Remarks
1	2	3	4	5	6	7	8

GOVERNMENT ANALYST

MONTHLY PERFORMANCE REPORT OF SENIOR SCIENTIFIC OFFICER /GOVERNMENT ANALYST SUBMITTED TO INSPECTOR GENERAL / DIRECTOR /J.D. (ENFORCEMENT) INCORPORATING THE UNIT OFFICERS PERFORMANCE

Performance report for the month of

Name of the Unit :

Sl. No.	Name of the JSO/Jr. Analyst	No.of samples pending from the previous month	No. of samples alloted for the month	Total no. of samples	No. of samples analysed during the month	No. of Ingredients	No of samples pending on the last day of the month	No. of days attended the office	Reasons for pending	Remarks of S.S.O./ Govt. Analyst
1	2	3	4	5	6	7	8	9	10	11

SIGNATURE OF SENIOR SCIENTIFIC OFFICER GOVT. ANALYST

FORMAT OF ANNUAL SELF APPARASIAL REPORT

ANNEXURE

FORM -A

PART - I

(TO BE FILED BY THE OFFICER REPORTED UPON)

1. A brief summary of duties and responsibilities (not more than 50 words)

2. Please specify important items of work in order fo priority where in quantitative /physical /financial targets /objectives /goals were set for you or set by y ourself for the reporting year and achievements made.

Item of work	Physical or financial target /objective /goal	Achievement

3. a) In case of a shortfall of expected quality/ quantity of performanc eplease state the reasons.

b) Please indicate your contribution in case of significantly higher achievement of the targe /goal /objective.

Name & Signature

of the Officer

FORM - A
PART -II

FORMAT OF ANNUAL CONFICENTIAL REPORT OF GAZETTED OFFICERS FOR THE YEAR

1. Name of the Officer :

2. Appointment held during the (with dates and Scale of pay :

3. General qualifications and aptitude for post held including any apecial or technical

4. a) Acceptance or otherwise of the self appraisal report of the Gazetted Officer Indicated in Part - I and if not agreed to the resons therefore.

   b) Manner in which the Officer discharged his duties during the year i.e., if satisfactorily or otherwise (specific on instances of unsatisfactory work of adversely commented on to be cited with number and date of orders passed.

5. Does the Officer exhibit :

   a) patience

   b) Tact

   c) Courtesy

d) Impartiality in his relations with the Public and subordinate or superior Staff with whom he comes in contact ?

6. Is the Officer

   i) Of good character ?

   ii) Of sound constitution ?

7. Is the Officer :

   i) Physically enrgetic ?

   ii) Mentally alert ?

8. Has the Officer.

   i) Initiative and drive ?

   ii) Powers of control ?

   iii) Power of application ?

9. Has the Officer any special characteristic and I or any outstanding merits or abilities which would justify his advancement and special selection for higher appointment in the service ?

10. Is the confirmed in this post ?
    If not, what is his substanctive Post ?

11. Punishments, censures or special commendations in the period under report.

12. a) Date of Communication of adverse remarks since last report.

    b) Orders on the representation if any arising from (a) above.

13. General remarks (comment generally on the way the Officer has carried put his duties estimate of his personality etc.)

14. Grading :

i) Outstanding

ii) Very Good

iii) Good

iv) Satisfactory

v) Poor

(Clearly indicate the reason for grading of the Officer)

15. Reporting Officer :

Date :

SIGNATURE
NAME AND DESIGNATION
(IN BLOCK LETTERS)

16. Remarks of the counter signing Officer :

Date :

SIGNATURE
NAME AND DESIGNATION
(IN BLOCK LETTERS)

17. Opinion of the Head of the Department (when not reporting Officer) on Conduct and efficiency of Officer reports on.

Date :

SIGNATURE
NAME AND DESIGNATION
(IN BLOCK LETTERS)

FORM - E.R. - I

Format of Quarterly Return to be submitted to the Local Employment Exchange for the Quarter ended : 31.12.199

The following information is required under Employment Exchanges (Compulsory Notification of, Vacancies) Rules 1960 to assist in evalutation trends in employment and for action correct imbalances between labour supply and demand.

NAME AND ADDRESS EMPLOYER : O/o Inspetor General
Drugs and Copyright
Drugs Control Administration
Vengalraonagar, Hyderabad

WHETHER HEAD OFFICER / BRANCH OFFICE : Directorate

NATURE OF BUSINESS : Enforcement of Drugs and Cosmetics Act.

PRINCIPAL ACTIVITY

1(A) Employment :

Total number of persons working proprietor /partners contingenment paid contractual worker on the pay roll of the establishment excluding part time worker and apprenticeship (the figure should include every every persons whose wage of salary is paid by the establishment.

	ON LAST WORKING DAY OF THE PREVIOUS QUARTER AS ON 30 -09 - 1999	ON THE LAST WORKING DAY OF PRESENT QUARTER 31 -12 - 1999
MEN		
WOMEN		

a) Number of vacancies occurred and notified during the quarter and the number filled during the quarter

Quarter Occurred	Notified Local Employment	Central Employment Exchange	Filled	Sources Describe the source s filled
1	2	3	4	5

2. (b) Reasons for not notifying the vacancies occurred during the Quarter under the report vide 2(a) above.

3. MAN POWER SHORTAGES :

VACANCIES /POSTS UNFILLED BECAUSE OF THE SHORTAGE OF SUITABLE APPLICANTS :

Name of the Occupation or designation of the posts.	Number of Unfilled vacancies /Posts		
	Essential Qualification prescribed	Essential Experienced	Experience not necessary
1	2	3	4

Should be sent to :

To
Regional Employment Officer
Regional Employment Exchange
H.No.1-1-79, Bhagyanagar Complex
R.T.C. X Road, Hyd -20

This return should be sent relate to quarter ending 31s March 30 th June /30th June /30the September and 31 st December and shall be rendered to Local Employment Exchange within 30 days after the end of the Quarter concerned.

FORM - II

FORMAT OF OCCUPATIONAL RETURN TO BE SUBMITTED TO THE LOCAL EMPLOYMENT EXCHANGE ONCE IN TWO YEARS AS ON 30 TH SEPTEMBER,199

Vide the Employment Exchange (compulsory notification of vacancies) Rules, 1960

Name and address ot the Employer :

Nature of busines (Please Describe what the Estt. Makes of does as its Principal activity).

1. Total number of persons on the pay rolls of the Estt. On (Specified date).
2. Occupational classification of all employees as given in item 1 above (please give below the number fo employees in each occupation separately).

Occupation	Number of Employees			
Use exact terms such as Engineer (Mechanical) Teacher (domestic Science) Officer on Special Duty (Actuary), Asst. Director (Metallurgist), M Scientific Asst. (Chemist) Research Office (Economist) Instructor (Carpenter) Supervisor (Tailor) Fitter, (Int ernal Combuston Engine) Inspector (Sanitary) Supdt. (Office) Apprentice (Electrician)	Women	Men	Total	Please give as far as possible approximate number of vacancies in each occupation you are likely to fill during the next calendar year due to retirement, expansion of reorganisation.
1	2	3	4	5

1	2	3	4	5

Date :

To
The Employment Exchange ,

Note, Total of Col (4) of under item 2 should correspond to the figures given agains titem No. 2.

SIGNATURE OF EMPLOYER

FORMAT OF STATEMENT OF VACANCIES REPORTED TO THE COLLECTOR /GENERAL ADMINSTRATION (I.C) DEPARTMENT
AS ON
(IN TERMS OF G.O.MS. NO. 215, G.A. (SER.A) DEPARTMENT, DATED : 03 -04-1993

NAME OF THE DEPARTMENT /OFFICE : INSPECTOR GENERAL, DRUGS AND COPYRIGHT, DRUGS CONTROL, ADMINISTRATION, ANDHRA PRADESH, HYDERABAD.

PART - I

STATEMENT OF VACNACIES

Sl. No.	Category	Total No of Vacancies				Total	Reason for post remaining vacant and whether the vacancies have been notified to the appropriate recruiting agency	Whether any applicant (s) for compassionate appointment (s) pending if so the dae (s) of such application (s)	REMARKS
1	2	3	4	5	6	7	8	9	10

PART - II

PROPOSALS FOR PLACEMENT /INTIMATION REGARDING APPOINTMENT OF BENEFICIARY

Sl. No.	Name of the deceased employee or employee retired on medical invalidation post held date of demise / retirement on medical invalidation	Name of the beneficiary pot for which the beneficiary is qualified dated of application made for compassionate appointment	Whether the beneficiary can be appointed to an existing vacancy by the appointing authority himself subject to the provisions of the Rule of Reservation	The date fo which the vacancy was utilised for appointing the beneficiary and the date fo which the act of utilising vacancy wa intimated to the collector /G.A.(IC)	In case the beneficiary cannot be accommodated in the office /unit for want of an appropriate vacancy, the date on which proposals for his placement were notified to the collector /G.A.(IC) Dept.	Remarks
1	2	3	4	5	6	7

PART - II

PROPOSALS FOR PLACEMENT /INTIMATION REGARDING APPOINTMENT OF BENEFICIARY

Reservation brought forward from previous years			Recruitment (Specify calendar year)	Cycle No year and point number of the vacancy in the Cycle of rotation	Specify whether the vacancy unreserved/ for SCs/ STs/BCs (Groups ABCD according tot he rule of rotation	Name of the person appoint and date fo appoint-ment	Whether he is SC/ ST/BC (with group details)	If any open competi-tion candidate has been appointe against reserved vacancy please indicate whether permission of Government was obtained and furnish the No. of the Govern-ment order permitting such appointment	Reserva-tion carried forward to next recruitment			Signature of the appointing authority	Remarks
SCs	STs	PH							SCs	STs	PH		
1	2	3	4	5	6		7	8	9	10	11	12	13

CONSOLIDATED MONTHLY PERFORMANCE REPORT OF DRUGS INSPECTORS IN THE REGION SUBMITTED BY REGIONAL ASSISTANT DIRECTORS PROFORMA

Sl. No.	Particulars	DRUGS INSPECTOR OFFICES									Total
		1	2	3	4	5	6	7	8	9	
	No. of Inspections										
	a. Manufacturing Units										
	b. Blood Banks.										
	i. Government										
	ii. Private										
	c. Re-packing Units										
	d. Cosmetic Units										
	e. Sales Concerns										
	i. Detailed Inspections										
	ii. Routine Inspections										
	f. Hospitals										
	i. State - Government										
	ii. Central Government /ESI										
	iii. PVt. Nursing Homes & Others										
	1. No. of violations detected under Drugs & Cosmetics Act 1940 & Rules 1945										
	2. No. of D.P.C.O.Cases										
	a. Scrutinised										
	b.Violations Detected and Reported										
	SEIZURES										
	No. of Sample Sent for text /Analysis										
	1. To the Drugs Control Labs, Hyderabad.										
	a. State Govt. Hospitals										
	b. Cental Govt. Hospitals										
	C. E.S.I. Hospitals /Dispensaries										
	d. E.S.I Dispensaries										
	e. Manufacturing Units										
	f. Trade										
	g.Others										

Sl. No.	Particulars	DRUGS INSPECTOR OFFICES									TOTAL
I	2. To the Drugs Control Lab. Vijayawada a. State Govt. Hospitals b. Central Govt. Hospitals c. E.S.I Hospitals/Dispensaries d. Manufacturing Units e. Trade f. Others	1	2	3	4	5	6	7	8	9	
V	No. of Certificates of Test/Analysis Received										
	1. Manufactured within the state a. Declared as standard quality b. Declared as not of standard Quality.										
	2. Manufactured Outside the State a. Declared as standard quality b. Declared as not of standard quality.										
	3. Pending Analysis a. with Vijayawada Lab b. With Hyderabad Lab										
VI.	No. of Licences issued / recommanded a. Drug manufacturing Units b. Re-packing units c. Blood Banks. d. Cosmetics Units										
	2. Sales Concerns - Licences issued										
	1. Medical Shops a. Retail b. Retail & Wholesale c. Wholesale										
	II. House Hold Remedies a. Retail b. Retail & Wholesale c. Wholesale										

Sl. No.	Particulars	DRUGS INSPECTOR OFFICES									TOTAL
		1	2	3	4	5	6	7	8	9	
VII	For Renewals 1. a. Drugs Manufacturing Units b. Re-packing Units c. Blood Banks d. Cosmetics Units										
	2. Sales Concerns Renewed 1. Medical Shops a. Retail b. Retail & Wholesale c. Wholesale										
	2. House hold Remedies a. Retail b. Retail & Wholesale c. Wholesale I										
VIII	No. of Complaints a. Received b. Investigated										
IX.	Value of Drugs Recalled										
X	Value of NSC Bonds/ Small Saving Etc.										
XI	Consolidated Expenditure Statement 1. Plan 2. Non-Plan										
XII	Revenue Realised/Collected 1. by way or Fresh Licences 2. By way of Renewals 3. By way of Penality (additional Fee) 4. Others										
XII	Total No. of suspensions in the month										
XIII	No. of Cancellations in the month										
XVI	Total no. of warning issued in the month										
	Total										

Regional Assistant Directr

Monthly Statement of Details of Departmental actions taken on sales concerns submitted by regional Assistant Directors

Sl. No.	Particulars	DRUGS INSPECTOR OFFICES									TOTAL
		1	2	3	4	5	6	7	8	9	
1.	No. of violations reported										
2.	No. of Shows cause notice issued										
3.	No. of suspensions of Drugs Licences										
4.	No. of Cancellations of Drugs Licence										
5.	No. of Warning issued										
6.	No. of pending actions										
7.	No. of Cases Referred to Directorate										

PROFORMA - 2

Sl. No.	Particulars	DRUGS INSPECTOR OFFICES									TOTAL
		1	2	3	4	5	6	7	8	9	
1.	No. of violations reported										
2.	No. of Inspection reports received										
3.	No. of show cause noticed issed										
4.	No. Inspection reports yet to be received										
5.	No. of DPCO violations detected										
6.	No. DMRO violations detected										

REGIONAL ASSISTANT DIRECOTR

MONTHLY PERFORMANCE REPORT OF DRUGS INSPECTORS SUBMMITTED TO REGIONAL ASSISTANT DIRECTOR - PROFORMA

Sl. No.	Particulars	Name of the Drugs Inspector Office
I	No. of Inspections	
	a. Manufacturing Units	
	b. Blood Banks.	
	i. Government	
	ii. Private	
	c. Re-packing Units	
	d Cosmetic Units	
	e. Sales Concerns	
	i. Detailed Inspections	
	ii. Routine Inspections	
	f. Hospital	
	i. State-Government	
	ii. Central Government/ ESI	
	iii. Pvt. Nursing Homes & Others	
II	1. No. of violations detected under Drugs & Cosmetics Act 1940 & Rules 1945	
	2. No. D.P.C.O. Cases	
	a. Scrutinised	
	b. Violations Detected and Reported	
III	Seizures	
IV.	No. of Samples Sent for test / Analysis	
	1. To the Drugs Control Labs, Hyderabad.	
	a. Satate Govt. Hospital	
	b. Central Govt. Hospitals	
	c. E.S.I Hospitals/ Dispensaries	
	d. E.S.I Dispensaries	
	e. Manufacturing Units	
	f. Trade	
	g. Other	

Contd...2.

Sl. No.	Particulars	Name of the Drugs Inspector Office
I	2. To the Drugs Control Lab. Vijayawada a. State Govern. Hospitals b. Central Govt. Hospitals c. E.S.I Hospitals/ Dispensaries d. Manufaturing Units e. Trade f. Other	
V	No. of Certificates of Test/ Analysis Received	
	1. Manufactured within the state a. Declared as standard quality b. Declared as not of standard quality	
	2. Manufactured Outside the state a. Declared as standard quality b. Declared as not of standard qulity	
	3. Pending Analysis a. With Vijayawada Lab b. With Hyderabad Lab	
VI	No. of Licences issued / recommanded 1. For Fresh / grant-recommended a. Drug Manufacturing Units b. Re-packing Units c. Blood Banks d. Cosmetics Units	
	2. Sales Concerns - Licences Issued	
	1. Medicals Shops a. Retail b. Retail & Wholesale c. Wholesale	
II	House Hold Remedies a. Retail b. Retail & Wholesale c. Wholesale	

Sl. No.	Particulars	Name of the Drugs Inspector Office
VII	For Renewals 1. a. Drugs Manufacturing Units b. Re-packing Units c. Blood Banks d. Cosmetics	
	2. Sales Concerns Renewed 1. Medical shops a Retail b. Retail & Wholesale c. Wholesale	
	2. House hold Remedies a. Retail b. Retail & Wholesale c. Wholesale I	
VIII	No. of Complaints a. Received b. Investigated	
IX	Value of Drugs Recalled	
X	Value of NSC Bonds/Small Saving Etc.	
XI	Consoildated Expenditure Statement 1. Plan 2. Non-Plan	
XII	Revenue Realised / Collected 1. by way or Fresh Licences 2. By way of Renewals 3. By way of Penality (additional Fee) 4. Others	
XII	Total No. of suspensions in the month	
XIII	Total No. of warning received in the month	
	Total	

DRUGS INSPECTOR

यदैव विद्यया करोति श्रध्दयोपनिषदा
तदैव वीर्यवत्तरं भवति

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

Dr. MCR Human Resource Development Institute of Andhra Pradesh
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