DRUGS CONTROL ADMINISTRATION,A.P.

(Aims and Objectives)

Health is a Fundamental Right granted by the Constitution of India.

The Drugs Control Administration aims at assuring the availability of drugs & Cosmetics of proven quality, efficacy and safety at prices as announced. In addition, it also guards the public from the exploitation of misleading advertisements .

DRUGS CONTROL ADMINISTRATION, A.P. enforces

- Drugs & Cosmetics Act 1940 and Rules 1945,
- Drugs & Magic Remedies (OA) Act 1954 and Rules 1955,
- Drugs (prices Control) Order 1995 (an Order made u.s. 3 of Essential Commodities Act 1955),
- Narcotic Drugs & Psychotropic Substances Act 1985 and A.P. N.D&P.S. Rules 1986,
- Cigarettes & Other Tobacco products (prohibition of advertisements and Regulation of Trade & Commerce, production, supply and Distribution) Act, 2003

Act & Rules.

The Drugs and Cosmetics Act 1940

&

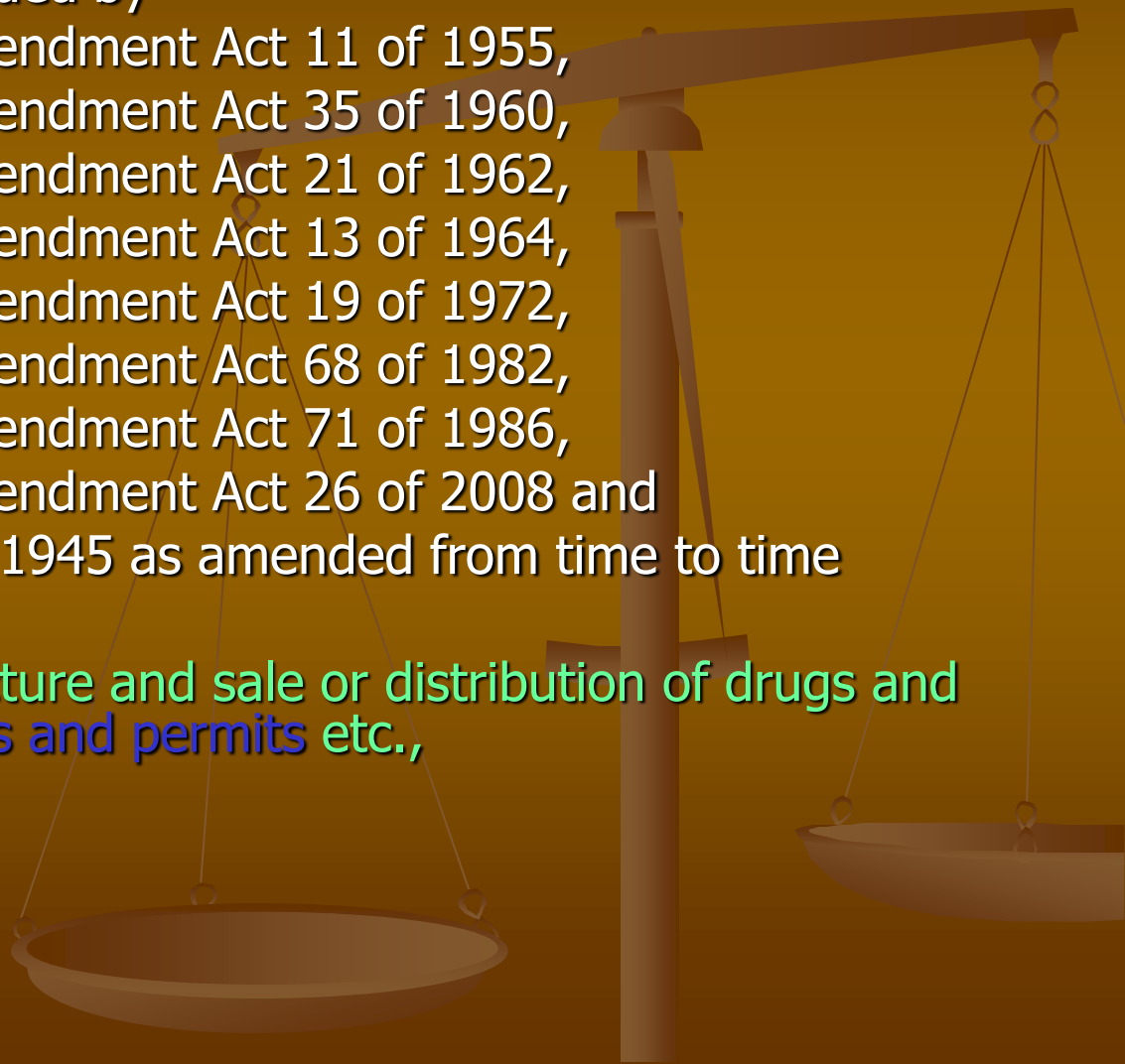
The Drugs and Cosmetics Rules 1945

(as amended from time to time)

Drugs & Cosmetics Act 1940 and Rules 1945

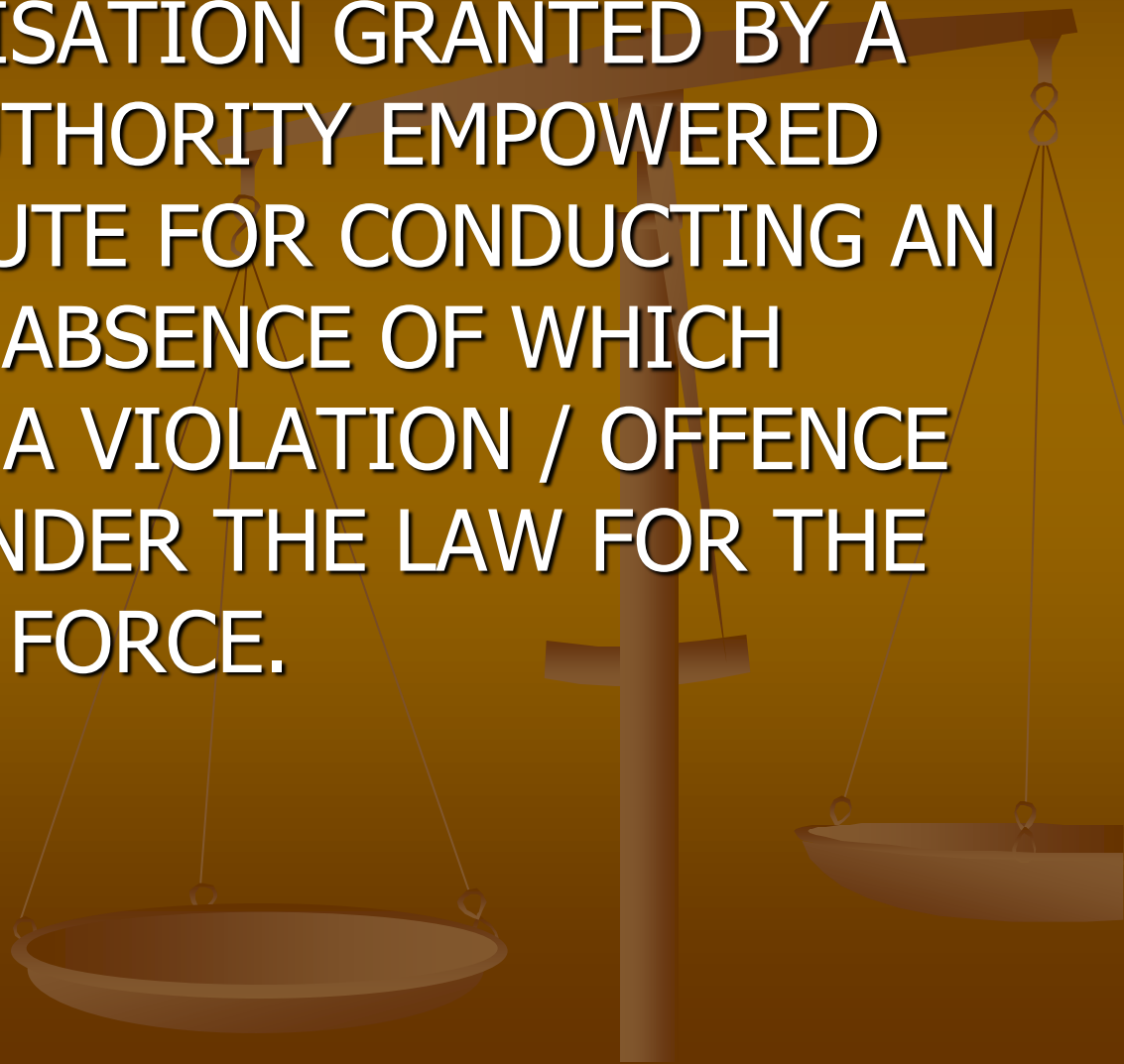
Drugs Act 1940 as amended by
Amendment Act 11 of 1955,
Amendment Act 35 of 1960,
Amendment Act 21 of 1962,
Amendment Act 13 of 1964,
Amendment Act 19 of 1972,
Amendment Act 68 of 1982,
Amendment Act 71 of 1986,
Amendment Act 26 of 2008 and
The Drugs & Cosmetic Rules 1945 as amended from time to time

Regulate the import, manufacture and sale or distribution of drugs and cosmetics through Licenses and permits etc.,



Licences / Permits to Regulate

IS AN AUTHORISATION GRANTED BY A STATUTORY AUTHORITY EMPOWERED UNDER A STATUTE FOR CONDUCTING AN ACTIVITY, THE ABSENCE OF WHICH CONSTITUTES A VIOLATION / OFFENCE PUNISHABLE UNDER THE LAW FOR THE TIME BEING IN FORCE.



SCHEME OF THE ACT and RULES

- THE ACT ------ SIX CHAPTERS.
- Chapter I:-PRELIMINARIES &DEFINITIONS
- Chapter II:- CDL,DCC,DTAB
- Chapter III:-IMPORT OF DRUGS & cosmetics
- Chapter IV:-MANUFACTURE and SALE OF DRUGS AND COSMETICS
- Chapter IV A:-AYURVEDIC DRUGS
- Chapter V:- MISCILANEOUS.

DRUG defined (an inclusive definition)

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the **diagnosis**, **treatment**, **mitigation** or **prevention** of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to **affect the structure** or any **function** of human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette after consultation with the Board.

DEVICE

(Draft Bill 2006)

- **Device:** an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Cosmetic

- "Cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the **human body** or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic

Manufacture,

- "manufacture" in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution, but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business; and "to manufacture" shall be construed accordingly;

THE CENTRAL DRUGS LABORATORY, Calcutta.

- To analyse or test such samples of drugs as may be sent to it under sub-section (2) of Section 11, or under sub-section (4) of Section 25 of the Act;
- To carry out such other duties as may be entrusted to it by the Central Government or, with the permission of the Central Government, by a State Government after consultation with the Drugs Technical Advisory Board.

Contd.,

Other laboratories with the status of CENTRAL DRUGS LABORATORY

- 1. Central Research Institute, Kasauli
- 2. Pasteur Institute of India, Coonoor.
- 3. Enterovirus Research Centre (Indian Council of Medical Research), Haffkin Institute Compound, Parel, Bombay-
- 4. The National Institute of Biologicals, NOIDA.
- 5. The Indian Veterinary Research Institute, Izatnagar or Mukteshwar
- 6. Central Indian Pharmacopoeia Laboratory, Ghaziabad,
- 7. Laboratory of the Serologist and Chemical Examiner to the Government of India, Calcutta
- 8. Central Drug Testing Laboratory, Thane, Maharashtra

contd.,

Other laboratories with the status of CENTRAL DRUGS LABORATORY

- 9. National Institutes of Communicable Disease, Department of Microbiology, Delhi.
- *10.* National Institute of Virology, Pune
- *11.* Centre of Advanced Research in Virology, Christian Medical College, Vellore.
- 12. Homoeopathy Pharmacopoeia Laboratory, Ghaziabad
- 13.The National Institute of Biologicals, NOIDA

- NOTE:-

  The Directors of these laboratories shall also exercise the functions in respect of the notified drugs.

The Drugs Technical Advisory Board.

- to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

- consists of *ex officio members,* nominated *members,* and elected *members,*
- Make bye-laws,
- constitute sub-committees
- Central Government shall appoint a secretary

The Drugs Consultative Committee

- To advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout India in the administration of this Act.
- consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned
- shall meet as and when required and shall have power to regulate its own procedure

Import of Drugs & Cosmetics

To import, with its grammatical variations and cognate expressions means to bring into INDIA.

Part IV of D&C Rules 1945 had under gone significant major changes vide Notification No.G.S.R.604(E) dated 24.8.2001 in respect of

IMPORT & REGISTRATION

Prohibition of import of certain drugs or cosmetics.

- any drug or cosmetic which is not of standard quality; misbranded ,spurious or adulterated misbranded,
- any drug or cosmetic without an import licence
- any patent or proprietary medicine, unless labelled as prescribed
- any drug with prohibitive claims
- any cosmetic containing any ingredient which is unsafe or harmful
- any drug or cosmetic the import of which is prohibited (small quantities are exempted by central government)

Drugs may be imported.

For PERSONAL USE

For SALE or DISTRIBUTION

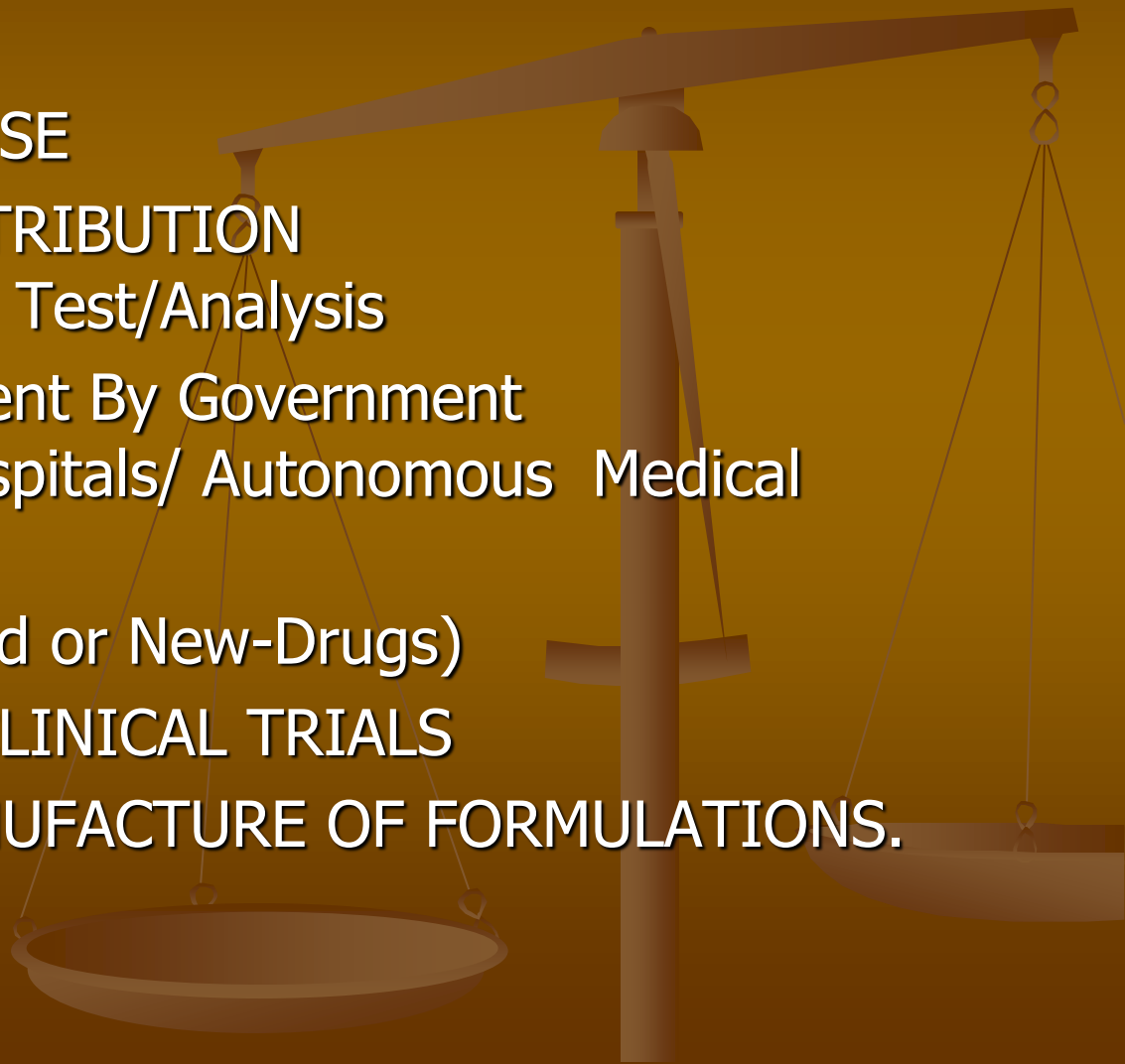
For Examination, Test/Analysis

For Treating patient By Government Hospitals/ Autonomous Medical Institutions

(Established or New-Drugs)

For conducting CLINICAL TRIALS

For USE IN MANUFACTURE OF FORMULATIONS.



IMPORT LICENSES

THOSE SPECIFIED in **schedule X**

For Examination, Test or Analysis.

Govt. Hospital / Autonomous Medical institute for treatment of a patient.

Small quantities of drugs for personal use. (not more than 100 doses.)

Small quantities of New drugs by **Govt. Hospital / Autonomous Medical institute for treatment of a patient.**

Application for grant of permission to import or manufacture a new drug or to under –take clinical trials.

Application for grant of permission to import or manufacture a new drug or to under –take clinical trials. ----- Bulk Drugs.

PRODUCT REGISTRATION

(For Import of DRUGS into INDIA)

- Application in Form ---- 40.
- Certificate in Form ---- 41.(valid for Three Years.)
- Over seas Manufacturer with whole-sale license in India or by his authorised agent -- manufacturer or wholesaler ---Shall Apply.
- Information & undertaking --- D. I & D.II
- Fee – Registration. . ……1,500 U.S dollars

  Single product ……1,000 U.S dollars

  Additional product…….. 1,000 U.S dollars

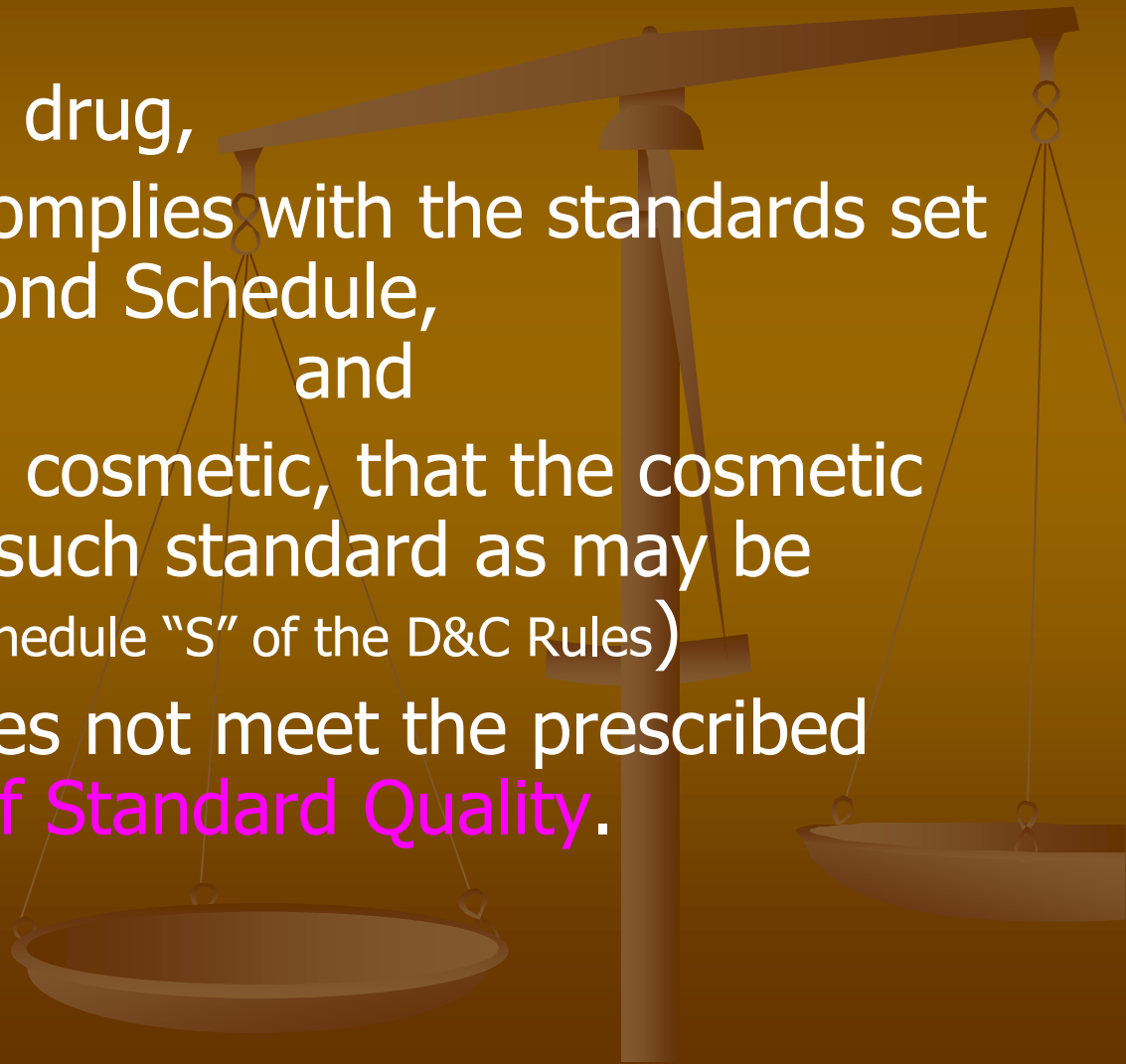
  Inspection / visit ……5,000 U.S dollars

  Duplicate copy …… 300 U.S dollars

IMPORT licences / permits.

- Licence to import drugs (excl., Schedule- X)- -Form 10.
- Licence to import Schedule X drugs- - - - - - - - Form 10A.
- Licence to import drugs for Examination, Test or Analysis – Form12.
- Licence to import drugs by Govt., Hospitals /Autonomous Medical Institutions for treatment of patient- - Form 12A.
- Permit to import small quantities for personal use not exceeding 100 doses - - - - - - - - - - - - - - - Form 12A.
- Licence to import NEW drugs by Govt., Hospitals /Autonomous Medical Institutions for treatment of patient Form - - - 12AA

“Standards of Quality”



- *(a)* in relation to a drug,

  that the drug complies with the standards set out in the Second Schedule,

  and

- *(b)* in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed. (Schedule “S” of the D&C Rules)
- The one which does not meet the prescribed standards is Not of Standard Quality.

Misbranded drugs.

a drug shall be deemed to be misbranded

- *(a)* if it is so coloured, coated, powdered or polished that damage is concealed, or
- if it is made to appear of better or greater therapeutic value than it really is; or
- *(b)* if it is not labelled in the prescribed manner; or
- *(c)* if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

Adulterated drugs. (deemed to be)

- *(a)* if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or
- *(b)* if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
- *(c)* if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
- *(d)* if it bears or contains, for the purpose of colouring only, a colour other than the one which is prescribed; or
- *(e)* if it contains any harmful or toxic substance which may render it injurious to health; or
- *(f)* if any substance has been mixed therewith so as to reduce its quality or strength.

Spurious drugs

a drug shall be deemed to be spurious

- *(a)* if it is manufactured under a name which belongs to another drug; or
- *(b)* if it is an intimation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack identity with such other drug ; or
- *(c)* if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug , which individual or company is fictitious or does not exist; or
- *(d)* if it has been substituted wholly or in part by another drug or substance; or
- *(e)* if it purports to be the product of a manufacturer of whom it is not truly a product.

Misbranded Cosmetics.

a cosmetic shall be deemed to be misbranded,

- *(a)* if it contains a colour which is not prescribed; or
- *(b)* if it is not labelled in the prescribed manner; or
- *(c) if* the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular

Spurious Cosmetics (deemed to be)

- (a) if it is manufactured under a name which belongs to another cosmetic; or
- (b) if it is an imitation of , or a substitute for , another cosmetic or resembles another cosmetic in a manner likely to deceive or bear upon it or upon its label or container the name of another cosmetic unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or
- (c) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or
- *(d)* if it purports to be the product of a manufacturer of whom it is not truly a product.

Adulterated cosmetics. (deemed to be)

- (*a*) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or
- (*b*) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
- (*c*) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
- *(d)* if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(*e*) if it contains any harmful or toxic substance which may render it injurious to health; or

- (*f*) if any substance has been mixed therewith so as to reduce its quality or strength.

Prohibition of manufacture and sale of certain drugs and cosmetics….

- From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—
- *(a)* manufacture for sale or for distribution ,or sell, or stock or exhibit or offer for sale —
  (i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;
- *(ii)* any cosmetic which is not of a standard quality, or is misbranded, adulterated or spurious;".
- *(iii)* any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;
- *(iv)* any drug which by means of any statement, design or device accompanying it or by any other means ,purport or claims to prevent ,cure or mitigate any such disease or ailment ,or to have any such other effect as maybe prescribed; contd.,

Prohibition of manufacture and sale of certain drugs and cosmetics.

- *(v)* any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;
- *(vi)* any drug or cosmetic in contravention of any of the provisions of Chapter IV or any rule made thereunder;
- *(b)* sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;
- *(c)* manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic ,except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter IV

Provided that nothing in this section shall apply to the manufacture, subject to prescribed condition of small quantities of any drug for the purpose of examination, test or analysis:

DRUGS ACT IMPLIMENTATION IN ANDHRAPRADESH STATE,

GAZETTE NOTIFICATION.

GAZETTE NO.31A.P.Gazette, Hyderabad Thursday, **August 6th 1959**

PART-I, DRUGS ACT:

Date on which Chapter IV of Drugs Act Shall come into force in ANDHRA PRADESH- APPOINTED.

(G.O.M.S.No.1182,Health and Local Administration (Health) **21st May,1959**

No.506,

In pursuanance of Sub-Section (3) of Section 1 of the Drugs Act, 1940 (Central Act XXIII of 1940) and in supression of Notification No.142 of the Madras Government of Composite State of Madras in so far it relates to the Andhra State published at page 48 of Part- I-A of Fort George Gazette, dated the 18th February, 1947, the Governor of Andhra Pradesh appoints the date of publication of this notification in the ANDHRA PRADESH GAZETTE as the date on which Chapter IV of the said Act shall take effect in the State of A.P.

In pursuanance of Section of the Drugs Act, 1940 (Central Act XXIII of 1940) the Governor of Andhra Pradesh hereby fixed the date of publication of this notification in the ANDHRA PRADESH GAZETTE as the date for the purpose of the said Section.

Sd/- A.R.Gopalan

Deputy Secretary to Government

Powers of Inspectors

- inspect any manufacturing or sales premises,
- take samples of any drug or cosmetic,
- at all reasonable times,

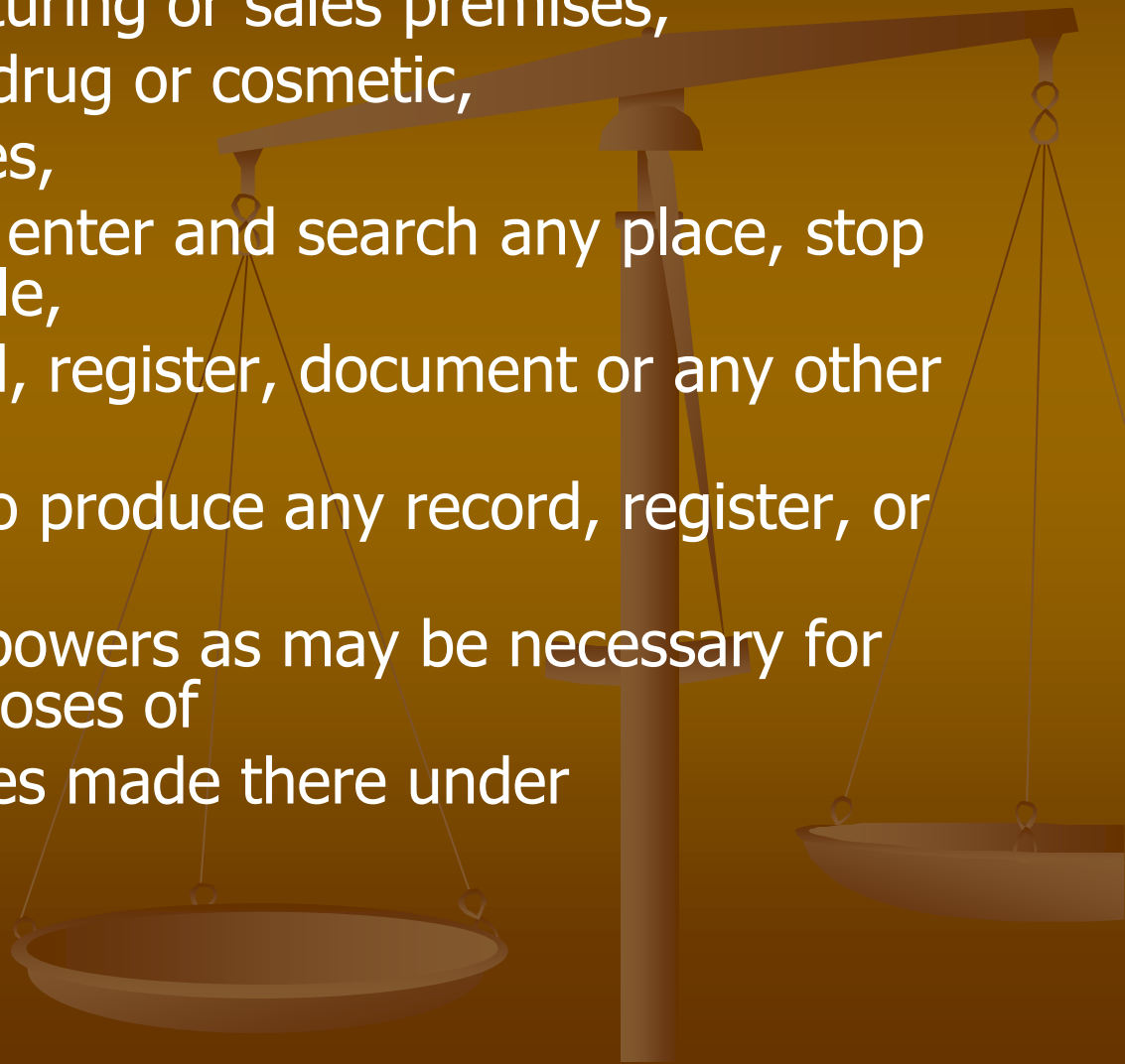
  - search any person, enter and search any place, stop and search any vehicle,

  - examine any record, register, document or any other material object,

- require any person to produce any record, register, or other document,

- exercise such other powers as may be necessary for carrying out the purposes of

Chapter IV or any rules made there under



Procedure of Inspectors.

Taking Samples of drugs / cosmetics for test or analysis

- Intimation – Form 17 and/or Form- 17A
- Three or four portions,
- One portion to be restored to the person,
- One portion to be sent to the G.A. forthwith,
- One portion to be sent to the person who was disclosed under section 18A,
- One portion to be deposited in the Court.

1FORM 17

[See Rules 56 and 145-A]

Intimation to person from whom sample is taken

To.....

I have this day taken from the premises 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 56-A and 145-AA)

Receipt for samples of drugs or cosmetics taken where fair price tendered thereof under subsection (I) of Section 23 of the Drugs and Cosmetics Act, 1940 is refused.

To .....

.....

Whereas I, this ..... day of .....19 ..... have taken, from the premises of situated

at ..... samples of drugs/cosmetics as specified below:-

Details of Samples .....

And where 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 the receipt as the fair price tendered for the samples of the drugs/cosmetics taken by me.

Date: ..... Inspector .....

FORM 15

[See Rule 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 this possession

Whereas, I have reasons 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 of drugs/ cosmetics

Date…… *Inspector*…….

FORM 16

(See Rule 55 and 145-B)

Receipt for stock of drugs or cosmetics or for record, register documents or material object seized under section 22 (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 (c) or clause (cc) of sub-section (1) of section 22 of the Drugs and Cosmetics Act. 1940 (23 of 1940) from the premises of M/S……situated at……..

Date…… *Inspector…….*

Details of drugs, cosmetics, records, registers, documents or material object seized

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.....

FORM 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 sample……
4. Date of receipt ……
5. Name of drugs purporting to be contained in the sample …….
6. Condition of seals on the [packet 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*……..

Reports of Government *Analysts.*

- The Government Analyst shall deliver to the Inspector signed report in triplicate (in Form-13)
- The Inspector shall deliver

  *one copy of the report to the person from whom the sample was taken

  *another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A, and
- *shall retain the third copy for use in any prosecution in respect of the sample.
- Report signed by a Government Analyst under this Chapter shall be evidence to the facts stated therein, shall be conclusive unless notified within 28 days.

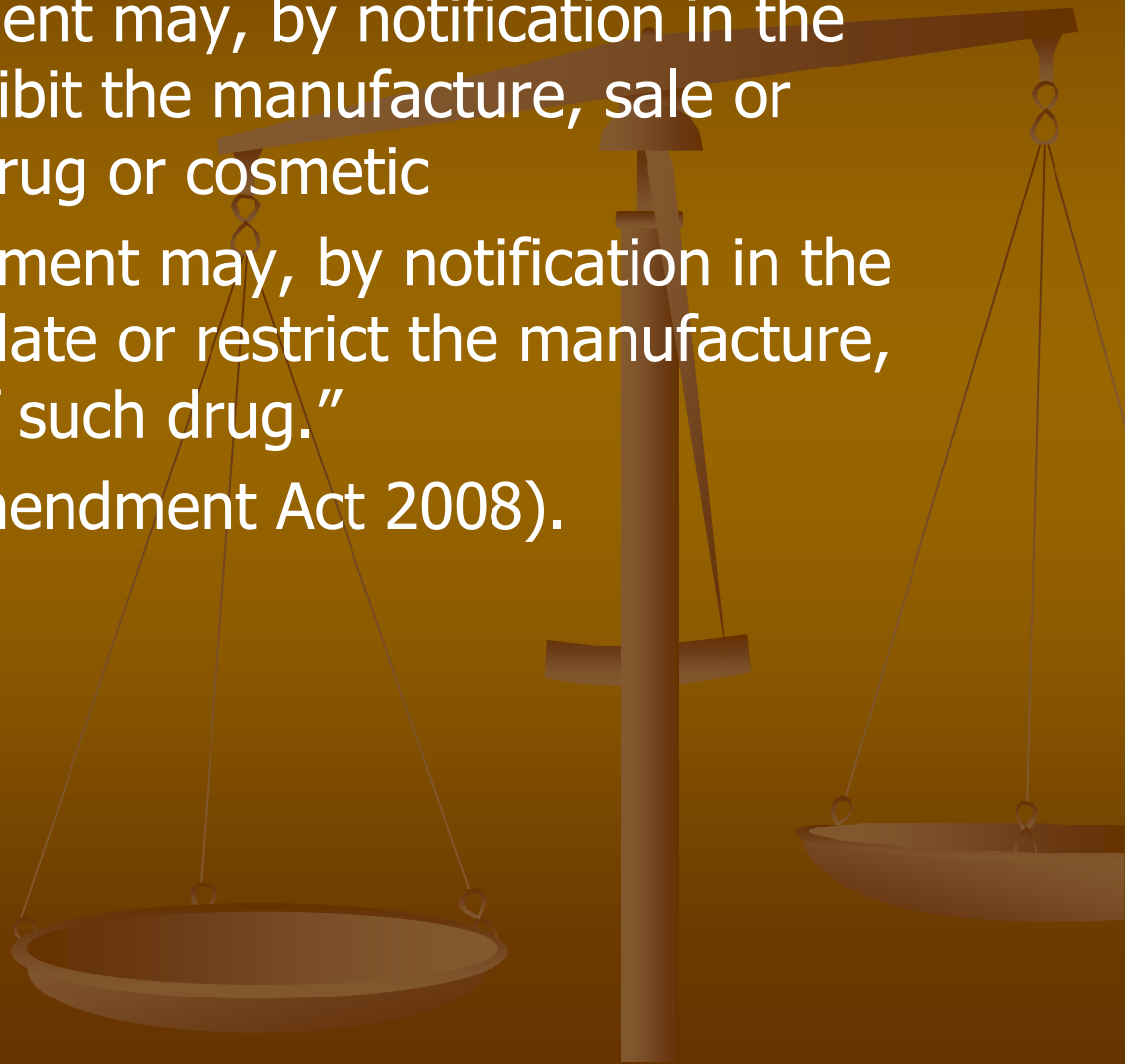
Reports of Government *Analysts*

- Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section *(3)* notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug 1[or cosmetic] produced before the Magistrate under sub-section *(4)* of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.
- The cost of a test or analysis made by the Central Drugs Laboratory under subsection shall be paid by complainant or accused as the Court shall direct.

Power of Central Government to regulate or restrict, manufacture, etc., of drug in public interest.

- The Central Government may, by notification in the Official Gazette, prohibit the manufacture, sale or distribution of such drug or cosmetic
- +The Central Government may, by notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug.”

  + (added be amendment Act 2008).



Cognizance of offence

"(*1*) No prosecution under this Chapter shall be instituted except by—

- (*a*) an Inspector; or
- (*b*) any gazetted officer of the Central Government or a State Government authorised in writing in this behalf by the Central Government or a State Government by a general or special order made in this behalf by that Government; or

(*c*) the person aggrieved; or

(d) a recognised consumer association whether such person is a member of that association or not.

(2) No Court inferior to that of a Court of Session shall try an offence punishable under this Chapter.".

Offences by companies.

- *(1)* Where an offence under this Act has been committed by a company, every person who at the time the offence was committed, was in charge of, and was responsible to the company for the conduct of business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

  Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

contd.,

Offences by companies *contd.,*

(2) Notwithstanding anything contained in sub-section *(1)*, where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly:

Penalties

S.No	Penal Sections & Nature	Penalties Imprisonment Act 1940-	Penalties Imprisonment Act 2008	Fine Act -1940	Fine Act -2008
2.	Section 27(b) [Violation of 17 A or 17 c] (i) other adulterated drugs (ii) without requisite valid license	Not less than1 year → 3 years	Not less than3 year → 5 years	Not less than Rs. 5,000/-	Not less than Rs. 1 lakh or 3 x (whichever is more)

Penalties

S.No	Penal Sections & Nature	Penalties Imprisonment Act 1940-	Penalties Imprisonment Act 2008	Fine Act -1940	Fine Act -2008	
3.	Section 27© [Violation of 17B] Other spurious drug	Not less than3 years → 5 years	Not less than 7 years → Life	Not less than Rs. 5,000/-	Not less than Rs 3 lakhs	
4.	Section 27(d) any other drug in contravention of away of the provisions of chapter-IV or any rule made	Not less than1 year → 2 years	Not less than1 year → 2 years	Fine	Not less than Rs. 20,000/-	

Penalties

S.No	Penal Sections & Nature	Penalties Imprisonment Act 1940-	Penalties Imprisonment Act 2008	Fine Act -1940	Fine Act -2008
5.	Section 27(A) [Violation of 17 D or 17 E]- (i) Spurious / adulterated cosmetic (ii) any other cosmetic in contravention of chapter IV or any rule	Not less than 3 years → 1 year	Not less than 3 years → 1 year	Fine Rs. 10,000	Not less than Rs. 50,000/- or 3 x (whichever is high)
6.	Section 28 [Violation of 18 A or 24] non disclosure of (i) the name & address of the manufacturer etc. (ii) the place where drugs / cosmetics are being manufactured d	Not less than 1 year	Not less than 1 year	Rs. 1000/-	Not less than Rs 20,000/-

Penalties

S.No	Penal Sections & Nature	Penalties Imprisonment Act 1940-	Penalties Imprisonment Act 2008	Fine Act -1940	Fine Act -2008
7.	Section 28 [Violation of 18 B] Failure to maintain & furnish records / registers	Not less than 1 year	Not less than 1 year	Rs. 1000/-	Not less than 20,000/-
8.	Section 28 B [Violation of 26A] Manufacture etc. of prohibited drugs / Cosmetics	Not less than 3 years	Not less than 3 years	Rs. 5000/-	Rs. 5000/-

Penalties

S.No	Penal Sections & Nature	Penalties Imprisonment Act 1940-	Penalties Imprisonment Act 2008	Fine Act -1940	Fine Act -2008
9.	Section23 -Violation of 22 (c) (c) (a) (i)] (i) obstructing the inspector (ii) refused to produce records / registers	Not less than 3 years	Not less than 3 years	Fine	Fine

Penalty for Subsequent offences

S.No	Penal Sections & Nature	Penalties Imprisonment Act 1940-	Penalties Imprisonment Act 2008	Fine Act -1940	Fine Act -2008
10.	30 (1) (a) [Violation of 27(b)]	Not less than2 years → 6 years	Not less than7 years → 10 years	Not less than Rs. 10,000/-	Not less than Rs. 2 lakhs
11.	30 (1) (b) [Violation of 27(c)]	Not less than 6 years → 10 years	Not less than 10 years → Life	Not less than Rs. 10,000/-	Not less than Rs. 3 lakhs

Penalty for Subsequent offences

S.No	Penal Sections & Nature	Penalties Imprisonment Act 1940-	Penalties Imprisonment Act 2008	Fine Act -1940	Fine Act -2008	
12 .	30 (1) (c) [Violation of 27(d)]	Not less than 2 years → 4 years or	Not less than 2 years → 4 years or	Not less than Rs. 5000/- or both	Not less than 50,000/- or both	
13.	30 (1A) [Violation of 27(A)]	Not less than 2 years or		Not less than Rs. 2000/- or both		
14.	30 (2) [Violation of 29]	→ 10 years	Not less than 2 years or	Fine or both	Not less than 10,000/- or both	

D & C RULES

- THE RULES ------- 19 PARTS.
- PART I – Preliminaries
- PART II – The Central Drugs Laboratory
- PART IV- Import and Registration
- PART V – Government Analysts, Inspectors, Licensing Authority and Controlling Authority

PART VI – Sale of Drugs other than Homeopathic Medicines

PART VI A – Sale of Homeopathic Medicines

D&C Rules contd.,

- PART VII – Manufacture for sale or for Distribution of drugs other than Homeopathic Medicines
- PART VII A- Manufacture for sale or for Distribution of Homeopathic medicines
- PART VIII – Manufacture for Examination, Test or Analysis

PART IX – Labeling & Packing of Drugs other than Homeopathic Medicines

D&C RULES contd.,

- PART IX A – Labelling & packing of Homeopathic Medicines
- PART X – Provisions applicable to BIOLOGICAL PRODUCT and Other Special Products.

PART X A – Import or Manufacture of NEW DRUG for CLINICAL TRIALS or for MARKETING

PART X B – Provisions applicable to BLOOD-BANK and BLOOD PRODUCTS.

PART XI – EXEMPTIONS

PART XII – STANDARDS

PART XIII – Import of cosmetics

PART XIV – Manufacture of Cosmetics for Sale or Distribution

PART XV – Labelling, Packing and Standards of Cosmetics

D&C Rules. Contd.,

- PART XV(A) – Provisions applicable to APPROVED LABORATORIES
- PART XVI – Manufacture for sale of AYRVEDIC DRUGS

PART XVI(A) –Provisions applicable to APPROVED LABORATORIES

D&C RULES contd.,

- PART XVII – Labelling, Packing and limit of alcohol in Ayurvedic, Siddha or Unani Drugs.

PART XVIII – Govt. analysts and Inspectors for Ayurvedic, Siddha, or Unani Drugs.

PART XIX – standards for Ayurvedic, Siddha and Unani Drugs.

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D&C RULES contd (sch A to Y)

- SCHEDULE – A - FORMS
- SCHDULE – B – Fee for Test or Analysis
- SCHEDULE- C –Biological & Special Products

SCHEDULE – C1- Other Special Products

SCHEDULE- D –Exemptions u. c. III

SCHEDULE- D(I)- Information –Mfg. unit Registration for import

D&C RULES contd.,

- Schedule – D(II)-Information –product Registration for import
- SCHEDULE- E(1) – Poisonous Substances
- SCHEDULE F – PART I to PART XII(A) OMITTED
- PART XII - B - Blood &Blood BANKS
- PART XII – C - BLOOD PRODUCTS.
- SCHEDULE F(1) – Bacterial Vaccines, Sera
- SCHEDULE F(II) - Standards, Surgical Dressings
- SCHEDULE F(III) – Standards Umbilical Tapes
- SCHEDULE FF – Standards Ophthalmic preparations

D&C RULES contd.,

- SCHEDULE G – Drugs to be used under the supervision of Regd.Medical Practitioners.

SCHEDULE H – Prescription Drugs

SCHEDULE J – Prohibition on advertisements on drugs.

SCHEDULE K – Exemptions-Chap IV

SCHEDULE L1 – Good Laboratory practices.

D&C RULES contd.,

- SCHEDULE M – Good Mfg Practices
- SCHEDULE M-I –GMP Homeo Medicines
- SCHEDULE M II – Factory-cosmetics
- SCHEDULE M III -Factory medical Devices
- SCHEDULE N - Pharmacy- requirements
- SCHEDULE O – Standards for Disinfectant fluids

D&C RULES CONTD.,

- SCHEDULE P – Life Period of drugs
- SCHEDULE P 1 –Pack size of drugs
- SCHEDULE Q- Colours Cosmetics
  SCHEDULE R- Standards for Condoms
- SCHEDULE R1-Stds for Medical Devices
- SCHEDULE S- Standards for cosmetics
- SCHEDULE T-GMP- Ayurvedic Drugs

D&C RULES contd.,

- SCHEDULE U – RECORDS-DRUGS
- SCHEDULE U1- Records Cosmetics
- SCHEDULE V- Stds for P&P Medicines
- SCHEDULE X- Class of Drugs- XRx
- SCHEDULE Y- Requirements and Guide-
  - lines for permission to import and/or manufacture of New Drugs for sale or undertake Clinical Trials.

Thanks for your attention.

Questions / Comments ?

- D. Hanumantha Rao
040-23813040 (Res)
94408-97896 (Mobile)