

# **Division of Blood Transfusion Services**

**Ministry of Health and Family Welfare**



# **Licensing and Regulation Drugs and Cosmetics Act**



# Teaching Aim

You will learn about the licensing and Regulations, legal aspects for the license, forms to be filled ,requirements for the blood bank, organization of blood donation camps, facility and man power etc.

# **The Drugs & Cosmetics Act 1940 & The Drugs & Cosmetics Rules, 1945**

**The Drugs & Cosmetics Act 1940** is a Substantial part, where we could find the definitions, prohibitions & punishments and are divided into various Chapters and Sections &

**The Drugs & Cosmetics Rules, 1945** is Procedural part, where the processes are defined to implement the relevant Sections of the Act and are divided into various Parts, Rules and Schedules.

# Drugs & Cosmetics Rules, 1945

- In the year 1967, Central Govt. (Ministry of Health) enacted a separate provision in Schedule F Part XII B of Drugs & Cosmetics Rules.
- State Drugs Controllers were authorized to issue the licenses for blood banks.
- The standards for ‘Whole Human Blood’ are prescribed in Indian Pharmacopoeia.

# Drugs & Cosmetics Rules, 1945

Due to prevalence of AIDS virus, the Ministry of Health & Family Welfare (Govt. of India) issued a notification in the year 1989 under the Drugs and Cosmetics Rules and made the test HIV 1&2 antibodies of Whole Human Blood as mandatory requirement before transfusion.



# Drugs & Cosmetics Rules, 1945

D&C Rules were amended (Rules 68A, Part XB and Part XIIB of Schedule F) in the year 1992-93 and Drugs Controller General (India) was vested with the power of Central License Approving Authority.





Central License Approving Authority

Central Drugs Standard Control Organization

[www.cdsco.nic.in](http://www.cdsco.nic.in)



# Drugs & Cosmetics Rules, 1945

- Human blood is covered under the definition of ‘Drug’ under Sec. 3(b)(i) of Drugs & Cosmetics Act; which reads as follows:
  - 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.
- Hence, it is imperative that Blood Banks need to be regulated under the Drugs & Cosmetics Act and rules there under.
- License is required to Manufacture/Collect, Sale/Distribution of ‘Whole Human Blood’ and other blood products.

# Drugs & Cosmetics Rules, 1945 (contd...)

- **‘Blood’** means and includes whole human blood, drawn from a donor and mixed with an anti-coagulant
- **‘Blood Component’** means a drug prepared, obtained, derived or separated from a unit of blood drawn from a donor.
- **‘Blood Product’** means a drug manufactured or obtained from pooled plasma or blood by fractionation, drawn from donors.

# **Part X B : Conditions For License**

## **( Rule 122EA to Rule 122P)**



# **Part X B : Procedure and Conditions For License ( Rule 122EA to Rule 122P)**

- Drugs and Cosmetics Rules, Part X-B
- **Rule - 122 EA** – Definitions
- **Rule – 122F to 122N** - License Application Procedure / Inspection / Reporting by Inspection Team / Grant or Rejection of Licence / Duration of licence / Appeal provision
- License granted by Licensing Authority
- Approval by Central License Approving Authority
- License is granted & delivered to Applicant.

# **Part X B : Procedure and Conditions For License ( Rule 122EA to Rule 122P)**

- **Rule - 122 O** – Procedure of Cancellation and Suspension of Licenses.
- **Rule – 122P** – Conditions of licenses:
  - Maintenance of Staff / Plant / Premises / Equipment.
  - Testing of whole blood / Component / Product.
  - Inspections.
  - Reporting to SLA / CLAA about changes in staff / premise.

# **Part X B : Procedure and Conditions For License ( Rule 122EA to Rule 122P)**

- **Rule – 122P – Conditions of licenses:**
  - Directions issued by SLA / CLAA / Recall Directions.
  - Conditions for distribution of whole blood / component / products.
  - To comply provisions of the Act and Rules
  - Destruction of infected blood and implementation of Bio-Medical Wastes (Management and Handling) Rules, 1996

# Forms for License

	Application	License	Renewal
<b>Blood and Components</b>	<b>27-C</b>	<b>28-C</b>	<b>26-G</b>
<b>Blood Products</b>	<b>27-E</b>	<b>28-E</b>	<b>26 - I</b>



**Part XII B :** Requirements for the functioning and operation of a blood Bank and / or for preparation of **blood components.**

1. Requirements for Blood Bank / Blood Components.
2. Blood Donation Camps.
3. Processing of Blood Components.

**Part XII C :** Requirements for manufacture of **blood products.**

1. Requirements for manufacture of blood products.
2. Requirements for manufacture of blood products from bulk finished products.

## **Schedule F Part XII    B - Subpart I**

### **Requirements for Blood Bank / Blood Components.**



# **Schedule F Part XII B – Subpart I**

## **Requirements for Blood Bank / Blood Components.**

- A. General
- B. Accommodation
- C. Personnel
- D. Maintenance
- E. Equipments and Calibration
- F. Supplies & Reagents
- G. Good Manufacturing Practises
- H. Criteria for Blood Donation



# **Schedule F Part XII B – Subpart I**

## **Requirements for Blood Bank / Blood Components.**

I. List of Equipments

J. Special Reagents

K. Testing of whole blood

L. Records

M. Labels.

# **Schedule F Part XII B – Subpart II**

## **Blood Donation Camps**



# **Schedule F Part XII B – Subpart II**

## **Blood Donation Camps**

Permission for camps to:

- Licensed designated Regional Blood Transfusion Centre
- Licensed Govt. Blood Bank
- Indian Red Cross Society
- Licensed blood bank run by registered voluntary or charitable organisations recognised by SBTC

A. Personnel for out-door camps

B.  Equipment

# **Schedule F Part XII B – Subpart II**

## **Blood Donation Camps**

A. Premises

B. Personnel for out-door camps

C. Equipment



# **Schedule F Part XII B – Subpart III**

## **Processing of Blood Components**



# **Schedule F Part XII B – Subpart III**

## **Processing of Blood Components**

- A. Accommodation
- B. Equipment
- C. Personnel
- D. Testing facility

# **Schedule F Part XII B – Subpart III**

## **Processing of Blood Components**

### **E. Categories of Blood Components**

1. Concentrated Red Blood Cells
2. Platelet concentrate
3. Granulocytes
4. FFP
5. Cryo-precipitate

### **F. Apheresis**

Donor Criteria

Monitoring

# **Schedule F Part XII C**

## **Manufacturing of Blood Products**



# **Schedule F Part XII C**

## **Manufacturing of Blood Products**

- A. General Requirements
- B. Collection and Storage of Plasma for Fractionation
- C. Personnel
- D. Production Control
- E. Viral Inactivation Process
- F. Quality Control
- G. Testing



# **Schedule F Part XII C**

## **Manufacturing of Blood Products**

H. Storage of Finished products

I. Labeling

J. Records

K. Master Formula Records

**Compliance must be specifically observed in the following aspects.**

# Staff

- Change of staff must be informed to the FDA.
- All staff members must be vaccinated and the records be available.
- Record of the staff training, training manual and training calendar must be available.
- Medical examination of the donors must be carried out by the Medical Officer.

# Facility Layout

- Any modifications must be notified to the Licensing Authority.
- Rest and Refreshment room must be available for the donors.
- Reception area must not be used as refreshment room for donors.
- Privacy must be available for the medical examination of the donors.



# Equipments

- Alarm systems of the blood storage refrigerators must be functional.
- Recording thermograph must be available and functional for the blood storage areas.
- Instruments must be periodically calibrated.
- Emergency medicines must be checked for expiry dates.

# Testing

- Sterility test of CPDA solution must be performed at the time of receipt. Manufacturer's report must be available.
- Sterility test of the blood bags after the blood collection must be performed.

# Grouping & Cross-matching

- Grouping and cross matching must be carried out by tube technique and not by slide technique.
- Tests for atypical antibodies must be carried out.

# ELISA test

- Test method including the Positive and Negative control must be as per the literature.

# Documentation

- Laboratory manual must be prepared and available.
- Standard Operating Procedures must be prepared, reviewed and available.
- Donor's records, including the address, must be complete.
- Batch number of the blood bag must be recorded in the Donor Blood Collection Record.

# Documentation

- Calibration records must be available.
- Records of disposal of Sero-reactive blood and its components must be maintained appropriately.
- Records of sterilization must be maintained.

# Processes

- Labels must be affixed only after complete testing.
- Two separate storages must be available for under testing and tested blood and components.
- Hospital Transfusion Committee must be formed and should be functional.

# Learning Outcome

Enabled knowledge on licensing and regulations , legal aspects for the license, forms to be filled ,requirements for the blood bank, organization of blood donation camps, facility and man power etc.



NACO website: [www.naco.gov.in](http://www.naco.gov.in)

