“Labeling & Pack Size of Drugs under Drugs Act, 1940 & Rules 1945”

A Presentation by

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All Drugs should be labelled in the Prescribed Manner

Labelling Rules:-

Rules 94 to Rule 106 B

Contraventions of Labeling

Contravention - Section 17

Misbranded Drugs

Misbranded is classified as a category 'C' defect as per the DCGI office letter dt.

05-12-2008

Export of Drugs - Rule 94

1. Exemptions

2. Must meet the requirements of the exporting country.

Rule 96

1. The Labelling on the outer and inner containers should be the same.

Rule 96

Font Size of Name of the Drug

1.‘**Generic name**’ [larger than the ‘Brand name’]

2.‘Brand name’ [written below the ‘Generic name’]

Example:-

Paracetamol Tablets IP

Crocin Tablets } **OK**

Crocin

Paracetamol Tablets IP } Wrong

Labeling Provisions

for Loan Licensee Firms

Following are the labeling requirements:

- Address of the Host Firm.
- Name of the Loanee Firm.
- No other details of the Host firm.

Rule 96 (1) xi

Schedule H warning is not required to be labelled on the following:

- Veterinary Drugs.
- External Preparations (except preparations containing steroids and hydroquinone).
- Eye Drops/ Ear Drops (except preparations containing antibiotic or steroids).
- Parenteral Preparations.

Notification – **G.S.R. 408 (E) dated 26.04.2018**
(w.e.f – 01.11.2018)

Red line not required

As per Notification no. **GSR 408 dt. 26.04.2018**

Dry Syrups

It is mandatory to mention the weight of the granules on the label of dry syrups.

Batch number can be written on the label in following ways:

Batch No.

B. No.

Batch

Lot No.

Lot

Manufacturing License Number can be written in following ways:

- Manufacturing License Number
- Mfg. Lic. No.
- ML

Date of Manufacturing	=	**Mfg. Date**
Date of Expiry	=	**Expiry Date**
Physician's Sample	=	**'Physician's sample-Not to be sold'**

External preparation

- Warning –

'**For External use only**' should be written on the label.

Very Important :-

If the medicine contains industrial methylated spirit, it should be labelled in capital letters as:

" **FOR EXTERNAL USE ONLY**"

Veterinary Drugs

Labelling –

'**Not for human use, for animal treatment only**.'

Standards of Veterinary Drugs are also mentioned in the IP.

Veterinary Drugs

- The term "Bolus" should be used for veterinary tablets of higher weight intended for administration to large animals.

Standards of Veterinary Drugs

- Rule 124A has been omitted.

- **GSR 103(E) dated 02.02.2017, the expression "IP (Vet.)" has no regulatory significance.**

Rule 104-A

- No alteration shall be made to the label without permission from the **Licensing Authority**.

- Permission for alternative packing material is not allowed under **Rule 104-A.**

Rule 105 - Packing of Drugs

- Packs size of Tablets or Capsules

1. 1 to 10
2. Multiple of 5
3. Multiple of 7

Example:-

1,2,3,4,5,6,7,8,9,10

14,15,20,21,25,28, etc.

Notification:-

GSR216 (E), dt.18.03.2024.

Rule 105
Pack Size of 'Diclofenac Injection'

- Diclofenac Injection for Human use only and shall be sold in only in single-dose packs.
- Packs of 10 ml are not permitted.

As per Notification GSR 558 (E) dated 17 July 2015

- **Pack Size of Pediatric oral drops**

1. 5 ml.
2. 10 ml.
3. 15 ml.

- **Pack size of Eye, Ear & Nasal Drops**

1. 3 ml.
2. 5 ml.
3. 10 ml.

Pack Size of Eye Ointments

1. 3 gms.
2. 5 gms.
3. 10 gms.

Pack size of Injectables

1. No specific packing rules are available for injectables.
2. However, the Licensing Authority may seek justification for pack size.
3. S.V.P. up to **99 ml**.
4. LVP from 100 ml and above.
5. The manufacturer **cannot classify 100 ml** injectables for veterinary use as S.V.P.

Packing of Combipacks of Drugs

Example

1. **Nandrolone Inj. + Syringe**

- Complete details of syringe must be mentioned on the outer carton.
- A Whole sale Drug License is required for the purchase syringes/ water for injection

Pack size is not applicable to the following:

1. Imported Formulations.
2. Veterinary Drugs.
3. Drugs for export.
4. Vitamin Preparations.
5. Cough Syrups.
6. Antacids.
7. Laxatives.
8. Sold to hospitals/Hospital Supply.
9. Large Volume parenterals.
10. Physician Samples Drugs.

Rule 105 - Schedule P1

Only **20** Drugs under **Schedule P1**

Some Examples:

1. Albendazole Suspension = 10 ml
2. Catalin Eye Drops = 15 ml
3. Pyrantel Pamoate Syrup = 08 ml or 10 ml
4. Piperazine Syrup = 30 ml.
5. Vitamin A oral Drops= 7.5 ml.
6. Cotrimoxazole Suspension = 50 ml. (GSR 753 (E) dt. 04.11.99)

Rule 124 – Standards of Drugs

Labeling of pharmacopoeia status of drugs

Domestic use

1. If a drug available in the IP then it must be labeled as IP
2. If a drug is not available in the IP but is available in another pharmacopeia, it must be labeled as BP/ USP/JP, etc.
3. If a drug is not available in any pharmacopeia, it is “In-House”

Rule 124 – Standards of Drugs

Export

- Drug should be labeled with BP/USP/JP, or as per the requirements of the importing country.
- They can be labeled as per the importing country's specific requirements
- IP is currently recognized by 24 countries.

Example :-

For Domestic Sale

Paracetamol Tablet IP - **OK**

Paracetamol Tablets BP - **Wrong**

Rule 127 - Colours

- The name of the colour (if added) must be mentioned on the drug label.
- The name of the approved colour must be mentioned on the drug label.
- The list of permitted colours is specified under Rule 127 of the Drugs Act.

Rule 127 - Colours Gelatine Capsules

Notification - G.S.R. 1186(E) dt. 07.12.2018.

1. Only permitted colours shall be used in the manufacture of gelatin capsules.
2. The name of the colour added to the gelatin capsule is not required to be mentioned.
3. Only permitted colours may be used in gelatin capsules.

Example:

How to label Ciprofloxacin tablet for domestic use?

1. Tablets Ciprofloxacin IP

or

2. Ciprofloxacin tablets IP

or

3. Ciprofloxacin IP tablets

or

4. Ciprofloxacin BP tablets

or

5. Ciprofloxacin IP tablets

Correct is:

(2) Ciprofloxacin Tablets IP

Correct License number:

- Two type of allopathic drug manufacturing License are granted by the SLA under different form numbers (Form 25 and Form 28)
- Non – Biological and Biological
- The Manufacture must mention the correct license number on the drug label.
- Mentioning both license numbers on the drug label is incorrect.
- Permission is granted by the SLA for a specific license number only

Non-Biological License on Form-25

1. Paracetamol
2. Nimesulide
3. Ciprofloxacin.

Biological License on Form-28

1. Parenterals .

2. Vitamins.

3. Antibiotics.

4. Hormones.

Rule 97

NDPS Drug Labelling

- ND means Narcotic drugs
- PS means Psychotropic substances
- The word NRx is Labelled on the top left corner for all ND and PS drugs.

Examples of such drugs are:

- Pentazocine
- Alprazolam
- Chlordiazepoxide
- Diazepam
- Nitrazepam
- Buprenorphine

Schedule P

The label of the drug must bear the storage conditions as mentioned in Schedule P of the Drugs Rules.

Examples:-

1.	Adramycin	30	In a cool place
2.	Carbenicillin Sodium Injection	24	At temperature not exceeding 5°C.
3.	Colistin sulphate	60	Protected from light
4.	Framycetin sulphate	48	In a well closed container with temperature no exceeding 30°C
5.	Streptomycin Sulphate	48	At temperature not exceeding 20°C
6.	Thiamine Hydrochloride	48	In a well closed container, protected from light, in a cool place
7.	Vitamin B6	60	In a well closed container, protected from light, in a cool place
8.	Golbuline Zinc Insulin Injection	24	At temperature between 2°C and 8°C must not be allowed to freeze
9.	Dried Plasma	60	At temperature not exceeding 25°C
10.	Frozen Plasma	60	In deep freeze
11.	Whole Human Blood- (a) Collected in ACD solution (b) Collected in CPDA solution	 21 days 35 days	 At temperature between 4°C and 6°C At temperature between 4°C and 6°C
12.	Alum Precipitated Diphtheria Toxoid	24	In cold place
13.	Cobra Venom in Solution	3	Between 2°C and 5°C protected from light
14.	Liquid Serum	12	Between 2°C and 10°C preferable at the lower limit
15.	Polio Vaccine	36	In cold place
16.	Adrenaline for injection	12	As prescribed in India Pharmacopoeia
17.	Chorionic Gonadotrophin for injection (Lyopholised)	36	At temperature not exceeding 20°C
18.	Paraldeyude Injection	6	In cool place protected from light

Notes:-

- The term "cool place" means place having a temperature between 10°C and 25°C.
- The term "cold place" means a place having a temperature not exceeding 8°C.
- Capsules should be kept in a well-closed container at temperature not exceeding 30°C.
- Where condition of storage is not specified in Column 4, it may be stored under normal room temperature.

Example

Adrenaline Injection-

- The expiry date of this product is 01 year only.
- Storage condition “Protected from light”.
- Storage conditions are as per IP.

G.S.R. No. 175 (2)(E) dated 16.03.2005

Example

Atropine Injection :

- Storage condition and expiry date are not mentioned under Schedule P
- Therefore, the manufacturer may fix the expiry date based on stability studies conducted by the firm.
- The storage conditions may be obtained from the IP

The Legal Metrology Act, 2009

- As per **Rule 26 C**, all allopathic scheduled drugs and non scheduled drugs are exempted from the provisions of this Act.
- However, medical devices are not exempted under this Act

Example

Labelling of Phenobarbitone Tablets:

- This drug was deleted from Schedule X in the year 1993.
- It is a Psychotropic substances, therefore the manufacturer should mention word NRx on the label of the drug.

Example

Ketamine Drug:

- It is Psychotropic Substance (NDPS) vide S.O. No. 1430 (E) dated 21.06.2011.

- It is also a Schedule X Drug vide G.S.R No. 724 (E) w.e.f. 07.11.2013.

Indian Pharmacopoeia

- IP word must be mentioned if the product is official in IP.
- Paracetamol Tablets IP- Correct.
- Paracetamol Tablets I.P.- Not Correct.

Coating

- If coating mentioned in official monograph that is this mandatory make the coated tablets.
- The colour of the coating should be as per approved list as mentioned Rule 127.
- If a manufacturer has permission to manufacture a coated drug, they cannot manufacture an uncoated version of the same drug.

Some Labeling Examples

Example

- Proper name (Generic name) of Drugs Should always suffix with pharmacopoeia abbreviations (if in pharmacopoeia)

Ibuprofen Tablets IP ⟶ OK

Ibuprofen Tablets ⟶ **Not Ok**

- Brand names are not pharmacopoeial

Example : **Brufen Tablets** ⟶ Ok

Brufen Tablets IP ⟶ **Not Ok**

Generic name of the Drug should be suffixed with dosage form

Example : Ofloxacin Tablets IP ⟶ **OK**

Ofloxacin IP Tablet ⟶ **Not Ok**

Labelling of Ciprofloxacin Eye Drops

- Ciprofloxacin Eye Drops IP (**correct**)

- Ciprofloxacin Eye / Ear Drops IP (Not Correct)

Labelling of Drug official in 1966

Example- linseed Oil

- This drug was official in IP since 1966.
- This drug was deleted from IP in 2010.
- Now, this drug is official in BP.
- So, manufacturer can label this drug as linseed oil BP only.
- Labelling of linseed oil as IP (1966) is wrong.

Labelling

- It is not mandatory to write on the drug label.
- Keep out of reach of children on the label.

Paracetamol Warning

- Overdose of paracetamol may be injurious to the liver. Taking more than daily dose may cause serious liver damage or allergic reaction (e.g swelling of the face, mouth and throat, difficult in breathing, itching or rash).

Flavour

- Flavour cannot be added to an uncoated tablet unless specifically permitted.
- In dispersible tablets, flavour is allowed in both coated and uncoated tablets.
- Flavour is permitted in chewable tablets.
- Flavour is permitted in all coated tablets.
- It is not mandatory to mention the name of the flavour added to the drug.
- The manufacturer should test the flavour in-house.
- The flavour used should be of food-grade quality.

Phenytoin Injection

- Phenytoin Sodium for Injection IP (Dry Injection)
- Phenytoin Sodium Injection USP (Sterile Solution)

Phenytoin Schedule G

- 5- Phenylhydantonic, its alkyl and aryl derivatives its salts.

Labelling of Ceftazidime for Injection IP

- Ceftazidime IP eq. to Anhydrous Ceftazidime 1000mg

(A sterile mixture of Ceftazidime Pentahydrate & Sodium Carbonate).

Penalty under Drugs Act

Section 27 (d)

Thank You !!!