Labelling & Pack Size of Drugs under Drugs Act, 1940 & Rules 1945

Presentation by

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All Drugs should be labelled in the Prescribed Manner.

Provisions for labelling and Packing of Drugs are mentioned in Part-IX (94 to Rule 106 B) of the Drugs Rules.

Unlabelled Drugs

No Drug can be sold without proper label, if so it contravenes Rule 95 of the Drug Rules.

Contravention of Drug Act

Misbranded Drug

Section 17 (c)

Export of Drugs (Rule 94)

For export of drugs, certain exemptions from the labelling are given to meet the requirements of importing country.

Rule 96

Labelling on the outer and innermost container of any Drug should be same.

Rule 96 GSR 222 (E) dated 13.03.2018 effective from 01 April 2019

‘Proper name’ should be larger than the ‘Brand name’ and Brand name should be mentioned below the Proper name.

Example:

Paracetamol Tablets I.P.
Crocin Tablets — **OK**

Crocin
Paracetamol Tablets IP — Not OK

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

- Example : Ibuprofen Tablets I.P. ⟶ OK

  Ibuprofen Tablets ⟶ **Not Ok**

- Brand names are not pharmacopeial

Example : Brufen Tablets ⟶ Ok

Brufen Tablets I.P ⟶ **Not Ok**

Generic name of the Drug should be suffixed with dosage form

Example : Ofloxacin Tablets I.P. ⟶ **OK**

Ofloxacin I.P. Tablet ⟶ **Not Ok**

- If any Drug formulation is official in I.P. then it should be sold in India with word ‘I.P.’ on the label.

Example : For Sale in India

Paracetamol Tablet I.P. - OK

Paracetamol Tablets B.P. - Wrong

If the product is not in I.P. then it can be labeled as B.P., U.S.P. & In house specifications.

- Labelling Provisions for loan licensed firms or Loanee firms:

Example :

- Suppose Drugs are manufactured by M/s Cubic Pharma, 8 ,HSIDC, Karnal, Haryana i.e. **Host firm** and Minto Pharma, Jalandhar is its **loanee firm**, then labelling manufacturers address will be as under:

Labelling of Drugs Under Loan License for Manufacturing Address

- **With Example**
- Name of Loanee firm: Glaxo Pharma.
- Address of Host firm: Syntex Ltd. Address Industrial Area Phase-I, Baddi, Himachal Pradesh.

Address: **Glaxo Pharma, Industrial Area Phase-I, Baddi Himachal Pradesh.**

Dose of Active Ingredients

1. **Liquid Oral** : Each 5ml _____mg.
2. If dose is below 5ml then it can be each ml.
3. If dose is above 5ml then it should be approved by Licensing Authority as minimum single dose.

Dry Syrups

It is mandatory to mentioned weight of Granules in Dry Syrups.

Labeling of Tablets

1. Each Uncoated.
2. Film coated.
3. Sugar coated.
4. Enteric coated.
5. Sustained Release.
6. Bi-layer Tablet.
7. Chewable Tablet.
8. Sub-Lingual Tablet.

Name of Manufacturers with Address where the Drug has been manufactured

- If the Drug is in 01 ml only the name of the manufacturer and the principal place of the manufacturer is to be mentioned.

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 as under in following ways:

Manufacturing License Number

Mfg. Lic. No.

ML

Drugs containing Alcohol

If a Drug formulation contains Alcohol more than 3 % then volume of Alcohol should be mentioned on the label of that Drug.

- Ointments/ Lotions .

‘For External use only.’

- Veterinary Drugs.

‘Not for human use for animal treatment only.’

If the Drug is official in I.P. as Veterinary then labeling should be I.P. vet.

Rule 104-A

No alteration on the label of a drug can be done without permission of Licensing Authority.

Packaging of Drugs-Rule 105

- Tablets & Capsules if less then ten in number then it can be packed as one to ten.
- If pack size is above ten then it should be packed as multiple of five.

Packaging of Drugs-Rule 105

Oral preparation.

1. 30 ml for paediatric use only.
2. 60 ml/ 100 ml/ 200ml/450 ml.

- **Paediatric oral drops**

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

- **Eye, Ears & Nasal Drops.**

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

Eye Ointments

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

Pack size of Injectables

1. No such packing rules are available for injectables.
2. Licensing Authority can ask for justification of pack size.
3. SVP upto 99ml.
4. LVP from 100ml and above.
5. So the manufacturer cannot claim 100ml veterinary use as SVP.

Pack size is not applicable to the following:

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

Exemption for Pack Size

There are **23** Drugs under **Schedule P-1** with fix pack sizes.

Examples:

1. Cotrimoxazole Suspension = 50ml.
2. Atenolol Tablets = 14 Tablets.
3. Aspirin Tablets = 14 tablets.
4. Piperazine Syrup = 30 ml.
5. Vitamin A oral Drops= 7.5 ML.

Combipack of Drugs

Examples

1. **Nandrolone Inj. + Syringe**

On the outer Carton of the above Combipack Drug complete details of syringe must be given i.e – exp. Date, Batch No., Mfg. Lic. No., Mfd. By etc.

Storage of drugs as given in Drug Act (schedule P)

- Cool place **10** to **25 degree C**
- Cold place upto 8 degree C

Room Temp: If storage temperature is not mentioned on the drug then it should be kept at room temperature.

- Cold place …. **Refrigerator**
- Cool place ….. **AC**

Colour in the Drugs

- Name of the Colour should be labeled on the label of the Drugs (if added).
- List of Permitted colours is given under **Rule 127** of the Drugs Act.

Colour in the Capsules

1. As per G.S.R. 186(E) dated 07.12.2018.
2. Colour used in capsule need not to be mentioned on the label.
3. Only approved or permitted colour shall be mentioned used.

License No.

- **Biological or Non Biological.**

- **Biological preparations :-**
  1. Parenterals .
  2. Vitamins.
  3. Antibiotics.

- **Non biological preparations :-**

  Paracetamol, Nimesulide, Ciprofloxacin.

How to label Ciprofloxacin tablet?

1. Ciprofloxacin tablet IP.

2. Tablet Ciprofloxacin IP.

3. Ciprofloxacin IP tablet.

4. Ciprofloxacin BP tablet.

Correct :

Ciprofloxacin Tablet IP.

Labeling of this Drug under which license?

This drug comes under license Form-25.

You have to label only 01 license number on 01 product.

Example:

Combination Drug:
Ofloxacin + Ornidazole Tablet IP.

If the firm has taken permission to manufacture a drug/ formulation without any Pharmacopoeia status and same has been included in I.P. then firm should have to obtain fresh permission from the SLA for that formulations.

Anhydrous

- Wherever pharmacopoeia Status of API in anhydrous form, it is mandatory to labeled word anhydrous.

Examples :-

1. Cephalexin (anhydrous) I.P.
2. Caffeine (anhydrous) I.P.

Schedule G Drugs

Its warning should be printed on a box

1. There are approximately 50 drugs which are covered under Schedule G Drugs
2. No Rx on these Drugs.

Examples

1. Chlorpheniramine.
2. Cyproheptadine.
3. Diphenhydramine.
4. Pheniramine.
5. Promethazine.

In case of a Pharmacopoeial drug if strength is not given in the Pharmacopoeia then what will be the labelling status of that Drug

Example:-

- If SLA has given permission for manufacturing of Prednisolone tablet 20 mg but usual strength is not given in I.P. then this tablet should be labelled as I.P. only.

- Ciprofloxacin Eye / Ear Drops U.S.P.

- Ciprofloxacin Ophthalmic solution U.S.P is official and correct.

Status of Drug Paracetamol tablet & syrup:

- This drug is not covered under any schedule.
- Hence, can be sold without prescription.

Labeling of Paracetamol with other Drugs:

- Paracetamol with Non-steroidal anti-inflamatory drug.
- The strength should be upto 325mg or should not be exceed from 325 mg.
- E.g. Paracetamol- **325mg**

  Nimesulide-**100mg**
- Instruction as per DCGI letter dated **04.04.2012**.
- Box warning about the 'lever toxicity' must be given on the label of above mentioned combination.

Enteric Coated Drugs:

If the Drugs are Enteric coated it should be mentioned as Enteric coated.

- Pantoprazole.
- Rabeprazole.
- Esomeprazole.
- Diclofenac.
- Domperidone.
- Pancreatin.
- Trypsin Chymotrypsin.
- Aspirin.
- Sodium Valproate.

Expiry Date

- Example – Analgin Tablets expiry date **March 2007**
- It means its expiry is 31-3-2007
- Last day of the month.

Labelling of Medical Devices Rule 44:

- The label of a medical device shall bear expiry date of the product.
- The word ‘shelf life’ can also be used on the label of Medical Device.
- Shelf life of the Medical Device shall not exceed 60 months.

Repacking of Medical Devices:

- There is no provision for repacking of medical devices under MDR, 2017.

Metrology

- Drugs are exempted.
- Medical Devices are not exempted.
- As per Rule 26 C, all the schedule drugs and non schedule drugs are exempted from this Act but not medical devices are not exempted under these Rules.

Psychotropic Substances

Word NRx is required to be labeled on such formulations. (On Top left Corner)

Examples are:

1. **Pentazocine**
2. **Alprazolam**
3. **Chlordiazepoxide**
4. **Diazepam**
5. **Nitrazepam**
6. **Buprenorphine**

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

Now, there is no need

No need to put red line on Schedule Drugs

- **Vide Notification No. GSR 408 dated 26.04.2018.**

Adrenaline Injection

- As per notification number GSR 174 (2) dated 16 March 2005 storage condition of this drug has been changed from 'cold place to protection from light'.
- Expiry date of this product is one year from manufacturing date only.

Atropine Injection

- No storage condition and expiry date has been mentioned in Schedule P.
- So, the manufacturer can fix the expiry date as per the stability study performed by the firm and storage condition manufacturer can be at room temperature.

Paracetamol Paediatric oral suspension IP

- If manufacturer is labelling as ‘Paracetamol Suspension I.P. ’ then this labelling is wrong.
- Paracetamol Suspension IP.

Labelling of Albendazole Tablet I.P.

- For this drug/ tablet, IP mentions ‘that this tablet should be chewed before swallowing.’
- So, this chewable condition should be mentioned on the label of the drug.

Example:

Labelling of Linseed oil

- This drug was official in IP 1966.
- This drug was deleted in IP 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 of Phenobarbitone Tablets

- This drug was excluded from Schedule X in the year 1993.
- This drug is a Psychotropic drug so manufacturer should mention NRx on the label as per provisions.

Notification GSR 219 (E) dated 26.03.2022

- Hydroxychloroquine Drug comes under Schedule H1 through Section 26 B of the Act.

Notification under NDPS Act

- Drug Etizolam has been notified as Psychotropic Drug vide (**S.O. – 1276 (E) dated 23.03.2021),** so should be labelled with 'NRx' as per the provisions**.**

- Drug Tramadol has been notified as Psychotropic Drug vide notification no. S.O. 1761 (E) dated 26.04.2018. So should be labelled with NRx as per the provisions.

Status of Ketamine Drug

- It is covered under NDPS Act.
- It is a Psychotropic Drug. (S.O. No. 1430 (E) dated 21.06.2011).
- It is also a Schedule X Drug included on 07.11.2013 in Schedule X.

Notification 558 (E) dated 17 July 2015

- Diclofenac Injection for Human use shall be sold in single dose pack only.

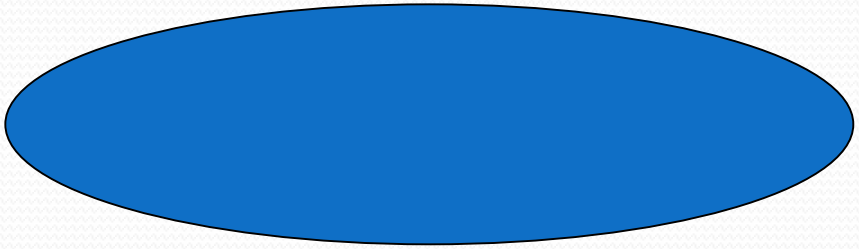
Notification 28 (E) dated 17 January 2012

- For Veterinary Drugs under Rule 97, 'withdrawal period of the drugs for the species on which it is intended to be used' should be labelled/ mentioned.

Penalty under Drugs Act

Section 27 (d)

Punishable with imprisonment for a term which shall not be less than one year but which may extended to 2 years & with fine.



Thank You !!!