

THE DRUGS (LABELING & PACKAGING) RULES, 1986

0- INTERNATIONAL- Non-proprietary NAME

↳ name recommended by WHO or as other name notified by fed gov in official gazette

0- pharmacopoeial ~~name~~ = mean publication in sub-clause-11 of clause 2 of sec-3 Drug Act 1976 (XXXI of 1976)
Mentioned in pharmacopoeia.

MANNERS OF LABELING:- Rule-3

Particulars shall on → ① innermost container of drug.

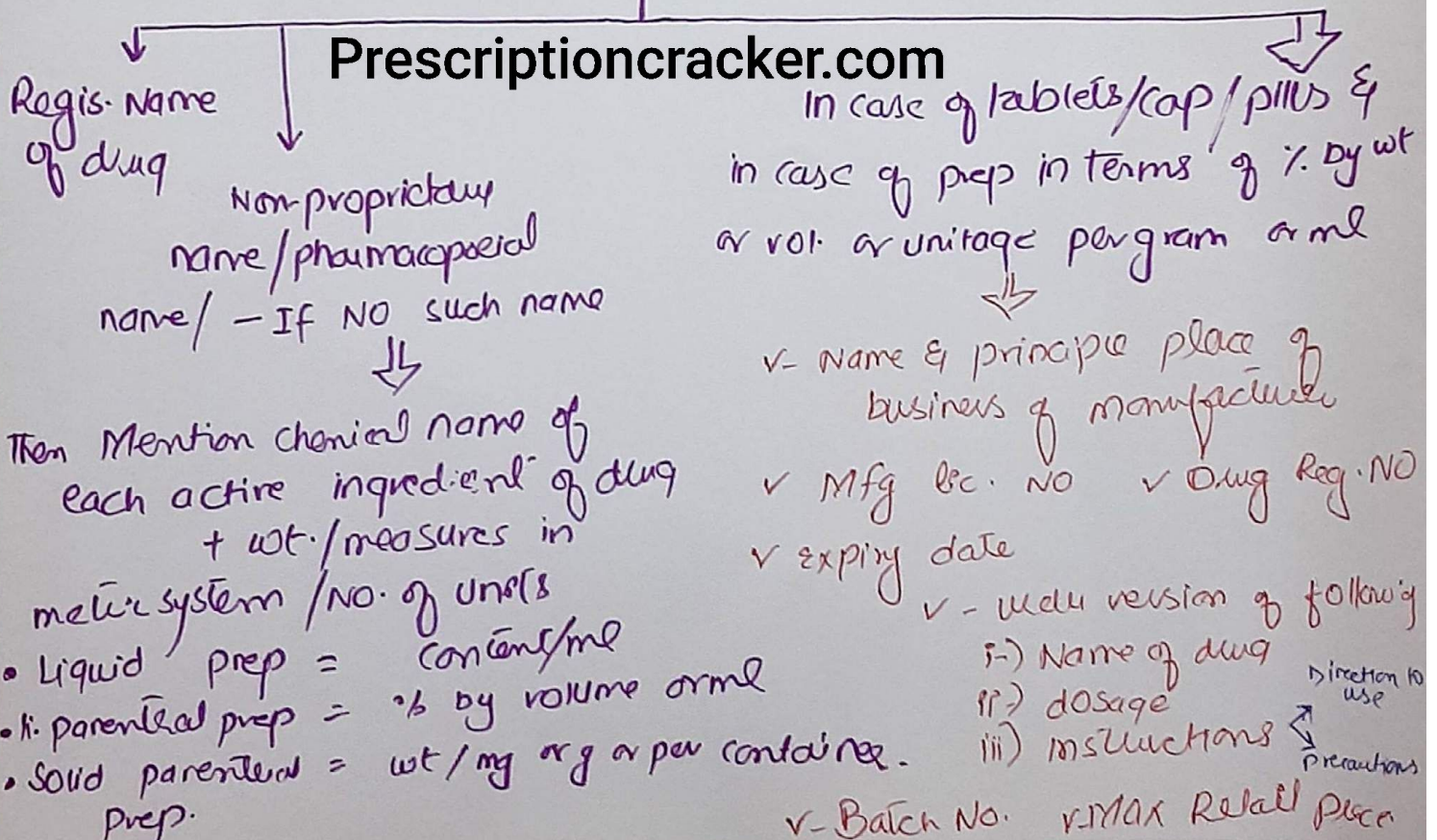
② on which the container is pack.

✓ print / write

✓ indeleble ink

✓ conspicuous manner.

PARTICULARS



- Provided that Drug packaged in → Strip of Paper/blister/foil
→ ampoule capacity NMT 2ml
→ printed collapsible tubes → amp containing sterile suture/ligature
- Sufficient to give info in outer packaging containing.
Such Amps / foils / blister / ampoule.

- (4) ★ Drug For internal use: → "For internal use"
- ↓ If contained drugs mention in Schedule → "To be sold on prescription of Reg. Med. practitioner only"
 - Contains NMT 3% alcohol by vol = Mentions the quantity in terms of % by vol

- ★ External use → "For External use ONLY"
- ↓
Cream / liniment / lotion / antiseptic

- ★ - PHYSICIAN'S SAMPLE → 'P. Sample NOT FOR SALE'

- ★ - "Government supply" → For Gov. agencies / semi-gov.
 (NOT For sale.)
- Pack & label should be in pale-green colour
 - Govt. logo
 - Red color writing in urdu + Eng.

- ★ - "For veterinary use ONLY" → vet. medicines
 (Red ink)

- ★ - Outer transparent wrapper NOT require labelling.

- ★ - Non-sterile Surgical ligature/suture:- "Non-sterile surg. suture/lig"
- ↓
label → present on every wrapper/container
- in indeleble Red ink:
NOT TO BE used For operation
sterilized upon Human body unless properly

- ★ Letters of Specification → P.P, Ph.I, Eur. P, B.P, B.P.C & USNF
- ↓
 - Pak. Pharmacopoeia → British pharm
 - International pharmacopoeia → British pharmaceutical code
 - Eur. pharm. → US - National Formulary

DO WATCH LECTURE ON PHARMACO-STUDY YOUTUBE CHANNE

- Type of NOZZLES:
- integrated needle
 - non-integrated needle
 - fixed needle
 - slip-tip needle
 - luer-lock needle

Always check recent amendments in law

Needle size & Dimension

Nominal capacity

auto-disable symbol
"in case of auto-disable syringe"

Type of syringe, in case of insulin syringe

Labelling of Medical devices

"disposable syringe, disposable set for collection or transfusion of blood or giving an infusion, cannula, catheter, Stent, auto-disable syringe or butterfly needle."

Sterile

For single use only

A warning to check the integrity

of primary container e.g. "Don't use if the blister is punctured or not intact"

Units of activity like U-40 or U-100 in case of insulin syringe

4 Disposable syringes shall be packed only in blister packs and NOT in polyethylene packing. - allows sterilisation via gas permeation.

SCHEDULES

(1) CNS-stimulants

(2) Drugs Affecting uterine Motility

(3) Drugs - inhibit hormonal produc.

(4) Hormone & other steroidal prep

Except - For external/topical

(5) Narcotic drugs as per single convention on narcotic drug 1954

(6) Psychotropic Subs. mentio. as per convention on psycho-sub 1971