

Drugs Category Rules, 2043(1986)

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In exercise of the powers conferred by the Section 40 of the Drugs Act, 2035 (1978), Government of Nepal has framed the following Rules.

1. **Short Title & Commencement** :- (1) These Rules may be called "Drugs Category Rules, 2043 (1986)".

(2) These Rules shall come into force on the date and in the area assigned by the Government of Nepal by publishing a notice in Nepal gazette.¹

2. **Definitions**:- Unless the subject or context otherwise requires in these Rules :

(a) "Act" means Drugs Act, 2035 (1978).

(b) "Department" means Department of Drugs Administration.

(c) "Container" means a pot of any shape, size or kind where the drugs (medicine) can be stored safely & without any adverse effect.

(d) "Dose" means the quantity of any drugs that has been prescribed for the purpose of taking by a patient at a time.

3. **Nepal Pharmacopoeia**: The department shall prepare an official Nepal pharmacopoeia and an encyclopedia related to it and this pharmacopoeia and encyclopedia shall come into force after taking approval from the Government of Nepal.

¹ These Rules were made effective on 2046.5.26 A.D. on the whole part of Nepal (Nepal Gazettee 2046.5.26)

4. **The Category of drugs shall be in accordance with Nepal pharmacopoeia** :- After coming into force of the official Nepal pharmacopoeia and encyclopedia related to it pursuant to rule 3, The category of drugs for the purpose of Section 12 of the Act, shall be in accordance to the such pharmacopoeia and the encyclopedia.

5. **Other encyclopedia may be Recognized** :- (1) Till the Nepal official pharmacopoeia or encyclopedia related to it has come into force the categorization of drugs shall be in accordance to any pharmacopoeia or encyclopedia mentioned in Schedule – 1.

(2) Notwithstanding anything contained in sub-rule (1), Even after the Nepal official pharmacopoeia or encyclopedia has come in to force, If the Government of Nepal deemed necessary, then any pharmacopoeia or encyclopedia mentioned in Schedule–1 may have given recognition in relation to the categorization of drugs.

6. **Categorization of the Drugs** :- (1) If the categorization & tests or analytical method of any drug has not been mentioned in the pharmacopoeia or the encyclopedia pursuant to rule 4 & 5, then if it has to be intended to determine that whether such drug has been safe to the people, efficacious or qualitative or not ? or whether the methodology to be followed to test or analyze such drug has been appropriate or not ?, the department may take consultation of Drug Advisory Committee and the department shall determine the methodology for categorization, related test or analysis of such drugs.

(2) If the categorization of any drugs, can not be made due to the reason of not mentioned in Nepal official pharmacopoeia or encyclopedia related to it or any other pharmacopoeia or encyclopedia pursuant to Schedule–1, the person producing the drug shall submit an application, in the department, to categorize such drug, in the format prescribed in Schedule–2.

(3) If the application pursuant to sub rule (2) has been submitted, the department may take consultation of the drug Advisory Committee about the categorization of such drug and the department shall determine the category of such drug also on the basis of such consultation.

(4) While making categorization of drug pursuant to sub rule (3). If it has been found necessary that any scientific and technical methodology have to be determined for the test and analysis of the drug, the department shall also determine such methodology by taking the consultation of the drug Advisory Committee on it.

(5) In determination of the category of drugs that have been imported in Nepal, If the department asks for the category or methodology for categorization of such drug to the person or agency importing such drug, then the person or agency who imports such drug shall submit the category or methodology for categorization of such drugs to the department.

7. Implementation of the category & test or analysis methodology of

the Drug :- (1) After determination of category of a drug and test or analysis methodology of such drug pursuant to rule 6, the department shall implement the category & test or analysis methodology of the drug.

(2) The department may take consultation with Drug Advisory Committee about the problems arising during the implementation of the category test or analysis methodology of the drug pursuant to sub rule (1), and also on the basis of the consultation of the committee, the department shall implement the test or analysis methodology of such drug.

8. Compensation to be provided :- (1) The compensation for the purpose of Section 15 of the Act, has to be provided by the person or the agency producing such drug to the person who is harmed by taking the

drug or in case of death of such person to the close successor of such dead person shall be as follows & in the following conditions:

<u>Particulars</u>	<u>Compensation Amount</u>
(a) If Heart, Liver, Brain, Kidney (both), Lungs (both) has been damaged in such way they shall not be used then for each.	– Three Hundred Thousand
(b) If only one kidney or lung harmed being unusable then for each	– One Hundred Thousand
(c) If the following organs harmed being unusable –	
(1) For both eyes	– Two Hundred Thousand
(2) For both ears	– Two Hundred Thousand
(3) For Nose	– One Hundred Thousand
(4) For tongue	– One Hundred Thousand
(5) For Penis	– One Hundred Thousand
(6) for one eye	– One Hundred Thousand
(7) For one ear	– Seventy thousand
(8) For both hands or both legs	– Two Hundred Twenty Thousand
(9) For one hand or one leg or some parts of one hand or one leg	– Eighty Thousand

- (10) For some part of both
hands or both legs – Eighty Thousand
- (11) For each fingers of hand
or leg – Five Thousand
- (d) If the other internal organs
except included in part (a), (b)
& (c) has been damaged being
useless. – One Hundred Thousand
- (e) If the other outer organs except
included in part (a), (b) & (c)
has been damaged being useless. – Eighty Thousand
- (f) If any organs has been harmed
without being useless, the
compensation may be upto two
third amount of as being useless. –
- (g) If miscarriage of fetus before
Twenty Eight weeks. – Ten Thousand
- (h) If miscarriage of fetus of
Twenty Eight weeks or more
than that. – Twenty Five Thousand
- (i) If a child born with deformities
abnormal organs due to adverse
effect on pregnancy. – Fifteen Thousand
- (j) If a person dies. – Thirty Thousand

(2) Not withstanding anything contained in sub rule (1), the compensation provided under this rule shall not be more than 3,00,000/- (Three Hundred Thousand) rupees.

9. **Format of Guarantee Document (letter)** :- The format of guarantee letter for the purpose of Section 16 of the Act shall be as prescribed by Schedule – 3.
10. **The classification of drugs in categories & sub categories** :-
- (1) For the purpose of categorization of drugs pursuant to Section 17 of the Act, drugs are classified in categories "a", "b" and "c" and every categories may have sub categories. The drugs classified in categories "a", "b" and "c" and sub categories under such categories shall be as mentioned in Schedule –4.
- (2) Out of the categories classified pursuant to rule (1).
- (A) Category "a" consists of narcotic and poisonous drugs and category "b" consists Antibiotics, Hermons etc drugs. The drugs under these categories shall be sold only on the prescription of a Doctor and these drugs shall be sold by a pharmacist or professional ownself or only in the presence of any one out of either a pharmacist or a professional.
- (AA) The drugs under category "c" may be sold by any seller on the basis of experience and even without the prescription of doctor and the presence of a pharmacist or a professional shall not be compulsory while selling the drug.
- (3) Under the categories "a" –
- (A) Sub category 1 shall consists of the narcotic drugs mentioned in that subcategory and the drugs which contains any substance related to it.

(AA) Sub category 2 shall consist of the poisonous drugs consisting the active ingredients mentioned in the sub category or any substance related to it.

(4) Category "b" shall consist of the drugs containing the active ingredients mentioned in that category or any substance related to it.

(5) Under the category "c",

(A) Sub category 1, shall consist the drugs that contain prescribed percentage of prescribed drugs in that sub category.

(AA) Sub category 2, consist of the drugs containing the active ingredients mentioned in that sub category or any substance related to it.

11. **Already Used (Prescription Filled) stamp shall be put** :- Anyone while selling any drug under category "a", on the prescription of a Doctor shall put a stamp mentioning the words "Already Used (Prescription Filled)" on that prescription.

12. **Label to be put on each drug container** :- (1) A Person producing drugs, after keeping the each drugs produced by himself/herself in a container in such away that has not been mixed with other drugs or things, shall put a label on the outer side of such container.

(2) The label put on outer side of a container pursuant to sub rule (1) shall mention about the drugs kept in the container the matters prescribed in Schedule – 5, written in brief in Nepali or English or both Nepali & English or any other language approved by Government of Nepal.

13. **Insert slip to be kept inside the Packing Box** :- (1) On the process of producing a drug, the producer of the drug may keep the container inside a packing box for the protection of the container of the drug and while

keeping the container inside the packing box an insert slip may be kept along with such container.

(2) The insert slip kept inside the packing box pursuant to sub rule (1), shall mention about the drug kept in the container, the matters prescribed in Schedule – 6 mentioned in detail in Nepali or English or both Nepali and English or any other language approved by government of Nepal.

14. Narcotic & poisonous drugs to be kept safe :- For the purpose of sub Section (1) of Section 33 of the Act, in case of Narcotic drugs, the drugs mentioned in sub category – 1 of category "a" and in case of poisonous drugs, the drugs mentioned in sub category – 2 of the same category has been prescribed and Each such drug shall be kept safe being under the rule 12 in the following way –

- (a) Kept in a certain place,
- (b) While keeping in certain place, managed in such way that has not been dropped from such place.
- (c) Unconcerned/unauthorized person has not been able to easily access or touch, and
- (d) Has not been mixed with any other drugs or things.

15. The Record of Narcotic and Poisonous Drugs:- For the purpose of sub Section (2) of Section 33 of the Act, The record of the narcotic and poisonous drugs shall be in the format prescribed in Schedule – 7.

16. Schedules may be changed:- Government of Nepal may make change as per the need in the Schedules by publishing a notice in Nepal Gazette.

Schedule – 1

(Related to rule 5)

Pharmacopoeia or encyclopedia related to the category of drugs

1. "International Pharmacopoeia" published by World Health Organization.
2. "European Pharmacopoeia" published by Council of Europe.
3. "Pharmacopoeia of India" published by the Ministry of Health of Government of India.
4. "British Pharmacopoeia" published by Ministry of Health and Social Services of British Government under the Medicine Act, 1968.
5. "The United States Pharmacopoeia" made under the United States Pharmacopoeia Convention.
6. "State pharmacopoeia of the union of Soviet Socialist" published by the Ministry of the Health of the USSR.
7. "Pharmacopoeia of Japan" published by Ministry of Health and welfare of Government of Japan.
8. "Indian Pharmaceutical Codex" published by Council of Scientific and Industrial Research of India.
9. "British Pharmaceutical Codex" published by Pharmaceutical Society of Great Britain.
10. "National Formulary" published by American Pharmaceutical Association.
11. Pharmacopoeia and any encyclopedia related to it, of any other country prescribed by the Government of Nepal.

Note: For the purpose of encyclopedia mentioned in this Schedule, the category of any drug if has not been available in the prevailing edition, and if it has been mentioned the previous edition of such encyclopedia, then it shall be as according to such edition.

Schedule – 2

(Related sub rule (2) of Rule (6))

Format of the application for the categorization of the drug

The Administrator

Department of Drug Administration

Ministry of Health.

I/we have submitted this application, to categorize the drug pursuant to the sub rule (2) of rule 6 of Category of Drugs Rules, 2043 mentioning the following details and sticking a stamp of Rs. 1.00 (One Rupee).

- (a) The chemical or biological name and quantity of the drug :
- (b) The purity of the drug :
- (c) The identification of the drug :
- (d) Test or analytical methodology of the drug and result :
- (e) The methodology for qualitative and quantitative evaluation of the drug :
- (f) The solvent substance contained in the drug :
- (g) The limit of solvent substance and the methodology to determine it:
- (h) The utility of the drug and using methodology :
- (i) Dose of the drug :
- (j) If the production license has been taken for the production of the drug then the date and the office from which such production license has been taken :
- (k) The attested copy of production license has been attached or not :

The drug producing person or agency's

Signature :

Name & Surname :

Address :

Date :

Schedule – 3

(Related to Rule 9)

Format for Guarantee Letter

I/we residing in have made the guarantee letter for the following drugs produced by me/us, has been qualitative, effective and safe for public as per the Drugs Act, 2035 and the rules made under the Act.

The drugs

Name :-

Type :-

System :-

Category or sub category :-

Active Ingredients

(a) Name :

(b) Quantity :

Batch Number :-

Sold / Distributed :-

(a) Quantity :

(b) Date :

Date of Production :

Date of Expire :

Drug Producers'

Signature :

Name & Surname :

Address :

Date :

For Reference & Implementation :

Government of Nepal,

Department of Drug Administration :- The detail description related to the categorization of the drug has been attached herewith.

Note : The wholeseller of the drug shall take the guarantee letter made as according to this Schedule from the drug producer and give two attested copies to the retailer of the drug. Such retailer who has received such attested copies from the wholeseller shall submit one copy in the department and shall keep a receipt of it.

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Schedule – 4

(Related to Rule 10)

Classification of drugs in categories & sub categories

Category "a"

This category has the following sub categories 1 & 2 :-

Sub category – 1

This sub category has the following Narcotic drugs and the drugs containing the related substances to it :-

- (1) Acetyl methadol
- (2) Allyl prodine
- (3) Alpha acetyl methadol
- (4) Alpha meprodine
- (5) Alpha methadol
- (6) Aceterphin hydrochloride
- (7) Acetyl dihydrocodeine
- (8) Alpha prodine
- (9) Anileridine
- (10) Acetyl dihydrocodinon
- (11) Apomorphine
- (12) Benzithidine
- (13) Bita acetyl methadol
- (14) Bitameprodine
- (15) Bitamethadole

- (16) Bitaprodine
- (17) Benzyl morphine
- (18) Benzitramide
- (19) Clonitazine
- (20) Codeine Methyl Bromide
- (21) Codeine–N–oxide
- (22) Cyprine phine
- (23) Codeine
- (24) Dextro Moramide
- (25) Dextroraphan
- (26) Diamprenmide
- (27) Diethyl thyambutine
- (28) Dimenoxadole
- (29) Dimephoptanole
- (30) Dimethyl Thyambutine
- (31) Dioxaphetyyle Butieret
- (32) Dipipanone
- (33) Desomorphine
- (34) Dihydro morphine
- (35) Dihydro Codeine
- (36) Dihydro Codeinone
- (37) Dihydro hydroxy Codeinone
- (38) Dihydroxy Dyhydro morphine hydrochloride
- (39) Ethyl methyl Thyambutine
- (40) Etonitazine

- (41) Etoceridine
- (42) Etomorphine
- (43) Ethyl morphine
- (44) Phurethidine
- (45) Phentanyle
- (46) Hydroxy pethidine
- (47) Heroine or Diacetyl morphine
- (48) Hydro morphone
- (49) Phitobemidone
- (50) Levomoramide
- (51) Levo phenacylemorphan
- (52) Levo metharphan
- (53) Levarphanole
- (54) Marpheridine
- (55) Methyl desarphine
- (56) Methyl dihydromerphine
- (57) Morphine Methyl Bromide
- (58) Morphine–N–oxide
- (59) Myrophine
- (60) Metazosin
- (61) Methadone
- (62) Moramide
- (63) Morphine
- (64) Nullophine
- (65) Naracymethadol

- (66) Narliverphenol
- (67) Narmethadone
- (68) Narpipanone
- (69) Nicocodeine
- (70) Nico morphine
- (71) Narmorphine
- (72) Narcodeine
- (73) Oxymorphone
- (74) Opium
- (75) Phenadoxon
- (76) Phenampromide
- (77) Phenomorphan
- (78) Phenoperidine
- (79) Piritramide
- (80) Proheptazin
- (81) Proparidine
- (82) Pethidine
- (83) Phenazocine
- (84) Piminodine
- (85) Phenmetrazine
- (86) Recimoramide
- (87) Recimeatharphan
- (88) Recimorphan
- (89) Trimeperidine
- (90) Amphetamin

- (91) Bufetenin
- (92) Diethyl triptamin
- (93) Dymethyl triptamin
- (94) Evogen
- (95) Lycergic Acid Diethylamide
- (96) Active Ingredients of Marijuana
- (97) Methamphetamin
- (98) Mescyalin
- (99) Methyl phenidet
- (100) Peyot
- (101) N-ethyl-3 piparidyle Benzilet
- (102) Cilocybin
- (103) Barbiqueric Acid & Itis Derivatives
 - a. Amobarbital
 - b. Barbital
 - c. Methyl Pheno Barbital
 - d. Pheno Barbital
- (104) Cloro Hexadol
- (105) Cocaine
- (106) Ethchlor Vinyl
- (107) Ethinamet
- (108) Glutethimide
- (109) Lycergic Acid
- (110) Lycergic Acid Amide
- (111) Meprovet

- (112) Methacoilan
- (113) Methiprilan
- (114) Methohexital
- (115) Petrichloral
- (116) Phencyclidine
- (117) Sulphone diethyl Methene
- (118) Sulphone Methene
- (119) M-Methyl-3 pipradyle Bengilet
- (120) Cilocine
- (121) Morphine Methyl Salphonet

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Sub Category – 2

This sub category consists the drugs containing the following active ingredients or any substance related to such ingredients :-

- (1) Raolphia Alcolides
- (2) Yohimba Alcolide
- (3) Veratram Alcolide
- (4) Quinidine
- (5) Procainamide
- (6) Codoxim
- (7) Lobelia Alcolide
- (8) Chloroform
- (9) Orthocaine
- (10) Procaine
- (11) Tropa cocane
- (12) 6 - Mercaptopurine
- (13) Methotrexate
- (14) Vincristine
- (15) Vinblastine
- (16) Chloromethene Hydrochloride
- (17) Beladona & it's Alcolide
- (18) *Dhatura*
- (19) Biperidine
- (20) Di-isopropyle Fluorophosphate
- (21) Ayl Isopropyle Acetyl Uria
- (22) Butyl cloral Hydrate

- (23) Cloral Pharmamide
- (24) Cloral Butane
- (25) Cloral Hydrate
- (26) Paraldihyde
- (27) Phenyl Acetyl Urea
- (28) Troxidone
- (29) Benoctizine
- (30) Hiparin
- (31) Warfarin
- (32) Echonite Alcolide
- (33) Phenyl Cinchoninic Acid
- (34) Propoxyphine
- (35) Epiyol
- (36) Amayl Nitrite
- (37) Mannitol Hexamitrate
- (38) Ergot Alcolide and Its Derivatives
- (39) Mustin-Hydrochloride
- (40) Aminopterin
- (41) Busulphan
- (42) Chlorambucil
- (43) Cyclophosphamide
- (44) Monomustin Hydrochloride
- (45) Triethinyl Thayo phosphoramide
- (46) Guanidine
- (47) Berium or Its compound except Berium sulphate

- (48) Gyalavine
- (49) Lodexium
- (50) Iletarium
- (51) Conin
- (52) Antimani Potasium Tartrate
- (53) Imetine
- (54) Stilbocaptate
- (55) Digitalics and Its Glycosides
- (56) Disulphiram
- (57) Cantharidine
- (58) Epinephrine
- (59) Liverternal
- (60) Lead and it's compound
- (61) Methanol
- (62) Zinc and it's compound
- (63) Mercury and It's compound
- (64) Phennformin
- (65) Azathioprine
- (66) Sabidila Alcolide
- (67) Thaliium
- (68) Pomegrenet Alcolides
- (69) Nicotine
- (70) Noxmomica and Its Alcolides
- (71) Arsenic and It's compound
- (72) Gelsimium Alcalide

Category – b

This category consists the drugs containing the following active ingredients or any substance related to such ingredients :-

- (1) Anti Rabies Serum
- (2) Antigen
- (3) Antitoxin
- (4) Antivenom
- (5) Sera
- (6) Serum Protein
- (7) Toxin
- (8) Penicillin and its penicillins
- (9)
 - (a) Benzyl Penicillin
 - (b) Benzathine Benzyl Penicillin
 - (c) Procaine Benzyl Penicillin
 - (d) Phenoxymethylpenicillin
 - (e) cloxacillin
 - (f) Ampicillin
 - (g) Amoxycilin
- (10) Tetracycline and its Derivatives
 - (a) Oxytetracycline
 - (b) Chlortetracycline
 - (c) Doxycycline
- (11) Gramacidine
- (12) Wacitracin

- (13) Polymyxcin B
- (14) Nistatin
- (15) Amphotericin B
- (16) Viomycin
- (17) Rifampin
- (18) Streptomycin
- (19) Canamycin
- (20) Neo mycin
- (21) Paramomycin
- (22) Gentamycin
- (23) Erythromycin
- (24) Chloramphenicol
- (25) Carbomycin
- (26) Faramycitine
- (27) Griseofulvin
- (28) Navobiocin
- (29) Olindomycin
- (30) Spyromycin
- (31) Bancomycin
- (32) Sulfamethoxazole
- (33) Sulfameopyrazin
- (34) Sulfamethoxine
- (35) Sulfadoxine
- (36) Sulfaurazole
- (37) Sulfamethoxy Pyridizine

- (38) Sulfasomizole
- (39) Sulfasalazine
- (40) Benzocaine
- (41) Ether
- (42) Luracine
- (43) Halothane
- (44) Leaocane
- (45) Nitrous Oxide
- (46) Tribromethanol
- (47) Theopental Sodium
- (48) Ethambutol
- (49) Isonicotinic Acid Hydrozide and It's Derivative
- (50) Isoniazid
- (51) Pyrizinamide
- (52) Paraminosolisilic Acid
- (53) Thiacetazone
- (54) Protamine Sulphate
- (55) Acetazolamide
- (56) Bendrofluazide
- (57) Chlorothiazide
- (58) Frusemide
- (59) Hydrochlorothiazide
- (60) Methyl Chlorothiazide
- (61) Polythiazide
- (62) Spironolactone

- (63) Triamterene
- (64) Dimercoprol
- (65) Phytomenadione
- (66) Triethanolamine
- (67) Paraleadoxin
- (68) Vitamin D. as Single preparation
- (69) Ethosoximide
- (70) Hydentwine
- (71) Methosoximide
- (72) Oxazolidine
- (73) Paramethadione
- (74) Phensoximide
- (75) Endomethacin
- (76) Metamezole
- (77) Oxiphen Butazone
- (78) Phenyl Butazone
- (79) Pentazocine
- (80) Pyrivinium
- (81) Thiobendazole
- (82) Nitrofurantoin
- (83) Verapamil Injection
- (84) Erythrityle Tetranitrate
- (85) Glyceryl Trinitrate
- (86) Isosorbide Dinitrate or sorbide Nitrate
- (87) Iso prenaline

- (88) Isosuprine
- (89) Chlorisandamin chloride
- (90) Cyclopentiazide
- (91) Hydrolazine Injection
- (92) Methyldopa
- (93) Bitablockers
 - (a) Propanolol
 - (b) Isopreterenol
 - (c) Sotalol
 - (d) Dichloro Isopreterenol
- (94) Captodine
- (95) Amitriptyline
- (96) Amipramine
- (97) Triamipramine
- (98) Trianyle Cipromine
- (99) Promethazine Hydrochloride
- (100) Pecazine
- (101) Phenylzine
- (102) Provazine
- (103) Prochloro Perazine
- (104) Acepromazin Maliate
- (105) Azamaline and Its compounds
- (106) Diazepam
- (107) Haloperidol
- (108) Isocarboxazid

- (109) Triflupromazine
- (110) Theo Propazet
- (111) Chlormezanon
- (112) Chlor Promazine
- (113) Chloro Prothioxine
- (114) Hydroxizine
- (115) Diphenyl Pyraline Hydrochloride
- (116) Prophen Pyridomine
- (117) Chlophazimine
- (118) Dapsone
- (119) Iopanoic Acid
- (120) Sodium Amidotrizoate
- (121) Tuberculin
- (122) Phentolamine
- (123) Azapentine
- (124) Brethilium Tosilate
- (125) Probenicid
- (126) Stilbogluconate
- (127) Primaquine
- (128) Levodopa
- (129) Allopurinol
- (130) Carbutamide
- (131) Chloropropamide
- (132) Metamorphine
- (133) Talbutamide

- (134) Dextran 40
- (135) Dextran 70
- (136) Hexocyclian Methyl Sulphate
- (137) Suxamethonium
- (138) Pempidine
- (139) Polytheouracil
- (140) Pentamidine
- (141) Iserine
- (142) Neostigmine
- (143) Carbacoal
- (144) Pilocarpine
- (145) Pyridostigmine
- (146) Trihexyphenidyl
- (147) Hermons :-
- (a) Insulin
 - (b) Thyroid Extract & Thyroxin
 - (c) Pitutory Extract
 - (d) Oxitocin
 - (e) Vaso precin
 - (f) Edrenocarticotropic Hermons
 - (g) Benzoistrol
 - (h) Dexamethasone
 - (i) Ethinylestradiol
 - (j) Betamethasone
 - (k) Cartisone

- (l) Hydrocortisone
 - (m) Norethisterone
 - (n) Prednisolone
 - (o) Testosterone
 - (p) Triamcnenolone
- (148) Meglumin
- (149) Salbutamol
- (150) Trimethoprim
- (151) Stropine
- (152) Retinal as single preparation
- (153) Triameparazine

Category – c

This category has the following sub category 1 and 2

Sub category – 1

This sub category consists of the following drugs out of the drugs mentioned in category A and B, not exceeding the percentage mentioned herewith –

	<u>Percentage</u>
(1) Econite Alcolide	0.20
(2) Amino Alcohol	10.00
(3) Antimani & it's compound	1.00
(4) Apomorphine	0.20
(5) Arsenic & it's compound	0.01
(6) Stropin	0.15
(7) Beladona Alkalide	0.15

(8)	Brucin	0.20
(9)	Catharidine	0.10
(10)	Coca Alkalide	0.10
(11)	Cocaine	0.10
(12)	Codeine	1.00
(13)	Colchicum	0.50
(14)	Coneine	0.10
(15)	Cotarnine	0.20
(16)	<i>Dhatura</i>	0.15
(17)	Desomorphine	1.50
(18)	Dextromethorpha	1.50
(19)	Dihydroxy Dihymorphine	0.10
(20)	Emetine	1.00
(21)	Ephdra Alkalide	1.00
(22)	Ethyl Morphin	0.20e
(23)	Gelcemium Alkalide	0.10
(24)	Homatropine	0.10
(25)	Hyocymine	0.15
(26)	Hydrocynic Acid	0.15
(27)	Lovelialcolide	0.50
(28)	Morphine	0.20
(29)	Mercuricchloride	1.00
(30)	Mercuriciozide	2.00
(31)	Mercuricnitrate	3.00
(32)	Mercury	0.20

(33)	Mercuric Potassium Iodide	1.00
(34)	Naxmomica	0.20
(35)	Nicotine	0.20
(36)	Pomegrenet Alcocide	0.50
(37)	Opium	0.20
(38)	Solenicious Alcolide	0.15
(39)	Stavsakar Alcolide	0.20
(40)	Striquinine	0.20
(41)	Veratram Alcolide	1.00
(42)	Hyoscine	0.15

Sub category – 2

This sub category consists the drugs containing the following active ingredients or any substance related to such ingredients :-

- (1) Ibuprofen
- (2) Paracetamol
- (3) Nitrezepam
- (4) Promethazine Thioclate
- (5) Antazolin
- (6) Promazine
- (7) Chlorcyclizine
- (8) Chlorpheniramine
- (9) Dyphenhydramine
- (10) Pheniramine
- (11) Milkizine

- (12) Phenindamine
- (13) Thianalidine
- (14) Sulphadimidine
- (15) Sulphadizine
- (16) Sulphamerazine
- (17) Sulphamethizole
- (18) Sulphanilamide
- (19) Sulphathiozole
- (20) Sulphasomidine
- (21) Sulphaguanidine
- (22) Sulphacetamide
- (23) Tyrothricine as local use
- (24) Biphenium
- (25) Diethyl carbamazine
- (26) Mebendazole
- (27) Nilcosamide
- (28) Piparazine
- (29) Tetramesol
- (30) Amodioquine chlorhydrate
- (31) Chloroquine
- (32) Pyrimethamine
- (33) Ascorbic Acid
- (34) Ergocalciferol
- (35) Nicotinamide
- (36) Pyridoxine

- (37) Reboflavin
- (38) Thiamine Hydrochloride
- (39) Cyanocobalamine
- (40) Nicothiamide
- (41) Metronidazole
- (42) Aminophylline
- (43) Papaverine
- (44) Diloxanide
- (45) Clinidium Bromide
- (46) Folcodeine

This category shall consist other similar simple drugs.

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Schedule – 5

(Related to sub rule 2 of rule 12)

The matters to be mentioned in a label

1. Name of the drug and quantity.
2. Category and sub category of the drug.
3. Out of Allopathic, Ayurvedic, Yunani and Homeopathic system the drug belongs to which system.
4. The name of the major (active) ingredient, quantity and the name of the encyclopedia with which the drug belongs to.
5. The name of the drug production company, address and country.
6. The serial number of recommendation letter provided for the establishment of drug industry.
7. The serial number of production license provided for the production of the drug.
8. The Batch No. of the drug.
9. The date of production of the drug.
10. The date of expiry for the drug that expires.
11. The price of the drug.
12. The storing method (technique) and management of the drug.
13. If the drug belongs to the sub category 1 & 2 of category "a" the words "Caution Poison" and "May not be sold without the prescription of a register medical practicer" and if the drug belongs to the category "b" then the words "Caution" and "May not be sold without the prescription of a register medical practicer".
14. The quantity of the drug that may be used in relation to the age.

15. The method of use of the drug.
16. If for the drug that have been used for external use only then the words "only for external use."
17. If the drug that have been used only for the animal except than the human being then the words "Not for human use".
18. If the drug that have been used in operation or injection or similar other technique of sending the drug inside the body has not been sterilized during the production then the words "Not sterilized, shall not be used without sterilization".

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Schedule – 6

(Related to sub rule (2) of Rule 13)

The Matters to be Mentioned in Insert Slip

1. The matters to be mentioned pursuant to Schedule – 5.
2. The disease for which the drug to be used and the details of the condition of the disease.
3. If the Age, Condition & Sex of the patient varies the quantity of use of drug then such quantity for use.
4. The time & duration of use of the drug.
5. The method of using the drug.
6. If some preparation method have to be made before the use of the drug then such method.
7. The probable adverse effects of the use of the drug and the remedies for such effect.
8. The condition in which the drug shall not be used.

Schedule – 7

(Related to Rule 15)

The Record of the Narcotic & Poisonous Drugs

- (a) The wholeseller shall keep the record mentioning the following, after making the wholesale / distribution of the narcotic and poisonous drugs :-
1. Name of the drug :-
 2. Name of the Person or Agency producing the drug :-
 3. The date of production of the drug :-
 4. The batch no. of the drug :-
 5. The expiry date of the drug :-
 6. The date of receipt of the drug & quantity :-
 7. The name, surname & address of the person from whom the drug has been received :-
 8. The type and quantity of such drug which has been sold to the retailers :-
 9. The retailers :-
 - (a) Name, surname & address :-
 - (b) Date of signature :-
 10. The quantity of such drug remaining in his/her own stock :-

.....

(The name & surname of the wholeseller)

Date :

(b) The retailer shall keep the record mentioning the following, after making the retail sale / distribution of the narcotic & poisonous drugs :-

1. The name of the drug :-
2. The name of the person or agency producing the drug :-
3. The date of production of the drug :-
4. The date of expiry of the drug :-
5. The date of receipt of the drug & quantity :-
6. The name, surname & address of the person from whom the drug has been received :-
7. The person purchasing such drug for use;
 - (a) Name, surname and address :-
 - (b) Date of signature :-
8. The quantity of the drug that has been sold to such person for the use :-
Signature of the person verifying that the details mentioned above are true :-

(The Retailer's name & surname)

Date :-