

# **\*THE DRUGS RULES, 1945<sup>1</sup>**

[21st December, 1945]

*In exercise of the powers conferred by <sup>1</sup>[sections 6(2), 12, 33 and 33(N)] of the Drugs <sup>2</sup>[and Cosmetics] Act, 1940 (23 of 1940), the Central Government is pleased to make the following Rules:—*

## **PART I PRELIMINARY**

1. **Short title, extent and commencement.**—(1) These Rules may be called the Drugs <sup>3</sup>[\*\*\*] Rules, 1945.

(2) They extend to the whole of India <sup>3</sup>[\*\*\*].

2. **Definitions.**—In these Rules, unless there is anything repugnant in the subject or context—

(a) "the Act" means the Drugs and Cosmetics Act, 1940 (23 of 1940), as amended from time to time;

<sup>6</sup>[(aa) "biopharmaceutical classification system" means a system used to classify drugs on the basis of solubility and permeability, classified as category I-high solubility and high permeability, category II-low solubility and high permeability, category III-high solubility and low permeability, and category IV-low solubility and low permeability;] <sup>7</sup>[(b) "Central Licence Approving Authority" means the Drugs Controller, India, or the Joint Drugs Controller (India) or the Deputy Drugs Controller (India) appointed by the Central Government;]

(c) "Director" means the Director of the Central Drugs Laboratory;

(d) "Form" means a Form set forth in Schedule A;

<sup>8</sup>[(dd) "Homoeopathic medicines" include any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature of India and abroad and which is prepared according to the techniques of Homoeopathic pharmacy and covers combination of ingredients of such

and Psychotropic Substances that they do not have any objection for the import of the drug with code number;

(iii) the state Licensing Authority shall issue the manufacturing licence for these formulations on each export order on the basis of a no objection certificate from Drugs Controller, India;

(iv) a no objection certificate shall be obtained from the Drugs Controller, India for export of each consignment; and

(v) a no objection certificate shall be obtained from the Narcotic Commissioner of India, Gwalior for export of each consignment of the drug.]

<sup>2</sup>[(2) The provisions or rules 96 to 101 inclusive, shall not apply to a medicine made up ready for treatment, whether after or without dilution, which is supplied on the prescription of a registered medical practitioner provided that—

(i) the medicine is labelled with the following particulars:—

- (a) the name and address of the supplier;
- (b) the name of the patient and the quantity of the medicine;
- (c) the number representing serial number of the entry in the prescription register;
- (d) the dose, if the medicine is for internal use;

<sup>3</sup>[(e) the words 'For External use only' shall be printed on the label if the medicine is for external application;]

(ii) Condition (3) of the conditions in rule 65 is satisfied.]

**95. Prohibition of sale or distribution unless labelled.**—Subject to the other provisions of these rules, no person shall sell or distribute any drug (including a patent or proprietary medicine) unless it is labelled in accordance with these rules.

<sup>4</sup>**[96. Manner of Labelling.**—(1) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink

and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely:—

(i) The name of the drug:

(A) <sup>135</sup>[For this purpose, the proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be <sup>136</sup>[\*\*\*] at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written <sup>137</sup>[\*\*\*] below or after the proper name and shall be.]—

(a) for drugs included in Schedule F or Schedule F(1), the name given therein;

(b) for drugs included in the Indian Pharmacopoeia or the official Pharmacopoeias and official compendia of drug standards prescribed in rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters 'L.P.' or, as the case may be, by the recognised abbreviations of the respective official pharmacopoeia and official compendia of drug standards;

(c) for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters 'N.F.I';

(d) for other drugs, the international non-proprietary name, if any, published by the World Health Organisation or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance.

<sup>5</sup>[(AA) Notwithstanding anything contained in these rules, the additional requirements of labeling specified *vide* notification number G.S.R. 222(E) dated the 13th March, 2018 published in the Gazette of India, Extraordinary, Part-II - Section (3) - Sub-section(i) shall be on voluntary basis for a period beginning on the 13th September, 2018 and ending on the 31st March, 2019 and thereafter shall be mandatory.]

(ii) A correct statement of the net contents in terms of weight, measure, volume, number of units of contents, number of units of activity, as the case may be, and the weight, measure and volume shall be expressed in Metric system.

(iii) The content of active ingredients—

This shall be expressed—

(a) for oral liquid preparations in terms of the content per single dose, the dose being indicated in 5 millilitres <sup>138</sup>[\*\*\*]:

Provided that where the dose is below 5 millilitres the contents of active ingredients may be expressed in terms of one millilitre <sup>7</sup>[or fraction thereof];

<sup>1</sup>[Provided further that where the single dose is more than 5 millilitre, the content of active ingredients shall be expressed in terms of minimum single dose as approved by the licensing authority,]

(b) for liquid parenteral preparations ready for administration, in terms of 1 millilitre or percentage by volume or per dose in the case of a single dose container:

Provided that if the preparation is contained in an ampoule it will be enough if the composition is shown on the label or wrapper affixed to any package in which such ampoule is issued for sale;

(c) for drugs in solid form intended for parenteral administration in terms of units or weight per milligramme or gramme;

(d) for tablets, capsules, pills and the like, in terms of the content in each tablet, capsule, pill or other unit, as the case may be;

(e) for other preparations, in terms of percentage by weight or volume or in terms of unitage per gram or millilitre as the case may be:

Provided that clause (ii) shall not apply to a pharmacopoeial preparation where the composition of such preparation is specified in

the respective pharmacopoeia and to a preparation included in the National Formulary of India;

(iv)<sup>2</sup>[The name of the manufacturer and the address of the premises of the manufacturer where the drug has been manufactured:]

Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the manufacturer and his principal place of <sup>3</sup>[manufacture] is shown.

(v)A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words 'Batch No.' or 'B No.' or 'Batch' or 'Lot No.' or 'Lot'.

#### Notes.

(1) In the case of drugs manufactured by a continuous process, like manufacture of magnesium sulphate, pharmaceutical chemicals, etc., the production resulting in one homogeneous mix of the finished products shall be considered as one "Batch".

(2) In the case of powders, liquid orals, ointments, etc., one "Batch Number" shall be assigned to all the containers filed from one homogeneous bulk.

(3) In the case of tablets, capsules, lozenges, torches, etc. one "Batch Number" shall be assigned to the products manufactured from one homogeneous mix ready for compression or filing.

(4) In case of parental preparations sterilized by steam under pressure, one "Batch Number" shall be assigned to all containers filed from one homogeneous bulk solution and sterilized load.

(5) In the case of containers of parental preparations filed from one homogeneous bulk solution and sterilized in more than one sterilizer load, the "Batch Number" as signed to the containers in the different sterilizer loads shall be same "Batch Number" as is assigned to the homogeneous bulk solution, provided the samples taken from all the



sterilizer loads pass the sterility test, and kept separate from one another until the report of the sterility test is available.

*Explanation.*—For the purpose of chemical and other tests, representative samples from all containers filled from the homogeneous bulk solution should be taken.

(6) In the case of parental and other sterile products filled aseptically a "Batch Number" shall be assigned to all containers filled from one homogeneous mix during one filling operation, the filling operation being completed in a period of not more than a day during which no schedule change in the filling assembly is made. When containers are filled from one homogeneous mix, in a number of filling operations, the "Batch Number" assigned to the containers filled in individual filling operations shall be the same "Batch Number" as is assigned to the homogeneous mix, provided the samples taken from all the direction filling operations pass the sterility tests, and are kept separate from one another until the report of the sterility test is available. *Explanation.*—For the purpose of chemical and other tests, representative samples from all containers filled from the homogeneous mix should be taken.

(7) In the case of medicinal gases produced by a continuous process of operation a week's production from one tank load shall be considered as a Batch.

(vi) Every drug manufactured in India shall bear on its label the number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words 'Manufacturing Licence Number' or 'Mfg. Lie. No.' or 'M.L.'.

(vii) Drugs specified in Schedule P and their preparations including combinations with other drugs shall bear on their labels the date of manufacture and the date of expiry of potency, and the period between the date of manufacture and the date of expiry shall not exceed that laid down in the said Schedule <sup>139</sup> [under the conditions of storages specified therein. <sup>140</sup>[Drugs and their] preparations not included in Schedule P, shall bear on their labels the date of their manufacture and also the date of their expiry which shall not exceed sixty months from the date of manufacture]:

Provided that this period may be extended by the licensing authority specified in clause (b) of rule 21 in respect of any specified drug if satisfactory evidence is produced by the manufacturer to justify such an extension.

<sup>1</sup>[(viii) drugs specified in schedule C(l) and their preparations including combinations in other drugs shall bear on their labels (a) the date of manufacture, and (b) date of expiry of potency fixed by the manufacturer:]

<sup>2</sup>[Provided that drugs in bulk form included in Schedule C(l) which are not ready for use and not included in Schedule P need not bear on the label the date of expiry of potency:]

Provided further that no reference shall be made to any other licence number granted by any authority outside India on any label or container or in any covering in which the container is packed or in any other matter or advertisement enclosed therewith.

(ix) Every drug intended for distribution to the medical profession as a free sample shall, while complying with the labelling provisions under clauses (i) to (viii), further bear on the label of the container the words 'Physician's sample—Not to be sold' which shall be overprinted.

<sup>3</sup>[(x) If any preparation contains not less than 3 per cent, by volume of alcohol the quantity of alcohol shall be stated in terms of the average percentage by volume of absolute alcohol in the finished products.]

<sup>4</sup>[(xi) <sup>5</sup>[In addition to the other particulars which are required to be printed or written under these rules, the label of inner most container of the following categories of drugs and every other covering in which the container is packed shall bear a caution or warning, as applicable, depending on whether the drug is covered under Schedule G or Schedule H or Schedule H 1 or Schedule X, as specified in rule 97, in legible black coloured font size in a completely red rectangular box without disturbing other conditions printed on the label under these rules, namely:—

Narcotic analgesics, hypnotics, sedatives, tranquillisers, corticosteroids, hormones, hypoglycemic, antimicrobials, antiepileptics, antidepressants, anticoagulants, anti-cancer drugs and all other drugs falling under

Schedules G, H, H 1 and Schedule X whether covered or not in the above list:

Provided that if any of the drug referred above category is not covered under any of the Schedule, namely, Schedule G, Schedule H, Schedule H 1 and Schedule X, the label of inner most container of drugs and every other covering in which the container is packed shall bear caution or warning, as the case may be, applicable for that drugs covered under Schedule H as specified in rule 97:]

<sup>1</sup>[Provided further that] the provisions of this clause shall not apply to—

- (a) preparations intended for animal treatment;
- (b) preparations intended for external use;
- (c) ophthalmic preparations and ear drops; and
- (d) sterile preparations such as sutures, surgical dressings and preparations intended for parenteral use.]

<sup>2</sup>[(xii) Drugs and their preparations including combinations with other drugs imported into the country shall also bear on the label, the licence number under which the drug is imported, preceded by the words "Import Licence" and the name and address of the importer.]

<sup>3</sup>[(xiii) The name of the marketer of the drug and its address, in case the drug is marketed by a marketer:

Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the marketer is shown.]

(2) (i) The particulars to be printed or written on the label of a mechanical contraceptive shall be as specified in Schedule R.

(ii) The following particulars, in addition to those specified under sub-rule(1) shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container and on every other covering in which the container of a contraceptive, other than a mechanical contraceptive, is packed, namely:—



- (a) the date of manufacture;
- (b) the date up to which the contraceptive is expected to retain its properties;
- (c) the storage conditions necessary for preserving the properties of the contraceptive up to the date indicated in sub-clause (b):

Provided that for oral contraceptives it shall be sufficient to display on the label of the container the date of manufacture only.

(3) (i) The particulars prescribed in sub-rule (1) shall be printed or written in indelible ink either on the label borne by a container or vaccine lymph or on a label or wrapper affixed to any package in which the container is issued for sale. The said particulars shall be indelibly marked on the sealed container of surgical ligature or suture or printed or written in indelible ink on a label enclosed therein.

(ii) Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.

(4) Where by any provision of these rules any particulars are required to be displayed on a label on the container such particulars may, instead of being displayed on a label, be etched, painted or otherwise indelibly marked on the container:

Provided that, except where otherwise provided in these rules, the name of the drug or any distinctive letters intended to refer to the drug shall not be etched, painted or otherwise indelibly marked on any glass container other than ampoules.

*Explanation.*—For the purpose of this rule, the date of expiry shall be in terms of month and year and it shall mean that the drug is recommended till the last day of the month. The date of expiry shall be preceded by the words 'Expiry date'.]

**97. Labelling of medicines.**—<sup>141</sup> [(1) The container of a medicine for internal use shall—

<sup>2</sup>[(a) if it contains a drug substance specified in Schedule G, be labeled with following words in legible black coloured font size in completely red rectangular box:

**SCHEDULE G PRESCRIPTION DRUG - CAUTION**

It is dangerous to take this preparation except under medical supervision.

(b) if it contains a drug substance specified in Schedule IT, be labeled with symbol Rx and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

**SCHEDULE H PRESCRIPTION DRUG - CAUTION**

Not to be sold by retail without the prescription of a Registered Medical Practitioner.

(c) if it contains a drug substance specified in Schedule H and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) be labeled with symbol NRx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

**SCHEDULE H PRESCRIPTION DRUG - WARNING**

To be sold by retail on the prescription of a Registered Medical Practitioner only.

(d) if it contains a drug substance specified in Schedule X, be labeled with symbol XRx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

**SCHEDULE X PRESCRIPTION DRUG - WARNING**

To be sold by retail on the prescription of a Registered Medical Practitioner only.

(e) if it contains a drug substance specified in Schedule HI, be labeled with symbol Rx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

**SCHEDULE HI PRESCRIPTION DRUG - CAUTION**

- It is dangerous to take this preparation except in accordance with the medical advice.
- Not to be sold by retail without the prescription of a Registered Medical Practitioner.

(f) if it contains a drug substance specified in Schedule HI and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) be labeled with symbol NRx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

**SCHEDULE HI PRESCRIPTION DRUG - CAUTION**

- It is dangerous to take this preparation except in accordance with the medical advice.
- Not to be sold by retail without the prescription of a Registered Medical Practitioner.]

(2) The container of an embrocation, liniment, lotion, <sup>142</sup>[ointment, antiseptic cream,] liquid antiseptic or other liquid medicine for external application shall be labelled with the words in capital 'For External use only'.

<sup>2</sup>[(3) The container of a medicine made up ready only for treatment of an animal shall be labelled conspicuously with the words 'Not for human use; for animal treatment only', and shall bear a symbol depicting the head of a domestic animal.]

<sup>3</sup>[(3A) The container of a medicine for treatment of food producing animals shall be labelled with the withdrawal period of the drug for the species on which it is intended to be used:

Provided that if the specific withdrawal period has not been validated, the withdrawal period shall not be less than seven days for eggs or milk, twenty eight days for meat from poultry and mammals including fat and offal, five hundred degree days for fish meat.

*Explanation.*—For the purpose of this rule, the withdrawal period is the period of interval between the last administration of a veterinary medicine to animals under the normal conditions of use and the production of food stuff from such animals to ensure that food stuffs do not contain residues in quantities in excess of the maximum residue limits laid down.]

<sup>1</sup>[(4) The container of a medicine prepared for treatment of human ailments shall if the medicine contains industrial methylated spirit, indicate this fact on the label and be labelled with the words—

"FOR EXTERNAL USE ONLY".]

<sup>2</sup>[(5) Substances specified in Schedule X in bulk form shall bear a label wherein the symbol as specified in sub-rule (1) shall be given conspicuously in red letters.]

<sup>3</sup>**[97A. Modified application of rules 96 and 97 for certain period.**—Notwithstanding anything contained in these rules, the modified or additional requirements of labelling as may be specified in the notification of the Government of India in the Ministry of Health and Family Welfare number G.S.R. 408(E), dated the 26th April, 2018, shall be on voluntary basis for a period commencing on the date of coming into force of this rule and ending on the 31st day of March, 2019, and thereafter shall be mandatory.]

<sup>5</sup>**[102. Non-Sterile Surgical Ligature and Suture.**—Every container of, and wrapper enclosing surgical ligature or suture other than a ligature or suture offered or intended to be offered for sale as sterile, shall bear a label on which are printed or written in a conspicuous manner in indelible red ink the words "Non-sterile surgical ligature (suture)—not to be used for operations upon the human body unless efficiently sterilized".]

**103.** <sup>6</sup>[\*\*\*]

(2) The name and address of the manufacturer shall be printed on the label of the container of a patent or proprietary medicine.

<sup>7</sup>[(3) The true formula or list of the ingredients shall be printed or written in indelible ink on the outer label of every package containing patent or proprietary medicine ]

<sup>8</sup>[**104. Use of letters I.F., etc.**—The letters T.P., and recognised abbreviations of pharmacopoeias and official compendia of drug standards prescribed under these rules shall be entered on the label of the drug only for the purpose of indicating that the drug is in accordance with standards set out in the Indian Pharmacopoeia or in any such pharmacopoeia or official compendium of drug standards recognised under the rules.]

<sup>9</sup>[**104A. Prohibition against altering inscriptions on containers, labels or wrappers of drug.**—No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any drug: Provided that nothing in this rule shall apply to any alteration, any inscription or mark made on the container, label or wrapper of any drug at the instance or direction or with the permission of the licensing authority.]

<sup>10</sup>[**105. Packing of drugs.**—(1) The pack sizes of drugs meant for retail sale shall be as prescribed in Schedule PI to these rules.

(2) The pack sizes of drugs not covered by the Schedule PI shall be as given below:

Unless specified otherwise in Schedule PI,—

(i) The pack sizes for Tablets/Capsules shall be—

Where the number of Tablets (coated or uncoated)/Capsules (hard or soft gelatine) is less than 10, such packing shall be made by the integral number. For numbers above 10, the pack sizes of Tablets/Capsules shall contain multiples of 5.

(ii) The pack sizes for liquid Oral preparations shall be 30 ml. (paediatric only) 60 ml./100 ml./200 ml./450 ml.



<sup>3</sup>[*Explanation.*—This clause shall not apply to a Homoeopathic mother tincture manufactured outside India.

(C) No Homoeopathic medicine containing a single ingredient shall bear a proprietary name on its label.]]

<sup>4</sup>[**106B. Prohibition of quantity and percentage.**—No Homoeopathic medicine containing more than 12% alcohol v/v (Ethyl Alcohol) shall be packed and sold in packing or bottles of more than 30 millilitres, except that it may be sold to hospitals/ dispensaries in packings or bottles of not more than 100 millilitres.]]

## PART X

### SPECIAL PROVISIONS RELATING TO BIOLOGICAL AND OTHER SPECIAL PRODUCTS

<sup>5</sup>[**107. Name of substance.**—If any substance specified in Schedule C is advertised or sold as a proprietary medicine or is contained in a medicine so advertised or sold, the proper name of the substance shall appear on the label in the manner prescribed in this Part.

<sup>6</sup>[*Explanation.*—For the purpose of this rule the expression "proper name" means the proper name stated in Schedule F or if no such name is stated, the name descriptive of the true nature and origin of the substance:

Provided that in the case of veterinary biological product the expression "proper name" means the proper name stated in Schedule F(1) or if no such name is stated, the name or synonym given in the current edition for the time being of the '[British Pharmacopoeia (Veterinary)], or, if no such name is stated either in Schedule F(1) or the '[British Pharmacopoeia (Veterinary)], the name descriptive of the true nature and origin of the substance approved by the licensing authority.]]

**108. Container.**—<sup>2</sup>[(1) No substance specified in Schedule C shall be sold or offered for sale unless it has been sealed in a previously sterilised container made of glass or any other suitable material approved for the purpose by the licensing authority appointed under rule 21, in such manner as may, in the opinion of the licensing authority, suffice to preclude the access of bacteria:

Provided that it shall not be necessary to use a previously sterilised container if the filled and sealed container is to be sterilised after the sealing and such sterilising procedure would render the products sterile. However, the licensing authority may, for any special reasons, direct the licensee to pre-sterilise such containers.]

(2) When any such substance is issued in liquid form in containers which are sealed in such a manner that portions of the contents can be withdrawn for use on different occasions, the liquid shall contain a sufficient proportion of some antiseptic to prevent the growth of any organism which may be accidentally introduced in the process of removing a portion of the contents of the container:

<sup>3</sup>[Provided that nothing in this sub-rule shall apply to a penicillin suspension in oil and wax.]

<sup>4</sup>[(3) The container shall comply with such further requirements, if any, as are specified in Schedule F or Schedule F(1) as the case may be, in that behalf.]

<sup>4</sup>[(4) The licensing authority may in the case of particular preparation of any such substance dispense with any of the requirements of this rule or of Schedule F or Schedule F(1), as the case may be, and may make such additional requirement, as having regard to the nature of the preparation, they may deem necessary.]

<sup>5</sup>**[109. Labelling.]**—(1) The following particulars and such further particulars, if any, as are specified in Schedule F or Schedule F(1), as the case may be, shall be printed or written in indelible ink on the label of every phial, ampoule or other container of a substance specified in Schedule C and on every other covering in which such phial, ampoule or container is packed:—

(a) Where a drug is imported, the number of licence under which it is imported, preceded by the words "Import Licence":

Provided that no reference shall be made to any other import licence number granted by any authority outside India on any label or container or in any covering in which the container is packed or in any other matter of advertisement enclosed therein.

(b) Where a test for potency in units is required by these rules, a statement of the potency in units defined in terms of relating to the standard preparation specified in Schedule F or F(1), as the case may be:

Provided that this clause shall not apply in the case of vaccine lymph.

(c) Where a test for potency of maximum toxicity is required the date up to which the substance if kept under suitable conditions may be excepted to retain a potency not less than that stated on the label of the container or not to acquire a toxicity greater than that permitted by the test, as the case may be. The date of expiry shall be in terms of month and year and it shall mean that the drug is recommended for use till the last day of the month. The date of expiry shall be preceded by the words 'Expiry date':

Provided that nothing in these rules shall be deemed to require the labelling of any transparent cover or any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.

(2) The particulars prescribed in clause (a) of the preceding sub-rule shall be printed or written in indelible ink either on the label borne by a container of vaccine lymph or on a label or wrapper affixed to any package in which the container is issued for sale. The said particulars shall be indelibly marked on the sealed container of surgical ligature or suture or printed or written in indelible ink on a label enclosed therein.

(3) The following particulars, and such further particulars, if any, as are specified in Schedule F or Schedule F(1), as the case may be, shall be printed or written in indelible ink either on the label borne by the container of any substance specified in Schedule C or on a label or wrapper affixed to any package in which any such container is issued for sale, namely:—

(a) the date on which the manufacture of the particular batch from which the substance in the container is taken was completed as defined in Schedule F or Schedule F(1) or if there is no definition in Schedule F or F(1) as hereafter defined in this rule and in the case of vaccine prepared from concentrates, the date of completion of the final products and the bottling for issue;

(b) where an antiseptic substance has been added, the nature and the percentage proportion introduced;

(c) the precaution necessary for preserving the properties of the contents up to the date indicated in clause (c) of sub-rule (1)

(4) For the purpose of clause (a) of sub-rule (3), the date of which the manufacture of a batch is completed shall be—

(a) in cases where a test for potency or toxicity is required, by these rules not being so required, is accepted by the licensing authority as sufficient for the purpose of fixing the date of completion of manufacture, the date on which the substance was removed from cold storage after having been kept at a temperature not exceeding 5°C continuously for a period not exceeding two years from the time when the last test was completed;

(b) in cases where no such test is required or accepted—

(i) if the substance is a serum obtained from a living animal, the earliest date on which any material contributing to the batch was removed from the animal;

(ii) if the substance was obtained by the growth of organisms on artificial media, the earliest date on which growth was terminated in any of the material contributing to the batch:

Provided that if a batch of the substance (including all material contributing to this batch) has for a period of not more than three years been kept in cold storage at a temperature not exceeding 5°C continuously from the earliest practicable date after that on which growth was terminated in the material as the case may be, the date of removal from cold storage shall be treated as the date on which the manufacture of the batch is completed;

(c) in all other cases, the date on which the substance is filled in the container.]

**<sup>1</sup>[109A. Labelling of medical devices.**—Subject to the other provisions of these rules, the following particulars shall be printed in indelible ink on the label or sticker on the shelf pack of the medical device or on the outer cover of such

medical device and on every outer covering in which the medical device is packed, namely;—

- (a) proper name of the medical device;
- (b) the details necessary for the user to identify the device and its use;
- (c) the name of the manufacturer and address of the manufacturing premises where the device has been manufactured;
- (d) the correct statement of the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package shall be expressed in metric system; and
- (e) the date of manufacture and date of expiry; alternately the label shall bear the shelf life of the product;

Provided that in the case of sterile devices the date of sterilisation may be given as date of the manufacture of the device:

Provided further that the device is made up of stable materials such as stainless steel or titanium, and supplied non-sterile, date of expiry may not be necessary;

- (f) to provide, wherever required, an indication that the device contains medicinal or biological substance;
- (g) to provide, a distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No.";
- (h) to indicate, wherever required, any special storage or handling conditions applicable to the device;
- (i) to indicate, if the device is supplied as a sterile product, its sterile state and the sterilisation method;
- (j) to give, if considered relevant, warnings or precautions for the attention of the user of the medical device;
- (k) to label the device, if the device is intended for single use;



(1) to overprint on the label of the container, the words "FOR CLINICAL INVESTIGATION ONLY", if the device is intended for clinical investigation;

(m) to overprint on the label of the device, the words "Physician's Sample—Not to be sold", if a medical device is intended for distribution to the medical professional as a free sample,

(n) to provide, except for imported devices, the manufacturing licence number by preceding the words "Manufacturing Licence Number" or "Mfg. Lie, No." or "M. L";

(o) Devices or In-vitro diagnostics which are not sold to customer or patient directly and are sold for use by hospitals or diagnostic labs shall provide the information affixing additional label or sticker on outer shelf pack;

(p) to provide on the label, in case of imported devices, with the approval of the licensing authority mentioned in rule 21, the import licence number, name and address of the importer and address of the actual manufacturing premises, date of manufacture, (if not already printed at the time of import):

Provided that the label may bear symbols recognised by the Bureau of Indian Standards or International Organisation for Standardisation (ISO) in lieu of text and the device safety is not compromised by a lack of understanding on the part of the user in case the meaning of the symbol is not obvious to the device user.]

**<sup>1</sup>[109B. Exemption of certain labelling requirements for medical devices for export from India.**—The labels on packages or container of devices for export shall be adopted to meet specific requirements of the law of the country to which the device is to be exported, but the following particulars shall appear in conspicuous manner on the label of the shelf pack of the medical device in which the device is packed and every other outer covering in which the container is packed—

(a) name of the Device;

(b) the distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No.";

(c) the date of expiry, if any;

(d) the name and address of the manufacturer and address of actual premises where the been manufactured;

(e) the manufacturing Licence No. preceded by the letters "M.L. No" or "Manufacturing Licence No";

(f) the internationally recognised symbols in lieu of text, wherever required:

Provided that where a device is required by the consignee not to be labeled with the name and address of the manufacturer, the label on the packages or container shall bear a code number as approved by the licensing authority and the code number shall bear the name of the State or Union territory, in abbreviation, followed by the word "Device" and "manufacturing licence number:

Provided further that where a device is required by the consignee not to be labeled with the code number also, the label on the packages or container shall bear a special code number, as requested by the consignee, and approved by the licensing authority under rule 21.]

<sup>1</sup>[**109C. Shelf life of the medical devices.**—The shelf life of the medical devices shall not exceed sixty months from the date of manufacture:

Provide that the period may be extended by the licensing authority in respect of any specified medical device, if satisfactory evidence is produced by the manufacturer to satisfy such an extension.]

**110. Prohibition of sale of substance after prescribed date.**—No person shall sell, or exhibit for sale any substance specified in Schedule C after the date recorded on the container, label or wrapper as the date up to which the substance may be expected to retain a potency not less than, or not to acquire a toxicity greater than that required or permitted by the prescribed test as the case may be.

<sup>3</sup>[**111. Standards.**—Every substance specified in Schedules C and C(1) intended for sale shall conform with the standards of strength, quality and purity specified in these rules and in Schedule F or F(1) as the case may be, and the tests for determining such conformity shall be applied to samples taken from the final product after every manufacturing process has been completed.]

(2) The information uploaded by the licensee in the portal under sub-rule (1) shall be verified by the concerned licensing authority.]

## <sup>2</sup>[PART XVII

### <sup>3</sup>[LABELLING, PACKING AND LIMIT OF ALCOHOL IN] AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

**161. <sup>3</sup>[Labelling, packing and limit of alcohol].—(1)** There shall be conspicuously displayed on the label of the container or package of an Ayurvedic (including Siddha) or Unani drug, the true list of all the ingredients <sup>4</sup>[with the botanical names of plant based ingredients along with plant part(s) and form of ingredients, in which, these are] used in the manufacture of the preparation together with the quantity of each of the ingredients incorporated therein and a reference to the method of preparation thereof as detailed in the standard text and Adikarana, as are prescribed in the authoritative books specified in the First Schedule of the Act <sup>4</sup>[and in respect of Patent or Proprietary Ayurveda, Siddha or Unani drugs, the true list of all the ingredients with the botanical names of plant based ingredients along with plant part(s) and form of ingredients, in which, these are used in the formulation, with their quantity:

Provided that if needed, standardized abbreviations prescribed for part(s) and form of Ingredient(s) in the official Ayurveda, Siddha and Unani Pharmacopoeias and Formularies, may be used on the label:]

Provided that if the list of ingredients contained in the medicine is large and cannot be accommodated on the label, the same may be printed separately and enclosed with the packing and reference be made to this effect on the label.

(2) The container of a medicine for internal use made up ready for the treatment of human ailments shall, if it is made up from a substance specified in Schedule E(1), be labelled conspicuously with the words 'Caution: to be taken under medical supervision' both English and Hindi languages.

(3) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any Ayurvedic (including Siddha) or Unani drug <sup>4</sup>[and Patent or Proprietary Ayurveda, Siddha

or Unani drugs] and on any other covering in which the container is packed, namely:—

- (i) The name of the drug. <sup>5</sup>[For Ayurveda, Siddha or Unani Drug] purpose the name shall be the same as mentioned in the authoritative books included in the First Schedule of the Act.
- (ii) A correct statement of the net content in terms of weight, measure or number as the case may be. The weight and volume shall be expressed in metric system.
- (iii) The name and address of the manufacturer.
- (iv) The number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words 'Manufacturing Licence Number' or "Mfg. Lie. No." or "M.L."
- (v) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words "Batch No." or "Batch" or "Lot Number" or "Lot No." or "Lot" or any distinguishing prefix.
- (vi) The date of manufacture. For this purpose the date of manufacture shall be the date of completion of the final products, or the date of bottling or packing for issue.
- (vii) The words "Ayurvedic medicine" or "Siddha medicine" or "Unani medicine" as the case may be.
- (viii) The words "FOR EXTERNAL USE ONLY" if the medicine is for external application.
- (ix) Every drug intended for distribution to the medical profession as a free sample shall, while complying with the labelling provisions under clause (i) or (viii), further bear on the label of the container the words "Physician's sample. Not to be sold" which shall be overprinted.

<sup>1</sup>(x) (a) Preparation (Asavas) with high content of alcohol as base.

<i>Name of the drug</i>	<i>Maximum size of packing</i>	
(i) Kapur Asava	15 ml.	
(ii) Ahiphenasava	15 ml.	
(iii) Margamadasava	15 ml.	
(b) Preparation containing self-generated alcohol.		
<i>Name of the drug</i>	<i>Maximum content of alcohol (Ethylalcohol v/v)</i>	<i>Maximum size of packing</i>
(i) Mritsanjivani Sura	16 per cent	30 ml.
(ii) Mahadrakshava	16 per cent	120 ml.]

(4) Nothing in these rules shall be deemed to require the labelling of airy transparent cover or of any wrapper-case or other covering used solely for the purpose of packing, transport in delivery.]

<sup>2</sup>[161A. **Exemption in labelling and packing provisions for export of Ayurvedic (including Siddha) and Unani Drugs.**—(1) Label and packages or containers of Ayurvedic, Siddha and Unani Drugs for export may be adapted to meet the specific requirements of the law of the country to which the said drugs is to be exported, but the following particulars shall appear in conspicuous position on the container in which drug is packed and on every other covering in which that container is packed, namely:—

- (a) name of the Ayurvedic, Siddha and Unani drug (single or compound formulation);
- (b) the name, address of the manufacturer and the number of licence under which the drug has been manufactured;
- (c) batch or lot number;
- (d) date of manufacture, along with date for "Best for use before".
- (e) main ingredients, if required by the importing country;
- (f) for EXPORT:



Provided that where Ayurvedic, Siddha and Unani single or compound drug not classified under the First Schedule or Schedule E(1), is required by the consignee to be not labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the licensing authority mentioned in rule 152.

(2) The provisions of rule 161 shall not apply to a medicine made up ' ready for treatment" whether after, or without, alteration, which is supplied on the prescription of a registered medical practitioner, if the medicine is labelled with the following particulars, namely:—

(a) the name and address of the suppliers;

(b) the words "For External Use Only", if the medicine is for external application.]

**<sup>1</sup>[161B. Shelf life or date of expiry of medicines.—(1)** The date of expiry of Ayurvedic, Siddha or Unani medicines shall be conspicuously displayed on the label of container or package of Ayurvedic, Siddha or Unani medicine, as the case may be, and after the said date of expiry, no medicine shall be marketed, sold, distributed or consumable;

Provided that this rule shall apply to Ayurvedic, Siddha and Unani medicines seeking licence or renewal of licence for manufacturing after the date of notification of the rules.

Provided also that this rule shall not be applicable to the Ayurvedic, Siddha or Unani medicines manufactured and marketed prior to the date of this notification.

(2) Every person applying for licence or renewal of licence for the manufacturing of Ayurveda, Siddha or Unani medicines defined under clause (h) of section 3 of the Act shall submit to the State Licensing Authority scientific data based shelf life or date of expiry of the medicine based on the Real time stability studies of medicines in accordance with the guidelines prescribed in the Ayurvedic Pharmacopoeia of India.

Provided that this sub-rule shall be applicable after three years from the date of notification of the rules.