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# Labelling Guidelines in AYUSH: Ayurvedic, Unani and Siddha Drugs

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## ABSTRACT

The label content on package of product is the identity and source of information about the product. Labels play a vital role in ensuring consumer safety and product transparency. In addition to name of the product and its manufacturer, it provides essential information, mfg. & expiry date, composition, usage instructions and warnings. Information like quantity and retail price ensure consumer protection and transparency. Labels also serve as promotional tool in marketing and sales. Recent amendments provide additional options such as QR codes, GTIN/barcodes and specific product codes. Proper implementation of these requirements promotes transparency, traceability and safe use of AYUSH medicines.

***KEYWORDS:*** *AYUSH, Labelling Guidelines, Regulatory Compliance, Shelf Life, GTIN, Legal Metrology.*

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## INTRODUCTION

A label of a product is one of its most notable features that leads to product identification. In the normal parlance, the process of labelling, thus, involves affixing or inscribing information onto a product as a way of imparting a distinct identity to it as well as to make available certain indispensible particulars about it to the public. Therefore, uniformity in the labelling requirements of different categories of products is a necessary corollary. ASU product labelling in India must comply with the Drugs and Cosmetics Act, 1940 & its Rule 1945. The Rule 161/169 of the Drugs and Cosmetics Rules, 1945 provides a detailed account of the manner in which the labelling of an Ayurvedic, Siddha or Unani drug must be undertaken.

## METHODS AND PROCEDURES

### 1. Labelling Guidelines for Ayurvedic (including Siddha) and Unani Drugs (D&C Rule 161)[1]

1.1. 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 with the botanical name, Plant part(s) and form of ingredients, with quantity of each ingredients, method of preparation thereof as detailed in the standard text and Adikarana as are prescribed.

1.2. Drugs from Schedule E (1) for internal use **"Caution: To be taken under medical supervision"**

**सावधान : चिकित्सक की देख–रेख में लें।**

Should be written both in Hindi & English Language

1.3. 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 [and Patent or Proprietary Ayurveda, Siddha or Unani drugs] and on any other covering in which the container is packed, namely:-

1.3.1. The name of the drug. [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.

1.3.2. Net contents in weight, measure or Noumber, as the case may be. The weight and volume shall be expressed in metric system.

1.3.3. The name and address of the manufacturer.

1.3.4. License number being preceded by the words "Manufacturing License Number" or "Mfg. Lic. No.'' or "M. L."

1.3.5. Batch number being preceded by the words "Batch No." or "Batch" or "Lot No." or "Lot"

1.3.6. 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.

1.3.7. The words "Ayurvedic Medicine" or "Siddha Medicine" or "Unani Medicine" as the case may be.

1.3.8. The words **"FOR EXTERNAL USE ONLY"** if the medicine is for external application.

1.3.9. Drug for distribution to medical profession as free sample, shall contains "Name of Drug", **"Physician's sample. Not to be sold".**

**1. Preparation of (Asavas) with high content of alcohol as base-**

| Name of the Drug | Maximum size of packing |
|---|---|
| (i) Kapur asava | 15 ml |
| (ii) Ahiphenasava | 15 ml |
| (iii) Margamadasava | 15 ml |

**2. Preparation containing self-generated alcohol**

| Name of the Drug | Maximum content of Alcohol (Ethyl Alcohol v/v) | Maximum size of Packing |
|---|---|---|
| Mritsanjivani Sura | 16 Per cent | 30 ml |
| Mahadrakshava | 16 Per cent | 120 ml |

**After Drugs Eleventh Amendment Rules 2026 (D&C Rule 161)[2]**

1. 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 or **may be displayed through QR code or Global Trade Item Number (GTIN) or Bar code**."

2. The specific product code of the **drug being preceded by the words "specific product code or S.P.C.**", which shall be printed or written within two years of the commencement of the Drugs (Eleventh Amendment) Rules, 2026."

3. All the label **information may also be displayed through QR code or Global Trade Item Number (GTIN) or Bar code**."

**2. Labelling Guidelines for export of Ayurvedic (including Siddha) and Unani Drugs (D&C Rule 161A)[1]**

2.1. 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:-

2.1.1. name of the Ayurvedic, Siddha and Unani drug (single or compound formulation);

2.1.2. the name, address of the manufacturer and the number of licence under which the drug has been manufactured;

2.1.3. batch or lot number;

2.1.4. date of manufacture, along with date for "Best for use before".

2.1.5. main ingredients, if required by the importing country;

2.1.6. for EXPORT:

Provided that where Ayurvedic, Siddha and Unani single or compound drug not classified under the First Schedule or Schedule E(l), 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 **Neutral Code Number** as approved by the licensing authority.

2.2. 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:-

2.2.1. the name and address of the suppliers;

2.2.2. the words **"For External Use Only",** if the medicine is for external application.

**3. Shelf life or date of expiry of medicines (D&C Rule 161B)[1]**

3.1. 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.

3.2. The 'date of manufacture' and 'date of expiry' on the primary and secondary labels/packs of Ayurvedic, Siddha and Unani medicines shall be displayed in the 'numerical month and year i.e. **MM/YYYY format**'. Precisely, **the month shall be printed as two digits and the year as four digits with a slash (/) in between**. For example, for a medicine manufactured in September, 2025, the manufacturing date shall be written as '09/2025'. [3]

3.3. The shelf life or date of expiry of an Ayurveda, Siddha or Unani medicine defined under clause (a) of section 3 of the Act shall, unless otherwise determined on the basis of scientific data, be as follows:-

**"Shelf life starts from date of manufacture''**

**After Drugs Eleventh Amendment Rules 2026 (D&C Rule 161B)**[2]

1. after sub-rule (2), the following sub-rule shall be inserted, namely: -

(2A) If the approval of the drug has been granted **on the basis of accelerated stability studies**, then, -

1.1. the licensee shall determine the **shelf-life of the respective medicine for one or two years based on the report of three months or six months accelerated stability study respectively** and the said report shall be submitted to the licensing authority as referred to in rule 151.

1.2. the report of the **real-time stability study shall be submitted by the licensee within one year from the expiry** of the shelf life granted based on the accelerated stability data.

*Explanation*.- For the purpose of this sub-rule, determination of shelf-life beyond two years shall be based on real-time stability study."

2. after sub-rule 8, the following sub-rule shall be inserted, namely: -

2.1. (9) In cases of change in dosage form of any Ayurvedic, Siddha or Unani drugs defined under clause (a) of section 3 of Drugs and Cosmetics Act, 1940, the expiry date of particular drug category shall be supported by accelerated or real-time stability study data, as the case may be."

**Essential Componenets of Ayurvedic Medicines Expiry Lebelling**[1]

| SI. No. | Dosage form | Shelf life or date of expiry with effect from the date of manufacture |
|---|---|---|
| (i) | Anjana | |
| | (a) Anjana made from Kasthaushadhi | 1 year |
| | (b) Anjana made from Kasthaushadhi along with Rasa/ Uprasa / Bhasma | 2 years |
| | (c) Anjana made only from Rasa/Uprasa/Bhasma | 3 years |
| (ii) | Arka | 1 year |
| (iii) | Asava Arista | 10 years |
| (iv) | Avaleha, Khanda, Paka, Guda | 3 years |
| (v) | Chuma, Kwatha Chuma, Lepa Chuma, Danta Manjan (Chuma) | 2 years |
| (vi) | Dhoopan | 2 years |
| (vii) | Dravaka, Lavana, Kshara | 5 years |
| (viii) | Ghrita | 2 years |
| (ix) | Guggulu | 5 years |
| (x) | Gutika/Vati | |
| | (I) Gutika or Vati containing Kasthaushadhi along with Rasa/Uprasa/Bhasma/Guggulu (including Lepa Gutika and GhanVati) | 5 years |
| | (II) Gutika or Vati containing only Kasthaushadhi (including Lepa Gutika and Ghan Vati) | 3 years |
| | (III) Gutika/Vati containing only Ras/Uprasa/Bhasma except Naga, Vanga and Tamra Bhasma | 10 years |
| (xi) | Kama /Nasabindu | 2 years |
| (xii) | Kupipakva Rasayana | 10 years |
| (xiii) | Malahar | 3 years |
| (xiv) | Mandura-Lauha | 10 years |
| (xv) | Naga Bhasma, Vanga Bhasma and Tamra Bhasma | 5 years |
| (xvi) | Netrabindu | 1 year |

| | | |
|---|---|---|
| (xvii) | Parpati | 10 years |
| (xviii) | Pishti and Bhasma except Naga, Vanga and Tamra Bhasma | 10 years |
| (xix) | Pravahi Kwatha | 3 years |
| (xx) | Rasayoga | |
| | (I) Rasayoga Containing only Rasa/Uprasa/Bhasma except Naga, Vanga and Tamra Bhasma | 10 years |
| | (II) Rasayoga Containing Rasa/Uprasa/Bhasma along with Kasthaushadhi/Guggulu | 5 years |
| (xxi) | Sattva (derived from medicinal plant) | 2 years |
| (xxii) | Sharkar/Panak / Sharbat | 3 years |
| (xxiii) | Shveta parpati | 2 years |
| (xxiv) | Taila | 3 years |
| (xxv) | Varti | 2 years |

**Essential Components of Unani Medicines Expiry Labelling[1]**

| SI. No. | Dosage form | Shelf life or date of expiry with effect from the date of Manufacture |
|---|---|---|
| (i) | Arq (except Arq-e-Ajeeb) | 1 year |
| (ii) | Arq-e-Ajeeb | 5 years |
| (iii) | Ayarij / Sunoon/Zuroor/Ghazah | 2 years |
| (iv) | Burood | 1 year |
| (v) | Shiyaf | 2 years |
| (vi) | Surma/Kohal | 3 years |
| (vii) | Habb | 3 years |
| (viii) | Halwa | 3 years |
| (ix) | Itrifai | 3 years |
| (x) | lauhar/Jawahir | 5 years |
| (xi) | Jawarish | 4 years |
| (xii) | Khamira | 3 years |
| (xiii) | Kushta | 10 years |
| (xiv) | Laboob | 3 years |
| (xv) | Laooq | 3 years |
| (xvi) | Majoon/Dawa | 3 years |
| (xvii) | Marham/Zimad/Qairooti | 2 years |
| (xviii) | Mufarreh | 3 years |
| (xix) | Murabba | 1 year |
| (xx) | Nabeez | 10 years |
| (xxi) | Qurs | 3 years |
| (xxii) | Qutoor | 1 year |
| (xxiii) | Raughaniyat/Tila | 3 years |
| (xxiv) | Sharbat,/ Sikajabeen | 3 years |
| (xxv) | (I) Sufoof (Without Salt) | 2 years |
| | (II) Sufoof (Containing salt) | 1 year |
| (xxvi) | Tiryaq | 3 years |

**Essential Componenets of Siddha Medicines Expiry Lebelling[1]**

| SI. No. | Dosage form | Shelf life or date of expiry with effect from the date of manufacture |
|---|---|---|
| (i) | **Curanam** | |
| | Kutinir Curanam / Adai Curanam / Kanchi Curanam / Utkali Curanam / Pittu Curanam / Podithimirthal Curanam / Podi / Pattru Curanam / Pottanam or Kizhi Curanam / Ottratam Curanam / Vethu Curanam / Pugai Curanam / Kali Curanam / Thuvalai Curanam | 2 years |

| | | |
|---|---|---|
| (ii) | **Mattirai / Vatakam** | |
| | Containing only Mooligai ingredients (including Kudineer Curanam Mattirai) (e.g. Nilavembu kutinir Mattirai) | 2 year |
| | Containing Mooligai ingredients along with Thathu Porutkal/Jeeva Porutkal/Parpam/Centuram/Cunnam. (including kutinir Curanam Mattirai) | 5 years |
| | Containing only Thathu Porutkal/Parpam/Centuram/ Cimnam/Kattu/Kalanku. | 10 years |
| (iii) | **Rasa-Paadana Marunthugal (All Mercurial Preparation)** | |
| | Containing Mooligai ingredients along with Thathu Porutkal/Parpan/Centuram/Cunnam/ Kattu/Kalanku | 2 years |
| | Containing only Thathu Porutkal/Parpam/ Centuram/Cunnam Kattu/Kalanku | 10 years |
| (iv) | **Parpam/Centuram** | |
| | Containing only Mooligai ingredients *(e.g.* Kungiliya Parpam) | 2 years |
| | Containing Mooligai ingredients with Thathu Porutkal/Parpam/Centuram/Cunnam/Kattu / Kalanku *(e.g.,* Aya Centuram) | 10 years |
| | Containing Mooligai ingredients with Jeeva Porutkal *(e.g.,* Sangu Parpam) | 10 years |
| (v) | **Karuppu** | |
| | Containing only Mooligai ingredients *(e.g.,* Vasambu Sutta Kari) | 2 years |
| | Containing Mooligai ingredients with Thathu Porutkal *(e.g.,* Sivanar Amirtham, Thalaga Karuppu) | 5 years |
| | Containing Mooligai ingredients with Jeeva Porutkal *(e.g.,* Kasthuri Karuppu, Pattu Karuppu) | 5 years |
| (vi) | **Patankam** | |
| | Mooligai based Patankam *(e.g.,* Sambirani Patankam) | 5 years |
| | Rasa based Patankam *(eg.,* Rasa Centuram) | 10 years |
| (vii) | **Kulampu** | |
| | Based on process- | |
| | Araippu Kulampu *(e.g.,* Agathiyar Kulampu) | 5 years |
| | Erippu Kulampu *(e.g.,* Kumatti Kulampu) | 3 years |
| (viii) | **Meluku** | |
| | Based on process- | |
| | Araippu Meluku *(e.g.,* Linga Meluku) | 5 years |
| | Idippu Meluku *(e.g.,* Rasa Gandhi Meluku/Idi Vallthi Meluku) | 3 years |
| | Based on raw materials- | |
| | Mooligai Meluku *(e.g.,* Malaikudara Meluku) | 3 years |
| (ix) | **Karpam** | |
| | Based on raw materials- | |
| | Mooligai Karpam *(e.g.,* Karisalai Karpam, Thiripala Karpam) | 2 years |
| | Mooligai Thathu Karpam *(e.g.,* Aya Bringaraja Karpam) | 5 years |
| | Based on process- | |
| | Araippu Karpam *(e.g.,* Irunelli Karpam) | 3 years |
| (x) | **Satthu** | |
| | Satthu derived from Mooligai *(e.g.,* Seenthil Satthu) | 2 years |
| | Satthu derived from Thathu Porutkal *(e.g.,* Aya Satthu, Eya Satthu,Thurusu Satthu) | 10 years |
| | Satthu derived from Jeeva Porutkal *(e.g.,* Sembu Satthu derived from Poonagam, Mayiliragu) | 5 years |
| (xi) | Ilakam/Legiyam/Iracayanaam | 3 years |
| (xii) | Kallikkam/Mai/Kalimbu/Neer/Venney | 1 year |
| (xiii) | Karam (Karanool) | 2 years |
| (xiv) | Kattu (Medicated bandage cloth)/See!ai/Varthy/Thiri | 1 year |
| (xv) | Kattu/Kalanku/Cunnam | 10 years |
| (xvi) | Kutinir/Kiyazham (with preservatives) | 3 years |

| | | |
|---|---|---|
| (xvii) | Manappaku/Panagam | 3 years |
| (xviii) | Nasiyathuli/Kanthuli/Sevithuli | 1 year |
| (xix) | Ney/Ghirutham/Kadugu | 2 years |
| (xx) | Oothal./Nasigaparanam/Thoopasarakku | 1 year |
| (xxi) | Pakkuvam, Thennoral | 1 year |
| (xxii) | Panda Vaippu | 10 years |
| (xxiii) | Peechu | 2 years |
| (xxiv) | Sutigai | 2 years |
| (xxv) | Tailam/Ennai/Poochu | 3 years |
| (xxvi) | Tinir | 1 year |
| (xxvii) | Tiravakam (derived from Thathu Porutkal) | 2 years |

**4. Labelling Guidelines for Permitted Excipients (D&C Rule 169)[1]**

Permitted Excipients along with their standards *i.e.,* additives, preservatives, antioxidants, flavouring agents, chelating agents, etc., permitted in the Indian Pharmacopoeia (IP), Prevention of Food Adulteration Act, 1954 and Bureau of Indian Standard Act, 1986 are permitted for use in Ayurveda, Siddha and Unani drugs with the following conditions, namely:-

4.1. The above excipients shall be used in the permissible limits as prescribed in the Indian Pharmacopoeia/Prevention of Food Adulteration Act, 1954/Food Product Order/Bureau of Indian Standard Act, 1986.

4.2. **Colouring Agent:** Only natural colouring agents as permitted under rule 26 of Prevention of Food Adulteration Rules, 1955 will be used for Ayurveda, Siddha and Unani drugs and additionally, **colours permitted under rule 127** of Drugs and Cosmetic Rules, 1945 shall be used for Proprietary Ayurveda, Siddha and Unani drugs.

4.3. Preservatives and Colouring agents shall be mentioned on the label for the information of the consumer as required under rule 161 of the Drugs and Cosmetics Rule, 1945.

4.4. Additives used in various processes and in formulating dosage forms shall be mentioned clearly with quantities used, in the application for licenses and the record for the same shall be maintained by the manufacturers.

4.5. Manufacturers shall be responsible to ensure rationality, safety and quantity used of various excipients in the formulation.

4.6. If any excipients or additive or preservative etc., referred in Indian Pharmacopoeia/Prevention of Food Adulteration Act, 1954/Food Product Order/Bureau of Indian Standard Act, 1986 is deleted at a particular point of time, this will also be deleted simultaneously for the use in Ayurveda, Siddha and Unani drugs.

4.7. **Artificial Sweetners:** Following artificial sweeteners as per maximum limit indicated below may be used in various dosage forms of Ayurveda, Siddha, Unani Proprietary Medicines:-

Artificial sweeteners may be used only in proprietary ASU products and the label of such products should **carry a statutory warning stating the name and quantity of the artificial sweetener used; for example-**

The recommended Acceptable Daily Intake (ADI) of these sweeteners as laid down by US FDA is as follows:

| S. No. | Sucralose | Aspartame | Saccharin | Acesulfame K |
|---|---|---|---|---|
| 1. | 5 mg/kg body weight | 40 mg/kg body weight | 3 mg/kg body weight | 15 mg/kg body weight |

One-third of the above ADI would be permissible for use in Ayurveda, Siddha, Unani Patent and Proprietary drugs.

**After Drugs Eleventh Amendment Rules 2026 (D&C Rule 169)[2]**

**1.** In the said rules, in rule 169, after clause 3, the following clause shall be inserted, namely:-

1.1. "3A. In addition to the information mentioned under clause 3, the **quantity of Base material shall also be mentioned on the label for the category of Saundarya Prasadak (Husane afza)/ Azhagh-sadhan and shall be printed or written over label.**

**5. Legal Metrology (Packaged Commodities) Rules- (Statement of units of weight, measure or number–)** [4]

**5.1. When expressing a quantity less than-**

5.1.1. One kilogram, the unit of weight shall be the gram

5.1.2. One litre, the unit of volume shall be the millimeter

**5.2. When expressing a quantity of equal to or more than-**

5.2.1. One kilogram, the unit of weight shall be kilogram and any fraction of a kilogram shall be expressed in terms of decimal of sub-multiple of kilogram or in terms of grams

5.2.2. One litre, the unit of volume shall be litre and any fraction of a litre shall be expressed in terms of decimal of of sub-multiple of kilogram or in terms of litre

**5.3. Symbol of units –**

5.3.1. No system of units other than the International System of Units shall be used in furnishing the net quantity of the package.

5.3.2. For items sold by number, the number or unit or piece or pair or set or such other word which represents the quantity in the package shall be mentioned.

**[Explanation -** For the purposes of this sub-rule, it is clarified that for indicating **the unit for litre, the letter 'L'** may be adopted to avoid confusion with the letter 'I' and figure '1'

5.3.3. Where there are number of packages of the same commodity in a prepackage and the quantity of each package shall be indicated as supplementary quantity declaration in the package.

**[Explanation –** For the purposes of this sub-rule, where the net quantity of a package is one hundred grams, the number of packages multiplied by **the net quantity of each package package shall be separately indicated in numbers multiplied by weight (i.e. 10 number its individual x 10 grams].**

**5.4.** No number called the dozen, score, gross, great gross or the like shall be specified or indicated on any package.

**5.5. Principal display panel**[5]

For label declarations affixing individual stickers is not permissible. Principal display panel mean the total surface area in relation to the package where all the information and declarations as required under the Rules are to be grouped together and given preferably in one place. In the case of a package having a capacity of 10 cubic centimeters or less, the principal display panel may be a card or tape affixed firmly to the package and shall bear the required information. The height of letters in the declaration shall not be less than 1 mm height and when blown, formed, molded, embossed or perforated, the height of letters shall not be less than 2 mm. The height of any numeral in the declaration required under these rules, on the principal display panel shall not be less than as shown in below Table and the width of the letter or numeral shall not be less than one third of its height, except in the case of numeral `1' and letters (i), (I) and (l).

| Serial Number | Area of Principal display panel in square centimetres (A) | Minimum height of numerals and letters in millimetres | Minimum height of numerals and letters when blown, formed or molded on surface of container in millimeters |
|---|---|---|---|
| 1. | $A \leq 50$ | 1.0 | 1.5 |
| 2. | $50 < A \leq 100$ | 1.5 | 3.0 |
| 3. | $100 < A \leq 500$ | 2.5 | 4.0 |
| 4. | $500 < A \leq 2500$ | 4.0 | 6.0 |
| 5. | $2500 < A$ | 6.0 | 6.0 |

**6. Consequences of non-compliance in the labelling**[6]

It is also apposite to note at this stage that an Ayurvedic, Siddha or Unani drug is considered to be misbranded under Section 33E of the Act if it is not labeled in the prescribed manner. Any Ayurvedic, Siddha or Unani drug is deemed to be a *'Misbranded drug':-*

6.1. if it is so coloured, coated, powdered or polished that damage is concealed, or if it is made to appear of better or greater therapeutic value than it really is; or

6.2. if it is *not labelled* in the prescribed manner; or

6.3. if its label or container or anything accompanying the drug bears any statement, design or device *which makes any false claim for the drug or which is false or misleading* in any particular.

**Significance of Labelling Guidelines**

| S. No. | Rule No. as per D&C | Key Points to be checked | √ / X | Remark |
|---|---|---|---|---|
| 1. | Rule 161 | Brand Name and Dosage Form (Tablet/Capsule/Syrup/ Churna etc.) | - | To be checked from Drug License* |
| 2. | Rule 161 | Ingredients | - | Botanical Name, Plant part(s) and Form of ingredients, with quantity of each ingredients, method of preparation are prescribed in the authoritative books specifiedin the First Schedule. |
| 3. | **Rule 161 (After Drugs Eleventh Amendment 2026)** | **Ingredients** | - | **If the ingredient list is too long to fit on the medicine label, it can be provided through a QR code, GTIN, or barcode.** |
| 4. | - | Package Size and container | - | To be checked from Drug License* |
| 5. | Rule 161 | Ayurvedic Medicine | - | Applicable for Ayurvedic medicine only. |
| 6. | Rule 161 | Unani Medicine | - | Applicable for Unani medicine only. |
| 7. | Rule 161 | Siddha Medicine | - | Applicable for Siddha medicine only. |
| 8. | Rule 161 | For External use only | - | For topical application |
| 9. | - | Store in a cool & dry place and away fromdirect sunlight | - | Or Follow actually required Storage condition. |
| 10. | - | Indications | - | For classical formulations as per Authoritative text Book in compliance with Drugs and Magic Remedies rules 1955, or as directedby the physician.<br>OR,<br>For Proprietary formulations Specific indications in compliance with Drugs and Magic Remedies rules 1955, or as directedby the physician. |
| 11. | - | Dosage | - | For classical formulations as per Authoritative text Book or as directedby the physician.<br>OR,<br>For Proprietary formulations Specific indications or as directedby the physician. |
| 12. | - | Directions | - | If any |
| 13. | Rule 169 | Artificial Sweetener<br>10 ml Contains<br>…… | - | Name with quantity |
| 14. | Rule 169 | Permitted Excipients (i.e. Additives, Preservatives, Antioxidants, Flavouring | - | If in the Formulation |

| | | | | |
|---|---|---|---|---|
| | | agents, Chelating agents etc.) | | |
| 15. | **Rule 169 (After Drugs Eleventh Amendment 2026)** | **Permitted Excipients (Base Material)** | | **For Saundarya Prasadak (Husane Afza)/Azhagh-Sadhan, the quantity of base material must also be mentioned on the label and shall be printed or written over label.** |
| 16. | Rule 127 | Color (Name with color index no.) | - | If in the Formulation |
| 17. | Rule 161 | Mfg. Lic. No.: | - | For all products |
| 18. | **Rule 161 (After Drugs Eleventh Amendment 2026)** | **Specific Product Code (S.P.C.)** | - | **In place of the Manufacturing Licence No., the Specific Product Code (S.P.C.) will be mentioned.** |
| 19. | Rule 161 | Batch No. | - | Applicable to all products |
| 20. | Rule 161 | Mfd. | - | Applicable to all products |
| 21 | Rule 161B | Expiry Date: | - | Applicable to all products. Refer Ayush Expiry Guidelines according to Product category. |
| 22. | **Rule 161B (After Drugs Eleventh Amendment 2026)** | **Shelf life or date of Expiry of Medicines** | - | • **1 year shelf life**: 3-month accelerated stability study;<br>• **2 years:** 6-month study.<br>• **Shelf life beyond 2 years** requires real-time stability data.<br>• For classical medicines, any change in dosage form requires supporting accelerated or real-time stability data, as applicable. |
| 23. | - | Net Volume/Net Content/ Net Weight<br>[As per Legal Metrology (Packaged Commodities) Rules, 2011] | - | Applicable to all products<br>Net Volume: For Liquid/Taila (ml)<br>Net Content:<br>F o r Tablets/Capsules etc. (Nos.)<br>Net Weight: For Churna/Kawth Churna (g) |
| 24. (a) | - | M.R.P. `<br>(incl. of all taxes) | - | Applicable to all products |
| (b) | - | USP<br>(incl. of all taxes) | - | Applicable to all products (Carton available) |
| 25. | - | The Product is an Ayurvedic medicine for Curative and Preventive therapy. It is not a Cosmetic or Toiletry Preparation. | - | Applicable to only Saundarya Prasadak Toiletry products underAyurvedic license. |
| 26. | **Rule 161 (After Drugs Eleventh Amendment 2026)** | **QR code or Global Trade Item Number (GTIN) OR Bar Code** | - | **All label information may also be provided through a QR code, GTIN, or Barcode.** |

| | | | | |
|---|---|---|---|---|
| 27. a.) If Product is Manufactured and Marketed by same company | - | Manufacture & marketed in India by:<br>Name and address of the company | - | For all products |
| b.) In case Product is manufactured by one company (3rd party) and Marketed by another company | - | Name and address of the manufacturer /3rd party Company-<br><br>Marketed in India by:<br>Name and address of the Marketing company | - | For all products |
| 28. | - | Weight and Measurement act [As per Legal Metrology (Packaged Commodities) Rules, 2011] | mg/g/ml/ Standard | As per legal meterology |
| 29. | Rule 161 | Physician Sample | - | **‘’Physician’s sample. Not to be sold’’** |
| 30. | Rule 161A | Export | - | **For Export**<br>Label matter as per the importing countryrequirement |

**Drug License*:** Signed by Drug authority only.

## DISCUSSION

Label is a regulatory requirement for displaying the necessary information of the products to the purchaser but it is equally important for manufacturer and marketers. Package and labels are identity of product and brand, and also serves as promotion in sales and marketing. Clear disclosure of ingredients, manufacturer details, batch information, dosage form, warnings and expiry information supports safe and appropriate use. The requirements of bilingual cautation, usage instructions and product category prevent misuse especially for potent or alcohol-based formulations. Export provisions (Rule 161A) balance International compliance with retention of core Indian Labelling norms, thereby promoting global acceptance of AYUSH medicine. Recent amendments allowing QR codes/GTIN improve space management and tracebility, while the introduction of a specific product code enhance standardization and market surveillance. Collectively, these provisions contribute to informed use, prevention of inappropriate or expired product use, improved traceability and enhanced consumer protection. [1,2,3,4,5,6]

## CONCLUSION

Comprehensive and accurate labelling is an integral aspect of regulatory compliance, consumer protection and quality assurance of ASU medicines. Mandatory declarations regarding composition, manufacturing details, expiry dates, storage conditions, cautionary statements, and product classification help healthcare professionals, regulators, and consumers make informed decisions regarding the safe use of ASU medicines. Additionally, specific requirements for export products, permitted excipients, artificial sweeteners, and shelf-life declarations promote consistency with national and international regulatory expectations. Incorporation of digital labelling mechanisms such as QR codes, GTINs and barcodes may further enhance traceability and accessibility of information. The signifies checklist provided in this article serves as a practical tool for manufacturers and regulatory professionals to verify compliance and minimize the risk of misbranding or regulatory violations. Therefore, strict adherence to AYUSH labelling guidelines is crucial for maintaining product integrity, safeguarding public health, and strengthening the credibility and global acceptance of traditional Indian systems of medicine.

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Nil

**Conflicts of Interests**

Nil

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[2] Drug Eleventh Amendments Rules, 2026, revise product identifications, labelling, shelf-life, and GMP requirements for ASU drugs.

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[4] The Legal Metrology Act, 2009 with allied Rules

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[6] https://upscalelegal.com