

**LABELING - SKIN OF PRODUCT**Arun. N<sup>1</sup> Kadibagil vinay R<sup>2</sup> Ganti basavaraj Y<sup>3</sup><sup>1</sup>PG Scholar, <sup>2</sup>Associate Professor, <sup>3</sup>Associate Professor & Head Department of Rasashastra and Bhaishajya Kalpana, SDM College of Ayurveda, Hassan, Karnataka, India.**ABSTRACT**

Drug is important part of treatment and is identified by its label. If a medicine does not specify the proper label according to standards, there may be inappropriate use of the product can cause adverse drug reaction. As per GMP, the label should contain all information about the drug like ingredients with proportion, dose, and method of usage, manufacture date, expiry date, license number, batch number, manufacturer name, net weight, place and address of manufacture. This is also applicable to Ayurvedic products along with other rules like .for free sample “not for sale” has to be mentioned and the drug intended for external use should have “for external use only” printed. The word “Caution” has to be mentioned if toxic substance has been used. Label for few Ayurvedic drugs should contain percentage of alcohol in it. Certain rules have been mentioned for export of Ayurvedic product it is according to the rule of the exporting country.

Keywords: Labelling, GMP, D&C act

**INTRODUCTION**

Drug is an important aspect of treatment without which the treatment is not possible. and for identification of drug labeling is must which is one of the important aspect of GMP and as well as production. Labelling and packing is must for the drug without which it is not acceptable in the market. It acts as link between the patient and the drug. This gives information about the different aspect of drug like mode of handling, dose etc. though the labeling not only gives information about the above things it also acts as identity mark of manufacturing pharmacy. The labeling of drug has to be mentioned correctly because the wrong labeling may leads to improper use of drug which in turn may lead into adverse drug reaction to the individual and death may also take place. Due to development of technology and increased awareness about the Ayurvedic medicine, most of the Ayurvedic medicines being named as OTC product. The person may tend to use the medicines without prescription and solely depend on labeling on the product. This may cause more harm than

useful to user if improper Labelling is done on the product. So the Labelling as been mentioned in the Drugs and Cosmetics Act 1940, under the rule 161 it gives complete guidelines about the Labelling of a product. Here an attempt is being made know and understand the rule and its importance of Labelling in the Ayurvedic products.

**RULES AND REGULATION OF LABELLING**

The labeling and packing of Ayurvedic drug rules which has been mentioned in D&C act 1940 under the rule 161.

There shall be conspicuously displayed on the label of the container or package of an Ayurvedic medicine. The true list of all the ingredients used in the manufacture of the preparation together with quantity of each of the ingredients incorporated in them. And a reference to the method of preparation there of as detailed in the standard text and Adikarana, Are prescribed in the authoritative books specified in the First

Schedule to the Act. And 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 packing and reference be made to this effect on the label. This gives the information about the reference of the product and the method of preparation. It also acts as an identification of the product. In these either any one i.e. reference or the ingredients. There is also provision for mentioning of both. The name should be similar to that of authoritative book<sup>1</sup>.

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 in English and Hindi language. This gives an information about the use of toxic substance in the preparation of medicine like, vatsanabha, danti, arka, ahipena, bhallataka, sarpa visha, parada, hingula, haratala etc which must be used only after purification. These drugs containing medicine must be taken only under medical supervision<sup>2</sup>.

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 on any other covering in which the container is packed', namely<sup>3</sup>.

The name of the drug. For this purpose the name shall be the same as mentioned in the authoritative books included in the First Schedule of the Act. This gives information about the name of the product. The name should be same as in book if classical reference is followed.

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. It gives the information about total content of the product. And also helps in knowing the state of product whether liquid or solid.

The name and address of the manufacturer. It helps in knowing where the product has been manufactured and from which pharmaceutical company and detail of marketing company if any present.

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. Lic. No.' or 'M.L.' It is given to pharmacy after satisfying the standards. for the manufacturing of the product it is must without which the product cannot be manufactured.

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. It is a batch from which the drug has been prepared and it differs according to different product. Sample should be collected separately for each batch and also helps in discarding of product if it is improper.

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. It gives information about the date of production of product. it should specify the, month, and year of its production or month and year.

The words "Ayurvedic medicine" or "Siddha medicine" or "Unani medicine" as the case may be. It implies the product belong to that particular system.

The words “FOR EXTERNAL USE ONLY” if the medicine is for external application. It implies that the product cannot be used for internal purpose.

Every drug intended for distribution to the medical profession, as a free sample shall, while complying with the Labelling provisions under clauses (a) to (i), further bear on the label of the container the words “Physicians sample. Not to be sold” which shall be over-printed. It gives knowledge about the product cannot be sold and it is intended for free distribution.

Preparation (Asavas) with high content of self generated alcohol as base should be packed separately in different size like karpur asava 15ml, ahiphensava 15ml, mrgamadasava 15ml, mritsanjivani sura 30ml, mahadrakshasava 120ml.

Certain points which has not been mentioned in the drug and cosmetic act 1940 under schedule E of rule 161 and 161A<sup>4</sup> Best before means the date whicsignifies the end of the period under any stated storage conditions during which the product will remain fully marketable and will retain any specific qualities for which tacit or express claims have been made. It means the date which signifies the end of the estimated period under any stated storage conditions, after which the product probably will not show its effect.

- I. Information about the Dose of product and its indications.
- II. List of Preservatives used for the particular product.

#### **RULES FOR EXPORTING OF AYURVEDIC PRODUCT**

The rule 161a which implacable in case of export of product. It should contain the following content printed on it<sup>5</sup>.

1. Labels and packages or containers meet the specific requirements of the law of the country to which they said drug is to be exported.
2. Name of the Ayurvedic drug.
3. Name, address of the manufacturer and the number of licence under which the

drug has been manufactured and batch or lot number.

4. Date of manufacture, along with the date for “Best before use”.
5. Main ingredients, if required by the importing country;

#### **OTC PRODUCTS**

Medicines sold directly to a consumer without a prescription. OTC drugs are selected by a regulatory agency to ensure that there ingredients are safe and effective. When used without a physician care The phrase,, OTC“ has no legal recognition in India all the drugs not included in the list of prescription only drugs are considered to be non-prescription drugs (or OTC drugs). Hence,, OTC Drugs“ means drugs legally allowed to be sold „Over The Counter “by pharmacists, i.e. without the prescription of a Registered Medical Practitioner. Ayurvedic Medicines OTC drugs registered as „Ayurvedic Medicines“ (i.e. traditional Indian system of medicines containing natural/ herbal ingredients) is also regulated by the DCA and DCR Ayurvedic drugs are manufactured under a manufacturing licence issued by the Ayurvedic State Licensing Authorities. However, they do not require a drug Sale licence And can be sold Freely by non chemists. Some of the largest OTC brands in India are registered as „Ayurvedic Medicines“ because of their plant based natural active ingredients (e.g. sandiline, eladi soap, raktha chandhana soap, Dabur“s PudinaHara, chavanaprasha, etc.).

#### **DISCUSSION**

The Labelling helps in identification of product and also helps in knowing the type of product it belong to. The Labelling gives certain important information about the product like the name of product if classical preparation the name should be same as mentioned in books and for patent preparation the ingredients used along with quantity should be mentioned. The container of the product should contain the word “caution” if any toxic drugs are used which in turn gives an idea about use of

product in sensitive person. The law also specifies that it belong to ayurveda or unani medicine. Labelling should mention the net contain of each ingredient and total quantity or volume of product. The name and address of product gives information about the place of manufacture, along with contact no of manufacture. Each ayurvedic product must have manufacture licence mentioned on Labelling. Along with above the batch number must be specified on Labelling. This in turn comes in to play in case of complaint about particular batch or product. The date of manufacture of product is the date of final preparation of product. This Also gives an information about month and year of its production. If the product is intended for external use is should specify the word for external use. If the products are intended for free use or for sample it should be mentioned on label. There are certain rules which need to be followed for export of product. Though these Labelling act gives limited information to common man. It is a must for all ayurvedic products. There is a need for making certain modification in this rule as there is no mention of any preservative used in the product in this rule. And me-

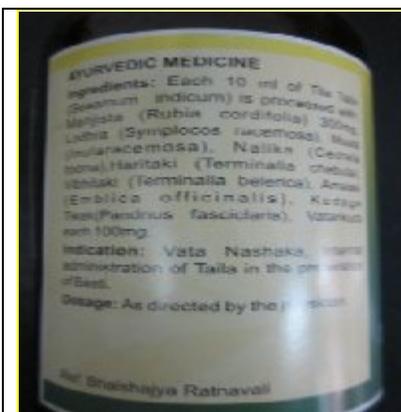
thod of preparation is also not seen in rule and mode and dose of use should have been mention in this law.

### CONCLUSION

Labelling is a must and it provides all the information about the product. It acts as an index and identity of product as well as the pharmaceutical company. This law also apply to Ayurvedic product according to rule 161. without which the product is termed to be invalid and cannot be sold in the market.

Though the drug and cosmetic act explains about the different aspect of Labelling. Which are must for the Ayurvedic product without which it is not liable to be sold in market and certain points are need to be considered in case of Labelling are like best before or expiry date, preservative added, indication, and dosage . This has not been explained in schedule E of D&C act. Because most of the Ayurvedic products are OTC products which can be sold in retail shop. So there is a chance of misuse of these product .which are to be considered. This is also important for the ayurvedic products.

### IMAGES OF DIFFERENT LABEL SHOWING IMPORTANCE OF LABELING



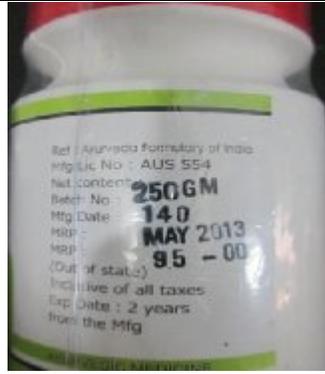
List of ingredients



Caution mentioned in label



Name of medicine



Weight of drug



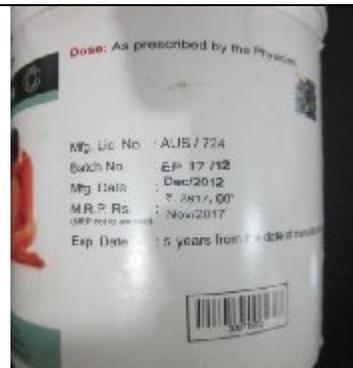
Name and address of manufacture



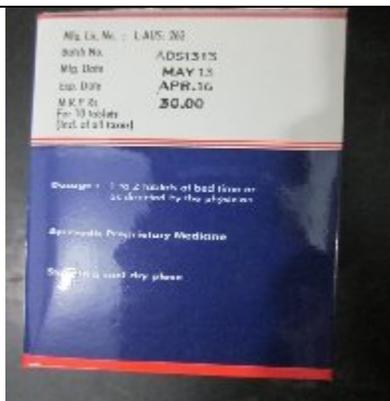
MFG. LIC. NO.



Batch no



MFG .date



EXP. Date



External use

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