



ASSESSMENT ON THE LABEL OF AYURVEDIC CLASSICAL AND PROPRIETARY MEDICINES IN ACCORDANCE WITH 'THE DRUGS AND COSMETICS ACT 1940'



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Abstract

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Aim: To study and evaluate the diagrammatic representation of Ayurvedic classical and proprietary medicine by developing a check list in accordance with Drugs & Cosmetics Act 1940 and Rule 1945. **Hypothesis:** Studying the norms as mentioned in the Drugs and Cosmetics Act 1940, regarding the label of Ayurvedic medicines. Creating a checklist, in order to evaluate the degree of compliance of the examined Ayurvedic medicines in accordance to Drugs and Cosmetics Act 1940. Establishing and evaluating the authenticity on the label of Ayurvedic medicine in accordance with the specificity as mention Drugs and Cosmetics Act 1940. **Result and discussion:** Total 50 labels were reviewed of which 27 were classical medicines and 23 were proprietary medicines. Amongst the label of 27 classical medicines that was reviewed, 17 of classical medicines that are 63% had the reference mentioned on it. The label of 13 classical medicine that is 48.15% where not in compliance, of which 4 classical medicine that is 14.8% did not have the expiry date mentioned on the labels and labels of 8 classical medicine that is 29.63% did not bear the dose & direction of use, and label of 1 classical medicine that is 3.7% did not have therapeutic index or indication mentioned on the label. Moreover ingredient was not mentioned on the label of classical medicine that is 33.33%. 14 classical medicines that is 51.85% complied with Drug & Cosmetic Act 1940. In case of proprietary medicine (2) that is 8.69% were not in compliance as they did not have the indication mentioned on the label.

INTRODUCTION

An Ayurvedic medicine has commenced its existence and efficacy since Vedic period. Now-a-days labels of medicines are an important factor in communication and treatment of patients. This is because, when a layman purchases a medicine, this label will provide a rough guideline for usage of this medicine. If a medicine does not specifies the proper label according to standards, there may be misuse of the product and adverse drug action can be involved. The guidelines of the labels of Ayurvedic medicine is mentioned in The Drugs and Cosmetics Act, 1940. Every manufacturer must maintain this guideline for the labeling of medicines. This survey is an attempt to secure the efficacy of Ayurvedic classical and proprietary medicines by heralding a frequency of reflectance to the common consumers who are merely dependent on physicians and directions of usage as mentioned on the labels of Ayurvedic medicines. The modern era is an era of technological advancements, thus pursuing a sound knowledge on the available literatures about the basic composition of the medicines with their side effects and

contra-indications are of utmost necessity which can only be achieved through stringent rules and regulations that should be maintained on the label of Ayurvedic medicines which demands a regularization that should be compiled with a honest visualization of understanding the standards that are mentioned for human betterment and development.

METHODOLOGY

a) Study The Norms As Mentioned In The Drug And Cosmetic Act 1940

Review of Literature:

Any kind of label on an Ayurvedic medicine implies the complete specification of the ingredients present in the formulation and also the details of the manufacturer, manufacturing condition, storage and expiry date, adverse effects that should comply with the standard as mentioned in the drug and cosmetic act 1940.

Regulation as per The Drugs & Cosmetics act 1940; Part xvii—1[labeling, packing and limit of alcohol in] Ayurvedic (including siddha) or unani drugs 1[161. Labeling, packing and limit of alcohol.]

1. There shall be considerably displayed on the label of the container or package of an Ayurvedic (including Siddha) or Unani drug, the true list of all the ingredients used in the manufacture of the preparation together with 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 to the Act: 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.
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 in English and Hindi language.
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 on any other covering in which the container is packed namely--
 - a. 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.
 - b. 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.
 - c. The name and address of the manufacturer.
 - d. 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.'.
 - e. 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 No." or "Lot" or any distinguishing prefix.

- f. 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.
- g. The words "Ayurvedic medicine" or "Siddha medicine" or "Unani medicine" as the case may be.
- h. The words "FOR EXTERNAL USE ONLY" if the medicine is for external application.
- i. 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.

Compliance: As referred from the journal IJAR, 190 labels of Ayurvedic medicines were reviewed (101 classical formulations and 89 proprietary medicines), out of which only 55% of classical formulations and 88% of proprietary medicines showed a proper ingredient list that complied with the standard. More over only 20% of classical medicines a 15% of proprietary medicines illustrated the 'CAUTION', 'WARNING', only in one language that is English. This implies that Labels on Ayurvedic formulations is not in compliance with the standard and the data shows that the classical medicines are lacking information's which may lead to hazard for the customers, majority of which are layman with respect to the field. Thus a thorough review of the current formulations is of utmost importance to understand the present condition of the medicines.

Importance: Most of the customers using Ayurvedic medicines are layman with very little or no knowledge about the field and are dependent on the physicians mainly. Thus a proper label on the medicine is very essential to make the patient independent and to reduce the dependence over the physicians. Information specifying the

method of application, dose, storage, adverse effects, caution, indication, manufacturing date, expiry date, etc is of utmost important. Again the details of the company manufacturing the medicines (address, certifications, registration no., e-mails, customer care help line, etc) and the ways of manufacturing like batch no., license no. Should be specifying for the safety of the customers and also to establish a trustworthy relationship with the customers.

b) Create A Check List

Theoretical in formations, to formulate a standard checklist will be accumulated from The Drugs & Cosmetics Act 1940 and Rule 1945^{2,3}.

The following points will be covered in the check list:

- References will be taken form authoritative books and the check list that will be made from the data's collected and also by reviewing classical text, schedule to the act will be evaluated and the percentage that complies with the standard checklist will be reported separately for classical and proprietary Ayurvedic Medicines.

Roughly the following observations will be reported;

- Name and address of the manufacturer.
- License number (the number of license under which drug is manufactured; it has to be in figures preceded by words like, Manufacturing License Number/ Mfg. Lic. No/M.L).
- Batch number (figure representing batch number preceded by words like lot. number, Batch no.).
- Manufacturing date and Expiry date.
- Net content of the formulation (in terms of weight, measures or number as the case may be. This weight and volume should be expressed in metric system).
- References from standard authorities texts to be considered in case of classical formulations.
- Ingredient list with quantity.
- Formulations which are made for external use should have the caption specified as 'For External Use Only'.
- It should be mention 'Ayurvedic Medicine' or 'Siddha Medicine' or 'Unani Medicine'.

- CAUTION should be mentioned if poisonous substance (drug specified in Schedule E) is present in the formulation.

c) Gather Ayurvedic Classical And Proprietary Medicines From The Medicine Shop and Compare The Medicines In Respect To The Check List

Various medical shops and pharmacies will be approached to gather information's regarding Ayurvedic medicines within the approachable limits. Then compare the labels of those medicines with the check list.

Compare the label with the Check list.

RESULT AND DISCUSSION

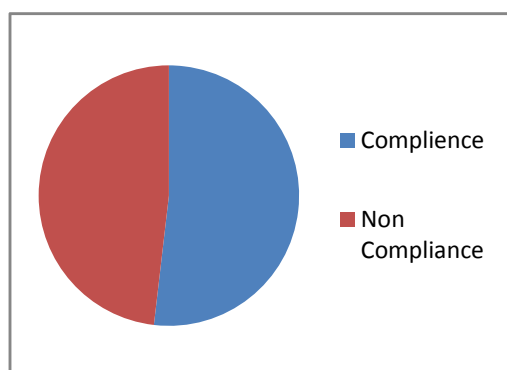
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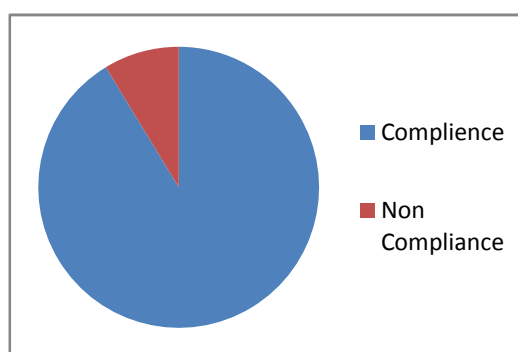
Table 1 (The comparison of classical and proprietary medicine)

	Classical Medicine	Percentage (%)	Proprietary Medicine	Percentage (%)
Total Number	27		23	
Non Compliance	13	48.15	2	8.69
Reference	10	37.04	0	0
No Exp. Date	4	14.81	0	0
No Dose/Direction	8	29.63	0	0
No Indication	1	3.7	2	8.69
No Ingredient	9	33.33	0	0

Classical Medicine



Proprietary Medicine



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