Role of Pharmacognosists in Regulating Herbal Industry

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Abstract

Herbal medicines are widely used all over the world for the treatments of various diseases. Hence regulation is necessary for herbal medicinal products. Different countries have different regulation for herbal medicinal products. Standardization is an important part of regulation in which raw material and finished products specification, analytical and in process methods, stability study are required. In this article herbal products and its regulatory requirements are discussed. This is useful for marketing herbal medicinal products particularly in India.

Keywords: Herbal medicines, Chromatogram, Ayurvedic drugs.

Introduction

The indiscriminate use of synthetic drugs have caused serious symptoms all over the world. More over the demand for plant based raw material have increased as synthetic drugs are costly. Therefore the World health organization has emphasized the use of traditional medicine which include the use of drugs from plant origin. Today almost 1/3rd of the drugs are obtained from plant origin. If fungi and bacteria are included, over 60% of the pharmaceutical preparations are plant based. Therefore regulation is necessary for herbal medicinal products [1].

Regulatory Requirements for the Herbal Products in India

Legal Status

In India there are Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945 Traditional medicines are governed by these act and rule. These Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945 regulate the import, manufacture, distribution and sale of Herbal drugs and cosmetics. Products derived from traditional systems should be manufactured after obtaining licence from the State Drug Control Authorities. According to Drugs and Cosmetics Rules of 1945 provisions relating to Ayurvedic, Sidda and Unani drugs are given. Regulation of manufacture for sale of Ayurvedic drugs are mention. As per the regulation no person shall manufacture for sale or for distribution any Ayurvedic drug except in accordance with the Ayurvedic standard, if any, as may be prescribed in relation to that drug. Manufacture of Ayurvedic drug is permitted for Vaidyas if he use them for his own patient. Manufacture of Ayurvedic drug is permitted if it is prepared in small quantity for the purpose of examination, test or analysis. Manufacture of patent and proprietary medicine is allowed if all the ingredients are displayed in prescribed manner on the label. Any misbranded, adulterated or spurious Ayurvedic drug is prohibited from manufacture. The Drugs and Cosmetics Rules of 1945 also mentioned the manner of labeling the Ayurvedic drugs. The label should contain true list of all the ingredients, quantity of each ingredients and a reference to the method of preparation as detailed in standard text and Adikarana. If the list of ingredients cannot accommodated on the label, the same may be printed separately and enclosed in the packing and reference to be made to this effect on the label. Following particulars must be printed on the label namely: 1. The name of the drug. 2. Net content in terms weight or volume which should be expressed in matric system. 3. Name and address of the manufacture. 4. The number of licence under which the drug
is manufactured or manufacturing licence number. 5. Batch number 6. Date of manufacture 7. The word “Ayurvedic medicine”. 8. The word “External use only” if the medicine is for external application. 9. If the drug is distributed to Medical professionals then the label should contain the word ‘Physician sample. Not to be sold’.

Legal aspects of Herbal drugs also include Good Agricultural and Harvesting Practices, Quality assurance and stability testing of Herbal Drugs, Analytical Profiles of medicinal Plants. Cultivation, Harvesting and processing of medicinal plant material must be monitored. For this purpose the European organization for growers of medicinal plants has developed GAP (Good agricultural Practice) guidelines [2]. The person who collect the must possess good knowledge in identifying the plants. He should also know the requirement of the environmental factors like requirement of shade, Moisture, soil for the cultivation of plants. The person who collect should have knowledge to distinguish the medicinal plant form its closely related species. Collector must have knowledge about the time of collection. Collector must be free from infectious disease. The knowledge of collector must be monitored by specialist and it has to be documented. The guideline for packed materials is as follows, the packed material must be eliminated by the low quality product and it should be stored in cleaned and dry place. The guidelines for equipment and machinery are, the machinery must be able to clean easily. The different types of Herbal medicines are Creams, Capsules, Emulsions, Ointments, Suppositories, Tinctures and Extracts. The different types of equipments used are Measuring instruments, size reduction equipment (Hammer mil), drying equipment (Tray drier) Percolator, press and blender, Containers, Scoops and Labeller. The different menstruum required are Water, Vinegar, Wine, Alcohol, Ether, Glycerol and Oil Built area must contain Security area or watchman area, toilets and changing room for the staff, raw material storage room, equipments or manufacturing process department, quality control or laboratories area and finished goods department. The person who is working must be skilled and should have pharmaceutical knowledge. The Documentation of various department must be recorded. It must contain information about the temperature of each department, process of manufacturing, the pressure, signature of authorized person, date, time of manufacture, number of lots, batch number, the ingredients, quantities etc must be completely recorded in different departments. Aseptic conditions in each department must be maintained. The employers should be provided with nose mask, gowns, slippers. Cotton cloths must be free from lints. The floor must be coated with ceramic epoxy and cutting edge must be free from the cracks. Raw materials obtained must be stored aseptically and must undergone sterility test, the foreign organic matter must be removed. It should be stored in a different department far off from the manufacturing area to avoid the contaminations. Sterility test is carried out by microbial viable count Herbal products like tablets should undergo process validation which involves Hardness test, weight variation test and uniformity test. Stability study must be carried out for herbal material or finished herbal product. For this purpose finger print method is used by comparing the chromatogram (HPTLC or IR) of the active constituent or marker compound of the herbal material with that of finished formulation [3, 4].

Conclusion
Pharmacognosists have important role in manufacturing of various herbal products and in regulating them. Standardization, documentation, shelf life study, personnel requirements, aseptic conditions, process validations, guidelines for packed materials, guidelines for labeling are the important part of regulation of Herbal industry.

References


