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# Regulatory Requirement Of Herbal Medicine In India

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**Abstract**

Natural products have been used all across the world since the Vedic period. Though minerals & animal products have long been utilized as natural goods in some nation. Herbal medicine is still used for basic health care by around 75-80% of the world population, primarily in developing countries. There are significant variances in the classification and categorization of herbal medication. According to the laws of the respective countries, they are currently classed in several medical systems, Such as the Allopathic, Homeopathic, Unani and Siddha and Ayurvedic systems of medicine in India. Herbal remedies herbal medicines are gaining popularity worldwide due to their potential benefits in preventing and treating various diseases. India has a rich tradition of using herbal medicines for centuries. The use of herbal medicine is also regulated by the government to ensure their safety, efficacy, and quality. These review aims to provide an overview of the regulatory requirements for herbal medicines in India. The regulatory framework for herbal medicines in India is provided by the Drug and Cosmetic Act 1940, and its amendment. The act defines herbal medicine as drugs that are exclusively derived from plants, there parts, or their extracts, and are used for medicinal purposes. The act also lays down the guidelines for the manufacturing, labeling and marketing of herbal medicines.
Herbal drug regulations in India is discussed in detail, followed by an overview of regulatory status of herbal medicine in USA, CHINA, AUSTRALIA, BRAZIL, CANADA AND GERMANY.

**Keywords:** Herbal medicine, Regulatory Requirements, WHO.

## INTRODUCTION

Herbal medicines are being used in India since Vedic age and it has been documented in Rigveda. It has been mentioned in Charak Samhita. Initially herbs have been used by the people traditionally from their experience and gradually a group of experts evolves who were called as apothecaries. Herbal medicines are also used since long back in other different countries like China. In India herbal medicines are being used in Ayurveda, Siddha, Unani & Homoeopathicsystem of medicines. Ayurvedic system is being practiced since 6000 B.C., Chinese herbal medicines being practiced since 5000 B.C. whereas the modern system of medicines started since 1800 A.D. This was popular may be because of the experience and abundant availability of plants in India due to its varied agro climatic zones. We are having around 45,000 species of plants in the Indian conditions, out of which 15,000-20,000 plants have proven medicinal value. The traditional system utilizes around 7,000-7,500 species in its formulations. Ayurveda uses 2000, Unani 1000, Siddha 1300, Tibetan 500 and 200 varieties in the

modern medicine (Mukherjee and Wahile, 2006). [1]

Interest on herbal products has been increasing since last few decades not only in underdeveloped and developing countries, but also in the developed countries. A large number of big pharma companies started to redirect their business strategy by investing large amount of finance in research and manufacturing of herbal medicines. Some Govt. institutions are also emphasizing on research on herbal medicines. Herbal medicine has a Global market of US$ 80
- 100 billion (Gohil and Patel, 2007) and this market is expected to reach US$2500 billion by the year 2010 and US$ 5 trillion by the year 2050 according to the World Bank report. The Indian herbal drug market is about $ 1 billion and the export of herbal crude extract is about $
80 million. (Mukherjee, 2001). We have about 7800 manufacturing units engaged in manufacturing of herbal drugs in India, which are consuming 200 tons of herbs annually. Initially there was no regulation for controlling the quality of herbal medicines and the practitioners relied on their experience on proper identification of the plant. Gradually some regulation developed and the first organized regulation on quality is the Drugs and Cosmetics Act 1940 and Drugs and Cosmetic Rules 1945. This act initially prescribed the standards of Ayurvedic, Siddha and Unani medicines and laid down rules and regulation on manufacturing.

India has Vedic history for herbal medicines used. Herbal medicinal products have increased the global demand and have led to the commercialization. In India herbal medicinal product (hmi) manufactured and marketed as Ayurveda. Siddha, Unani etc. imported herbal medicines must be registered and marketed in the countries of origin the safety and efficacy data have to be submitted to the national authority of the importing country and need to meet the requirements of safety and efficacy of regulation of herbal medicines in the recipient country recently the regulations of herbal medicinal products are varying from country to country, so it creates challenge to the manufacturing companies to sell herbal product in the global market. World health organization (who) and many regulatory bodies have adopted resolution to ensure safety, efficacy and quality of herbal medicinal product. Classification of herbal medicines as per who guidelines category 1: indigenous herbal medicines category 2 herbal medicines in systems category 3: modified herbal medicines

category 4 imported products with herbal medicine base safety is fundamental principle in the provision of herbal medicines and herbal products for health care, and a critical component of quality control these guidelines provide practical technical guidance for monitoring the safety of herbal medicines within pharmacovigilance systems.

## HISTORY OF HERBAL MEDICINE [3]

Archaelogical evidence indicates that the use of medicinal plants dates back to the paleolithic age, approximately 60000 year ago. Written evidence of herbal remedies dates back over 5000 years to the sumerians, who complied lists of plants. Some ancient culture wrote about plants and there medical uses in book called herbals. In ancients Egypt, herbs are mentioned in Egyptician medical papytri, depicted I tomb illustrations, or on rare occasions found in medical jar containing trace amounts of herbs. In ancient Egypt the ebers papyrus dats from about 1550 BC, and covers more than 700 compounds mainly of plant origin. The earliest lnown Greek herbals came from Theophrastus of Eresos who, in the 4$^{th}$ century BC, wrote in Greek Historia Plantarum, from Diocles of Carystus who wrote during the 3rd century BC. and from Krateuas who wrote in the In 1$^{st}$ century BC. Only a few fragments of these works have survive intact, but from the remains scholars noted overlap with Egyptian herbals. Seeds likely used for herbalism where found in archaeological site of bronze age China dating from Shang dinesty (c.1600C.1046 BC). Over a hundred of the 224 comonds mentioned in the Huangdi Neijing. An early Chienes medical text, are herbs. Herbs were also commonly used in traditional medicines of Ancient India, where the principal treatment for disease was diet.De Materia Medica, originally written in Greek by Pedanus Dioscorides (c.40-c.90 AD) of Anazarbus, Cilicia, a physician

and botanist, is one example of herbal writing used over centuries until 1600. [4]

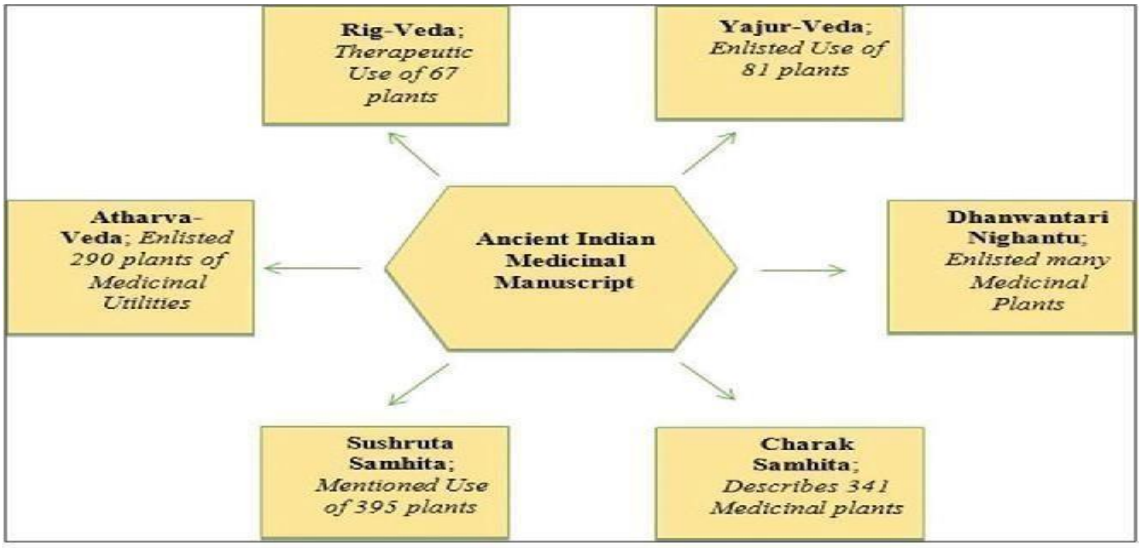


**Fig. 1: Enlisted plants of the ancient Indian medicinal manuscript**

## CLASSIFICATION OF HERBAL MEDICINE [14]

Herbal medicines can be classified into four categories as per WHO, based on their origin,evolution and the forms of current usage.

1) **Category 1**: Indigenous herbal medicines: This category of herbal medicines is historicallyused as local community or region and is very well known through long usage by the local population in terms of its composition, treatment and dosage.

2) **Category 2**: Herbal medicines in systems: Medicines in this category have been used for a long time and are documented with their special theories and concepts, and accepted by the countries. For example, Ayurveda, Unani and Siddha would fall into this category of TM.

3) **Category 3**: Modified herbal medicine: These are herbal medicines as described above in categories 1 and 2, except that they have been modified in some way-either shape, or form including dose, dosage form, mode of administration, herbal medicinal ingredients, methods of preparation and medical indications. They have to meet the national regulatory requirements of safety and efficacy of herbal medicines.

4) **Category 4**: Imported products with an herbal medicine base: This category covers all imported herbal medicines including raw materials and products. Imported herbal medicines must be registered and marketed in the countries of origin. Safety and efficacy data have to besubmitted to the national authority of the importing country and need to meet the requirementsof safety and efficacy of regulation of herbal medicines in the recipient country

[15]

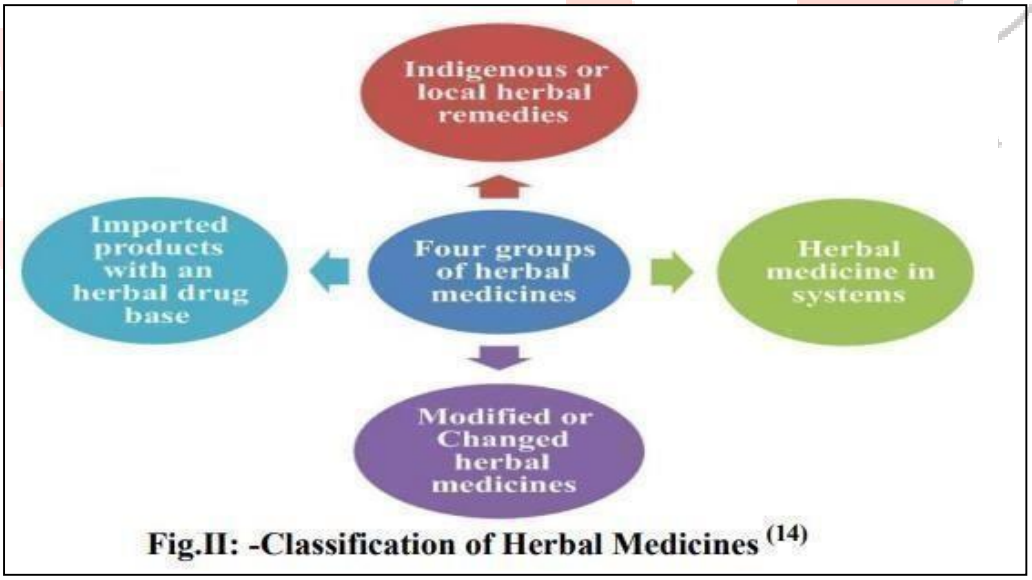


**Fig.II: -Classification of Herbal Medicines** (14)

**OBJECTIVE**: [20]

- Requirements for quality, safety and efficacy of herbal medicines.
- WHO Guidelines on safety monitoring of herbal medicines.
- To assess the regulatory requirements for Indian herbal drug industry with respect to and commercialization of herbal medicines.

- This involves setting standards for product labeling, manufacturing processes, and testing methods to ensure that herbal medicines meet established criteria for purity, potency, and composition.

SCOPE OF HERBAL MEDICINE [24]

Herbal Medicinal Products are gaining acceptance among people across the world due to rising awareness of lifestyle diseases and improper food habits. Plants are the curator of the vault oftreasure medicines that save the human civilization from various diseases. The medicinal values of the extract of our surrounding living but immovable creatures are now the basis of research using modern biological techniques, proteomics, genomics, transcriptomics, metabolomics etc. Since the inception of the civilization man rely on plants for curing diseases and in our country the sole ground ancient intelligence nurtured the benefits of the plant in several aspect of our daily life not only as medicine but as nutraceuticals, food, cosmetics andwhat not. Incidentally Indian subcontinent is the breeding house of so many exotic and endemic plants of medicinal importance which were recorded by our ancestors. The fundamental principal of herbal plants in making several outcome is a very interesting chapter to be realizedin daily life and capable of making professions of common people. The scope of this course will subsidize different sections related to herbal plants starting from their identification to utility. The unique objective will train the candidates developing true concept on medicinal plants, their built treasure for the sustenance of the quality life of mankind and also to save plants from extinction. Medicinal plants are used in many traditional systems and in modern phytochemical formulations. Many drugs for the treatment of cancer, diabetes and heart disease are currently made from molecules derived from medicinal plants.

[30]

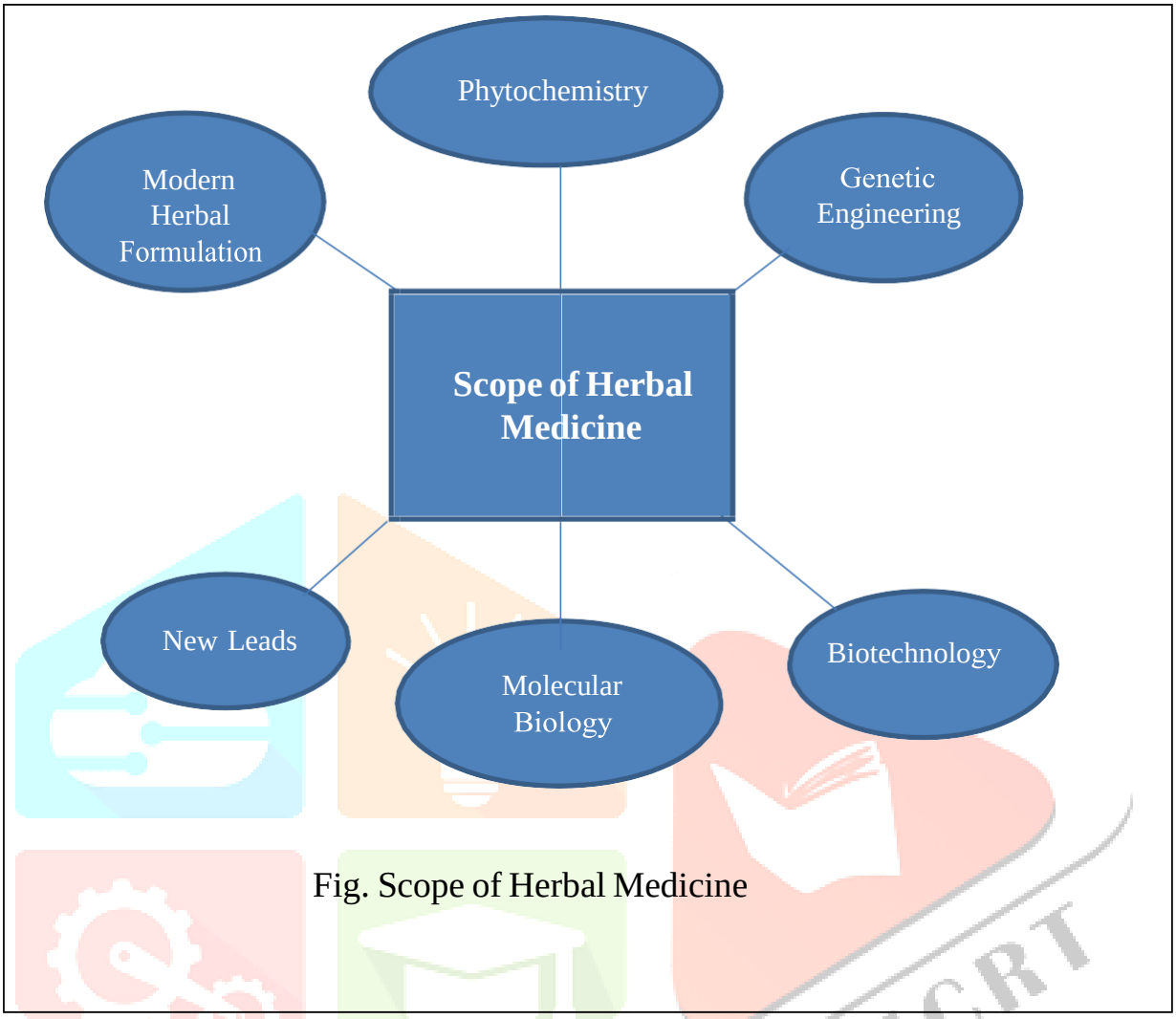


Fig. Scope of Herbal Medicine

IMPORTANCE OF HEBAL MEDICINE [7,8]

Herbal medicine holds significant importance for several reasons. Firstly, it offers a natural and holistic approach to healthcare, utilizing plants' therapeutic properties to promote healingand well-being. This aligns with the growing global trend towards embracing natural remedies and reducing reliance on synthetic drugs, which can have adverse side effects.

An herb is a plant or plant part used for its scent, flavors, or therapeutic properties. Herbal medicines are one type of dietary supplement. They are sold as tablets, capsules, powders,teas, extracts, and fresh or dried plants. People use herbal medicines to try to maintain or improve their health.

Herbal medicine is the use of medicinal plants for prevention and treatment of diseases: it ranges from traditional and popular medicines of every country to the use of standardized andtitrated herbal extracts

- The 100% safe **herbal products** are known to induce a healthy lifestyle by balancingthe mind, body, soul, and the environment.
- Ayurvedic treatment also focuses on inducing good sleep.

- Helps detoxify body with several detoxification practices.
- Helps improve body health with yoga, different physical exercies, body massage,meditation, etc.
- Helps avoid stress, anger or anxiety.
- Focuses on balanced diet, good clothing habits and motivates to drink more fluids.
- Helps control ‘kapha’, ‘pitta’, ‘vata’, and balances ‘dosha’ in each individual.


**Figure: Importance & Benefits of Herbal Medicine** [9]

**DRUG & COSMETIC ACT 1940:** [2]

In India, traditional medicine governed by the Drug and Cosmetic Act 1940 & the Drug & cosmetic rules of 1945 & they regulate the import, manufactured, distribution & sale of drug & cosmetic.

In 1959, the government of India recognize the traditional Indian system of medicine & amendment the Drug & Cosmetic Act to include drug which are derived from traditional Indian medicine. No product derived from traditional system may be manufactured without license from the state Drug Authorities.

Patent & proprietary medicine derived from the traditional system must contain ingredients which are mentioned in the recognized books of the above system, as specified in Drug and Cosmetic Act.

The government is advised by a special committee and an advisory board for Ayurvedic, Siddha, & Unani drugs. Pharmacopoeia committees have been constituted to prepare

pharmacopoeias for all these systems.

**Schedule T** [2]

Schedule T describe the good manufacturing practices for Ayurvedic, Siddha, Unani medicine. The good, manufacturing practices (GMP) are prescribed as fallow in part 1 &part 2 to ensurethat: Raw materials used in manufactured of drugs are authentic, of prescribed quality & are free from contamination.

GMP have been made mandatory by incorporation of revised Schedule T in the year of 2003.Important features of Schedule T are as follows:

i) Raw materials to be used in manufacture of medicines must be authentic, of prescribed quality and free from contamination

ii) Manufacturing process is as prescribed to maintain the standard.

iii) Adequate quality control measures to be adopted

iv) Drugs released for sale Drug released for sale shall be of acceptable Quality.

v) To achieve the objectives listed above, the firm is required to maintain the following conditions stringently-

A) Well designed factory premises with sufficient space required to be provided.

B) Proper machineries require to be provided.

C) Quality control laboratory require to be provided with required instrumentations and well qualified personnel.

D) Shall evolve methodology and procedures for following the prescribed process of manufacture.

E) Which should be properly documented and kept for reference and inspection.

**Table: List of ASU drug regulation different section:** [31]

| Sections | Title |
|---|---|
| 33C. | Ayurvedic, Siddha and Unani Drugs Technical Advisory Board. |
| 33D. | The Ayurvedic, Siddha and Unani Drugs Consultative Committee. |
| 33E. | Misbranded drugs. |
| 33EE. | Adulterated drugs. |
| 33EEA. | Spurious drugs. |
| 33EEB. | Regulation of manufacture for sale of Ayurvedic, Siddha and Unani drugs. |
| 33EEC. | Prohibition of manufacture and sale of certain Ayurvedic, Siddha and Unani drugs. |
| 33EED. | Power of Central Government to prohibit manufacture, etc., of Ayurvedic, Siddha or Unani drugs in public interest. |
| 33F. | Government Analysts. |
| 33G. | Inspectors. |
| 33H. | Application of provisions of sections 22, 23, 24 and 25. |
| 33-I. | Penalty for manufacture, sale, etc., of Ayurvedic, Siddha or Unani drugs in contravention of this Chapter. |
| 33J. | Penalty for subsequent offences. |
| 33K. | Confiscation. |
| 33L. | Application of provisions to Government departments. |
| 33M. | Cognizance of offences. |
| 33N. | Power of Central Government to make rules. |
| 33O. | Power to amend First Schedule. |

**Indian Regulations of Herbal Medicine:** [10]

Herbal drugs represent a main part of all the known system of health in India that is Ayurveda, Yoga, Unani, Naturopathy, Siddha and Homeopathy except Allopathy. In India, herbal medicines are regulated under the Drug and Cosmetic Act (D and C) 1940 and Rules 1945, where regulatory provisions for Ayurveda, Unani, Siddha medicine are clearly laid down.

Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) isthe regulatory authority and mandate that any manufacture or marketing of herbal drugs haveto be done after obtaining manufacturing license, as applicable.

The main focus of this department is on development of Education and Research in Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy systems. Laws and regulations on herbal medicines are partly the same as those for conventional pharmaceuticals. The D&C Act extends the control over licensing, formulation composition, manufacture, labelling,

packing,quality, and export.

Schedule "T" of the act lays down the good manufacturing practice (GMP) requirements to be followed for the manufacture of herbal medicines. The official pharmacopoeias and formularies are available for the quality standards of the medicines. First schedule of the D&C Act has listed authorized texts, which have to be followed for licensing any herbal product under the two categories: Ayurvedic, Siddha or Unani drugs Patent or proprietary medicines.

**Table: Schedule for Herbal Medicine Product in India (CDSCO)** [29]

| Part of Act / Rule | Chapter / Part | Nature of Activity |
|---|---|---|
| **Drugs & Cosmetics Act 1940** | Chapter IV-A (section 33-B to 33-N) | Provides provisions related to *Ayurveda, Siddha* and *Unani* Drugs |
| **Drugs & Cosmetics Act 1940 - Schedules** | The First Schedule | List of scheduled books |
| | The Second Schedule | Standards to be complied with by imported drugs and by drugs manufactured for Sale, Stocked or Exhibited for Sale or Distributed |
| **Drugs & Cosmetics Rules 1945** | Part XVI (Rule 151-160) | Manufacture for sale of *Ayurvedic* (including *Siddha*) or *Unani* Drugs |
| | Part XVI-A (Rule 160 A - 160 J) | Approval of institutions for carrying out tests on ASU Drugs and Raw material used in their manufacture |
| | Part XVII (Rule 161) | Labeling, Packing and Limit of Alcohol in ASU Drugs |
| | Part XVII (Rule 161-B) | Shelf life and date of expiry for ASU Medicines |
| | Part XVIII (Rule 162-167) | Government analysts and Inspectors for ASU Drugs |
| | Part XIX (Rule 168-170) | Standards of ASU Drugs |
| **Drugs & Cosmetics Rules 1945 - Schedules** | Schedule A | Different types of forms, particularly 24D, 24E, 25D, 25E, 26D, 26E, 26E-1, 47, 48, 49 |
| | Schedule B-1 | Fees for the test or analysis by Pharmacopeial Laboratory for Indian Medicine or the Govt. Analyst |
| | Schedule E-1 | List of poisonous substances under ASU Systems of Medicine |
| | Schedule FF | Standards for Opthalmic Preparations |
| | Schedule T | Good Manufacturing Practices for ASU Medicines |
| | Schedule Y | Requirements and Guidelines for permission to import and / or manufacture of new drug for sale and to undertake clinical trials |
| | (Proposed) Schedule Z | Requirements and Guidelines for permission to manufacture of ASU Drugs for sale or for clinical trials. |

1. **Good Agricultural and Collection Practice (GACP)**: [14] GACP applies the guidance to the cultivation and collection procedures, right from selection of herbs, botanical identity, soil, seed, cultivation techniques, environment and surroundings, climate, irrigation, maintenance, harvesting and drying. The collection procedures should be carried out by trained personnel withadequate knowledge about cultivation techniques including; the use of pesticides, etc. Well- organized quality assurance should be maintained with active principle content, morphological and microscopical features, limit values for microbial contamination, chemical residues, heavy metals, etc.Documentation of process and procedures, fumigants, labeling, agreements, audit results should be maintained. Post harvesting procedures are to be inspected. The processing of the collected herbs is to be carried out in specified facilities and stored appropriately. Testing details, solvents used purification stages, standardizations, etc. details of impurities like: pesticides, fumigants, microbial contamination and its control should be documented.

2. **Good Manufacturing Practice (GMP)**: [14] Regulatory Requirements for Herbal Medicines Implementation of GMP ensures product uniformity batch to batch and assists to comply with the quality standards to meet the requirements. The quality assurance system and documentation are crucial for GMP. Research and development laboratory in accordance withthe GLP is mandatory, along with compliance to GACP. This set up will qualify for standardized manufacturing of herbal medicines. Standardization should be followed right from seed to shelf with well-planned analytical method development and analytical method validation. A detailed product development report for herbal preparation and herbal product with a well-defined process flow accompanied by process controls will ensure that quality is built into the product. Manufacturing flow chart with process control specification and standard testing procedures are must for processing of herb, herbal preparation and herbal medicines. The active herb specification should include; physical and chemical parameters, impurities, microbial contaminants and adulteration. As the extraction and processing of herbal preparation involve the use of solvents, the parameter on residual solvents should be a part of the specification. The Medicinal Plants Division of ICMR as per WHO guidelines and with the involvement of approved laboratories has addressed the data generation for monographs. Each monograph is titled with botanical nomenclature, macroscopic and microscopic characteristics and phytochemical constituents, identification criteria using fingerprinting techniques (TLC/GLC/HPLC), quantitative estimation and marker principles. It also includes: information on pharmacological, clinical, toxicological aspects, dose, adulterants /substitutes etc.

3. **Good Laboratory Practice (GLP)**:[14] Well planned analytical method development and analytical method validation in approved laboratories as per GLP, will help in setting up of a quality management system to ensure uniformity, consistency, reliability, reproducibility ofthe testing parameters. It ensures reliable & quality-oriented data and contributes towards a quality product. Stability study of herbal substances, herbal preparations and herbal medicines should be carried out. The container closure system also plays a major role.

4. **Good Clinical Practice (GCP)**:[14] Herbal Medicines under the Herbal Anatomical Therapeutic Chemical (HATC) are Classified based on nomenclature and therapeutic activityto aid the study of safety and Clinical data. Department of AYUSH implemented pharmacovigilance program keeping in mind the growing demand of acceptance of Ayurvedaand thus, to ensure its safety and efficacy and reporting of adverse reactions and to investigate the same.

The Health Authority and Ethical committee give clearance for conducting a clinical trial. For health conditions, well-established usage in the country of origin would serve the requirementwith the supporting ancient texts, pharmacopoeia and monographs stating the same, whereas,in case of acute and chronic disease conditions, a clinical trial is to be carried out. The trial when conducted requires a detailed protocol, a principle investigator and evidence of safety and efficacy of the herbal medicine.

**Ministry of AYUSH** [22]

The Ministry of Ayush, a ministry of the Government of India, is responsible for education, research & propagation Of Traditional Medicine & Alternative Medicine system, in India. Ayush is name derived from the names of alternative healthcare systems covered by the Ministry: Ayurveda, Yoga & Naturopathy, Unani, Siddha & Homeopathy.

The Department of Indian System of Medicine and Homeopathy was firstly established in 1995 Under the Ministry of Health & Family Welfare. ISM&H was renamed as The Department ofAYUSH in 2014.

**Objective of AYUSH [29]**

The main objective is to upgrade the educational standards of Indian System in Medicines and Homoeopathy Universities and college in the country. To build-up the existing research institutions and make sure a one-time research program on identifiable diseases that these systems have an efficient treatment. To make the plan for promotion, cultivation and regeneration of medicated plants utilized in all the above systems. To develop Pharmacopoeial standards for Indian System of Medicines and Homoeopathy drugs. Objective of AYUSH is to control the drug quality, laying down pharmacopoeial standards, overseeing working of pharmacopoeial Laboratory of Indian Medicines, by the Quality Council of India and observe the process of Indian Medicine Pharmaceutical Company Limited. AYUSH also controls implementation of Good Manufacturing Practices, setting up of common facilities following Cluster approach and execute the scheme on Drug Quality Control with the disclosure of herbal medical formulations, knowledge & manuscripts, documentation and promotion of regional health traditions.

**Ayurveda**

The literal meaning of Ayurveda is "The Science of Life;" the combination of two *Sanskrit* words "ayur" (life) and "veda" (science or knowledge). Ayurveda involves a logical convention of harmonious living, and its beginning can be drawn from ancient information in *Rigveda* and*Atharva veda*. The source of Ayurveda has been lost in ancient relic, yet its ideas and methodologies have been idealized in between 2500 and 500 BCE in India.

The central objective of Ayurvedic treatment is "Ayurveda deals with happy and unhappy life. It explains what is appropriate and what is inappropriate in relation to the life, as well as it measures the life expectancy and the quality of life." It is a holistic arrangement of medical services with the idea, that the human body is a network of seven fundamental tissues ("Rasa," "Rakta," "Mansa," "Meda," "Asthi," "Majja," and "Shukra") and the waste results of the body, for example, excretion, urine, and sweat, which are derived by the five fundamental components fire, water, air, ether, and earth and three dynamic energies or functional philosophies "vata, pitta, and kapha" (*Tridosha*). Any unevenness or unsettling influence in these fundamental standards of the body causes disease

**Siddha**

Siddha system of medicine is settled since the ancient human civilization in India, around 10,000 BCE–4000 BCE. Like Ayurveda, it is developed through everyday skills of utilizingnatural resources for maintaining good health and remains as an oldest medicinal practice inSouth India. Siddha system of medicine is believed to be established by 18

"Siddhars;" Thirumoolar, Ahappe, Agathiyar, Sunthara ananthar, Bogar, Machchamuni, Konganar, Korakkar, Therayar, Karuvoorar, Nandi Devar, Idaikkadar, Iraamathevar, Sattamuni, Kuthampai, Paampaatti, Aluhanna, *and Kahapusundar*. This medicinal practice believes preserving the human wellbeing is crucial to succeeding the eternal bliss and the philosophical idea includes "food is medicine, medicine is food" and "sound mind makes a sound body."

**Unani**

The Unani system of medicine pioneered in Greece, and it was urbanized by Arabs into an elegant medical science established on the framework of the Greek philosopher and physician Hippocrates (460–377 BCE). Unani system of medicine is a comprehensive medication where single or in the formulation, in crude form is preferred, which miraculously deals with numerous states of health and disease. This system extends great solutions for gastrointestinal, nervous disorders, and cardiovascular disease.

**Yoga and naturopathy**

Yoga is a Sanskrit word, composed and spoken limitedly in India. The word yoga has changing interpretations yet is most usually comprehended as significance union. Yoga explores preventive and curative aptitudes as a training exercise for people to improve mindfulness.

Naturopathy is a particular type of essential drugs that balances age-old healing traditions with logical progress and current research. Naturopathy is guided by an interesting arrangement of the rule that perceives the body's inborn healing capacity, emphasizes disease prevention, and urges singular responsibility to get ideal well-being.

**Homeopathy**

The principle of Homoeopathy stays one of the most debatable therapeutic practice and been known Hippocrates from Greece around 450 BCE. The word "Homoeopathy" has been derived from Greek words, "Homois" which means similar and "pathos" which means suffering.

The methodology is believed to work on two main principles:

1. "Like cures like;" a healthy individual would manifest the same symptom with the drug,that particular drug is the cure for the same illness.
2. "Infinite dilution;" therapeutic activity is enhanced by repeated dilution and succession even when diluted beyond Avogadro's number.

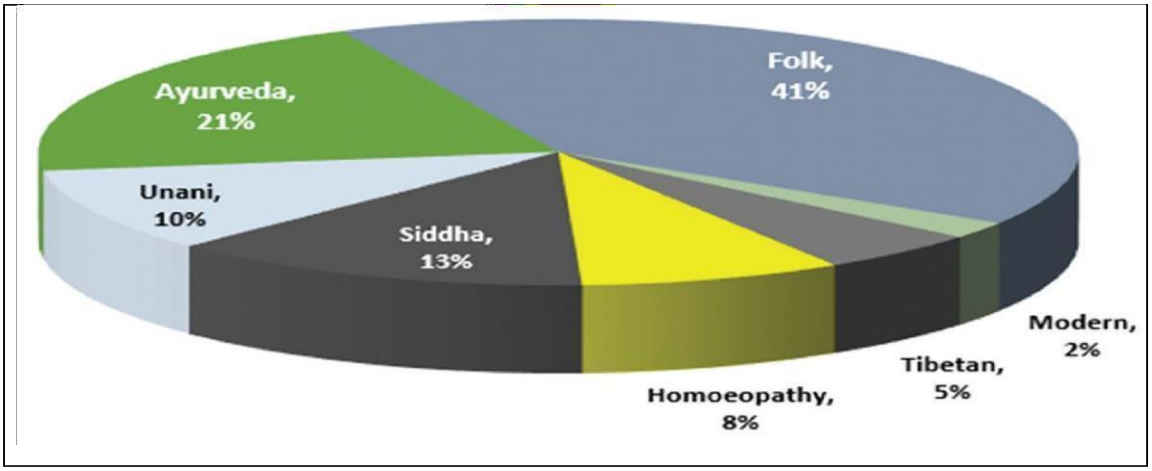


**Fig.: Displaying the percentage of plants used in different systems of medicines in India**

## WHO GUIDELINES ON SAFETY MONITORING OF HERBAL MEDICINES:[2]

Herbs are often taken concomitantly with therapeutic drugs, raising the potency but many times it may lead to show side effect too. Herbal formulation have reached widespread acceptability as therapeutic agents for treatment & prevention of disease.AS herbal medicine belongs to natural source so it assumes or said that they are with less no side effects. However, some medicinal plants are inherently toxic. Further, as with all medicines, herbal medicines are expected to have side effect, which may be of an adverse in nature. Some adverse events are reported in association with herbal products are attributable to problems of quality.

The medicines & healthcare products Regulatory Agencies, UK has launched 'yellow card' scheme for ADR reporting for monitoring the safety of herbal medicines. Indian Drug Regulation has not fully integrated traditional herbal medicines into all aspects of the health care system.

Herbal pharmacovigilance should be implemented in Indian herbal regulatory system to access various aspects of ADR, delayed or acute toxicities, allergies etc. associated with single herb &polyherbal formulation.

The World Health Organization (WHO) recognized the arising importance of consumption of herbal medicines worldwide & developed guidelines for monitoring of herbal safety within thecurrent pharmacovigilance framework- "WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems".

**The objective of these guidelines:[1]**

- Support Member States, in the context of the WHO International Drug Monitoring Programme, to strengthen national pharmacovigilance capacity in order to carry outeffective safety monitoring of herbal medicines.

- Provide technical guidance on the principles of good pharmacovigilance and the inclusion of herbal medicines in existing national drug safety monitoring systems & where that system are misplaced, to facilitate the establishment of inclusive national drug safety monitoring system.
- Provide standard definitions of terms relating to pharmacovigilance, and safety monitoring of herbal medicines. Promote and strengthen internationally coordinates information exchange onpharmacovigilance and safety monitoring of herbal medicines among Member States.
- Promote safe and proper use of herbal medicines. The regulation of herbal medicines and theirplace in national healthcare systems differ from country to country and these guidelines will therefor need to be adapted to meet the needs of the local situation.

**Standards of Drugs as per existing legislature of India:**[27]

Standards of medicines are prescribed in the Drugs and Cosmetic Act 1940 and individual monographs has been prescribed in the respective Pharmacopoeias. Recently the Govt. of India has published 4 volumes of Ayurvedic Pharmacopoeia encompassing standards of 326 drugs, which is grossly inadequate in comparison to the number of herbs used in the Ayurvedic system of medicines. A positive step has been taken in this direction by publishing of the Herbal Pharmacopoeias, having standards of 52 drugs (IDMA, 2002). Unfortunately neither the herbal products nor the herbal Pharmacopoeias have any statutory standing in our country (Govt. of India, 2005). That there are a large number of 4herbal products in the market though it is difficult to categorize these products as per the Drugs and Cosmetics Acts & Rules. Some herbal drugs are also marketed as food or nutritional supplements, with medicinal claims. Keeping this problemin mind, status of herbal products was surveyed through different sources including Pharmacopoeias of different countries (WHO, 1998; WHO 2001; WHO, 2005). In some countries herbal products are considered as drugs, e. g. China, UK, Canada, Germany, etc. while some countries do not grant herbal products, the status of drugs e.g., USA, Netherlands etc. They consider it as nutritional supplements, and have framed definite legislation for it e. g. USA (Marwick, 1995). In India there are some gray areas in case of status of herbal drugs (Table –I) and there exists no definite policies about food supplements. Recently Govt. of India has published Food Safety act to resolve this problem (Govt. of India, 2006). As per the experts this said act has not been implemented and failed to resolve the problem. Sometimes mere mentioning of a drug in some textbooks is considered sufficient as per existinglegislature, whereas the texts are not properly defined (Govt. of India, 2005).

**Table: – Standard of herbal drug as per Indian legislation**

| System of Medicine | Standard |
|---|---|
| Modern Drug | The SECOND SCHEDULE OF Drugs & cosmetics Act |

| | |
|---|---|
| Homeopathic Drugs Ayurvedic, siddha & Unani Drugs | The second schedule of Drug & cosmetic Act<br><br>Rule 168 of Drugs & cosmetic Act |

**Standards of Ayurvedic Drugs:**

Standards required to be complied with in manufacturing for sale or distribution of Ayurvedic, Siddha and Unani Drugs are laid down in Drugs & Cosmetics Rules, which are given in the table below.

**Table – II: Standards of Ayurvedic, Siddha and Unani drugs as per D & C Rules**

| Sr No. | Class of Drugs | Standard to be complied with |
|---|---|---|
| 1. | Single drugs included in Ayurvedic Pharmacopoeia | The standard for identity, purity & strength as given in the edition of Ayurvedic Pharmacopoeia of India for the time being in force<br>. |
| 2. | Asavas & Aristas | The upper limit of alcohol as self generated alcohol should not exceed 12% v/v excepting thosethat are otherwise notified by the central Government from time to time |

Till date, only four volumes of Ayurvedic Pharmacopoeia having monographs of about 326 herbs have been published, which is quite inadequate with respect to the huge number 6 of herbs used in the Ayurvedic system of medicines (IDMA, 2002). Mere mentioning of preparation method in a list of 57 texts, are sufficient for manufacturing such Ayurvedic drugs. All of these books are old texts except the Ayurvedic Formulary of India (Part I) & AyurvedicPharmacopoeia of India. There is ample scope of misuse of this provision, as 55 books out of 57 are not properly defined in the legislature.

The monographs cover only a few parameters, which are considered to be quite inadequate for standardization (Govt. of India, 1990; Govt. of India, 1999; Govt. of India, 2001;Govt. of India, 2004). Monographs of herbs in British Herbal Pharmacopoeia prescribe chemical characterization involving TLC, GC & PC electrophoresis, whereas no such modern methods are required in the Ayurvedic Pharmacopoeia. Minimum pharmacological characterization is required, which is quite inadequate, compared to characterization specified by other Pharmacopoeias. No standards for combination products are prescribed in statute, except Asavas and Aristas. Only alcohol content of these two products is given in D & C Act.

**Standards of Siddha drugs:**

As per the Drugs Act, simply mentioning of manufacturing process in a list of 30 books allows production of Siddha Drugs. Amongst these 30 books, 29 are old texts and Siddha Formularyof India (Part I) is the only book published by the Govt. of India recently.

**Standards of Unani Tibb System of Drugs:**

As per the Drugs Act mere mentioning of manufacturing process in a list of 13 books allows production of Unani & Tibb drugs. Amongst these 13 books, 12 are old texts and the only modern book is National Formulary of Unani Medicine (Part I) published by Govt. of India.

**Standard of Homeopathic Medicines:**

Standard of Homoeopathic medicines has been prescribed in Second schedule of the Drugs and Cosmetics Act, 1940, which is given in Table-III

**Table: Standards of Homeopathic Medicines as per Drugs & Cosmetic Act**

| Sr. No. | Class of Drug | Standard to be complied with |
|---|---|---|
| 1. | Drugs included in homeopathicpharmacopoeia of India | Standards of identity, purity and strength specified in the additionof homeopathic |
| | | pharmacopeia of India for the time being and such standards asmay be prescribed. |
| 2. | Drugs not included in homeopathic pharmacopeia of India but which are included in United State of America or United Kingdom or German homeopathic pharmacopeia | Standards of identity, purity andstrength prescribed for the drugsin the edition of such pharmacopeia for the time beingin which they are given and such other standards as may be prescribed |
| 3 | Drugs not included in theHomoeopathic Pharmacopoeia of India or the Homoeopathic Pharmacopoeia of the United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia. | The formula or list of ingredients displayed in the prescribed manner on the label of the container and such other standards a may be prescribed by the Central Government. |

In addition to this, three more parameters are required to be controlled for mother tincture, which are- identification of crude drugs, total solids & alcohol content. For the first category presently we have eight volumes of Pharmacopoeia prescribing the monographs including identity, purity and strength of several raw materials (Govt. of India, 1971). But no

standard for finished product was included till publication of fifth volume in the year of 1987. Sixth and eighth volume included standard of a few finished products of Mother Tinctures & Mother solutions (Govt. of India, 2000). Standards include a few preliminary criteria like pH, wt. per ml, alcohol percentage, γ max and identification, which are considered inadequate for proper quality control at this age when sophisticated techniques like HPTLC are easily available. Schedule M1: In order to ensure proper quality of Homoeopathic medicines manufacture, Schedule M1 was introduced in 1987 specifying requirement of technical staff, manufacturing plants, testing equipments etc. (Govt. of India, 2005). Experts feel that this is quite inadequate in this age of science. Recently Government of India has taken an initiative to implement Good Manufacturing Practices (GMP) and a guideline has already been published,which is effective from 2nd October 2008. This guideline is more detailed and prescribed minimum requirement of manufacturing areas, equipments, minimum qualification required for the personnel engaged in manufacturing and quality control, documents to be maintained etc. for manufacturing quality medicines.

**Current Scenario of Herbal Industry**: [28]

Herbal Medicine trends in most of the European & Non- European countries become popular with WHO traditional medicine strategy 2002-2005 and with development of their own documentation format and their safety concerns. Indian herbal medicine market is 50 billion rupees with 14% annual growth. According to WHO financial report global herbal market in2050 will reach up to 5 trillion Indian rupees. Prior herbal market for Indian raw material andproducts are EU, USA, Canada, Australia, Singapore, and Japan while Brazil, Argentina, Mexico, China and Indonesia are the newly growing market with tremendous possibility.

With the increase in pollution and global warming, global population is bending towards the herbal medicine and cosmeceuticals. Simultaneously Global and domestic manufacturer's interest is also increasing against the bulky demands from the populations and also engaged themselves in exhaustive promotion and incremented supplement of the herbal products towards both developed and developing countries.

According to Indian Brand equity Foundation (IBEF) survey, estimated valuation of Indian domestic pharmaceutical industry was $26 billion which was expected to increase at a growing rate of 20% resulting in expected evaluation of $50 billion in 2020. There are more than 200 manufacturing company in India serving about 130 billion of people.

According to the Ministry of AYUSH, Exports of all AYUSH components and herbal Products has seen a 27% growth during 2021 as compared to the previous financial year. In contrast, Imports grew about 28% during the same financial year. Ministry of AYUSH also informed about export of AYUSH and herbal products in the financial year 2020-21 to be as $539.57million as compared to $425.80 million in 2019-20. Among the states Gujarat came out as the highest exporter of AYUSH and herbal components in 2020-21 with a 32.3% growth than the 2019-20($189.59 million) resulting in an escalated exporting value of $246.78 million.

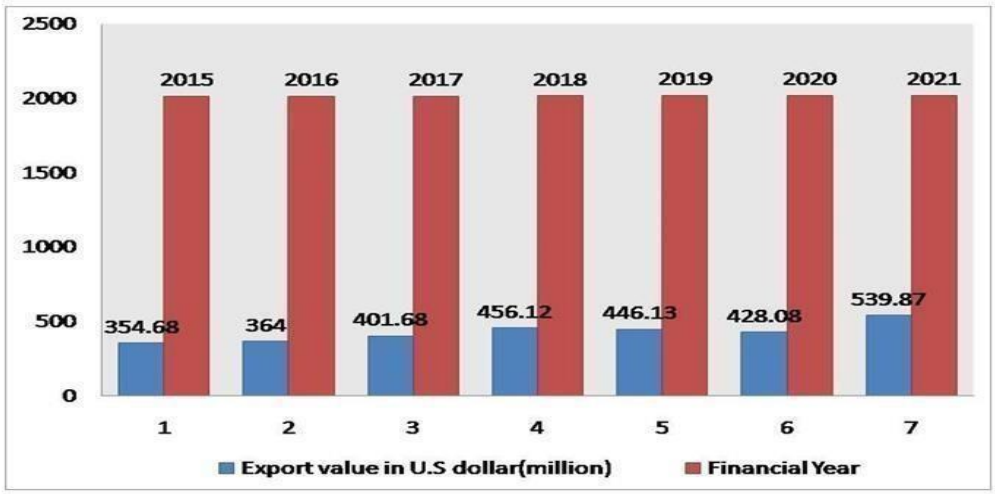


Figure 1 Herbal Export of India from 2015-21[11]

Table 2:- Popular Herbal Industry in India

| Sl.No | Name of Company |
|---|---|
| 1 | Ansar Drug Laboratories, Surat |
| 2 | Acis Laboratories |
| 3 | Amil Pharmaceuticals, New Delhi |
| 4 | Allen Laboratories, Kolkata |
| 5 | Bharti Rasanagar, Kolkata |
| 6 | Dabur India Limited, Ghaziabad |
| 7 | Dattatraya Krishan Sandu Bros, Mumbai |
| 8 | Herbals Pvt.Ltd, Patna |
| 9 | Herbo-med(P) Ltd.Kolkata |
| 10 | The Himalaya Drug Co,Bangalore |
| 11 | Indian Herb and research supply Co,Saharanpur |
| 12 | J&J Dechane Laboratories Pvt. Ltd, Hyderabad |
| 13 | Madona Pharmaceutical Research Pvt.Ltd., Kolkata |
| 14 | Kruzer Herbals, New Delhi |
| 15 | Silpachem, Indore |
| 16 | Hamdard (Wakf) Laboratories, New Delhi |
| 17 | Zandu Pharmaceutical Works Ltd., Mumbai |
| 18 | Badyanath Ayurveda Bhavan, Jhansi |
| 19 | Charak Pharmaceuticals, Mumbai |
| 20 | Patanjali Ayurved Ltd.,Uttarakhand |

**Industrial Perspective of Herbal Drug's Commercialization and regulation:[28]**

As previously discussed India's herbal export is primarily consists of formulated finished products along with plant extracts. Although rich in herbo-diversity global export of India isonly about 1% [14]. Surveys accessed the reasons of being backbenchers in the herbal exportas the constraints concerning regulation, production and commercialization of ethno medicinal or traditional drugs.

i. Commercialization Constraints: Indian herbal industry the most common Constraints faced by the Indian herbal Industry is to achieve the regulatory compliance of the exporting countries towards herbal materials. Individualized regional GMP standard, differential registration requirements are the most important hindrance for the Indian manufacturer and exporters.

ii. Country Specific Regulatory Requirements: Different approval requirements and unpleasant prolongation of application review processes are also one of the serious obstacles in the export of herbal drugs. In India, According to Drug and Cosmetic Act, 1940(DCA), Domestic manufacturers don't need to provide any safety and efficacy datain manufacturing traditional herbal medicines under traditional medicinal system of Ayurveda, Siddha and Unani. In USA, majority of Indian exports are approved and marketed under dietary supplements following Health and Education Act of1994. It does not require any safety and efficacy data prior to marketing approval

iii. Limited market: Survey suggested the limitation of global market as one of the major obstacle for Indian herbal Industrial exporters. Indian companies suggested an extensive promotion of Indian herbal medicines in the foreign countries with the exhibition and trade fair arrangement.

iv. Issues with standardization of raw materials- Authentication and standardization of raw material and formulated herbal products is one of the questionable aspects of concern towards Indian Herbal Industrial manufacturer. Department of AYUSH informed regarding the use of about 600 medicinal plants, 50 animal derivatized products in ethnomedicinal Ayurvedic preparations.

v. Lack of regulatory guidelines Regulation of quality is directly depends on quality control processes, good agricultural and collection practice and good storage practice. Although survey suggested the guidelines as impractical due to insufficient awarenessand education among cultivators and associated high cost. Majority of the surveyed Industry suggested implementation of proper standard documentation process and guidelines regarding quality control and quality assurance process

According to IP 2007, minimal mentioning of herbal preparation doesn't specifies the formulation as approved drug. To be manufactured or marketed as IP grade, a drug license is mandatory for herbal Industries. Specific IP graded equipment is required for the manufactureof an IP grade substance. In India, most of the herbal Industries are small or midsized manufactures, thus it is not economical for them to establish a dedicated infrastructure facilityfor country / Pharmacopoeia specific Herbal standards.

## CONCLUSION

The present review gives the detailed information about Regulatory requirement of Herbal Medicines in India. In the next few decades, herbal medicine may become a new era of medicinal system for the management of human diseases. About 80% world population rely on traditional medicine for primary health care. There is a need to advance research for the development and characterization of new natural drug with aid of better screening method from plants and other natural sources. Medicines of herbal origin are being used since time immemorial throughout the globe. This

discipline has developed gradually in terms of its quality, safety and efficacy. Status of herbal medicines also varies from country to country. InIndia herbal medicines and used in Ayurveda, Siddha, Unani and homeopathic system of medicine AYUSH department introduced certification scheme for AYUSH drug products.

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