REVIEW ARTICLE

ISSN: 2455-8095
doi: https://doi.org/10.21477/ijapsr.7.3.1

# Regulatory Status of Herbal Drugs in India

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**ABSTRACT**

India is the leading supplier of medicinal plants and herbs. Plants and herbs are commonly utilized as medications, and many choose them since they have less adverse effects. Herbal drugs have been used in various medical systems around the world, including Ayurveda, Siddha, Homeopathy, Unani, and Chinese medicine, and are classified as complementary medicines, nutraceuticals, prescription drugs, over the counter (OTC) drugs, supplements, and conventional herbal drugs. If sold commercially, herbal drugs must adhere to country-specific safety, quality, and potency requirements. Currently, herbal medication legislation varies per nation. As a result, herbal medicine manufacturers are unable to provide a standardized product for the worldwide market. Therefore, international regulatory agencies and institutions such as the World Health Organization (WHO) work together to develop a unified and standardized regulation for herbal drugs. The regulatory status of herbal drugs in India and strategies to improve it are highlighted in this article. Herbal products are regulated under the Drug and Cosmetic Act (DCA) 1940 and Rules 1945, and the governing agency is the Department of AYUSH. A manufacturing permit is needed to produce or trade herbal drugs.

**Keywords**: AYUSH, Herbal drugs, India, Quality control, Regulation, Standardization.

## 1. INTRODUCTION

Plants have been utilized to treat sickness and alleviate bodily pain since the dawn of humanity. From the beginning, the knowledge of herbal medications was inventive and significant, and it was typically limited to the tribe's medicine men. The origins and usage of various components of medicinal plants were passed down through the generations. Numerous emerging nations now have well-organized and deeply ingrained traditional medical systems, such as Ayurveda, Siddha, and Unani, which have existed for millennia. Over a thousand species are commonly employed in herbal medicine, the majority of which are obtained in their natural state. Herbal medicinal therapy complements contemporary therapy in the healthcare needs of individuals, especially in impoverished areas where western medication is inaccessible for a variety of reasons, including cost.[1] The clinical utility of herbal drugs requires strict quality control. The authenticity, homogeneity, composition, and other physical, botanical, chemical, or biological qualities of a medicine, as well as the production procedures, establish its quality.[2]

Except for Allopathy, herbal formulations account for a significant portion of all formally approved Indian healthcare systems, including Ayurveda, Unani, Siddha, Homeopathy, and Naturopathy. Medicinal herbs are regulated in India under the CCIM (Central Council of Indian Medicine) Act, the Research Councils (ICMR-Indian Council of Medical Research and CSIR-Council of Scientific and Industrial Research), the Department of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy), and the Drugs and Cosmetics Act 1940. Herbal formulations and medicinal herbs that are to be introduced into the contemporary system must adhere to the requirements of the Drug Controller General of India (DCGI).[3]

According to the Drugs and Cosmetics Act of 1940, as revised in 1964, "Ayurvedic, Siddha, or Unani drug" refers to all medicinal products designed for using internally or externally in the diagnosis, therapeutic interventions, countermeasures, or prevention of the disease or disorder in humans or animals,[4] and are produced strictly in conformance with the formulae mentioned in the instructive documents of the Ayurvedic, Siddha,

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**Received:** 12-04-2022 **Accepted:** 20-05-2022 **Available Online:** 01-07-2022

and Unani (Tibb) medicinal systems manufacture under defined sanitary conditions under the guidance of a certified expert, utilisation of authentic raw materials, and marking of all substances used were all included in the revised edition.[5] The Ministry of Health and Family Welfare created the Pharmacopoeial Laboratory for Indian Medicine (PLIM) to address the problem of adopting the Act's revision.[6] The Product Standardisation and Test Unit, the Drug Depot, and the Herbarium and Reference Collection are all located within PLIM. Pharmacopoeias for every Indian medical system too was made accessible.[7] The Indian system of natural medical product certification includes provisions for Ayurvedic, Sidha, and Unani medications in each state via the state drug licensing agency. Schedule TA for documentation of raw material utilization by Ayurvedic, Sidha, or Unani authorized manufacturing plants was later added to the Drugs and Cosmetics Rules 2008.[8]

Drugs and Cosmetics (Second Amendment) Rules 2008 authorized the inclusion of additives as per Indian Pharmacopoeia or Bureau of Indian Standards Act 1986 or Prevention of Food Adulteration Act 1954 and Food Products Order in preparation of herbal formulations.

The ICMR's Good Clinical Practice (GCP) rules also apply to natural medications.[9] Traditional herbal products have been divided into three classes based on these guidelines:

- Traditional herbal medications according to classical texts, frequent usage, and specified pharmacopoeia
- Traditional preparations for a novel indication/combination/herbal or plant-based NCE (new chemical moiety) – short-term, medium-term, and long-term toxicity data required (Schedule Y of Drugs & Cosmetics Act, 1940).
- Formulation that comply with GMP (Goods Manufacturing Practices) standardization

## 1.1. Standardization, Quality Control & Quality Assurance

Standardization refers to how similar and equal various goods, isolates, or even different proportions of the same isolate are.[10] Echinacea formulations, for instance, can encompass multiple plant extracts, be made from various plant species (E. purpurea, pallida, or angustifolia), have various plant areas (shoot, root, or both), and be extracted in a variety of ways (hydro or lipophilic extraction). All herbal preparations must follow WHO criteria. The WHO guidelines aim to provide fundamental criteria for assessing the quality, tolerability, and effectiveness of pharmaceuticals and herbal drugs. Standardization parameters for herbal drugs are presented in Figure 1.

There are various procedures involved in quality control and standardisation of herbal drugs.[11] The origin and quality of raw materials, as well as proper farming and manufacturing techniques, are all critical aspects in ensuring the quality and sustainability of herbal drugs. The quality of a natural product is dictated by the growing circumstances, which may be controlled using established Good Agricultural Practices (GAP).[12] Seed selection, growing environment, fertilizer usage, reaping, washing, and preservation are all examples. GAP processes are, and will continue to be, an important aspect of quality control, and thus the therapeutic benefit of herbal drugs. Aside from such parameters, issues including extraction process, microbe contaminants, heavy metals, & pesticides might affect the quality, tolerability, and potency of herbal medicines.[13] As a result, both the raw material and finished products should undergo thorough standardization and quality control.[14] By introducing additives or combining herbal medications, the herbal products formulation can be adjusted to a specific proportion of an ingredient or a set of compounds with recognized therapeutic efficacy. The content, quality, and therapeutic benefits of botanical extracts prepared freshly from crude plant parts vary significantly.[15] Standardized preparations are high-quality extracts that contain uniform quantities of certain chemicals and are exposed to stringent quality standards throughout growth, reaping, and processing.[16]

Only a thorough and precise description of the raw materials, which is typically performed using a pharmacopoeia compendium, can ensure high quality for herbal medical products.[17] It may be required to employ medicinal herbs from several harvests and/or collecting zones in an attempt to uphold constant quality of naturally derived medical goods.[18] If the active substances are unknown, quality assurance does not entail standardization as per particular compounds, but rather manufacturing quality. Professionals in this subject should write herbal manuals for herbal medications, which have a lengthy history in the Western World. If diverse phyto-

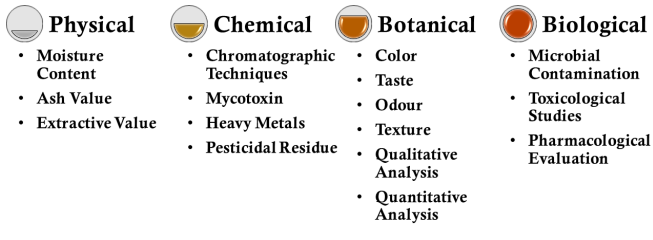


**Figure 1:** Standardization Parameters for Quality Control of Herbal Drugs

nutrients are to be designated as drugs, reliable data is required. The factors that hinder the effective Quality Control of herbal drugs are listed in Figure 2.

## 2. REGULATORY STATUS OF HERBAL DRUG RESEARCH IN INDIA

Herbal products are regulated under the DCA 1940 and Rules 1945, and the governing agency is the Department of AYUSH. A manufacturing permit is needed to produce or trade herbal drugs.[19] The DCA's Schedule T (Chapter IV-A) establishes GMP for herbal drug companies.[20] The Department of AYUSH engages in the development of the AYUSH healthcare system. Sections 33C to 33O include information on the manufacturing, certification, sales, licensing, GMP certificate, and penalties. Since 2017, the provision of the production and expiry dates on the product description has been required. In India, drug trials require around 3 months to get approved.[21] For the quality requirements of medications, established pharmacopoeias and guidelines are provided. The DCA's first schedule contains a list of allowed texts that must be adopted when registering any herbal drug.[22]

### 2.1. Rules, Regulation & Governing Body

The Government of India acknowledged the conventional Indian System of Medicine (ISM) in 1959, and the Drug and Cosmetic Act was updated to reflect this.[23] Numerous experts working groups (EWG) for various ISM were quickly created throughout time, with the first official EWG being constituted in 1962. Act 13 of 1964 established a distinct chapter for Ayurveda, Siddha, and Unani medications.[24] The statute was amended in the years 1983, 1987, 1994, and 2002. In 2006 and 2008, the DCA Rules 1945 provided guidelines for the analyzation of pharmaceuticals under ISM.

The CCIM was established in 1970, and it formulated and executed several rules, as well as curriculum and syllabus for ISM. During the year 2012, the CCIM adopted the traditional Tibetan medical system. The Department of Indian Medicine and Homeopathy (ISM & H) was established in 1995 to promote the ISM. In 2003 and 2014, a distinct department of AYUSH was founded, which in partnership with Quality Council of India (QCI), created an accreditation mechanism for AYUSH herbal drugs in 2009. Concerns concerning the quality, effectiveness, and safety of AYUSH products have been highlighted for some years. To address these issues, a new voluntary approval process for AYUSH goods has been launched in conjunction with QCI.[25]

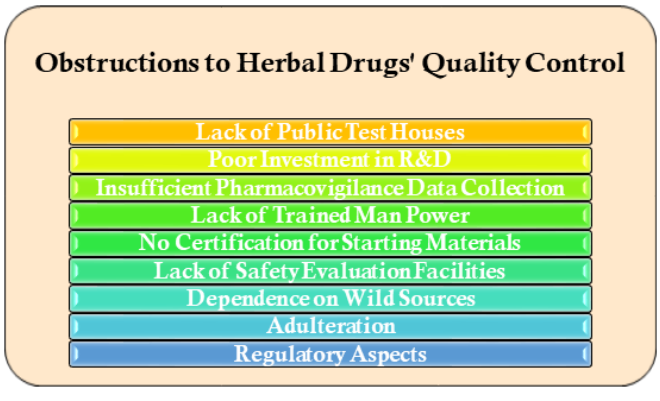


**Figure 2:** Obstruction to Effective Quality Control of Herbal Drugs

### 2.2. AYUSH and Health Policy

The Department of AYUSH in India is responsible for setting standards, regulations, promotion, ISM expansion, and general supervision. National agencies, research organizations, academies, professional councils, pharmacopeial labs, and hospitals are among the independent entities and subordinate departments that make up this organization. The main goal of ISM & H policy is to use AYUSH to achieve excellent health by promoting assistance to people with respect to safe and efficient services and pharmaceuticals that fulfill Pharmacopeial criteria and AYUSH quality standards.[26] Several legal and administrative procedures exist in India to regulate the manufacture and distribution of Ayurveda, Siddha, and Unani (ASU) drugs. The basis for rules of ASU product manufacture, packing, branding, and marketing was put forth in Chapter IVA of the DCA 1940. Periodic updates are required for the progress of ASU medicines, and the most current updates to this chapter IVA were made in March 2013. A separate ASU Drugs Technical Advisory Board (ASUDTAB) was formed in the supervision of ASU pharmaceuticals to handle and advise the authorities regarding tech issues. The ASU Drugs Consultative Committee (ASUDCC) was established in India to ensure compliance with the 1940 DCA. The Council for Scientific and Industrial Research (CSIR) laboratories, along with the Central Council for Research in Unani Medicine (CCRUM), and other laboratories have worked tirelessly to ensure the safety and purity of mixed herbal extracts formulations.[27]

Department of AYUSH (Ayurveda, Yoga, Unani, Siddha and Homeopathy), ICMR and CSIR collaborate to create safe and efficient AYUSH products for illnesses recognized and novel medications.[28] Controlling drug quality, establishing pharmacopoeial specifications, supervising the tasks of the PLIM, collaborating with the Quality Council of India (QCI), and monitoring the operations of the Indian Medicine Pharmaceutical Company Limited (IMPCL) are all objectives of the abovementioned regulatory bodies. AYUSH is also in charge of enforcing GMP, establishing shared facilities using the Cluster concept, and executing the Drug Quality Control System.

With the implementation of the Intellectual Property Right (IPR) system, the AYUSH department has been digitizing traditional pharmaceutical formulas, expertise & documents, and records, as well as promoting primary healthcare traditions.[29]

## 2.3. Methodology of Herbal drug research

### *2.3.1. Health Benefit*

A nutraceutical effect that protects against or decreases the likelihood of a disease, includes disease management, or promote a healthy lifestyle.[30]

### *2.3.2. Health Claim*

Health claims are one of the many sorts of claims that may be made on food labels. They demonstrate a link between a vitamin or other compound in a diet and a disorder or health problem.[31] These could be used on both traditional foods and nutritional supplements.

### *2.3.3. Safety*

It denotes the unintended consequences of a treatment. In comparison to conventional pharmaceuticals, herbal drugs are typically seen to be harmless. Although this is most likely accurate, case reports reveal that serious side effects and drug interactions may happen. Numerous reports have been published that summarize the herb's adverse effects and interactions.[32-34] Several plants are hazardous, and herbal formulations can be contaminated, falsified, or misunderstood, posing a higher incidence of side effects and complications than other integrative therapies.

# 3. CHALLENGES FACED BY HERBAL INDUSTRIES

The lack of stringent quality control standards for herbal ingredients and preparations is one of the primary issues affecting the herbal sector. The Ministry of AYUSH has initiated a central initiative to build a standard operating procedure (SOP) for the industrial process to produce herbal products of pharmacopeial standards.

## 3.1. Challenges Associated to The Regulatory Status of Herbal Medicines

A nutritional supplement, as per its definition, is a consumable product that has a "dietary element" and is designed to complement the diet. Various vitamins, herbs, minerals, and other phytonutrients may be included in the nutritional components of these supplements. Further toxicity studies are typically not necessary under the Dietary Supplement Health and Education Act (DSHEA) if the herbal supplement was on the market prior to 1994.[35] Food and Drug Administration (FDA) bears the onus of proof that a botanical therapeutic product or "dietary component" is harmful or unfit for human consumption. In so many other nations, an extra key difficulty is that regulatory data regarding herbal medications is frequently not exchanged between governing bodies and drug safety centres.

## 3.2. Challenges Associated to Quality Control of Herbal Medicines

The safety and effectiveness of herbal drugs are largely determined by the quality of the starting ingredients included in their formulation. The quality of raw ingredients is influenced by both intrinsic (genetic) and external elements such as environmental circumstances, excellent agriculture, and better plant gathering techniques, encompassing plant selection and cultivation. The difficulty of conducting quality controls on herbal formulations' raw ingredients is due to a variety of variables. Proper identification of medicinal herbs, specific storage, and unique cleaning processes for diverse materials are significant criteria for the quality control of raw materials, as per GMP. The Quality Control (QC) of final herbal preparations, particularly mixed herbal medicines, is a serious difficulty.[36] As a result, typical quality control standards and methodologies for manufactured herbal drugs are far more difficult than for conventional medicines. The WHO strives to support the implementation of Quality Assurance (QA) and QC methods including GMP, labeling, and manufacturer licensing systems to assure the safety profile of herbal drugs.[37]

**Table 1:** Recommendations for Efficient Regulation of Herbal Drugs

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| ✓ Development of AYUSH training, with a focus on technical learning |
| ✓ Expansion and propagation of the Indian medical system in other nations |
| ✓ Detailed quality control criteria for herbal medications |
| ✓ Establishment of monographs and standard criteria for marker-based evaluation of all botanicals utilized in herbal formulations. |
| ✓ Provision of standard and approved plant extracts, as well as the identification of favourable zones for medicinal plant farming. |
| ✓ Farmers and manufacturers should be more acquainted with GAP, GACP (good agricultural and collection practices), and GSP (good storage practices). |
| ✓ The DCA's adoption and monitoring |
| ✓ Creation of standardized methods, schedules, and specified recommendations for meetings with regulators |
| ✓ Monetary support |

## 4. STRATEGIES FOR IMPROVING HERBAL DRUGS' REGULATION

Improving the regulation of herbal drugs quality and ensuring the delivery of safe and effective drugs can be achieved by implementing the following strategies (Table 1).

## 5. FUTURE PROSPECTS

Demand for herbal medicines have unquestionably grown across the world and is expected to rise in the next years, owing to an increase in sales of herbal products and medicines. This implies that researchers, physicians, and pharmaceutical corporations will be depended on China, India, and other nations for their needs, since they contain the most varieties of herbal plants and are the leading producers. Herbs will persist to be used in healthcare as a source of medicinal ingredients and as an input materials foundation to produce semi-synthetic organic compounds in sectors such as cosmetics, fragrances, and food. For the growth of medicinal herbs, the government should promote and support the use of sophisticated chemical fertilizers. Simultaneously, immediate measures must be made to secure the protection of varied biological resources, as well as the retention and implementation of cultural information about their usage.

## 6. CONCLUSION

Even though enhancing the regulatory structure to ensure the quality of herbal products seems to have become a top priority for Indian drug authorities, pharma companies are battling with rising requirements for herbal medications. The Indian herbal sector's sluggish growth is attributable to fragmentation, inadequate information on raw material and finished goods, insufficient research and development, tardy advancements, and absence of intensive marketing and advertising. To create safe and efficacious herbal products in India, successful management of DCA, establishment of more extensive recommendations on QC and QA issues, and establishment of marker-based criteria are required. Considerable emphasis must be given to scientific and technical innovation in the realm of herbal drugs.

## REFERENCES


1. Oyebode O, Kandala NB, Chilton PJ, Lilford RJ. Use of traditional medicine in middle-income countries: a WHO-SAGE study. *Health Policy Plan*. 2016;31(8):984-991. doi:10.1093/heapol/czw022
2. Nafiu MO, Hamid AA, Muritala HF, Adeyemi SB. Preparation, standardization, and quality control of medicinal plants in Africa. *Medicinal Spices and Vegetables from Africa*. 2017 Jan 1:171-204.
3. Singh S, Shukla VK. Current regulations for Herbal Medicines in India. *International Journal of Drug Regulatory Affairs*. 2021;9(2):30-4.
4. Verma N. Herbal medicines: regulation and practice in Europe, United States, and India. *International Journal of Herbal Medicine*. 2013;1(4):1-5.
5. Saharan VA. Current status of regulations for herbal medicines in Europe, United States and India. *J Nat Conscientia*. 2011 May;2(3):406.
6. Mukherjee PK, Nema NK, Venkatesh P, Debnath PK. Changing scenario for promotion and development of Ayurveda–way forward. *Journal of ethnopharmacology*. 2012 Sep;143(2):424-34.
7. Oyedepo TA, Palai S. Herbal remedies, toxicity, and regulations. InPreparation of Phytopharmaceuticals for the Management of Disorders. *Academic Press*. 2021:89-127.
8. Barkat MA, Goyal A, Barkat HA, Salauddin M, Pottoo FH, Anwer ET. Herbal Medicine: Clinical Perspective and Regulatory Status. *Combinatorial Chemistry & High Throughput Screening*. 2021;24(10):1573-82.
9. Sahoo N, Manchikanti P. Herbal drug regulation and commercialization: an Indian industry perspective. *J Altern Complement Med*. 2013;19(12):957-963. doi:10.1089/acm.2012.0275
10. Singh HP, Sharma S, Chauhan SB, Kaur I. Clinical trials of traditional herbal medicines in India: current status and challenges. *Int J Pharmacogn*. 2014;1:415-21.
11. Kumari R, Kotecha M. A review on the Standardization of herbal medicines. *International Journal of Pharma Sciences and Research*. 2016 Feb;7(2):97-106.
12. Burrell A. 'Good Agricultural Practices' in the Agri-Food Supply Chain. *Environmental Law Review*. 2011;13(4):251-70.
13. Gupta P, Pal A, Trivedi S, Gupta RK. Review on quality control parameters for standardisation of herbal drug. *Journal of Advanced Scientific Research*. 2021;12(03):35-41.
14. Balekundri A, Mannur V. Quality control of the traditional herbs and herbal products: a review. *Future Journal of Pharmaceutical Sciences*. 2020 Dec;6(1):1-9.
15. Alamgir AN. Herbal drugs: their collection, preservation, and preparation; evaluation, quality control, and standardization of herbal drugs. *Therapeutic Use of Medicinal Plants and their Extracts*. Springer, Cham. 2017;1:453-495.
16. Kunle OF, Egharevba HO, Ahmadu PO. Standardization of herbal medicines-A review. *International journal of biodiversity and conservation*. 2012;4(3):101-12.
17. Mosihuzzaman M, Choudhary MI. Protocols on safety, efficacy, standardization, and documentation of herbal medicine (IUPAC Technical Report). *Pure and Applied Chemistry*. 2008;80(10):2195-230.
18. Yadav NP, Dixit VK. Recent approaches in herbal drug standardization. *Int J Integr Biol*. 2008;2(3):195-203.
19. Sharma S. Current status of herbal product: regulatory overview. *Journal of pharmacy & bioallied sciences*. 2015 Oct;7(4):293.
20. Giri RP, Gangawane AK, Giri SG. Regulation on herbal product used as medicine around the world: a review. *Regulation*. 2018 Oct;5(10).

21. Swathi. J, D. Nagasamy Venkatesh. A Review of Herbal Regulations in India and Worldwide. *Research Journal of Pharmacy and Technology*. 2022; 15(3):1348-2. doi: 10.52711/0974-360X.2022.00225
22. Kumar V. Herbal Medicines: Overview on regulations in India and South Africa. *World Journal of Pharmaceutical Research*. 2017;6(8):690-8.
23. Jose A, Manchikanti P. Traditional knowledge–the changing scenario in india. *Indonesian Journal of International Law*. 2021;18(3):5.
24. Navdeep S, Koyal S, Singh GK. Establishment of an herbal industry in India. *International Journal of Pharmaceutical & Biological Archives*. 2011;2(4):1011-9.
25. Wu LC, Raw A, Knöss W, Smith M, Zhang WD, Bedi YS, Gray E, Mulloy B. Regulatory Landscapes for Approval of Naturally Derived Complex Mixture Drugs. In The Science and Regulations of Naturally Derived Complex Drugs. AAPS Advances in the Pharmaceutical Sciences Series. 2019 (pp. 17-44). Springer, Cham.
26. Singh B, Kumar M, Singh A. Evaluation of implementation status of national policy on Indian systems of medicine and homeopathy 2002: Stakeholders' perspective. *Ancient Science of Life*. 2013;33(2):103.
27. Metta AM, Kingumahanthi NL, Kalidindi VR, Juturi RK, Boddu V. Scope for Harmonisation of Herbal Medicine Regulations. *Int. J. Pharm. Sci. Res.* 2021;12(4):2012-20.
28. Sen S, Chakraborty R. Revival, modernization and integration of Indian traditional herbal medicine in clinical practice: Importance, challenges and future. *Journal of traditional and complementary medicine*. 2017;7(2):234-44.
29. Sree D, Latha D, Padmavathi D, Bharathi P, Nagalakshmamma P. Role of ICTS in promoting and preserving the traditional medicinal knowledge in India. *World Journal of Pharmaceutical Research*. 2019;7(7):309-23.
30. Santini A, Cammarata SM, Capone G, Ianaro A, Tenore GC, Pani L, Novellino E. Nutraceuticals: Opening the debate for a regulatory framework. *British journal of clinical pharmacology*. 2018;84(4):659-72.
31. Ellwood KC, Trumbo PR, Kavanaugh CJ. How the US Food and Drug Administration evaluates the scientific evidence for health claims. *Nutrition reviews*. 2010;68(2):114-21.
32. Başaran N, Paslı D, Başaran AA. Unpredictable adverse effects of herbal products. *Food and Chemical Toxicology*. 2022;159:112762.
33. Parvez MK, Anjum N. Liver Diseases and Adverse Reactions Induced by Medicinal Herbs and Herb-Drug Interactions. *Gastroenterology & Hepatology Letters*. 2022;4(1).
34. Faisal R, Shinwari L, Aziz I, Khalil AT. Therapeutic and adverse effects of commonly used medicinal plants: standardization and quality assurance: adverse effects of commonly used herbs. *Proceedings of the Pakistan Academy of Sciences*: B. 2019;56(3):1-9.
35. Ekor M. The growing use of herbal medicines: issues relating to adverse reactions and challenges in monitoring safety. *Frontiers in pharmacology*. 2014 Jan 10;4:177.
36. Efferth T, Greten HJ. Quality control for medicinal plants. *Med. Aromat. Plants*. 2012;1(7).
37. Yadav P, Prajapati PK. Quality control parameters for medicinal plants, an overview. *Asian J Biomed Pharm Sci*. 2011;1(5):12-6.


**How to cite this article:** Anjana Devi, Rajni Devi, Sanjay Kumar, Kamal Jeet, Tushar Chauhan, Gaurav Dhatwalia, et al. Regulatory status of herbal drugs in India. Int. J. Appl. Pharm. Sci. Res. (2022);7(3): 30-35. doi: https://doi.org/10.21477/ijapsr.7.3.1

**Source of Support:** Nil.

**Conflict of Support:** None declared.