

**INTEGRATING AYUSH SYSTEMS INTO GLOBAL HEALTHCARE****Shaik Shireen\*<sup>a</sup>, Dr. Venu Madhav<sup>a</sup>, Dr. M. Kiranmai<sup>b</sup> and Sai Roopika**<sup>a</sup>Department of Pharmaceutics, St. Pauls College of Pharmacy, Hyderabad, Telangana, India.<sup>b</sup>Department of Pharmaceutical Chemistry, St. Pauls College of Pharmacy, Hyderabad, Telangana, India.Article Received on  
14 June 2025,Revised on 04 July 2025,  
Accepted on 24 July 2025

DOI: 10.20959/wjpr202515-37668

**\*Corresponding Author****Shaik Shireen**Department of  
Pharmaceutics, St. Pauls  
College of Pharmacy,  
Hyderabad, Telangana,  
India.**ABSTRACT**

This review presents the current status of the AYUSH system of medicine (Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy) in contemporary times. Rooted in traditional knowledge systems, AYUSH practice is globally recognized for its holistic approach to health and wellness. However, integration into modern healthcare systems presents unique management challenges. This article examines the regulatory framework for AYUSH practice. It focus on the Progress which has been made in the development of GMP guidelines and clinical trial protocols specific to AYUSH medicines, improving safety and quality assessment. Additionally, the review discusses the role of government agencies, professional bodies, and international collaboration in the development of AYUSH guidelines. It emphasizes the importance of combining traditional wisdom with modern scientific research to improve public safety and health care. The findings of this study highlight the need for applied and practical strategies that integrate the unique features of the

AYUSH system while complying with global health standards. Finally, the review outlines the future direction of the organization, which aims to promote the integration, adoption, and sustainable growth of AYUSH practices in the global healthcare system.

**KEYWORDS:** AYUSH, ASU Drugs, Herbal drugs, Regulatory Frame work, AYUSH process, Challenges in filing.

## INTRODUCTION

The word AYUSH is derived from the Sanskrit phrase "ayusmanbhava," which means long life. This phrase has been used since the time of Mahabharata to bless long life. Today, the term AYUSH is used worldwide to refer to traditional and non-traditional systems of medicine and healing, including Ayurveda, Yoga, Unani, Naturopathy, Siddha, Sowa Rigpa, and Homeopathy. AYUSH aims to provide comprehensive healthcare for physical, mental, social, and spiritual well-being. The AYUSH system is respected globally and has been serving people since ancient times. In post-independence India, the government actively supported AYUSH, establishing the Department of Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homoeopathy (Ayush) in 2003 and the Ministry of Ayush in 2014.<sup>[1]</sup>

### **The Ministry of Ayush's main objectives include**

- Raising the standard of education in Indian medical and homeopathic systems
- Strengthening research institutions
- Promoting the cultivation and development of medicinal plants
- Updating pharmacopeial principles.

### **The significance of AYUSH in India is deeply rooted in cultural, historical, and medical practices it implies**

**1. Rich Cultural Heritage:** The AYUSH system of medicine has been practiced in India for thousands of years and is rooted in traditional cultural heritage. They embody the wisdom and knowledge of antiquity and offer a holistic approach to health and wellness.<sup>[2]</sup>

**2. Holistic approach to health:** AYUSH emphasizes a holistic approach to health, which includes physical, mental and spiritual aspects in a healthy manner. It emphasizes preventive medicine, lifestyle change, and natural medicine to maintain health and treat diseases.

**3. Wide Acceptance and Use:** AYUSH medicine is a widely accepted practice and is used by millions of people in India. They often opt for comprehensive, low-impact and culturally relevant methods, especially in rural and urban areas where modern medical care may be limited.

**4. Various Treatment Methods:** AYUSH includes various treatment methods including herbal medicine (Ayurveda, Unani, Siddha), yoga and meditation (Yoga and Naturopathy) and energy-based medicine (Homeopathy). These differences allow people to choose medications that fit their beliefs, preferences, and health needs.

**5. Integration with modern medicine:** AYUSH is increasingly integrated into the Indian public health system. Government programs are promoting the integration of AYUSH and modern medicine through policies, programs and research collaborations to improve healthcare delivery and improve patient outcomes.

**6. Economic Contribution:** AYUSH contributes significantly to the Indian economy through the cultivation, production and trade of medicinal plants, herbs and AYUSH medicines. It provides employment, especially in rural areas, and contributes to the import of goods abroad.

**7. Global Benefits:** AYUSH has gained global attention and recognition for its holistic approach to health and wellness. India's initiative to promote AYUSH through international cooperation, research collaboration and cultural exchange has increased its value and recognition at the global level.<sup>[4]</sup>

**8. Research and Innovation:** There is interest and investment in research and innovation in AYUSH in India. Research institutes and academic institutions conduct studies to verify the safety, efficacy and effectiveness of AYUSH medicine, contributing to evidence-based practice and interventions.

**9. Development of Traditional Knowledge:** The AYUSH system preserves and promotes India's rich heritage of traditional knowledge in the fields of health, medicine, and wellness. It includes efforts to document traditional practices, and medicinal plants, and initiatives to preserve indigenous knowledge and promote sustainable health practices.

### **AYUSH Regulatory Framework in India**

- **Central Council of Medical Centers of India (CCIM):** CCIM is a statutory body established under the Central Council of India Medical Act, 1970. In India, Ayurveda regulates the education and functioning of the Siddha and Unani medical system. CCIM sets standards for undergraduate and postgraduate education, curriculum and infrastructure in Ayurveda, Siddha and Unani universities.<sup>[3]</sup> It also registers practitioners of Ayurveda, Siddha and Unani medicine and monitors their professional conduct.
- **Central Council for Research in Ayurvedic Sciences (CCRAS):** CCRAS is an independent body under the Ministry of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy) dedicated to Ayurvedic research. Conducts scientific research on the principles, practices and methods of Ayurveda to provide evidence of their safety, effectiveness and quality. CCRAS manages a network of research centers,

institutes and laboratories conducting basic research and medicine in the field of Ayurveda.<sup>[5]</sup>

- **Central Council for Research in Homeopathy (CCRH):** CCRH is an independent body under the Ministry of AYUSH responsible for promoting homeopathy research.<sup>[6]</sup> Conducts research studies to validate homeopathic treatment methods and develop evidence-based clinical protocols. CCRH collaborates with national and international institutions to promote homeopathy research.
- **Pharmaceutical Medicine Laboratory (PLIM):** PLIM is a National Laboratory under the Ministry of AYUSH, responsible for setting standards for Ayurveda, Siddha and Unani medicines. Prepares monographs, quality control methods and standards in the field of herbal medicine and traditional medicine. PLIM provides testing and certification services for the quality, safety and effectiveness of AYUSH.<sup>[7]</sup>
- **Ayurveda, Siddha and Unani Technical Advisory Board (ASUDTAB):** ASUDTAB advises the central government on the regulation of Ayurveda, Siddha and Unani medicines. Reviews and recommends amendments to the Drugs and Cosmetics Act and the laws relating to the manufacture, sale and distribution of Ayurvedic, Siddha and Unani medicines. ASUDTAB reviews proposals for inclusion of new drugs, ingredients or medicines in the Ayurvedic Pharmacopoeia of India, Siddha Pharmacopoeia of India and Pharmacopoeia of India.<sup>[8]</sup>
- **Drugs Controller General of India (DCGI):** DCGI is the regulatory authority for drugs and medical devices in India under the Drugs Control Organization (CDSCO). Monitors the approval, registration and control of AYUSH drugs including herbal drugs, traditional medicines and specialty products. DCGI ensures the quality, safety and efficacy of AYUSH products through pre-market approval, licensing and post-market surveillance.<sup>[9]</sup> These are some of the important regulatory bodies and organizations involved in AYUSH regulation in India. AYUSH regulation is governed by various laws, statutes and regulations, including the Drugs and Cosmetics Act, 1940 and the AYUSH Act, 2013. Requirements and regulations may continue to change to address emerging issues and improve the safety, quality and effectiveness of AYUSH. Apps and products in India.
- **Drugs and Cosmetics Act 1940:** Herbal medicines are governed by the Drugs and Cosmetics (D and C) Act 1940 and the Act 1945 in India where the Ayurvedic Drugs Act has been enacted. Unani, Siddha is mentioned in Chapter IV-A.<sup>[10]</sup> There are 18 different sections, from Section 33C to 33 O. All these sections provide all relevant information

regarding ASU pharmaceutical regulations regarding production, sales, registration, GMP certification, licensing and sanctions.

### **Schedule T - Good Manufacturing Practices for Ayurvedic, Siddha and Unani Medicines**

To manufacture or sell ASU medicines in India, the manufacturer must obtain GMP certification. According to rules D and C 157, in order to obtain the certificate "Best Practice for the production of ASU medical products", the applicant must submit an article on the standard form, which contains complete information about the existing infrastructure of the industry. After a full review of the by the licensing authority as specified in Annex 'T' requirements, including the name of available equipment, materials and qualified technical personnel, the licensing authority will issue a certificate on the page within 3 months.<sup>[11]</sup>

### **New Guidelines for Herbal Medicines**

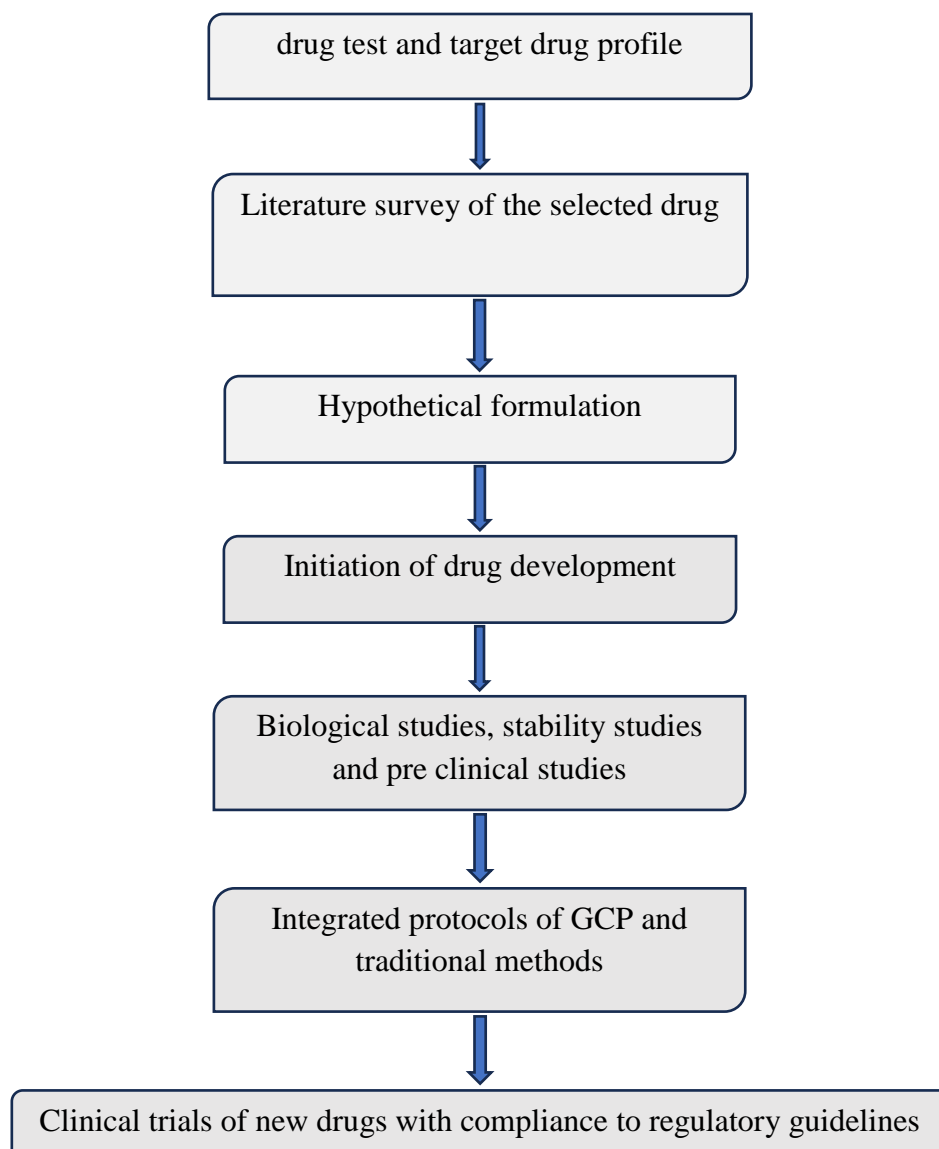
Ayush contains new updated guidelines for ASU Medicine. There were no such guidelines for conducting clinical trials earlier, but in March 2013, Ayush released new GCP guidelines for clinical trials of ASU drugs, Good clinical practice is a set of guidelines covering the design, conduct, termination, monitoring, analysis, reporting and documentation of studies involving human subjects. The fundamental principle of the GCP is that the interests of science and society are respected in human research. It never gets in the way of relevant considerations and academic excellence. Its goal is to ensure that research is scientifically and ethically sound and that ASU's pharmaceutical products are well documented.

The regulations aim to establish two main principles: the protection of human rights and the accuracy of ASU's medical information regarding medical treatment performed. These guidelines are based on the CDSCO document (2001) on GCP guidelines for clinical trials on pharmaceutical products. They will be applied for conducting ASU medical research in India at all stages of drug development, before or after product registration in India.

These GCP guidelines must be followed during clinical trials. If this is not complied with, clinical trials will be stopped by the competent authorities. The GCP guidelines also provide guidance on compensation to participants if adverse outcomes or participant death occur during the study.

**Drug Development Herbal Medicine:** The following are the components of the overall herbal medicine i) Development program: The first step is to make a synthetic version and isolate the bioactive components.<sup>[11]</sup>

ii) Performance and security analysis: Finally, when a new drug is developed, the regulatory process requires approval for human therapy or clinical trials.<sup>[12]</sup>



**Fig. 1: Steps in new drug development.**

Note: Fig 1 retrieved from Herbal Product Regulation and Development in India.<sup>[13]</sup>

DCGI guidelines require scientific evaluation of herbal and medicinal plants for use in allopathic systems and allopathic hospitals. This does not apply to clinical research proposals in institutions of Ayurveda, Unani or Siddha.

**Class I:** Since herbal medicines can be administered safely in fewer clinics, there is no need for phase 1 trials. But to ensure its potency, safety and efficacy it will be tested on 20-100 people which takes few months.

**Class II:** This class measures the dose for sick patients (100-300). This step determines the statistical scope and correlation of results for the design of large clinical trials. This step checks tolerance. Security considerations should guide literature reviews and recommendations. The phase II trials involved hundreds of patients over months and years.

**Class III:** This course is based on 2nd year security and research. This category includes 1,000 to 3,000 inpatients or outpatients. Side effects of herbal medicines are monitored. This confirms the safety and effectiveness of the drug. This period lasts 3 years.<sup>[14]</sup>

Phases 2 and 3 can compare treatment in the two groups. One group was given the experimental treatment and the other a placebo. Patients and researchers do not know who will receive the experimental treatment in the group phase.

#### **Guidelines on Good Clinical Practice for Drugs and Products in Clinical Trials in India:**

- Medicines and herbs should be issued according to the traditional medical system and produced according to good practice. There is no need for Phase 1 studies. To qualify, the unit must be located in the medical system's library.
- Animal toxicity should be reduced. No toxicity studies are required in Phase 2 studies until these studies demonstrate the toxicity or useful life of the herbicide. In all cases, two animal species should be tested for toxicity every four to six weeks.
- Clinical studies on herbal medicines show consistent results. Clinical studies on herbal medicines require informed consent, participants, introduction, patient data, withdrawal, and studies involving children or individuals with limited autonomy. This research requires scientific and ethical approval.
- Ayurvedic, Siddha or Unani physicians must be researchers. An allopathic physician who is not trained in the practice of multidisciplinary medicine should not conduct clinical research. Clinical trials should include a representative from each system.

#### **GCP guidelines**

**Annex I:** evaluation guidelines ayurvedic, unani and siddha medicines

**Annex II:** ethical issues Annex

**Annex III:** information note

**Annex IV:** essential documents.



Things like standards and herbal medicine became commercialized; Safety, quality and efficiency have become important issues. Green plants vary depending on many factors, including plant identification and seasonal changes (affecting collection time), ecotypic, genotypic and chemotype variations, drying and storage, and exposure to xenobiotics.

Standards defined by the American Plant Products Association: “Standards express the amount of information and control required to ensure product conformity”. Good agricultural and industrial practices reduce the volatility of natural products. Guidelines should cover sampling, organoleptic, pharmacogenetic, volatile, quantitative (ash, extractive), phytochemical, xenobiotic, microbial load, toxicity and activity assessment. Changes the medicinal activity of plants. Hand profile and brand size is another good measure as the level of medicinal phytochemicals to guarantee quality.

Phytochemical standards and marketing Pharmaceutical Standards Good Manufacturing Practices (GMP) are required for standardization of pharmaceutical products (WHO Guidelines, 1996).<sup>[15]</sup> Plants should be examined for their pharmacological, medicinal, medicinal, stability, health, toxicity and medicinal properties. Heavy metal pollution and good agricultural practices (GAP) is important in herbal medicine treatment. Problems in raw material balance Indian botanists are concerned with basic parameters when it comes to quality. According to AYUSH, Ayurvedic medicine contains 600 plants, 52 minerals and 50 animal products. Discover how to grow, harvest and process plants. More than 50% of organizations have difficulty finding and verifying raw materials, Obstacles to regulation of chemicals Food supplements are “foods”. These may contain vitamins, minerals, herbs or herbs. If the plant was on the market before 1994, DSHEA does not require toxicity testing. The FDA must declare the plant or 'food ingredient' as harmful.<sup>[12]</sup> In many countries, regulatory authorities, safety schools or pharmaceutical companies do not share information about herbal medicines. Obstacles to assessing safety and effectiveness: The laws, teachings, practices, principles and methods in the field of herbal medicine are complex. A single plant or herb can contain hundreds of natural compounds. Forum products may contain more. Many herbal medicines may contain many active ingredients. Obstacles to quality control of herbal medicinal products The quality of herbal medicines affects their safety and efficacy. The quality of the raw material depends on variables such as the type of trait (genetics) and the environment, intensive farming and crop selection, an GMP requires proper identification, storage and purification of herbs and ingredients. Herbal medicines, especially mixtures, are



difficult to track. Herbal products offer higher quality than traditional medicines. WHO promotes quality control systems such as national quality and botanical guidelines, GMP, labeling and licensing systems to ensure the safety and security of herbal medicines.

**Contraindications with medicinal herbs:** Population growth in developing countries such as India is alarming in terms of meeting daily food and medical needs, as the people's economy and livelihood depend on forest products. This phenomenon causes erosion and deforestation, making it difficult to meet demands and protect natural resources. Its quality and originality do not change as new species are added to *Materia Medica*. The market price of pharmaceutical products provides only a limited indication of turnover, market and demand. Due to price, quality and size, collectors and dealers have difficulty finding good markets. Insufficient information and misinformation about materials, markets and costs from suppliers, and lack of quality.

#### **Challenges in Regulatory filings of ASU Drugs in AYUSH**

- 1. Standardization:** ASU drugs are derived from natural sources, making standardization challenging due to variability in raw materials, harvesting, and processing.
- 2. Quality Control:** Ensuring consistency in quality, purity, and potency is difficult.
- 3. Safety and Efficacy:** Demonstrating safety and efficacy through conventional clinical trials is complex.
- 4. Intellectual Property:** Protecting traditional knowledge and formulations raises concerns.
- 5. Regulatory Framework:** Existing regulatory frameworks often focus on conventional drugs, requiring adaptation for ASU.<sup>[16]</sup>
- 6. Classification:** Categorizing ASU drugs as foods, supplements, or pharmaceuticals poses challenges.
- 7. Labeling and Claims:** Regulating labeling and claims to avoid misleading information.
- 8. Manufacturing Practices:** Ensuring Good Manufacturing Practices (GMP) compliance.
- 9. Ingredient Identification:** Difficulty in identifying and characterizing active ingredients.
- 10. Integration with Conventional Medicine:** Regulating combination product.<sup>[15]</sup>

**Table 1: List of ASU drugs.**<sup>[1]</sup>

Section	Title
33C.	Ayurveda, Siddha and Unani techniques consultancy.
33D	Advisory Committee on Ayurveda, Siddha and Unani Medicines.
33E	Illegal drugs
33EE	Medicines
33EER	Medicines
33EEB	Regulations regarding the sale of Ayurvedic, Siddha and Unani medicines.
33EEC	Banning the production and sale of some Ayurvedic, Siddha and Unani medicines.
33ED	The Central Government is not responsible for the use of Ayurveda, Siddha or Unani medicines etc. in the public interest. the power to ban its production.
33EF	Government analysts
33EG	Controllers.
33H	Application of the provisions of articles. <sup>[22,23,24and 25]</sup>
33I	Production, sale etc. of Ayurvedic, Siddha or Unani medicines in violation of this section. penalty due.
33J	Punishment for subsequent crimes.
33K	Deprivation.
33L	Follow rules in public sector
33M	Knowing sins
33N	The central government's power to make laws.
33O	The power to change the First Plan.

Note: The table 1 was retrieved from overview of regulations in India and South Africa, WJPR journal, 2017<sup>[17]</sup>

#### **ASU Pharmaceutical Standards & H. The goals of ASU&H's clinical pharmacy program are to**

- Promote patient care and safety in the use of ASU&H drugs and related practices
- Compare the effectiveness, benefits, risks, and adverse effects of drugs
- Promote safe, rational, and effective (including cost-effective) use of drugs.
- Enhance ASU&H's clinical acumen, clinical pharmacy education and training, and effective communication with the public.

**A) ASU&H Pharmaceutical technical terms:** i) **Adverse Reactions (ADR):** Drugs that are nontoxic, nontoxic, and are available in a standard dose for human use for the prophylaxis, diagnosis, or treatment of any disease or change in body function.<sup>[18]</sup>

ii) **Adverse Reactions (ADE):** Any side effect that may occur during combination therapy pharmaceutical product, but is not necessarily directly related to treatment.

iii) **Unwanted Adverse Effect (UAR):** An undesirable adverse effect that is undesirable in nature or its severity, or is not intended to be subject to national trademarks or copyrights drug property.

iv) **Serious Adverse Events (SAE):** Any unexpected medical event resulting in death, permanent or serious disability, requiring hospitalization or prolongs hospital stay or endangers life.

v) **Evidence:** A detailed report of a previously unknown or missing possible relationship between an adverse event and a drug.

vi) **Adverse Reactions (SE):** All adverse effects of pharmaceutical products are present in the dosage form. Is generally used for people who have a direct relationship with the pharmacy drugs.

vii) **Medication error (ME):** This is an error in the ordering or distribution process Medicines regardless of whether there is injury or risk of injury.<sup>[19]</sup>

## B) Types of Adverse Effects<sup>[20]</sup>

**Type A: Adverse effects (drug effect)** Adverse pharmacological effects for medicinal herbs, culture. Many variables make tracking medications difficult.

- Common (>1%)
- Dosage relationship
- Provide timely feedback
- Varieties
- Occurs in rare cases or in sensitive patients
- Organ injuries
- Delayed effects
- Cancer, mutagenicity
- Interaction
- Situations that may cause problems
- Childhood
- Young people
- Elders
- Kidney failure
- Hemodialysis

- Stomach
- Breasts
- Psychological effects

***Type B: Side effects (patient reactions)<sup>[21]</sup>***

- Protective behavior
- Metabolic intolerance
- Exception
- www. wpps. com Volume 9, Issue 9, 2020. 1194
- Mastan et al. World Journal of Pharmacy and Pharmaceutical Sciences.
- Rare (<1%)
- Suddenly
- Uncertainty
- Uncertain performance
- No connection
- Does not spawn during trials
- Features, powerful
- Provide timely feedback
- Small frequency

***Type C: Adverse effects (statistical effects)***

- Increase in the frequency of 'uncommon diseases
- Longest times
- Abnormalities in drug intake
- No time frame
- Usually a long delay
- Method unknown
- Difficult to repeat in experiments

**Barriers to launch of pharmaceutical products in AYUSH**

The National Pharmacopoeia Program has encouraged the reporting of all suspected drug overdoses, including herbal/traditional/alternative medicines, reporting of herbal medicines is low. Several detection-related barriers to detecting and reporting ASU&G adverse drug reactions can be identified. assessment and prevention of side effects. Perhaps because of the strong belief among doctors and pharmacists that ASU&H drugs are safe. Knowing the side

effects of these drugs is a big problem. From taking an accurate history to diagnosis and correct diagnosis, the process is fraught with obstacles, including :

- I. Herbal medicine from traditional systems in India, including Ayurveda, Unani, Siddha and homeopathy. These differences contribute to the challenges of herbal medicine, which include fundamental issues such as defining the appropriate nomenclature for medicinal plants (herbal, common, pharmaceutical name, or drug name) and verifying the herbal properties of medicinal plants. Detection of synthetic chemicals is generally not a problem.
- II. The fact that concepts and terms related to risk management are not included in the AYUSH system prevents the correct definition of risk factors.
- III. Approaches to studying drug safety issues in AYUSH are underdeveloped.
- IV. Although there is information about medicine in ancient texts, of AYUSH are not easily available
- V. The evidence is difficult to determine because there are common beliefs regarding the safety of ASU and H drug leading to incomplete reports and collection of relevant reports.
- VI. Patients often use medications from different medical systems simultaneously. causes problems in determining the causes.
- VII. Lack of proper supervision and control in ASU&H treatment serves as a confounder in measuring adverse effects.
- VIII. ASU&H's specialty is the production and sale of pharmaceutical products on a small scale.is large, which often makes identification of the agent impossible side effects
- IX. However, in rare cases, side effects and late effects may not be easily noticed. Traditionally is used, which contradicts the claim that most drugs are safe because for traditional use.

Unlike artificial drugs, herbal medicines are also rich in medicinal properties. complex and unassembled products. Many things are possible affects the general and general health of the body, including:

- Genotype.
- Parts of the plant – leaves, stems, root, root bark, etc.
- Geographical origin – climate, soil, photoperiod.
- Harvesting time (year, season, time of day) and conditions.
- Storage, processing, extraction.

- Combinations of herbs and/or processing of the combined herbs as medicines.

## CONCLUSION

The AYUSH medical system has advanced significantly in modern times and gained international acclaim for its all-encompassing approach to health and well-being. Improvements in safety and quality assessment have been made with the development of Good Manufacturing Practices (GMP) guidelines and clinical trial protocols tailored to AYUSH medicines, despite integration challenges with contemporary healthcare systems. The growth of the sector has been greatly aided by the Ministry of AYUSH; between 2014 and 2020, the Indian AYUSH industry grew by an astounding 17%, reaching a current turnover of US\$ 18.1 billion. In order to address non-communicable diseases, women's and children's health, and elderly care, AYUSH systems provide affordable solutions for preventive, promotive, curative, rehabilitative, and rejuvenatory needs.

To overcome management challenges, applied and practical strategies are necessary, integrating AYUSH's unique features while meeting with worldwide health regulations. Combining traditional wisdom with modern scientific research is crucial for improving public safety and healthcare.

## Key Takeaways from this article

- Worldwide Recognition: Because of their comprehensive approach, AYUSH practices are acknowledged worldwide.
- Regulatory Progress: GMP guidelines and clinical trial protocols are being developed.
- Growth and Adoption: The AYUSH Ministry fosters industry expansion.
- Integration Challenges: There are still special management difficulties.
- Future Course: Encouraging adoption, integration, and long-term expansion.

To sum up, the AYUSH method has enormous promise for comprehensive medical care. Through tackling regulatory obstacles, promoting cooperation, and stressing conventional knowledge in addition to contemporary research, AYUSH will be able to offer long-term healthcare solutions.

1. Acknowledgements We are grateful to the administration of St. Pauls College Of Pharmacy for providing the facilities needed to complete.
2. This work doesn't include any clinical trials included in this.

3. Ethics, Consent to Participate, and Consent to Publish declarations: not applicable.
4. Author contributions: All authors made contributions to the conception and design of the investigation. Shaik Shireen, Dr.Venu Madhav, Dr. M. Kiranmai, B. Sai Roopika for material preparation, data collection, and analysis. Shaik Shireen authored the initial draft of the manuscript, and all authors provided feedback on interim versions of the document. The final manuscript was reviewed and endorsed by all authors.
5. Funding: No funding was provided by a company, funding agency, or non-profit research body.
6. Data availability: The corresponding author can be reached for a reasonable request for the datasets used and/or analyzed in the current study.
7. Code availability Not applicable.
8. Declarations: Not Applicable
9. Consent to participation: Not applicable.
10. Competing interests: The authors have no relevant financial or non-financial interests to disclose.

## REFERENCE

1. Bansode M. Homoeopathic medical education in Maharashtra: growth and challenges. *Indian J Med Ethics.*, 2022; 27-32.
2. Goyal MR, Chauhan A. Holistic Approach of Nutrients and Traditional Natural Medicines for Human Health: A Review. *Future Integrative Medicine*, Sep. 28, 2024; 3(3): 197-208.
3. Jain AK, Sharma BK. Developments in the field of Ayurveda–Past to Present. *Ayushdhara*, 2014; 1(2): 51-64.
4. Chegu S, Nagabhushanam MV. A comprehensive study on regulation of herbal drugs in India, US and European Union. *Int J Drug Reg Affairs*, Mar. 19, 2021; 9(1): 78-6.
5. Nandini K, Vasantha M, Ganguly NK. Initiatives of Indian Council of Medical Research in scientific validation of traditional medicine. *Health Adm.*, 2013; 20: 115-9.
6. Mukherjee A, Taneja D, Khurana A. National Convention on World Homoeopathy Day– A conference report. *Indian Journal of Research in Homoeopathy*, 2021; 15(3): 5.
7. Devi A, Devi R, Kumar S, Jeet K, Chauhan T, Dhatwalia G, Nikhil N, Chandel S, Kumar A. Regulatory status of herbal drugs in India. *INTERNATIONAL JOURNAL OF APPLIED PHARMACEUTICAL SCIENCES AND RESEARCH*, Jun. 28, 2022; 7(03): 30-5.



8. Kaushik R, Upadhyaya K, Dixit T. Regulation of Ayurveda, Siddha and Unani (ASU) drugs: An overview of current framework, challenges and way forward. *Journal of Drug Research in Ayurvedic Sciences*, Mar. 1, 2025; 10(2): 104-12.
9. Anand M A. Global Regulatory Frameworks for Hair Care Industry: An Overview of Key Agencies and Guidelines. *Hair Care Products: Efficacy, Safety and Global Regulation*, Oct. 30, 2024: 201-21.
10. Lohar DR. Legal Status of Ayurvedic Siddha & Unani medicine. Dept of AYUSH, Ministry of Health & Family Welfare, 2006; 42.
11. Hu M. Global Pharmaceutical Outsourcing Strategy Report for Small Pharmaceutical Companies (Master's thesis, Case Western Reserve University).
12. Alamgir AN, Alamgir AN. Cultivation of herbal drugs, biotechnology, and in vitro production of secondary metabolites, high-value medicinal plants, herbal wealth, and herbal trade. *Therapeutic use of medicinal plants and their extracts: volume 1: pharmacognosy*, 2017; 379-452.
13. Bandaranayake WM. Quality control, screening, toxicity, and regulation of herbal drugs. *Modern phytomedicine: turning medicinal plants into drugs*, Sep. 20, 2006: 25-57.
14. Kumar V. Herbal medicines: overview on regulations in India and South Africa. *World Journal of Pharmaceutical Research*, Jun. 13, 2017; 6(8): 690-8.
15. Parveen A, Parveen B, Parveen R, Ahmad S. Challenges and guidelines for clinical trial of herbal drugs. *Journal of Pharmacy and Bioallied Sciences*, Oct. 1, 2015; 7(4): 329-33.
16. Bhairam M, Roy A, Bahadur S, Banafar A, Turkane D. Standardization of herbal medicines—an overview. *Journal of Applied Pharmaceutical Research*, Dec. 23, 2013; 1(1): 14-21.
17. Kumar V. Herbal medicines: overview on regulations in India and South Africa. *World Journal of Pharmaceutical Research*, Jun. 13, 2017; 6(8): 690-8.
18. Mastan A, Tripathi A, Rai SK, Pai V, Venkatachalam L. Pharmacovigilance: An approach towards safety of ayush drugs. *World J Pharm Pharm Sci.*, Jul. 9, 2020; 9: 1189-97. (adv effects)
19. Rajanandh MG, Chamundeeswari D. Need of pharmacovigilance in AYUSH drugs. *J Pharmacovigilance*, 2017; 5(1): 1-2. (need of pharmacovigilance)
20. Baghel MS. The national pharmacovigilance program for Ayurveda, Siddha and Unani drugs: Current status. *International journal of Ayurveda research*, Oct. 2010; 1(4): 197.

21. Bates DW, Boyle DL, Vliet MB, Schneider J, Leape L. Relationship between medication errors and adverse drug events. *Journal of general internal medicine*, Apr. 1995; 10(4): 199-205.
22. <https://ayushnext.ayush.gov.in/detail/post/ayush-an-introduction>
23. <https://ayush.mp.gov.in/index.php/en/about-us/brief-history>
24. [https://ayushedu.bisag-n.gov.in/AYUSH\\_EDU/unani](https://ayushedu.bisag-n.gov.in/AYUSH_EDU/unani)
25. [https://journals.lww.com/jpbs/fulltext/2015/07040/challenges\\_and\\_guidelines\\_for\\_clinical\\_trial\\_of.22.aspx](https://journals.lww.com/jpbs/fulltext/2015/07040/challenges_and_guidelines_for_clinical_trial_of.22.aspx)