

Review Article

Navigating the Global Terrain: Evaluation of Traditional Medicine and Regulatory Frameworks

Neelayathatchi P^{1*}, Chandra Shekhar Sanwal², Renjini Haridas³, Tanuja M Nesari⁴

1. Assistant Professor, All India Institute of Ayurveda, New Delhi. India.
2. Chief Conservator of Forests, Uttarakhand, and former Deputy CEO of the National Medicinal Plants Board (NMPB), Ministry of Ayush. India.
3. Consultant, Pharmacopoeia commission of Indian Medicine and Homoeopathy, Ghaziabad. India.
4. Director, ITRA, Jamnagar, Gujarat. India. Email:

Received: 11-08-2025

Accepted: 25-12-2025

Published: 31-03-2026

Abstract

The global resurgence of herbal medicine underscores a paradigm shift in healthcare and regulatory landscapes, with market projections reaching USD 160.6 billion by 2030. Despite widespread cultural acceptance and rising demand, significant disparities persist across national and regional pharmacopoeias in defining quality, safety, and efficacy benchmarks for herbal products. This review systematically examines the regulatory frameworks and pharmacopoeial monographs of key global players—including WHO, USP, Ph. Eur., API, and others—with a focus on standardisation challenges. A comparative case study on Valeriana species reveals divergent approaches to botanical identity, assay thresholds, contaminant limits, and therapeutic framing, highlighting gaps between traditional and modern standards. The analysis emphasises the urgent need for harmonisation, integrating validated analytical methods, safety protocols, and region-specific ethnopharmacological knowledge. Furthermore, the evolving landscape of national policies and WHO strategies from 1999 to 2018 reflects increasing institutional efforts toward formalising traditional medicine systems. The paper advocates for unified, evidence-based herbal monograph frameworks that reconcile scientific rigour with traditional practices, thereby enabling global acceptance and regulatory coherence for herbal medicinal products.

Keywords: Herbal Harmonisation, Pharmacopoeia, Traditional Medicine, Valeriana Monograph, Regulatory, WHO T&CM Strategy.

Access this article
online

Website:
<https://ijam.co.in>



DOI: <https://doi.org/10.47552/ijam.v17i1.6451>

Introduction

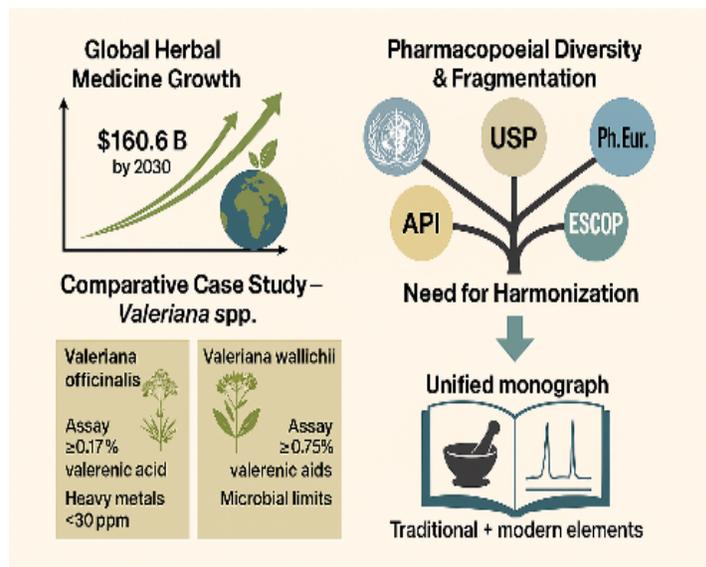
Herbal Medicines are of increasing importance due to their health-promoting and economic benefits in both developing and developed nations. An increase in herbal treatment, the expansion of traditional & Complementary medicine, and investment in plant-based products globally have boosted raw material trade. According to the WHO, 70-80% of the nation's rely on traditional or complementary medicine (1). The medicinal plants market globally, estimated at 72 billion in USD (2016) (2), rose to 90.7 billion in 2023 and is expected to reach 160.6 billion in 2030 (at CAGR -8.5%) (3). The estimated growth from 60 billion (USD in 2000) to 5 trillion (USD by 2050), with a 7% annual increase, as per the WHO (4).

*** Corresponding Author:**

Neelayathatchi P

Assistant Professor,
All India Institute of Ayurveda,
New Delhi. India.

Email Id: neelesyam@gmail.com



As the use of medicinal plants expands globally, their safety, efficacy, and quality of herbal medicines are crucial (5). Although

evidence to substantiate the biological uses of traditional herbs is available. Challenges still persist in terms of establishing similar standards and research strategies (6). The increase in research publications reflects a growing scientific consensus, while manufacturers and regulators emphasise standards and technical documents. To date, no single pharmacopoeia is universally applicable. This review sheds light on the global trends of Traditional and Complementary Medicine (T&CM), its regulatory and pharmacopoeial monograph status at national, regional, and international levels.

The study aims to critically analyse pharmacopoeial and regulatory trends for herbal medicines at the global level, using a case study on the *Valeriana* species. It compares the world's major pharmacopoeias (WHO, USP, Ph. Eur., API, IP), examines global regulatory aspects using WHO data, and highlights variations in parameters: identity, purity, safety & assay. The primary objective is to identify divergences and execute harmonisation strategies to enhance of herbal medicines. credibility, safety, & global acceptance.

Quality concerns - herbal medicines

Herbs are utilised to promote health and treat diseases, rooted in traditions (7). The public perception of safety persists, although challenges remain, which include: insufficient documentation, regulatory limitations, inadequate or poor-quality standards (8). Regulators, manufacturers, and the public face concerns over the safety of raw materials. According to the WHO, 80% of its member states utilise traditional or alternative medicine (9). Most countries lack adequate quality standards to fill regulatory gaps (10), with diversity in testing standards among professionals and manufacturers (11). Though national regulatory frameworks exist, global harmonisation is the need of the hour. The WHO's T&CM strategy (2014–2023) highlighted quality issues that remain unresolved (12).

Quality public standards

Quality standards are crucial for evidence-based policymaking and also ensure the quality & detection of adulterants in herbal medicine.

They must ensure that they include: titles, definitions, validated analytical methods, and safety limits (13). Development requires input from academia, industry, and regulators, addressing the needs of manufacturers, professionals, and the public (14).

Herbal Pharmacopoeias and Monographs standards

Pharmacopoeias aim to standardise herbal medicines by defining identity, purity, and potency (15). Initially focused on macroscopic/microscopic identification, they later incorporated impurity tests and assays (16). WHO's Good Pharmacopoeial Practices recommend monographs include title, definition, identity, purity, and strength (17). National pharmacopoeias are legally binding, covering identification, purity, assays, and potency (18). WHO's 2019 survey found 110 countries use pharmacopoeias, with 65 recognising them legally (9).

Pharmacopoeial Status of Herbal Drugs

National pharmacopoeias (BP, Ph. Eur., IP, JP, USP, etc.) include herbal monographs alongside chemical drug standards (19).

Overview of National and International Pharmacopoeias

Pharmacopoeias are either national (country-specific) or global. WHO's index lists both (20).

International Pharmacopoeia

WHO's International Pharmacopoeia sets global quality standards for drugs and excipients, though herbal monographs are often informational rather than legally binding (21).

United States Pharmacopoeia (USP)

USP establishes standards for medicines, supplements, and foods (22). Herbal monographs appear in the Dietary Supplements section (23, 24). USP–NF includes 28 official plant monographs (25), while the Herbal Medicines Compendium compiles additional entries, not all FDA-approved (23).

European Pharmacopoeia (Ph. Eur.)

Ph. Eur. defines herbal drugs as whole or fragmented plants, algae, fungi, or lichen, fresh or dried (26). Established in 1964, it regulates medicines across Europe and observer nations (27). The 10th edition comprised 2,500 monographs, 370 chapters, and 315 herbal entries, covering identity, contaminants, and analytical methods, such as HPTLC (28).

European - Scientific Cooperative on- Phytotherapy (ESCOP)

It was established in 1989, and ESCOP produced 60 monographs summarising scientific evidence for medicinal plants, which are widely used in regulatory submissions (29). Each monograph details names, constituents, clinical use, contraindications, interactions, pharmacology, and safety data (30).

British Herbal Pharmacopoeia (BHP)

First published in 1971, the BHP expanded in 1996 to 169 monographs, featuring macroscopic/microscopic analysis, as well as TLC identification (31). BHMA collaborates with ESCOP to harmonise European phytomedicine standards (32).

The People's Republic of China- Pharmacopoeia

The 2020 edition, i.e., 11th edition, includes 2,711 monographs on crude drugs and patent remedies, covering botanical sources, processing, identification, therapeutic actions, and safety (33).

Korean Herbal Pharmacopoeia (KHP)

Since 1984, KHP has evolved to 383 monographs. It includes principles, monographs, assays, and indices, with detailed standards for identity, purity, and storage (34–36).

Romanian Pharmacopoeia (RPh)

The 1993 edition (10th) contains 48 region-specific herbal monographs, which include names (Latin), synonyms, and standards of minimum content (37).

Hausa Herbal Pharmacopoeia

Documenting northern Nigeria's ethnopharmacology, it emphasises symptom-based remedies over biochemical profiling. Modern studies validate applications in antimalarial and oral disease management (38, 39).

Indian Herbal Pharmacopoeia (IHP)

Published in 1998–1999, IHP covers 40 plants with macroscopic/microscopic features, TLC, HPLC, GLC, and basic quality parameters (40).

Ayurvedic Formulary of India & Ayurvedic Pharmacopoeia of India (API)

In India, single drugs (1,000) and compound formulations (8,000) are utilised. AFI lists 444 formulations (41, 42). The API includes

600 crude drugs across six volumes, as well as extracts, minerals, and metals, with detailed identity and quality standards (43).

German Commission E Monographs

The 1998 edition (English) encompasses 299 plants, 73 combinations, & eight constituents, with therapeutic indices and regulatory references. Expanded monographs include 107 additions with clinical evidence (44, 45).

Japan Pharmacopoeia (JP)

JP includes crude drugs and Kampo formulations, which are updated regularly. Herbs not mentioned in JP are listed as Non-JPS standards, which are revised with new inclusions (46).

Pharmacopoeia of Russia

Dating to 1778, the Russian Pharmacopoeia includes 770 monographs, 316 herbal. The USSR's 11th edition (1990) listed 83 plant monographs and 119 species, many also used as food (47, 48).

Herbal Monographs – Regional/Sub-regional

- Malaysia: Three volumes (1999, 2010, 2013) with 20 species each, covering botanical traits, ash/moisture values, chromatography, toxicology, and traditional use (49).
- Egypt: Since 2020, EDA has published three volumes aligned with WHO/European standards, detailing botany, chemistry, pharmacology, dosage, contraindications, and safety (50).

Materials and Methods

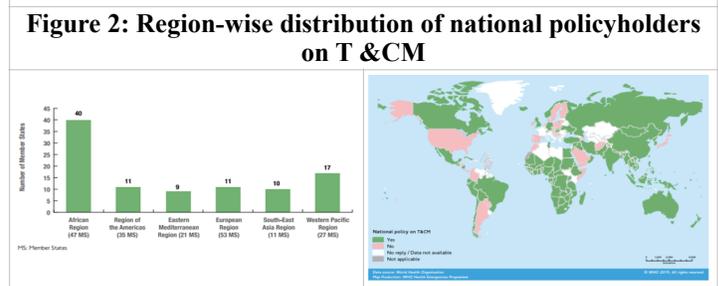
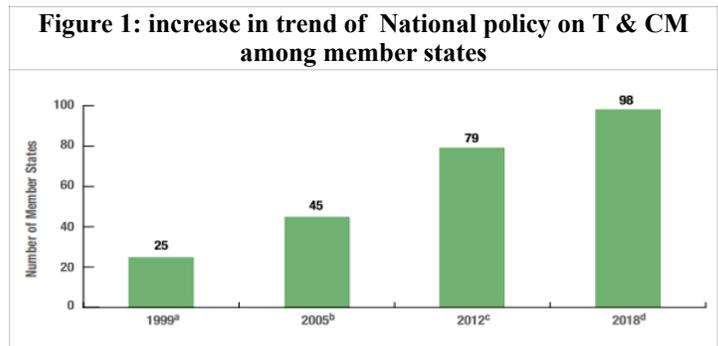
Conducted a comprehensive literature review using PubMed, Google scholar, and WHO databases with keywords "traditional medicine," "complementary medicine," "regulatory frameworks," and "pharmacopoeial monographs." Inclusion criteria covered peer-reviewed articles from 2004-2024. Web searches targeted WHO websites for regulatory data. Analyzed published data from reputable sources, focusing on WHO reports. Synthesized information to compare global regulatory frameworks and pharmacopoeial standards. Ensured reliability through cross-referencing and ethical considerations. Also case study on *Valeriana* species across major pharmacopoeias (USP, BP, IP, Ph.Eur) and API, WHO monographs were carried out with emphasis on assay, analytical methods, and incorporation of regional variants like *Valeriana wallichii* in the IP to encompass a comprehensive analysis among them. The concise methodology aimed for a comprehensive understanding of traditional and complementary medicine's global status, regulatory frameworks, and pharmacopoeial standards. This review followed PRISMA guidelines for transparent reporting of literature identification, screening, and selection; however, no quantitative meta-analysis was performed due to the qualitative and regulatory nature of the included studies.

Results

As of the WHO report 2019, on traditional & complementary medicine, there are a total of 194 WHO member states on T & CM. There has been a gradual addition of member states from 1999-2005, which has almost doubled from 2005-2018. In 2018, a sum of 98 countries, greater than 50% of 194 member states of WHO, reported having national-level policy over T & CM. (fig:1)

Region-wise distribution of national policyholders on T & CM among member states. The T & CM national policy holders among member states, distributed region-wise, include Africa, South-East

Asia, Eastern Mediterranean, Western Pacific, Americas, and Europe. (fig:2) out of 11 member states (MS) in South-East Asia, 47 member states (MS) in Africa, 27 member states (MS) in Western Pacific, 21 MS in Eastern Mediterranean, 35 MS in Americas and 53 MS in Europe; 10, 40, 17, 9, 11, and 11 MS possess national policy on T & CM respectively. (Table:1)



Region	Member States (MS)	No. of national policy (TCM) holders among MS
South-East Asia	11	10
Africa	47	40
Western Pacific	27	17
Eastern Mediterranean	21	9
Americas	35	11
Europe	53	11

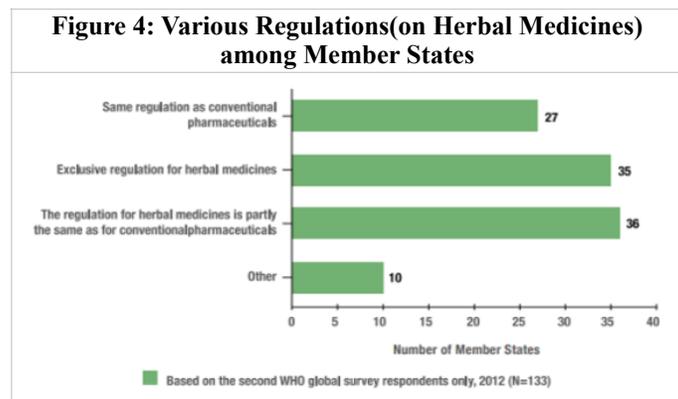
Status of member states with regulations for T & CM

The WHO member states reported to have a national level regulations for T & CM, includes Africa, South-East Asia, Eastern Mediterranean, Western Pacific, Americas, and Europe. (fig:3) out of 11 member states (MS) in South-East Asia, 47 member states (MS) in Africa, 27 member states (MS) in Western Pacific, 21 MS in Eastern Mediterranean, 35 MS in Americas and 53 MS in Europe; 9, 39, 13, 12, 15, and 21 MS possess national level regulations on T & CM respectively. (Table:2)

Region	Member States (MS)	No. of member states with national or state-specific regulations on T & CM
South-East Asia	11	9
Africa	47	39
Western Pacific	27	13
Eastern Mediterranean	21	12
Americas	35	15
Europe	53	21

Status of Herbal Medicines Regulations among WHO Member States

Based on the 2nd world survey conducted during 2012, a mere 133 member states responded. This depicts different types of herbal medicines regulations among member state respondents. (fig:4) Among which 27 member states follow the same regulation as conventional pharmaceuticals, 35 member states have specific regulation on herbal medicines, 36 MS have regulations for herbal medicines to some extent as of modern pharmaceuticals, while 10 of the MS follow the others.



Comparative analysis of WHO member states having a National policy (T&CM) and regulation (on Herbal medicine):

WHO member states with T&CM National policy and regulation on Herbal medicine during 1999 were 25 & 65, in 2005- 45 & 92, in 2012- 79 & 116 and as of 2018 estimate reported 98 & 124 respectively (Fig. 5)

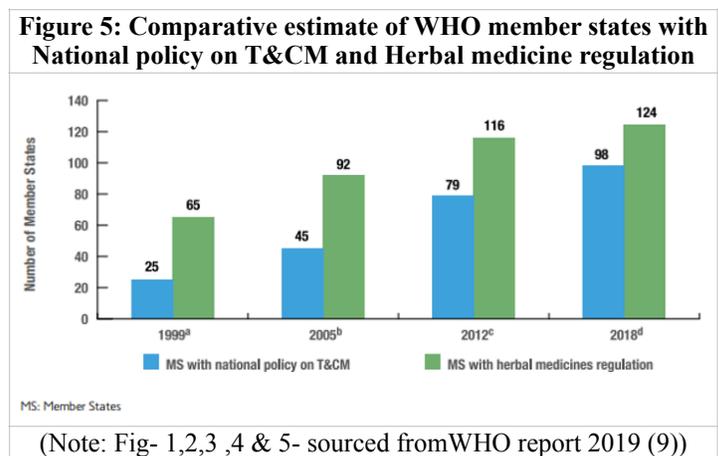


Table 3: List of pharmacopoeias at national, Regional and International Level

S. No.	Country	Title	Language
1	Argentina	Farmacopea Argentina	Spanish
2	Austria	(Austrian Pharmacopoeia)	Russian
3	Belarus	(State Pharmacopoeia of the Republic of Belarus)	Russian
4	Brazil	Farmacopeia Brasileira – FB (Brazilian Pharmacopoeia)	Portuguese English Spanish
		Farmacopeia Homeopática Brasileira (Brazilian Homeopathic Pharmacopoeia)	Portuguese English Spanish
		Formulário Nacional da Farmacopeia Brasileira (Brazilian National Formulary)	Portuguese English Spanish
		Formulário Homeopático da Farmacopeia Brasileira (Homeopathic National Formulary)	Portuguese
		Formulário de Fitoterápicos da Farmacopeia Brasileira (Herbal Medicines National Formulary)	Portuguese English Spanish
5	Chile	Farmacopoea Chilena	Spanish
6	China	Pharmacopoeia of the People's Republic of China	Chinese, English
7	Croatia	Hrvatska Farmakopeja HRF	Croatian Pharm.
8	Cyprus		
9	Czech Republic	Český lékopis (Pharmacopoea bohémica)	Czech
		Československý lékopis (Pharmacopoea bohemoslovaca)	Czech and Slovak
10	Denmark	European Pharmacopoeia Pharmacopoea Nordica, Danish Edition	Datin Latin
11	Egypt	Egyptian Pharmacopoeia	Arabic, English
12	France	Pharmacopée française	French
13	Germany	Deutsches Arzneibuch (DAB)	German
		Deutsches Homoeopathisches Arzneibuch (HAB)	German
14	Greece	Greek Pharmacopoeia	Greek

15	Hungary	Magyar gyógyszerkönyv (Pharmacopoea Hungarica)	Hungarian
16	India	Indian Pharmacopoeia	English
17	Indonesia	Farmakope Indonesia	Indonesian
18	Iran (Islamic Republic of)	Iranian Pharmacopoeia	Iranian
19	Italy	Farmacopea Ufficiale della Repubblica Italiana	Italian
20	Japan	The Japanese Pharmacopoeia (JP)	Japanese, English
21	Kazakhstan	The State Pharmacopoeia of the Republic of Kazakhstan (SPRK)	Kazakh Russian
22	Korea (Republic of)	The Korean Pharmacopoeia	
23	Lithuania	Lithuanian Pharmacopoeia (Lietuvos Farmakopėja)	Lithuanian
24	Mexico	Farmacopea de los Estados Unidos Mexicanos	Spanish
		Mexican Herbal Pharmacopoeia	Spanish
		Medical devices Supplement	Spanish
		Pharmacies Supplement	Spanish
25	Pakistan	Pakistan Pharmacopoeia	English
26	Philippines	Philippine Pharmacopoeia	English
27	Poland	Farmakopea Polska	Polish
28	Portugal	Farmacopeia Portuguesa	Portuguese
29	Romania	Pharmacopea Română	Romanian
30	Russian Federation	Государственная Фармакопея Российской Федерации (State Pharmacopoeia of the Russian Federation, former title: State Pharmacopoeia of the Union of Soviet Socialist Republics)	Russian
31	Slovakia	Codex Pharmaceuticus Slovacus MMVII/ Slovenský liekopisná komisia	Slovak
		Slovenský farmaceutický kódex	Slovak
32	Slovenia	Formularium Slovenicum	Slovene
33	Spain	Real Farmacopea Española	Spanish
34	Switzerland	Pharmacopoea Helvetica	French German Italian
35	Thailand	Thai Pharmacopoeia	English
		Thai Herbal Pharmacopoeia	English
36	Ukraine	The State Pharmacopoeia of Ukraine (ДЕРЖАВНА ФАРМАКОПЕЯ УКРАЇНИ)	Ukrainian, Russian
37	United Kingdom of Great Britain and Northern Ireland	British Pharmacopoeia	English
38	United States of America	The United States Pharmacopoeia and National Formulary (USP-NF)	English, Spanish
39	Uzbekistan	State Pharmacopoeia of the Republic of Uzbekistan	Uzbek/Russian
40	Viet Nam	Vietnamese Pharmacopoeia (Pharmacopoeia Vietnamica)	Vietnamese/English Vietnamese/English
Regional and sub-regional pharmacopoeia			
1	Eurasia	Pharmacopoeia of the Eurasian Economic Union (EAEU)	Russian
2	European Pharmacopoeia	European Pharmacopoeia	English French Spanish
		Pharmeuropa	
3	Africa	African Pharmacopoeia	English
		African Herbal Pharmacopoeia (AfrHP)	English
International			
1	WHO, Geneva, Switzerland	The International Pharmacopoeia	English

Table 4: List of pharmacopoeias and No. of monographs on Traditional medicine		Figure 6: Graph Depicting Pharmacopoeias with herbal monographs on TCM	
Pharmacopoeia	Monographs on Traditional Medicine		
Ayurvedic Pharmacopoeia of India (API)	847	Ayush monographs in total 2601	
Unani Pharmacopoeia of India (UPI)	498		
Siddha Pharmacopoeia of India (SPI)	139		
Homoeopathy Pharmacopoeia of India (HPI)	1117		
World Health Organisation (WHO)	147		
Indian Pharmacopoeia (IP)	165		
British Herbal Pharmacopoeia	169		
American Herbal Pharmacopoeia (AHP)	300		
European Pharmacopoeia	1433		
Japanese Pharmacopoeia	2042		
African Herbal Pharmacopoeia (AfrHP)	50		
Korean herbal Pharmacopoeia (KHP)	2462		
The Turkish Pharmacopoeia (TP)	32		
Brazilian Pharmacopoeia	146		
Pharmacopoeia of the People's Republic of China (ChP)	992		

Results

Comparative pharmacopoeial structure on testing and quality standards for Valerian Root, which will help identify harmonisation potential and gaps across API, IP, Ph. Eur., USP, and WHO Monographs shown in Table 5.

Table 5: Valerian Root – Comparative pharmacopoeial structure across API, IP, Ph. Eur., USP, and WHO Monographs

Test/Requirement	API (<i>V. wallichii</i>)	IP (<i>V. officinalis/wallichii</i>)	Ph. Eur. (<i>V. officinalis</i>)	USP (<i>V. officinalis</i>)	WHO (<i>V. officinalis</i>)
Botanical Identity	Macroscopic & microscopic; Sanskrit descriptors	Macroscopic & microscopic; cup-shaped apex scar	Macroscopic (cup scar); powder characteristics	Macroscopy + microscopy	Macroscopy & microscopy (starch, oil cells)
Foreign Matter	≤ 2%	≤ 2%	≤ 5% stem bases, ≤ 2% other	≤ 2%	≤ 2%
Loss on Drying	Not specified	≤ 12% @ 105°C	≤ 12%	≤ 12%	≤ 12%
Total Ash	≤ 12%	≤ 12%	≤ 12%	≤ 12%	Not specified
Acid-Insoluble Ash	≤ 10%	Not specified	≤ 5%	≤ 5%	Not specified
Alcohol-Soluble Extractive	≥ 30% (proxy for EO)	Not specified	Not defined (direct EO distillation)	Not defined	Not specified
Essential Oil Assay	Not direct; via extractive	Not specified	H ₂ O distillation: ≥ 4 ml/kg (whole); ≥ 3 ml/kg (cut)	≥ 0.5% (dry basis) via GC	Not specified
Valerenic Acid Assay	Not specified	HPLC (≥ 0.02% w/w dried)	HPLC (≥ 0.17% whole; ≥ 0.10% cut)	HPLC (≥ 0.05%); total acids ≥ 0.17%	HPLC method specified, content not defined
TLC (Identification)	Not specified	TLC profile match with anisaldehyde	TLC with anisaldehyde,	TLC + color tests	TLC: match to reference extract
Microbial Limits	Not specified	Not specified	Not specified	Specified (standard USP microbial)	Salmonella absent; quantitative
Heavy Metals	Not specified	Not specified	Not specified	Pb, Cd, Hg limits present	Pb ≤ 10 mg/kg; Cd ≤ 0.3 mg/kg
Pesticide Residue	Not specified	Not specified	Not specified	Specified per USP	Aldrin/dieldrin ≤ 0.05 mg/kg
Storage Conditions	Not specified	Protect from light, heat, pests	Dry, protected from light	Dry, cool, protected	Refrigerated for juice; dry forms
Dosage Recommendations	Powder: 1–3 g/day	Dry herb: 20 g; Fresh: 50 g/day	Not defined	Defined per extract	Dry: 20 g/day; Fresh: 50 g/day
Therapeutic Classification	Tridoṣahara, Mānasadoṣahara, Viṣaghna	Same as API	Mild sedative, sleep aid	Sedative, anti-anxiety	Sedative, anxiety, sleep disorders

Advancing API & IP: From Classical Roots to Global Relevance

A strategic approach to modernising valeriana standards.

The modernisation pathway for the Ayurvedic Pharmacopoeia of India (API) and Indian Pharmacopoeia (IP) seeks to advance both systems from their classical roots to global relevance through a strategic approach focused on enhancing analytical standards, harmonising safety parameters, and integrating traditional therapeutics with evidence-based methodologies—using *Valeriana* spp. as a model botanical for reform. (Table 6)

Table 6: shows global harmonisation strategies of API/IP to align with international Regulatory standards

Target Area	Current API/IP Practice	Global Harmonisation pathways	Regulatory alignment Justification
Marker Compound Assay	API lacks valerenic acid quantification	Introduce HPLC-based assay for sesquiterpenic acids (e.g. valerenic acid)	Aligns with Ph. Eur., USP, WHO for phytochemical standards
Essential Oil Testing	API uses alcohol-soluble extractive as proxy	Adopt steam distillation or GC for EO quantification	Precise measurement essential for therapeutic potency
Contaminant Limits	Not explicitly detailed	Set limits for heavy metals, pesticide residues, microbial load as per WHO/USP benchmarks	Ensures global safety and export readiness
TLC Fingerprinting	Not standardized in API monograph	Implement TLC identification using validated markers (valerenic, acetoxyvalerenic acids)	Supports traceability and botanical identity assurance
Standardized Extracts	IP includes blends but lacks extract profiles	Develop specifications for standardized dry extract with defined valerenic content	Facilitates harmonized dosage and therapeutic claims
Ayurvedic Integration	API uses Rasa, Guna, Karma metrics	Harmonize phytochemical data with traditional descriptors in dual-format monograph	Bridges classical and modern expectations

Discussion

The rise in herbal medicine usage stems from its affordability, accessibility, and perceived safety compared to conventional drugs, despite potential long-term safety concerns.(51). The reliance on traditional medicines, particularly in developing countries where over 80% of the population depends on them for primary healthcare, underscores their crucial role in filling healthcare gaps.(52). However, sourcing raw materials from wild populations without sustainable practices threatens biodiversity and the availability of medicinal plants.(53). Furthermore, inconsistent regulatory compliance and quality control in herbal medicine production raise concerns about product safety and efficacy, necessitating stringent regulatory frameworks to safeguard public health.(54).

Pharmacopoeia is a legal version of medicinal drugs whose formulations comprise identity, purity, and efficacy data. It encompasses the specifications that these herbs/preparations must comply with (55). Herbal monographs produced in different nations have various formats and provide multiple information. Pharmacopoeial Standards As noted, pharmacopoeial botanical drug monographs outline the standards of identity, purity, quality, and testing required to ensure the consistency of botanical drug ingredients. Additionally, these standards form the qualitative basis of the regulatory framework for botanical drug approval and, oftentimes, the availability of herbal drugs to the public through public health care systems. Pharmacopoeial drug monographs are generally officially accepted by the regulatory officials of a specific country. However, approximately 74% of countries do not have their pharmacopoeias. Of countries lacking their pharmacopoeia, approximately 56% utilise the monographs of the European Pharmacopoeia or USP; approximately 30% use no pharmacopoeia; and, perhaps most telling, 78% of countries do not include herbal medicines in their national drug lists (56).In both developed and developing nations, unless provisions for access to nonofficial plant drugs are in place, or at the very least not restricted, availability to herbal traditional medicines can be impeded, a situation currently in place in the US wherethere is no

formal regulatory allowance of traditional herbal medicines (there is a level of regulatory discretion applied to TCM and naturopathic practitioners(57).

Pharmacopoeial Status and Standardisation of Herbal Drugs

Global Pharmacopoeial Coverage of Herbal Drugs

Globally, many national pharmacopoeias have included monographs(herbal) to establish the quality, efficacy, and safe use of herb-based medicinal products. These include: British Pharmacopoeia(BP), European Pharmacopoeia (Ph. Eur.), Indian Pharmacopoeia, Japanese Pharmacopoeia, Pharmacopoeia of the People's Republic of China, and the United States Pharmacopoeia (USP). The majority are focused on chemical-based pharmaceuticals, though a paradigm shift occurred with the inclusion of many herbal(raw/finished product)monographs.(19).

Development of the Herbal Monograph

Herbal monographs documented so far include: WHO monographs, United States Pharmacopoeia - National Formulary (USP-NF), British Pharmacopoeia, E Monograph-German Commission, Ayurvedic Pharmacopoeia of India, Pharmacopoeia of People's Republic of China, & Japanese Pharmacopoeia. All four volumes of the WHO monograph aid other Nations by being a model in developing their regional monographs/ formularies, endowed with quality parameters and including relevant sections: therapeutic uses, pharmacology, safety concerns, and dosage forms (58)(WHO, 1999). WHO published the International Pharmacopoeia, which aligns with the Essential Medicines list contents, in terms of testing protocols & standardised methods. However, not all national pharmacopoeias are given the status of a regulatory document; some are used as a primary reference base.(21).

Regional Contributions to Herbal Pharmacopoeias

India: Indian Herbal Pharmacopoeia & Ayurvedic Standards

Collaboration of the Indian Drug Manufacturers' Association (IDMA) and CSIR resulted in the publication of the Indian Herbal

Pharmacopoeia in 2 volumes (1998-99). It includes 40 medicinal plants and their evaluation methods: TLC, HPLC, and GLC(40).

Further, the Ayurvedic Pharmacopoeia of India (API) and the Ayurvedic Formulary of India (AFI) serve as a tool for quality control(the gold standard) of Ayurveda formulations. The API attributes 600 single herbs with their botanical, chemical, and therapeutic characteristics.(43).

Europe: European Pharmacopoeia (Ph. Eur.) & ESCOP

The European Pharmacopoeia (Ph. Eur - 1964) of the European Council furnishes legal standards for herbal drugs. It includes over 315 herbal drug monographs (11th edition), six general monographs(herbal preparations), and 27 chapters (analytical and safety Profiles: pesticide residues and HPTLC). Include precise botanical name and part-wise categorisation: radix, rhizoma, cortex, folium, flos, etc.(26).

The European Scientific Cooperative on Phytotherapy (ESCOP-1989) includes 60 monographs endowed with a contemporary scientific research base to support the regulatory acceptance of Europe (phytomedicines)(29). These monographs include therapeutic indications, pharmacokinetics, contraindications, and preclinical safety data, significantly contributing to harmonised herbal regulation.

United Kingdom: The British Pharmacopoeia, developed since 1864, comprises UK medicinal products and pharmaceutical standards. British Pharmacopoeia Commission extends expert guidance to the European Pharmacopoeia. (59, 60).Based on the assessment of the European Medicines Agency's (EMA) Herbal Medicinal Products Committee (HMPC), accelerate the development and publication of European Union (EU) herbal monographs & list entries(61).

United States: The USP-NF (1820) determines the standard parameters for the identity, purity, strength & quality of medicines, food ingredients, and dietary supplements dispensed worldwide. The herbal monographs included under HMC define: potential herbs, constituents, identification features, assays, contaminants, specific tests, and industrial requirements(USP reference standards)(62, 63).

China and Japan: Traditional and Regulatory Integration

The Pharmacopoeia - People's Republic of China (2000 edition) contributed 992 monographs (Volume 1, on T&CM). These monographs document identity, preparation, and therapeutic usage.(33).

Likewise, the Japanese Standards for Herbal Medicines (JSHM-1993) document 248 herbal materials, a few sourced from the Japanese Herbal Medicine Codex, which supports Japan's integrative approach to include Kampo medicine(46).

Romania & Indigenous pharmacopoeias

The Romanian pharmacopoeia (R.Ph) in its 10th edition (1993) describes 48 herbal drug monographs specific to the region. It retreats to identity and analytical standards.(37)

The Hausa Herbal pharmacopoeia is not a recognised legal document, but it incorporates ethnopharmacological inputs of Nigeria (Hausa). The importance of oral healthcare and antimalarial treatments symbolises a traditional system that values scientific validation.(38)

Global Herbal Standardisation-WHO

The WHO has depicted significant quality, safety, and efficacy parameters to lay out regulatory standards through: Monographs -Volume I-III; Quality control methods -1998; & Guidelines-1991. It is recommended not to impose ill-defined restrictions on their long-term safe applications. (15, 58)

Status of National policies and regulatory systems on T&CM

The WHO has a significant role in promoting and monitoring T&CM integration with National healthcare systems. WHO Global Report on T&CM(2019) outlined a prompt increase among its member states to adopt National policies and regulatory systems that have evolved over the past two decades(9)

Growth in National Policies on T & CM

In 1999, 25 member states had executed national policy on T&CM, which doubled to 45 in 2005; 79 in 2012; and rose to 96 in 2018. In total, in 2018, 98 out of 194 member states reported having national policies on T&CM —over 50% of WHO members, showing a rising trend of organised responsibility to traditional medicine worldwide (Figure 1)(9).

Regional Variations in Policy Adoption

The WHO report stated regional discrepancies in policy adoption (Figure 2, Table 1). The African Region precedes with 40 out of 47 countries with national policies on T&CM, followed by South-East Asia, with 10 out of 11 countries. Other regions like the Western Pacific (17/27), Eastern Mediterranean (9/21), Americas (11/35), and Europe (11/53) show a lower ratio of policy acceptance.(9). This breaches the cultural and healthcare system inconsistency across regions.

T & CM Regulatory Frameworks

In total, 109 member states reported their national/ sub-national regulations on T&CM (2018) (Figure 3, Table 2). Africa (39/47) and South-East Asia (9/11) have effective regulatory system, which aligns with policy development & implementation. In Europe, 21/53 nations show progress in regulatory development compared to those countries with mere national policies.(9).

Herbal Medicines Regulations

The WHO's second global survey (2012) on T&CM revealed a complex picture of herbal medicine regulation (Figure 4). Among 133 responding member states, 27 regulated herbal medicines identically to conventional pharmaceuticals, 35 had separate specific regulations, 36 regulated them partially as modern pharmaceuticals, and 10 followed other types of regulation(9). Variation depicts differences in: national preferences, legal frames, and the coverage of traditional medicine utility.

Policy Growth vs. Regulation in T & CM

Indicates a clear uptrend in both T&CM national policies and herbal medicine regulation among several nations between 1999 and 2018 (Figure 5). While only 25 countries had a T&CM policy in 1999, 65 already had herbal medicine regulations. By 2018, this grew to 96 and 124, respectively, showing that while herbal medicine regulation often preceded policy development, both domains have consistently progressed.(9).

The increasing trend of national policies and regulations regarding traditional and complementary medicine and herbal medicine indicates a growing global recognition of their potential role in healthcare systems. (64)(Patwardhan et al., 2023). This is further promoted by the WHO's encouragement to integrate traditional

medicine into national healthcare systems, acknowledging the importance of herbal medicines in achieving health goals(65) (Abenwie et al., 2023) (Traditional, Complementary and Integrative Medicine, 2012).

Case study on Herbal (Monograph) across pharmacopoeias:

Pharmacopoeial approach to Valerian Root:

Ayurvedic Pharmacopoeia of India (API):

It includes *Valeriana wallichii* (Tagara), a monograph with system-based pharmacodynamics and indications. The macroscopic and microscopic features of the rhizome, stolon, and roots highlight leaf scars, isovaleric acidous odour, and parenchyma (rich in starch). The drug is classified by Rasa (taste: Kaṭu, Tikta), Guna (qualities: Laghu, Snigdha), Virya (potency: Uṣṇa), and Karma (actions: Tridoṣahara, Mānasadoṣahara). Parameters for identity, purity, and strength include total ash ($\leq 12\%$), acid-insoluble ash ($\leq 10\%$), alcohol-soluble extractive ($\geq 30\%$), and water-soluble extractive ($\geq 19\%$). No mention of assay methods for valerenic acid or essential oil was seen. Different dosage forms according to classics such as: Dhānvantara Taila and Jātīphalādi Cūrṇa, for ailments like epilepsy, mental disorders, and eye disease. This monograph highlights traditional value over contemporary quantitative techniques, ensuring it has a prospect for harmonisation with current phytochemical standards. (66).

Indian Pharmacopoeia (IP)

It includes *Valeriana officinalis* and *V. wallichii*, which provides space for botanical pliability. Official parts of rhizome, roots, and stolons are macroscopically described as follows: presence of apex scars (cup-shaped) and striated stolon internodes. Microscopy shows parenchyma (starch-rich) and cork cells (lignified). Identification is supported by thin-layer chromatography (TLC) using hexane-ethyl acetate-acetic acid as the mobile phase and anisaldehyde-spray visualisation. IP sets limits for foreign organic matter ($\leq 2\%$), total ash ($\leq 12\%$), and loss on drying ($\leq 12\%$), but omits acid-insoluble ash. A standardised HPLC method quantifies sesquiterpenic acids with valerenic acid as the marker, requiring $\geq 0.02\%$ content. The assay methods are similar to Ph. Eur. parameters but slightly differ in gradient and extraction process. More flexible than European or U.S. standards, IP's approach of dual species inclusion and established marker content locates it at the brim of traditional and modern trends—helping bridge the regulatory gap between API and international standards.

European Pharmacopoeia (Ph. Eur. 6.0)

Ph. Eur. defines *Valeriana officinalis* root as whole or cut underground parts—rhizome, roots, stolons—with essential oil content ≥ 4 ml/kg (entire) or ≥ 3 ml/kg (cut). It mandates a minimum of 0.17% sesquiterpenic acids (valerenic acid) for the whole drug, and $\geq 0.10\%$ for the cut drug. Identification parameters include: macroscopy (cup scar - apex), microscopy (size of compound starch grains $\leq 15 \mu\text{m}$), and TLC fingerprints. HPLC protocols- valerenic acid quantification are specified, with gradient steps, wavelength detection (220 nm), and column dimensions. Purity Parameters include: foreign matter ($\leq 5\%$ stem bases, $\leq 2\%$ other), loss on drying ($\leq 12\%$), total ash ($\leq 12\%$), and acid-insoluble ash ($\leq 5\%$). Dosages were not prescribed, but standards were built with accuracy, reproducibility, and marker compounds. Its robust analytics locates *Valeriana* as a sedative and sleep-aid constituent within approved European pharmaceuticals, with clear testing protocols for manufacturers, regulators, etc. (67).

United States Pharmacopoeia (USP)

USP states *Valeriana officinalis* as a dietary supplement entity. The minimum root standard is $\geq 0.05\%$ valerenic acid and $\geq 0.17\%$ total valerenic acid content. Identification was done with TLC colour tests and an HPLC confirmatory profile, similar to Ph. Eur. in marker compound authentication. Microscopy includes: starch, resin cells, & sclereids. Purity parameters: loss on drying ($\leq 12\%$), total ash ($\leq 12\%$), acid-insoluble ash ($\leq 5\%$), and foreign matter ($\leq 2\%$). It is unique to incorporate safety standards—strict limits on: heavy metals (Pb, Cd, Hg), microbial loads, and pesticide residues. Essential oil ($\geq 0.5\%$) quantification was done through GC. Valerian, a known sedative herb, is preferably administered in extract form (tinctures/ capsules). Special concern is to provide safe and supplement formulation, USP's methods harmonise phytochemical efficacy with industrial standards—offering precise test protocols and compliance aids appropriate for herbal product markets (international/national) (68).

World Health Organisation (WHO Monograph)

It includes *Valeriana officinalis* monograph, intended to provide global guidelines with the combined essence of scientific data and traditional wisdom. The officinal part includes rhizome, roots, and stolons; macroscopic and microscopic features emphasise starch grains and resin droplets. Imparts TLC profiles to establish botanical identity, while HPLC is used to quantify valerenic acid. However, no specification about the minimum content required. It comprises parameters like: moisture ($\leq 12\%$) and foreign matter ($\leq 2\%$), contaminant limits like: heavy metals (Pb ≤ 10 mg/kg & Cd ≤ 0.3 mg/kg), pesticide residues (aldrin/dieldrin ≤ 0.05 mg/kg), and microbial safety (absence of Salmonella). It includes Therapeutic uses like nervous tension, insomnia, and anxiety. Standardised dosages are prescribed (20 g/day dry, 50 g/day fresh). WHO's replica supports safety, efficacy, and accessibility—bridging traditional wisdom with evidence-based phytoanalysis and enabling national/regional pharmacopoeias to endorse harmonised herbal standards (69).

Comparative Analysis of Valeriana Species Across Pharmacopoeias

This comparative study of Valerian root standards across global pharmacopoeias reveals fascinating divergences in botanical scope, analytical rigour, and therapeutic framing. The data was analysed under different components like:

Botanical Source & Scope: API (Ayurvedic Pharmacopoeia of India) describes *Valeriana wallichii*, a species belonging to the Himalayan origin, utilised in Ayurvedic tradition (66). IP and WHO accept *V. wallichii*, *V. officinalis*, or combined—breaching Eastern and Western trends (69, 70). Ph. Eur., USP, and WHO accept *Valeriana officinalis* L. (European species), known to have sedative action (67-69).

Phytochemical & Assay: Valerenic acid is quantified via HPLC in IP, Ph. Eur., USP, and WHO—but lacks in API, which relies on traditional extractive standards (66-71). USP specifies a minimum presence of 0.05% valerenic acid and 0.17% total valerenic acids, combined with hydroxy- and acetoxy-valerenic acid (68). Ph. Eur. Prefers $\geq 0.17\%$ (whole) and $\geq 0.10\%$ (cut) of valerenic acid, indicating a stringent threshold. (67). IP determines a small range at $\geq 0.02\%$, providing space for harmonisation. (70).

Identification and Microscopy Analysis: USP and Ph. Eur. adopt TLC & HPLC for identification, including other methods like

colourimetric and chromatographic profiles(67, 68). Microscopical identity across pharmacopoeias depicts the presence of starch granules, sclereids, and oil cells; USP specifies: starch (size as $\leq 15 \mu\text{m}$) and resin cells.(68). IP includes granular distinctions like cup-shaped scars and scalariform xylem, as its anatomical peculiarity.(70).

Therapeutic alignment: API uniquely incorporates pharmacodynamic principles of Ayurveda—Rasa (taste), Guna (quality), Virya (potency), and Karma (action)—which are lacking in Western medical systems(66). USP and Ph. Eur. targets on sedative and sleep-promotion roles, strengthened by the GABAergic potency of valerianic acid(67, 68). WHO and IP substantiate its utility in ailments like nervousness, insomnia, and anxiety(69, 70).

Formulation & Storage: API furnishes traditional dosage forms like: Tailas (oils), Cūrṇas (powders), Āriṣṭas (fermented formulation)(66). USP and Ph. Eur. prefer capsules, tinctures, and standardised extracts, with strict moisture and light protection(67, 68). WHO suggests cold storage of fresh juice in a refrigerator, highlighting stability issues(69).

Highlights of Regional Distinctions: The Ayurvedic Pharmacopoeia of India (API) features *Valeriana wallichii*—Tagara—grounded in Ayurvedic principles. Traditional preparations like Dhānvantara Taila highlight their role in mental and neurological disorders. Identity is based heavily on organoleptic and microscopic features like lignified cork cells, abundant starch, and scalariform vessels.(66). The WHO monograph adopts a global standard of *Valeriana officinalis*, emphasising reliable test protocols like TLC and HPLC for valerianic acid—although without minimum assay values—and ensures safety using limit values for heavy metals, pesticides, and microbial contaminants.(69). The western pharmacopoeias (Ph. Eur., BP, USP), in respect to WHO's safety profile, prescribe valerianic derivatives thresholds ($\geq 0.05\%$ – 0.17%) and adhere to purity testing protocols per general monographs. (67, 68, 71). Anatomical features characterised like aromatic odour and starch-rich tissues, though IP specifically adds, cup-shaped scars and rounded starch cells, enriching identity demarcation(70). API details extractive values and general ash limits, but it lacks a description on aflatoxins, microbial quality, and pesticide residues, where WHO and Western pharmacopoeias are more stringent(66-69).

Areas need harmonisation across Pharmacopoeias with Global Standards for *Valeriana* spp:

To align Pharmacopoeias studied with global standards for *Valeriana* spp., several key areas need harmonisation, which include:

Analytical Standards

High-performance liquid chromatography (HPLC) assays for valerianic acid (bioactive-marker) are well-determined in pharmacopoeias like Ph. Eur., USP, IP, and WHO monographs. (67-70). However, the API lacks HPLC/ GC analysis for *Valeriana wallichii*, but relies on extractive values(proxy)for phytochemicals. (66).Also, including validated assays on markers would greatly enhance identity, authentication, reproducibility, and global compatibility.

Similarly, quantifying essential oil content via hydrodistillation or gas chromatography (GC) is defined in Ph. Eur. and USP monographs for *Valeriana officinalis*.(67, 68)[1,2] In contrast, API

lacks such provision, depending on weight-based extractive values—a limitation to ensure therapeutic consistency.

Safety Standards

USP and WHO monographs set rigorous limits for: microbial contamination, heavy metals, residual solvents, and pesticide residue. (68, 69) [2,4] These are absent in API's monographs, rendering a gap in global compliance. (66) Aligning the API with these thresholds would confirm wider acceptance of traditional herbal drugs in regulated international trade.

Therapeutic Framing and Botanical Scope

A specific strength of API is its integrative nature of therapeutic framework with emphasis on Ayurvedic principles—Rasa (taste), Guna (quality), Virya (potency), and Karma (action)—which are lacking in Western standards.(66)[5] This nourishes clinical administration but lacks phytochemical criteria.

While IP & WHO incorporate *V. wallichii* and *V. officinalis*, Western pharmacopoeias like Ph. Eur. and USP standardised *V. officinalis* and fix higher thresholds for valerianic acid (e.g., ≥ 0.05 – 0.17% total valerianic acids)(67-70).[1–4] This underscores a chance to enhance API's analytical approach to meet global quality requirements while preserving its traditional wisdom.

Need for Harmonisation of Herbal Monographs

The comparative analysis of *Valeriana officinalis* across pharmacopoeias emphasises the need to harmonise herbal monographs to ensure regularity in quality, safety & efficacy. While the Indian Pharmacopoeia (IP) values ethnobotanical relevance by adding *Valeriana wallichii*, it varies in assay limits, with less (0.02%) valerianic acid. In contrast, the European Pharmacopoeia (Ph. Eur.) and British Pharmacopoeia (BP) impose more thresholds ($\geq 0.17\%$ total valerianic acids), while the United States Pharmacopoeia (USP) accepts a medium standard of $\geq 0.05\%$ (67, 68, 71). These disparities mirror regional priorities but serve as a hurdle to regulatory compliance and the international market approach of herbals.

The lack of monograph harmony leads to poor quality control, hampers manufacturers from meeting multi-national compliance, and hinders regulators from evaluating imported herbals. According to Sakunthala and Ranjith (2021), divergent quality control and analytical methods result in needless testing and increased costs, affecting small /medium-scale manufacturers. (72). This challenge is depicted in *Valeriana*, where safety concern (valepotriates presence) accelerates the need for contaminant analysis; however, not all pharmacopoeias include aflatoxin, heavy metal & microbial limits. (68, 71).

Efforts undertaken to harmonise standards of herbals

The World Health Organisation (WHO) has emphasised the necessity of harmonising quality standards of herbal drugs by developing the International Herbal Pharmacopoeia and the Working Group on Herbal Medicines regulation. These promote harmony in monograph layout, marker compound, and testing methods, crucial in pharmacovigilance and evidence-based use. (73) . Harmonisation must be aligned with the regulatory objectives of ICH Q4B and WHO Technical Report Series 1013, strengthening the homogeneity of analytical standards.(74, 75)

Phytochemical and therapeutic equivalence are required for harmonisation. Pharmacopoeial monographs must integrate Western analytical rigour and traditional wisdom to promote safety without resurging cultural entity.(57) . The convergence can

be attained by unique monographs with prime global standards annexed by region-specific values that ensure pliability without sacrificing standardisation..

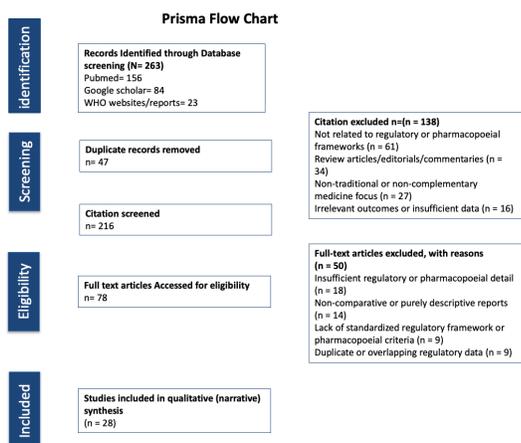
In a nutshell, pharmacopoeial harmonisation on monographs like *Valeriana officinalis* is a regulatory and scientific essential. Adherence to standards: assay range, botanical varieties, contaminant limits, and identification -authentication can bridge gaps among traditional practices and global pharmaceutical standards, ultimately rendering safe and effective herbal medicine practices worldwide. Thus, harmonisation efforts must reconcile API's ethnobotanical depth with WHO's accessibility model and Western rigour—particularly in quantitative assays, safety thresholds, and extract standardisation—making *Valeriana* spp an ideal candidate for integrative phytotherapeutic standardisation.

Conclusion

The rising trend of herbal and herbal medicines utilisation worldwide and the expansion of the global market for plant-based products require safety and quality profiling, which has become a significant concern for health, pharmaceutical industries, and the public. The WHO data (2019) highlights detrimental practices in integrating T&CM into the national health services globally. The increase in the number of countries in terms of national policies and regulatory frameworks mirrors a deliberate global paradigm towards legalising and institutionalising traditional wisdom. The comparison of *Valeriana* monographs interprets inconsistencies in regulation: assay thresholds, identification, and safety assessment. These regional discrepancies in regulatory processes accelerate international collaboration and the establishment of harmonisation to ensure safe, effective, and culturally accepted healthcare promotion with T&CM. The recent global effort to integrate herbal drugs into pharmacopoeial standards signifies growing acceptance of the traditional system within the modern regulatory approach. Countries & institutions across the globe are consistently making efforts to establish quality and safety profiles for herbals. The collective efforts of WHO, pharmacopoeias (regional), ESCOP, and USP (organisations) resulted in a valid and relevant pharmacopoeial framework. Consistent harmonisation and scientific rigour will support global marketing, regulatory constraints, and public health outreach.

Ethical Considerations

This study utilized **publicly available literature and official documents**; therefore, ethical approval was not required. Data reliability was ensured through cross-referencing multiple authoritative sources.



References

1. Ekor M. The growing use of herbal medicines: issues relating to adverse reactions and challenges in monitoring safety. *Frontiers in pharmacology*. 2014;4:177.
2. Herbal Medicine Market Size and Forecast, by Product (Tablets & Capsules, Powders, Extracts), Indication (Digestive Disorders, Respiratory Disorders, Blood Disorders), and Trend Analysis, 2014-2024. 2017.
3. Herbal Supplements and Remedies - Global Strategic Business Report. Dublin: Research and Markets. 2024. Available from: <https://www.globenewswire.com/news-release/2024/07/24/2917786/28124/en/Global-Herbal-Supplements-and-Remedies-Business-Report-2024-Market-to-Grow-by-70-Billion-to-2030-Latest-Product-Trends-Taking-Herbal-Supplements-Market-to-New-Level.html> (Retrieved on: 2025 June 21).
4. Ahmad S, Othman N. Strategic planning, issues, prospects and the future of the Malaysian herbal industry. *International Journal of Academic Research in Accounting, Finance and Management Sciences*. 2013;3(4):91-102.
5. Osman AG, Haider S, Chittiboyina AG, Khan IA. Utility of alkaloids as chemical and biomarkers for quality, efficacy, and safety assessment of botanical ingredients. *Phytomedicine*. 2019;54:347-56.
6. Jaiswal Y, Liang Z, Zhao Z. Botanical drugs in Ayurveda and traditional Chinese medicine. *Journal of ethnopharmacology*. 2016;194:245-59.
7. Joshi VK, Joshi A, Dhiman KS. The Ayurvedic Pharmacopoeia of India: development and perspectives. *Journal of ethnopharmacology*. 2017;197:32-8.
8. Medicines ISTH. Some Mycotoxins, Naphthalene and Styrene. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. 2002;82:171-300.
9. World Health Organization. WHO global report on traditional and complementary medicine 2019:226.
10. Organisation WH. National policy on traditional medicine and regulation of herbal medicines: report of WHO global survey. National policy on traditional medicine and regulation of herbal medicines: report of WHO global survey 2005. p. 156-.
11. Dwyer JT, Coates PM, Smith MJ. Dietary supplements: regulatory challenges and research resources. *Nutrients*. 2018;10(1):41.
12. Qi Z. Which traditional medicine strategy? 2014-2023. Geneva: World Health Organisation. 2013;188.
13. Kim N-C. Need for pharmacopoeial quality standards for botanical dietary supplements and herbal medicines. *Food Supplements and Biomaterials for Health*. 2021;1(1).
14. Zacchino SA. Celebration of the 50th anniversary of the Korean Society of Pharmacognosy (KSP). *Phytomedicine: international journal of phytotherapy and phytopharmacology*. 2020;71:153213.
15. Alamgir A, Alamgir A. Pharmacopoeia and herbal monograph, the aim and use of WHO's herbal monograph, WHO's guidelines for herbal monograph, pharmacognostical research and monographs of organised, unorganised drugs and drugs from animal sources. *Therapeutic Use of Medicinal Plants and Their Extracts: Volume 1: Pharmacognosy*. 2017:295-353.
16. Länger R, Stöger E, Kubelka W, Helliwell K. Quality standards for herbal drugs and herbal drug preparations—appropriate or improvements necessary? *Planta medica*. 2018;84(06/07):350-60.

17. Organisation WH. Good Pharmacopoeial Practices: Draft chapter on monographs on herbal medicines. Geneva: World Health Organisation, 2017: 1–12.
18. De A, De S, Saha N, Das B, Naskar S, Samanta A. Pharmacopoeias, national formulary and extra pharmacopoeia. Dosage Forms, Formulation Developments and Regulations: Elsevier; 2024. p. 83-98.
19. Mukherjee PK. Quality control of herbal drugs: an approach to evaluating botanicals: Business horizons; 2002.
20. World Health Organisation. Index of World Pharmacopoeias and Pharmacopoeial Authorities. Geneva: World Health Organisation; 2021, March. <https://iris.who.int/bitstream/handle/10665/340323/9789240020900-eng.pdf> (Retrieved on 2025 May 26)
21. Sarma N, Upton R, Rose U, Guo D-a, Marles R, Khan I, et al. Pharmacopoeial standards for the quality control of botanical dietary supplements in the United States. *Journal of Dietary Supplements*. 2023;20(3):485-504.
22. Pharmacopoeia US. USP–NF Dietary Supplements Monographs. Rockville (MD): United States Pharmacopoeia; 2022. [Available from: https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-commentary/usp-nf-2022-issue-3-commentary-20220601.pdf (Retrieved 20 Nov 25)]
23. Ma C, Oketch-Rabah H, Kim N-C, Monagas M, Bzhelyansky A, Sarma N, et al. Quality specifications for articles of botanical origin from the United States Pharmacopoeia. *Phytomedicine*. 2018;45:105-19.
24. Huynh-Ba K, Moreton RC. Development of United States Pharmacopoeia-National Formulary (USP–NF) Monographs and General Chapters. Specification of Drug Substances and Products: Elsevier; 2025. p. 185-204. (USP) USP. USP principles for a robust and trusted pharmacopoeia. 2023 . Rockville (MD): United States Pharmacopoeia, [Available from: <https://www.usp.org>. (Retrieved on 2025 Jun 28).
25. Care EDftQoMaH. European Pharmacopoeia 10.1. 2020. Strasbourg: European Directorate for the Quality of Medicines and Health Care. Available from: <https://pheur.edqm.eu/app/10-1/search> [Retrieved on 2025 Jun 28]
26. Medicines EDftQo, HealthCare. European Pharmacopoeia. The editor. Strasbourg: Council of Europe; 2023. [Available from <https://pheur.edqm.eu/app/10-1/search> [Retrieved on 2025 Jun 28]
27. European Pharmacopoeia. [Available from: <https://pheur.edqm.eu/app/10-1/search>. (Retrieved on 2025 June 21)]
28. ESCOP. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products. Second Edition Supplement 2009. Stuttgart, New York: Thieme Publisher; 2009.
29. Phytotherapy ESCo. ESCOP monographs, The Scientific Foundation for Herbal Medicinal Products. Exeter: ESCOP; 2017. Available from: <https://www.escop.com/example-monograph-escop-free-access/>. (Retrieved on 2025 July 28)
30. Association BHM. British Herbal Pharmacopoeia 1996. Bournemouth: BHMA Publications; 1996. [Available from: <https://bhma.info/product/british-herbal-pharmacopoeia-1996/> (Retrieved on 2025 June 25)]
31. D. L. Pharmacognostic Methods for Analysis of Herbal Drugs, According to European Pharmacopoeia. Internet. Ed: InTech; 2012. [Available from: https://cdn.intechopen.com/pdfs/37167/InTech-Pharmacognostic_methods_for_analysis_of_herbal_drugs_according_to_european_pharmacopoeia.pdf (Retrieved on 2025 May 20)]
32. Leong F, Hua X, Wang M, Chen T, Song Y, Tu P, et al. Quality standard of traditional Chinese medicines: comparison between European and Chinese Pharmacopoeia and recent advances. *Chinese medicine*. 2020;15(1):76.
33. Kim Y-K, Cho S, Kim J, Kang Y. Semantic Change of Crude Drug Preparations in Korea and Policy Evaluation. *Herbal Formula Science*. 2013;21(2):29-43.
34. Food K, Administration D. The Korean Herbal Pharmacopoeia 1984. [Available from: <https://www.scribd.com/document/157598757/The-Korean-Herbal-Pharmacopoeia> (Retrieved on 2024-Oct-27)]
35. Food K, administration d. Korean Herbal Pharmacopoeia: Korea food and drug administration; 2003. [Available from: <https://www.mfds.go.kr/eng/> (Retrieved on S 2025 April 25)]
36. Benedec D, Oniga I, Hanganu D. Medicinal Herbs in Romanian Pharmacopoeias - 155 Years of History. *Hop and Medicinal Plants*. 2017;XXV(1-2).
37. Etkin NL. A Hausa herbal pharmacopoeia: biomedical evaluation of commonly used plant medicines. *Journal of ethnopharmacology*. 1981;4(1):75-98.
38. Evbuomwan IO, Stephen Adeyemi O, Oluba OM. Indigenous medicinal plants used in folk medicine for malaria treatment in Kwara State, Nigeria: an ethnobotanical study. *BMC Complementary Medicine and Therapies*. 2023;23(1):324.
39. Pharmacopoeiae IH. Indian Drug Manufacturers Association (IDMA). Food and Drug Administration of Maharashtra, Mumbai. 2002. [Available from: <https://www.scirp.org/> (Retrieved on 2025 May 21)]
40. The Ayurvedic Formulary of India, Part I, second ed. New Delhi: Ministry of Health and Family Welfare, Dept. of AYUSH, Government of India, 2003 [Available from: <https://pcimh.gov.in> (Retrieved on 2025 June 20)]
41. The Ayurvedic Formulary of India, Part II. New Delhi: Ministry of Health and Family Welfare, Dept. of AYUSH, Government of India; 2000. [Available from: <https://pcimh.gov.in> (Retrieved on 2025 June 20)]
42. Pharmacopoeia Commission for Indian Medicine & Homoeopathy, Ayurveda Pharmacopoeial publication. Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH). Government of India. 2024 [. Available from: <https://pcimh.gov.in/cite>. Retrieved on 2025 July 15]
43. Blumenthal M. The complete German Commission E monographs. Therapeutic guide to herbal medicines. 1999. [Available from: <https://www.herbalgram.org/resources/commission-e-monographs/> (Retrieved on 15 May 2025)]
44. Gustafson, C., Mark Blumenthal: Quality and Efficacy of Herbal Medicines. *Integrative Medicine: A Clinician's Journal*. 2015;14(4):54.
45. Teng L, Zu Q, Li G, Yu T, Job KM, Yang X, et al. Herbal medicines: challenges in the modern world. Part 3. China and Japan. *Expert review of clinical pharmacology*. 2016;9(9):1225-33.
46. Shikov AN, Pozharitskaya ON, Makarov VG, Wagner H, Verpoorte R, Heinrich M. Medicinal plants of the Russian Pharmacopoeia; their history and applications. *Journal of ethnopharmacology*. 2014;154(3):481-536.
47. Shikov AN, Tsitsilin AN, Pozharitskaya ON, Makarov VG, Heinrich M. Traditional and current food use of wild plants listed in the Russian Pharmacopoeia. *Frontiers in pharmacology*. 2017;8:841.

49. Tan TYC, Lee JC, Yusof NAM, Teh BP, Mohamed AFS. Malaysian herbal monograph development and challenges. *Journal of Herbal Medicine*. 2020;23:100380.
50. Rosmarinus Spenn S. Egyptian Herbal Monograph.[Available from:<https://www.edaegypt.gov.eg/media/q2kblr3n/salvia-rosmarinus-spenn.pdf> (Retrieved on 2025 June 14)
51. Bandaranayake W, Ahmad I. Modern phytomedicine: turning medicinal plants into drugs. WILEY-VCH, Weinheim. 2006;1:25-57.
52. Mukherjee PK, Wahile A. Integrated approaches towards drug development from Ayurveda and other Indian systems of medicine. *J Ethnopharmacol*. 2006;103(1):25-35.
53. Nishteswar K. Depleting medicinal plant resources: A threat for the survival of Ayurveda. *Ayu*. 2014;35(4):349-50.
54. Sharma S. Current status of herbal product: Regulatory overview. *J Pharm Bioallied Sci*. 2015;7(4):293-6.
55. Calixto J. Efficacy, safety, quality control, marketing and regulatory guidelines for herbal medicines (phytotherapeutic agents). *Brazilian Journal of medical and Biological research*. 2000;33:179-89.
56. Organisation WH. National policy on traditional medicine and regulation of herbal medicines: a WHO global survey report. Geneva: World Health Organisation; 2005.[Available from: <https://www.who.int/publications/i/item/9241593237> (Retrieved on 2025 June 10)
57. RH RU. Traditional herbal medicine, pharmacognosy, and pharmacopoeial standards: a discussion at the crossroads. Evidence-based validation of herbal medicine: Elsevier; 2015. p. 45-85.
58. Organisation WH. WHO Monographs on Selected Medicinal Plants. 1999. [Available from: https://downloads.regulations.gov/FDA-2011-S-0933-0054/attachment_1.pdf (Retrieved on 2025 May 5)
59. Cartwright AC. The British pharmacopoeia, 1864 to 2014: medicines, international standards and the state: Routledge; 2016. [Available from: https://www.academia.edu/128582776/The_British_Pharmacopoeia_1864_to_2014_Medicines_International_Standards_and_the_State(Retrieved on 2025 April 27)
60. Directive E. 24/EC of the European parliament and the council. *Official Journal of the European Union*. 2006;105(54):2006.
61. Commission E. Herbal Medicinal Products: European Commission; 2018 [updated April 15, 2019. Available from: https://ec.europa.eu/health/human_use/herbal-medicines_en. (Retrieved on 2025 May 21)
62. Williams RL, Team P, Staff U. Official USP Reference Standards: Metrology concepts, overview, scientific issues and opportunities. *Journal of pharmaceutical and biomedical analysis*. 2006;40(1):3-15.
63. Kim N, Oketch-R H, Wu W, Ma C, Giancaspro G, Sharaf M. Herbal Medicines Compendium—A New Initiative from USP for Global Herbal Standards. *Planta Medica*. 2013;79(10):CL10.
64. Patwardhan B, Wieland LS, Aginam O, Chuthaputti A, Ghelman R, Ghods R, et al. Evidence-Based Traditional Medicine for Transforming Global Health and Well-Being. *Journal of Integrative and Complementary Medicine*. 2023;29(9):527-30.
65. Hoenders R, Ghelman R, Portella C, Simmons S, Locke A, Cramer H, et al. A review of the WHO strategy on traditional, complementary, and integrative medicine from the perspective of academic consortia for integrative medicine and health. *Frontiers in medicine*. 2024;11:1395698.
66. Government of India, MoHaFW, Department of AYUSH. Tagara (Valeriana wallichii DC). The Ayurvedic Pharmacopoeia of India. Volume I. New Delhi Controller of Publications; 1990. p. 109–10.
67. Medicines EDfTQo, HealthCare. European Pharmacopoeia. The editor. Strasbourg: Council of Europe; 2020. [https://www.edqm.eu/en/\(cited 2025 July 26\)](https://www.edqm.eu/en/(cited%2025%20July%2026))
68. Convention USP. United States Pharmacopoeia and National Formulary (USP 43–NF 38). Rockville, MD: United States Pharmacopoeial Convention; 2020. [Available from: <http://182.160.97.198:8080/xmlui/handle/123456789/1493>(Retrieved on June 20)
69. Organisation WH. Radix Valerianae. In: Organisation WH, editor. WHO monographs on selected medicinal plants: . Volume 1. Geneva: World Health Organisation; 1999. p. 267–76.
70. Commission IP. Indian Pharmacopoeia 2018. Ghaziabad: Ministry of Health & Family Welfare, Government of India; 2018. [Available from: <https://www.ipc.gov.in/>(Retrieved on 2025 May 23)
71. Commission BP. British Pharmacopoeia 2020. London: The Stationery Office; 2020. [Available from: <https://www.webofpharma.com/2021/02/british-pharmacopoeia-2020-bp-2020.html>(Retrieved on 2025 July 28)
72. Balekundri A, Mannur V. Quality control of the traditional herbs and herbal products: a review. *Future Journal of Pharmaceutical Sciences*. 2020;6(1):67.
73. Group PD. Pharmacopoeial Discussion Group welcomes the Indian Pharmacopoeia Commission as a member Hyderabad, India, 2023. [Available from: <https://www.pib.gov.in/> (Retrieved on 2025 June 28)
74. Use ICfHoTRfPfH. ICH Q4B: Evaluation and recommendation of pharmacopoeial texts for use in the ICH regions Geneva2010 [Available from: <https://www.ema.europa.eu/en/ich-q4b-evaluation-recommendation-pharmacopoeial-texts-use-ich-regions-scientific-guideline>. (Retrieved on 2025 July 20)
75. Organisation WH. WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-second report. WHO Technical Report Series, No. 1013 Geneva, 2018 [Available from: <https://apps.who.int/iris/bitstream/handle/10665/272452/9789241210195-eng.pdf>(Retrieved on 2025 May 16)
