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PHARMACOVIGILANCE IN AYURVEDA

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ABSTRACT

The field of pharmacovigilance in Ayurveda is at a pivotal juncture, balancing the ancient principles of holistic healing with the demands of modern safety surveillance. This abstract provides a comprehensive overview of the present status and future trajectories of pharmacovigilance in Ayurveda, shedding light on the challenges faced and the innovations required for enhanced patient safety. Presently, Ayurvedic pharmacovigilance involves a dynamic interplay between traditional wisdom and contemporary methodologies. The abstract delves into the current practices, emphasizing the integration of Ayurvedic principles into the framework of adverse event reporting and monitoring. Looking ahead, it envisions the future of Ayurvedic pharmacovigilance with a focus on technological advancements and interdisciplinary collaboration. In conclusion, we tried to provide a panoramic view of the evolving landscape of pharmacovigilance in Ayurveda, weaving together the threads of tradition and innovation to safeguard patient well-being in the present and the future.

KEYWORDS – *Pharmacovigilance, Ayurveda, Ayurvedic Drugs,*

INTRODUCTION

Pharmacovigilance is the scientific discipline focused on minimizing the potential harm from drug-related risks to patients. This involves the establishment of a reporting mechanism for adverse events linked to drug usage. Ayurveda, an ancient body of knowledge encapsulated in graceful Sanskrit verses within the samhitas, details the diagnosis, treatment of diseases, and strategies for maintaining overall well-being. While the term "Pharmacovigilance" is absent from Ayurvedic texts, the ethos of vigilant drug monitoring resonates strongly and is consistently underscored in major Ayurvedic scriptures. The primary objectives of pharmacovigilance, focusing on enhancing patient care, ensuring drug safety, and promoting rational drug use, are recurring themes within Ayurvedic pharmacology (dravyaguna vigyan) and therapeutics (chikitsa). The popularity of Ayurvedic medicines is on the rise, not only in India but also gaining acceptance in other nations. This growing usage has given rise to concerns regarding the safety of Ayurvedic medications.

Through this essay, we will explore Ayurvedic perspectives on adverse reactions to medicines, emphasizing the imperative need for pharmacovigilance in Ayurvedic practices. It delves into the challenges associated with introducing pharmacovigilance in Ayurveda, considering the need for adaptation of traditional concepts to meet modern standards. The discourse also presents recommendations for the successful implementation of pharmacovigilance activities, emphasizing collaboration between traditional and modern healthcare practitioners, public awareness initiatives, and the establishment of standardized reporting protocols. In essence, as Ayurvedic medicines gain global prominence, the incorporation of vigilant monitoring practices is crucial to address safety concerns effectively within the Ayurvedic healthcare system.

What is Pharmacovigilance?

Pharmacovigilance is defined as the ***detection, assessment*** *and* ***prevention*** of adverse drug reactions in humans.[1] Pharmacovigilance is the process of-

(a) Monitoring medicines as used in everyday practice to identify previously unrecognized adverse effects or changes in the pattern of their adverse effects.

(b) Assessing the risks and benefits of medicines in order to determine what action, if any, necessary to improve their safe use.

(c) Providing the information to users to optimise safe and effective use of ASU medicines

d) Monitoring the impact of any action taken.

National Pharmacovigilance Programme for Ayurvedic Drugs[2]

The global movement towards enhancing patient safety has gained momentum, underscoring the increasing significance of drug safety in today's context. Within the context of Ayurveda, Siddha, and Unani (ASU), the heightened usage of drugs from these systems has amplified the risk of adulteration, counterfeit drug production, and the formulation of products that lack a conceptual basis in the ASU system. Additionally, there is a growing trend of cultivating medicinal plants based on laboratory-generated species, relying on chemical composition, and intended for regular commercial use. These shifts pose potential profound impacts on the safety and efficacy of ASU drugs in the market. Consequently, there is a need for a robust

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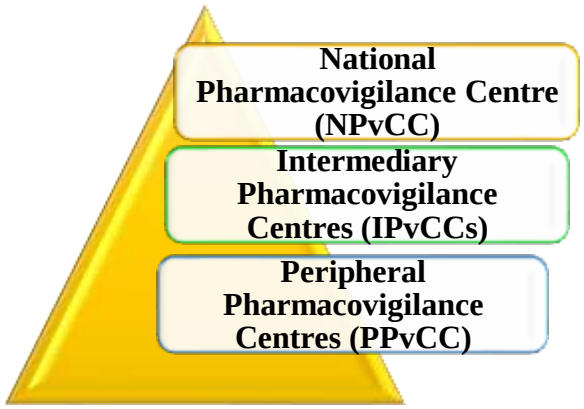
mechanism to address these challenges, leading to the establishment of a pharmacovigilance framework for ASU drugs in India. Despite having their own principles and pharmacopoeia, ASU medicines are often practiced in the country as over-the-counter drugs without the requirement of an authentic prescription.

In India, the National Pharmacovigilance Programme, overseen by the Central Drug Standard Control Organization (CDSCO), has been operational since 2003. Recognizing the importance of incorporating traditional medicine into the pharmacovigilance system, the World Health Organization (WHO) issued guidelines on the safety monitoring of herbal medicine in 2004. Acknowledging the significance of pharmacovigilance, the Institute for Post Graduate Teaching and Research in Ayurveda (IPGT & RA) in Jamnagar conducted a two-day workshop on December 3 & 4, 2007, titled 'Pharmacovigilance for Ayurvedic Drugs.' This workshop, funded by the WHO country office for India in New Delhi, led to the establishment of a Pharmacovigilance Cell (PV cell). Following workshop recommendations, a reporting form for suspected adverse reactions of Ayurvedic formulations was developed, distributed to faculty members, research scholars, and physicians, with notifications sent to the Department of AYUSH, Ministry of Health & Family Welfare, Government of India.

The coordination of the National Pharmacovigilance Programme for Ayurveda, Siddha, and Unani (ASU) drugs is facilitated by the National Pharmacovigilance Resource Centre (NPRC) for ASU drugs. This center aims to establish and manage a comprehensive database of adverse drug reactions (ADR) to inform consistent regulatory decisions concerning drug marketing authorization in India, ultimately ensuring drug safety. The inaugural national consultative meeting for the National Pharmacovigilance Programme for ASU drugs took place on August 29 & 30, 2008, in New Delhi, organized by the Department of Ayush, MOHFW. Sponsored by WHO, this meeting involved the technical review and finalization of the draft protocol. The National Pharmacovigilance Programme for ASU drugs also published a glossary of terms, including adverse events, side effects, adverse reactions, serious adverse reactions, and unexpected adverse reactions.

Central Sector Scheme of Pharmacovigilance of ASU&H Drugs[3] - The Ministry of AYUSH has launched a new Central Sector initiative aimed at promoting pharmacovigilance for Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) drugs. The primary goal of the scheme is to foster a culture of recording adverse effects, conducting safety monitoring for Ayurveda, Siddha, Unani, and Homoeopathy drugs, and overseeing misleading advertisements in both print and electronic media.

This initiative envisions the establishment of a three-tier network comprising the National Pharmacovigilance Centre (NPVCC), Intermediary Pharmacovigilance Centres (IPVCCs), and Peripheral Pharmacovigilance Centres (PPVCC).



In the initial phase of implementation, five National Institutes of AYUSH have been assigned roles as Intermediary Pharmacovigilance Centres, and forty-two AYUSH institutions equipped with clinical facilities are designated as Peripheral Pharmacovigilance Centres across India. The plan is to expand this network, aiming to establish over 100 peripheral pharmacovigilance centres in the coming years. The initiative involves collaboration with representatives from the Central Drug Standards Control Organisation, serving as the national drug regulatory authority, and the Indian Pharmacopoeia Commission, which acts as the WHO Collaborating Centre for Pharmacovigilance in the country, providing mentorship and guidance.

It's important to recognize that pharmacovigilance goes beyond spontaneous reporting, and the assessment of medicines extends beyond pharmacovigilance. This field encompasses the identification and reporting of adverse drug reactions (ADRs), constituting a broader framework for the comprehensive evaluation of medicines.
The World Health Organization (WHO) defines Adverse Drug Reaction (ADR) as an unintended, noxious response to a drug occurring at doses typically used for prophylaxis, diagnosis, therapy, or modification of physiological functions. Pharmacovigilance, also defined by the WHO, is characterized as a scientific discipline involving activities related to the detection, assessment, understanding, and prevention of adverse effects or other drug-related issues.

A prevailing misconception surrounding herbal medicines is the belief in their complete safety, leading individuals to self-medicate without a physician's prescription. This widespread practice has resulted in unfavourable outcomes, side effects, or undesired aftereffects. Consequently, AYUSH practitioners and consumers must now prioritize vigilance in monitoring drug safety for the benefit of public health.

The pharmacovigilance initiative aims to identify potentially unsafe ASU&H medicines and misleading advertisements, enabling regulatory measures to be taken against them. The scheme received approval from the Standing Finance Committee (SFC), chaired by the Secretary (AYUSH), on November 1, 2017, and it was subsequently implemented nationwide towards the conclusion of the financial year 2017-18.

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Aims & Objectives

- The pharmacovigilance program aims to bridge the divide between the potential and the actual outcomes of Ayurvedic drugs.
- The programme aims to keep the data of adverse drug reactions of herbal, mineral and metallic products.
- To engage health care professionals and the public at large, in a well structured programme to build synergies for monitoring adverse drug reactions of ASU medicines.
- To collect and collate data, analyse it and use the interferences to recommend informed regulatory interventions besides communicating risk to health care professionals and public.

The objectives of the national pharmacovigilance program for ASU (Ayurveda, Siddha, and Unani) drugs can be categorized into three timelines:

1. Short term objectives involve cultivating a culture of notification.
2. Medium-term objectives aim to engage healthcare professionals and professional associations in the monitoring of drugs and the dissemination of information.
3. Long-term objectives aspire to attain operational efficiencies that position the national pharmacovigilance program for Ayurvedic drugs as a global benchmark for drug monitoring efforts.

Frame work for Pharmacovigilance for Ayurvedic Drugs

The responsibility of coordinating a nationwide pharmacovigilance program for ASU drugs falls under the purview of the National Pharmacovigilance Resource Centre, overseen by the Department of AYUSH, Ministry of Health and Family Welfare, Government of India. This program is centrally managed at the Institute for Post Graduate Teaching & Research in Ayurveda (IPGT & RA) in Jamnagar, Gujarat, India. Under the guidance of the National Pharmacovigilance Technical Advisory Committee (NPTAC), the national pharmacovigilance program for ASU drugs is directed to recommend regulatory interventions by establishing procedures and guidelines.

The programme would comprise of the following steps-

(1) Step 1- Identifying the various centres across the country for recording ADR related data.

(2) Step 2- An induction training programme shall be arranged for healthcare professionals participating in the NPP for ASU drugs.

Intensive interactions/training sessions will be organized for all participants to

- Define individual and team roles and responsibilities clearly.
- Establish operational benchmarks.
- Develop Standard Operating Procedures (SOPs) for the capture, generation, and forwarding of Adverse Drug Reaction (ADR) data.

i. Acquire effective communication skills to extract information related to Adverse Drug Reactions (ADRs).
ii. Receive hands-on training for the accurate recording of ADR information.
iii. Attain skills for meticulous collation and ensuring data completeness.
iv. Promote a culture of notification through effective communication.

As per the provision of this programme any healthcare professional may report the suspected adverse drug event, but not from the layman or other person than the health care professional. The reporting should be submitted in the prescribed format to the pharmacovigilance centre. Confidentiality is assured through this programme.

What to Report

(i) All adverse reactions suspected to have been caused by Ayurvedic drugs alone or along with any other drugs.
(ii) All suspected drug interactions.
(iii) Reactions to any other drugs which are suspected of significantly affecting a patient's management, including reactions suspected of causing:

- Hospitalization (initial or prolonged)
- Death
- Required intervention to prevent permanent damage
- Life threatening (real risk of dying)
- Disability (Significant, persistent or permanent)
- Congenital anomaly

Ayurvedic View on ADR

A prevalent misconception suggests that Ayurvedic medicines are immune to adverse reactions. However, the classic Ayurvedic text, the Charaka Samhita, refutes this notion by meticulously detailing potential adverse reactions resulting from improper preparation or usage of medicines. The text emphasizes various factors, including the physical characteristics of the plant part (prakriti), its properties (guna), actions (karma; prabhava), habitat (desh), growth season (ritu), harvesting conditions (grahitam), storage method (nihitam), and pharmaceutical processing (upaskritam). These factors must be considered during the selection of starting materials for medicine.

Similarly, Maharishi Charaka elegantly outlines several patient-related considerations aimed at minimizing adverse reactions. These factors include the patient's constitution (prakriti), age (vayam), current health status (vikruti), tolerance based on previous exposure (satmya), psychological state (satwa), digestive capacity (ahara-shakti), exercise capacity (vyayama shakti), tissue quality (Sara), physical proportions of the body (sahanan), and strength (bala).[4]

Notably, classical Ayurveda recommends the use of metals and minerals as medicines, either as bhasmas (incinerated mineral formulations) or in combination with plants as herbo-mineral formulations (e.g., Chanderprabha Vati or Ekangveer Rasa). Strict manufacturing procedures are prescribed for these medicines, and the text describes adverse reactions that may occur when precautions are neglected during their production and administration. Despite their widespread use in India, concerns about the long-term safety of these medicines arise due to the presence of heavy metals[5], leading to reported instances of adverse reactions.

" यथा विषं यथा शस्त्रं यथाऽग्निरशनिर्यथा|
तथौषधमविज्ञातं विज्ञातममृतं यथा||१२४||" Ch.Sa. Sutra Sthana 1st Chapter

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Use of a drug which is equivalent to "Amruta" that is not understood perfectly may work as poison, weapon, fire or a "bolt of thunder"

"योगादपि विषं तीक्ष्णमुत्तमं भेषजं भवेत्|
भेषजं चापि दुर्युक्तं तीक्ष्णं सम्पद्यते विषम्||१२६||" Ch.Sa. Sutra Sthana 1st Chapter

Maharishi Charaka underscores the importance of proper administration, stating that even a potent poison can become an excellent medicine when handled correctly, while even the most beneficial drug can act as a poison if mishandled.[6]

Need of Pharmacovigilance for Ayurvedic Medicines

In ancient times, Ayurvedic physicians personally prepared medicines for their patients, but in contemporary times, this practice has changed, giving rise to a formalized industry for the production and sale of Ayurvedic drugs. The manufacturing and marketing of these drugs fall under the regulatory purview of the Drugs and Cosmetics Act of 1940. Ayurvedic medicines available in the market can be broadly categorized into classical formulations adhering to Ayurvedic samhitas descriptions (e.g., Kukkutanda twak Bhasma, Rasnadi Guggalu, Dashamoolarishta etc.) and patented or proprietary formulations made from herb extracts.

As per the research report on Ayush Sector by Forum on Indian Traditional Medicine (FITM) under Research and Information System for Developing Countries (RIS), the market size of Ayush industry is US$ 18.1 billion (INR 1,49,451 Crore as per current INR-Dollar rate)[7], constituting nearly a third of India's total pharmaceutical business, commercialization has brought forth challenges regarding the safe use of Ayurvedic medicines. This underscores the necessity for formalized pharmacovigilance programs in the field.

The number of reported adverse reactions to Ayurvedic drugs in the National Pharmacovigilance Program in India remains minimal. This can be attributed largely to the prevailing belief in the safety of Ayurvedic medicines. Additionally, the lack of awareness among Ayurvedic practitioners about the concept and significance of pharmacovigilance further contributes to this situation.

PRESENT CHALLENGE

Numerous obstacles hinder the recognition and reporting of adverse reactions to Ayurvedic drugs, encompassing issues in the detection, assessment, and prevention of such reactions.

1. Detection

The robust conviction among both doctors and prescribers that Ayurvedic drugs are inherently safe poses a significant challenge in detecting adverse reactions to these medicines. The path from obtaining an accurate medical history to diagnosis and pinpointing the causative medicine is laden with obstacles, including:

- The absence of coverage on concepts and terminologies related to adverse reaction monitoring in the Ayurvedic curriculum hampers the precise identification of adverse reactions.
- Inadequate evolution of methods for studying drug safety problems within Ayurveda poses a further challenge.
- Although information about medicines exists in ancient Ayurvedic treatises, accessing this information is not straightforward.
- Signal detection proves challenging due to the ingrained belief in the safety of Ayurvedic medications, resulting in underreporting and a lack of data collection on any formulation.
- Patients often simultaneously use medicines from various medical systems, complicating the assignment of causality.
- The absence of quality assurance and control in the manufacturing of Ayurvedic medicine adds a complicating factor to diagnosing adverse reactions.

2. Assessment

Assessing causality for Ayurvedic medicines poses a formidable challenge, primarily due to several reasons:

- Information on adverse effects is dispersed in Ayurvedic literature and lacks electronic accessibility, complicating the retrieval process. Many publications are not peer-reviewed, and their quality is questionable.
- The majority of Ayurvedic formulations are complex, multi-ingredient fixed-dose combinations seldom prescribed in isolation. Patients often concurrently consume multiple herbal and herbo-mineral formulations.
- The presence of a confounding factor arises from patients simultaneously taking allopathic medicines.
- Pharmacokinetics and toxicokinetic are exceptionally challenging, currently approaching near impossibility, making definitive causality determination extremely difficult.
- Dose-related responses are infrequently measured and reported.
- De-challenge and re-challenge procedures are rarely, if ever, performed, and there is a lack of objective evidence supporting the adverse event.
- A significant challenge lies in the scarcity of expertise in conducting causality analysis for Ayurvedic medicines. Individuals trained in pharmacovigilance often lack understanding of Ayurveda, while experts in Ayurveda may lack training in the science of pharmacovigilance.

3. Prevention

The effectiveness of any pharmacovigilance system lies in its capacity to successfully prevent further adverse reactions

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through the comprehension and utilization of collected information. However, in the case of Ayurvedic medicines, challenges arise at various levels:

- The availability of Ayurvedic medicines is unparalleled in India, with numerous books describing different formulations and containing over 100,000 formulations. The vast informal sector adds complexity to determining which medicines should be included in the pharmacovigilance system.
- Inadequate communication exists between practitioners of conventional Western medicine and traditional Indian medicine.
- In India, the current National Pharmacovigilance Program (NPVP) does not encompass Ayurveda, leading to a lack of awareness among Ayurvedic practitioners about the necessity and procedures for reporting adverse reactions.
- Access to unbiased drug information about Ayurvedic drugs, encompassing both classical and proprietary formulations, is not readily available.
- Patients lack sufficient awareness that Ayurvedic medicines can cause adverse reactions, and they may use these medicines for extended periods without monitoring, assuming their inherent safety. Consequently, patients may not disclose their use of these medicines in their medical history.
- Education in Ayurveda or modern medicine, at both undergraduate and postgraduate levels, neglects the topic of pharmacovigilance for Ayurvedic medicines, leaving young physicians uninformed about this crucial concept.
- The Ayurvedic pharmaceutical industry lacks motivation to prioritize pharmacovigilance for Ayurvedic medicines, resulting in a lack of efforts to generate safety data, both before and after the marketing of formulations.

Solutions to Further Strengthen Pharmacovigilance In Ayurveda

- Incorporate pharmacovigilance principles into the curriculum of Ayurveda at both the undergraduate and postgraduate levels.
- Promote research initiatives focusing on drug safety within the Ayurvedic domain.
- Mandate the reporting of adverse reactions to regulatory authorities for Ayurvedic formulations.
- Facilitate the availability of unbiased and easily accessible drug information, exemplified by initiatives like the Traditional Knowledge Digital Library[8] launched by the Government of India, showcasing how ancient knowledge can be digitally accessible.
- Raise awareness about the science of pharmacovigilance among Ayurvedic physicians, patients, and paramedical staff.
- Develop and validate scales for assessing the causality of reported reactions to Ayurvedic medicines.
- Encouraging the direct participation of Ayurvedic academic institutions in programs like the National Pharmacovigilance Program (NPVP) after suitable training represents an initial step in this direction.
- Training programmes and interaction meetings shall be held every 6 months after the initial training besides continuous communication through emails, carrying relevant information related to ADR monitoring methods to be maintained among the participating centres.
- A collaborative effort between experts in pharmacovigilance and Ayurveda ensures the effective implementation of this system.
- Enhancing pharmacovigilance in Ayurveda requires a multifaceted approach. Here are potential solutions to strengthen pharmacovigilance in Ayurveda:
- Promote communication and collaboration between practitioners of Ayurveda and Western medicine.
- Engage in international collaborations for sharing pharmacovigilance insights and best practices.
- Align Ayurvedic pharmacovigilance standards with global standards.
- Integration of Technology - Develop a dedicated mobile application for reporting adverse reactions to Ayurvedic medicines. This can streamline the reporting process and make it more accessible to both healthcare professionals and patients.
- Establish community-based pharmacovigilance programs that involve local communities in monitoring and reporting adverse reactions. This could enhance awareness at the grassroots level.
- Implement a crowdsourced monitoring system where individuals can voluntarily contribute their experiences with Ayurvedic medicines. This can provide real-time data and valuable insights.
- Create a centralized research hub specifically dedicated to pharmacovigilance in Ayurveda. This hub can serve as a repository for research findings, analysis, and advancements in the field.
- Launch initiatives to empower patients with information about the medicines they are taking. This can include patient education programs, informational pamphlets, and online resources.
- Organize workshops that bring together experts from Ayurveda, modern medicine, and pharmacovigilance. These workshops can facilitate cross-disciplinary discussions and foster collaboration.
- Involve traditional healers and practitioners from local communities in pharmacovigilance efforts. Their insights and experiences can contribute to a more comprehensive understanding of adverse reactions.
- Utilize social media platforms for pharmacovigilance monitoring. Create dedicated groups or pages where individuals can share their experiences and report any adverse reactions.
- Develop a safety rating system for Ayurvedic medicines, similar to the way pharmaceuticals are rated. This can guide both practitioners and patients in making informed choices.
- Introduce gamification elements in the reporting process to encourage more active participation.

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Individuals could earn rewards or recognition for contributing to pharmacovigilance.

- Launch national and regional campaigns specifically focused on Ayurveda safety. These campaigns can include TV and radio advertisements, as well as collaborations with influencers in the health and wellness space.
- Establish collaborations with other countries practicing traditional medicine systems to share best practices and collectively work towards global pharmacovigilance standards.
- These innovative ideas aim to leverage technology, community engagement, and collaborative efforts to enhance the effectiveness of pharmacovigilance in Ayurveda.

  By implementing these solutions, there is a potential to create a robust pharmacovigilance framework for Ayurveda, ensuring the safety and well-being of individuals who use traditional medicines.

CONCLUSION

The present state of pharmacovigilance in Ayurveda reflects a crucial need for heightened awareness, integration of reporting mechanisms, and systematic monitoring of adverse reactions associated with traditional medicines. The challenges, such as the lack of communication between different medical systems, insufficient education on pharmacovigilance, and the belief in the inherent safety of Ayurvedic medicines, underscore the urgency for comprehensive reforms. The incorporation of pharmacovigilance concepts into Ayurvedic education, encouraging research on drug safety, and making reporting mandatory are vital steps. The dissemination of unbiased drug information, coupled with the development of standardized scales for causality assessment, will contribute to a more robust and transparent pharmacovigilance framework. Human resource development, involving the training of Ayurvedic experts, and fostering collaboration between pharmacovigilance professionals and Ayurvedic practitioners, are pivotal for the success of these endeavours. As we navigate the future of pharmacovigilance in Ayurveda, the collective efforts of stakeholders can pave the way for a safer and more accountable healthcare landscape, ensuring the well-being of patients and fostering confidence in the use of Ayurvedic medicines.

Moreover, pharmacovigilance contributes to the overall credibility and trust in Ayurvedic medicine across globe for its globalisation. By proactively identifying and mitigating potential risks, the program helps to enhance the reputation of Ayurveda as a reliable and safe healthcare option. Looking to the future, the pharmacovigilance program holds the promise of continual improvement and refinement of Ayurvedic practices. It encourages a culture of responsible use, informed decision-making, and ongoing learning within the Ayurvedic community. As the program evolves, it is expected to contribute not only to the safety of Ayurvedic drugs but also to the advancement and modernization of Ayurveda as a whole, ensuring that it remains relevant, effective, and in harmony with contemporary healthcare standards.

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