International Journal of Environmental & Agriculture Research (IJOEAR)
ISSN: [2454-1850]
[Vol-12, Issue-3, March- 2026]
Website: www.ijoear.com
Journal DOI: 10.25125/agriculture-journal

Biotechnology-Driven Advances in Herbal Medicine and Natural Drug Discovery- A Review

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Received:- 12 March 2026/ Revised:- 20 March 2026/ Accepted:- 28 March 2026/ Published: 05-04-2026

Abstract— *Herbal medicine has served as a cornerstone of healthcare for thousands of years, with plant-derived remedies forming the basis of many traditional healing systems worldwide. Even today, a significant proportion of the global population relies on medicinal plants for primary healthcare, and nearly 25% of modern pharmaceuticals originate directly or indirectly from plant compounds. The growing demand for natural therapeutics, combined with the limitations of synthetic drugs, has renewed global interest in herbal medicine. However, challenges such as variability in plant composition, lack of scientific validation, and limited regulatory frameworks have restricted its broader integration into modern healthcare systems. Advances in biotechnology are playing a crucial role in overcoming these limitations by enabling the identification, characterization, and large-scale production of bioactive compounds from medicinal plants. Modern tools such as genomics, transcriptomics, and metabolomics provide deeper insights into metabolic pathways responsible for therapeutic compounds, thereby facilitating drug discovery and standardization of herbal products. Biotechnological techniques including DNA barcoding, chromatographic analysis, chemometrics, and Good Manufacturing Practices (GMP) ensure authenticity, quality control, and safety of herbal formulations. Furthermore, plant tissue culture technologies allow sustainable production of valuable secondary metabolites, reducing pressure on endangered medicinal plant species. Emerging approaches such as pharmacogenomics and personalized medicine are further enhancing the potential of plant-based therapeutics by tailoring treatments according to individual genetic profiles. In addition, bioassays and cell-based assays provide scientific validation of herbal extracts by evaluating their pharmacological activity at the cellular and molecular levels. Overall, the integration of traditional herbal knowledge with modern biotechnological tools offers a promising pathway for the development of safe, effective, and standardized plant-based medicines. Such interdisciplinary approaches will play a vital role in advancing herbal therapeutics and strengthening their contribution to future global healthcare systems.*

Keywords— Herbal medicine; Medicinal plants; Biotechnology; Bioactive compounds; Genomics; Transcriptomics; Metabolomics; Pharmacogenomics; Secondary metabolites; Tissue culture; Drug discovery; Personalized medicine; Quality control; Bioassays.

I. INTRODUCTION

Throughout history, plants have served as a foundation for healing practices in many cultures. According to the World Health Organization, herbs are crude plant materials such as leaves, roots, flowers, seeds, or bark—utilized in their natural or processed forms. Herbal medicine extends beyond this, encompassing raw herbs, formulations, and finished products derived from plants. In modern times, these remedies are recognized not only as traditional options but also as an essential component of global healthcare systems.

1.1 Historical Evolution:

The evolution of herbal medicine stretches back thousands of years, illustrating humanity's deep dependence on plants for healing across civilizations. The earliest recorded evidence appears around 3000 BCE in Mesopotamia, where clay tablets documented herbs like thyme and opium for medicinal use. In China, the Shennong Ben Cao Jing (circa 2700 BCE) emerged as the first known pharmacopoeia, while in Egypt, the Ebers Papyrus (around 1500 BCE) described over 700 therapeutic plants, including aloe and garlic. By 1000 BCE, India had developed a systematic body of knowledge in Ayurveda, compiled in classical texts such as the Charaka Samhita and Sushruta Samhita, which remain cornerstones of traditional Indian medicine.

During the Classical period, further advances were made: Hippocrates in Greece (~400 BCE) highlighted the medicinal value of plants, and in Rome, Dioscorides authored De Materia Medica (~77 CE), a work that shaped Western herbal traditions for centuries. The Medieval era (8th–12th century) saw Islamic scholars like Avicenna expand herbal knowledge in the Canon of Medicine, while European monasteries preserved plant remedies through handwritten manuscripts. The Renaissance and Early Modern periods (15th–17th century) witnessed rapid growth in herbal literature with the invention of the printing press, making works such as Culpeper's The English Physician (1653) widely accessible. The Modern Age marked a scientific turn: in the 19th century, bioactive compounds such as morphine (derived from opium) and quinine (from cinchona bark) were first isolated, paving the way for pharmacognosy, which became established in the 20th century. In the present day, the 21st century, herbal medicine has secured a place within complementary and alternative medicine (CAM). Endorsed by the World Health Organization, it continues to play a vital role in healthcare worldwide, reflecting its lasting significance.

1.2 The Herbal Medicine Market:

India's herbal medicine market has been experiencing remarkable expansion, fueled by growing consumer preference for natural remedies, heightened awareness of preventive healthcare, and strong governmental promotion of Ayurveda, Yoga, Unani, Siddha, and Homeopathy (AYUSH). Data indicates a consistent rise in market value since 2018, with projections estimating it will approach USD 26.8 billion by 2030. This surge is supported by India's vast reservoir of medicinal plants, continuous improvements in herbal product development, and the blending of traditional healing systems with modern healthcare.

Globally, the herbal medicine sector reveals distinct regional patterns. The Asia-Pacific region dominates, owing to established traditions such as Ayurveda in India and Traditional Chinese Medicine in China, strengthened by biodiversity and supportive policies. Europe represents a mature market, particularly in Germany, France, and the UK, where high regulatory standards are maintained. North America, led by the United States, is expanding due to the rising popularity of supplements and preventive health practices. Latin America—most notably Brazil—presents growth opportunities driven by its rich plant diversity, while the Middle East and Africa are emerging markets with increasing adoption in nations like the UAE, Saudi Arabia, and South Africa. On the global scale, China, India, the U.S., Germany, and Brazil stand out as key contributors, collectively shaping the trajectory of herbal medicine worldwide.

1.3 Plant Diversity and Medicinal Value:

Out of nearly half a million plant species known worldwide, only about 5,000 have been systematically investigated for medicinal purposes. In many developing regions, up to 80% of the population still relies on herbal remedies as their primary healthcare option. Around 25% of modern pharmaceuticals are derived directly or indirectly from plant compounds. Notable examples include:

- **Cancer therapies:** Paclitaxel from *Taxus* (yew tree), vincristine from *Catharanthus roseus* (periwinkle), and etoposide from *Podophyllum* (mayapple)
- **Anti-inflammatory and protective agents:** Curcumin from turmeric and silymarin from milk thistle

1.4 Pathways to Society:

Herbal medicine reaches communities through multiple channels shaped by culture, tradition, and advances in modern science:

1) **Traditional Healers and Home Practices:** For generations, herbal knowledge has been transmitted orally within families and communities. Local practitioners such as Vaidyas, Hakims, shamans, and folk healers prepare remedies

from native plants. Examples include turmeric milk for colds, tulsi leaves for coughs, and neem paste for skin ailments. These remedies are affordable, trusted, and often the first recourse in rural or underserved areas.

2) **Structured Traditional Systems:** Over time, traditional healing evolved into organized systems with written principles and institutional support. Examples include Ayurveda (India), Unani (Middle East/India), Siddha (South India), and Traditional Chinese Medicine (China). Backed by hospitals, universities, and practitioners, these systems offer formal healthcare grounded in cultural heritage.

3) **Government and NGO Initiatives:** To harness the benefits of herbal medicine, governments and NGOs have launched policies and programs. Examples include India's Ministry of AYUSH and WHO's Traditional Medicine Strategy (2014–2023), which encourages regulation and inclusion of traditional medicine in health systems.

4) **Pharmaceutical and Biotech Industries:** Scientists isolate, test, and refine bioactive compounds from plants to create standardized medicines. Examples include Taxol (*Taxus brevifolia*) for cancer, artemisinin (*Artemisia annua*) for malaria, and digoxin (*Digitalis purpurea*) for heart disease.

5) **Commercial Wellness and Lifestyle Products:** Beyond formal medicine, herbs are widely marketed as wellness and lifestyle products, including functional foods and drinks (herbal teas, juices, nutraceuticals), supplements (ashwagandha, spirulina, ginseng capsules), cosmetics (aloe vera gels, neem-based skincare, turmeric creams), and wellness products (herbal oils, aromatherapy).

II. INDIA'S BIODIVERSITY HOTSPOTS AND MEDICINAL FLORA

India's biodiversity hotspots, particularly the Himalayan belt and the Indo-Burma region, are rich repositories of medicinal plants with significant therapeutic potential.

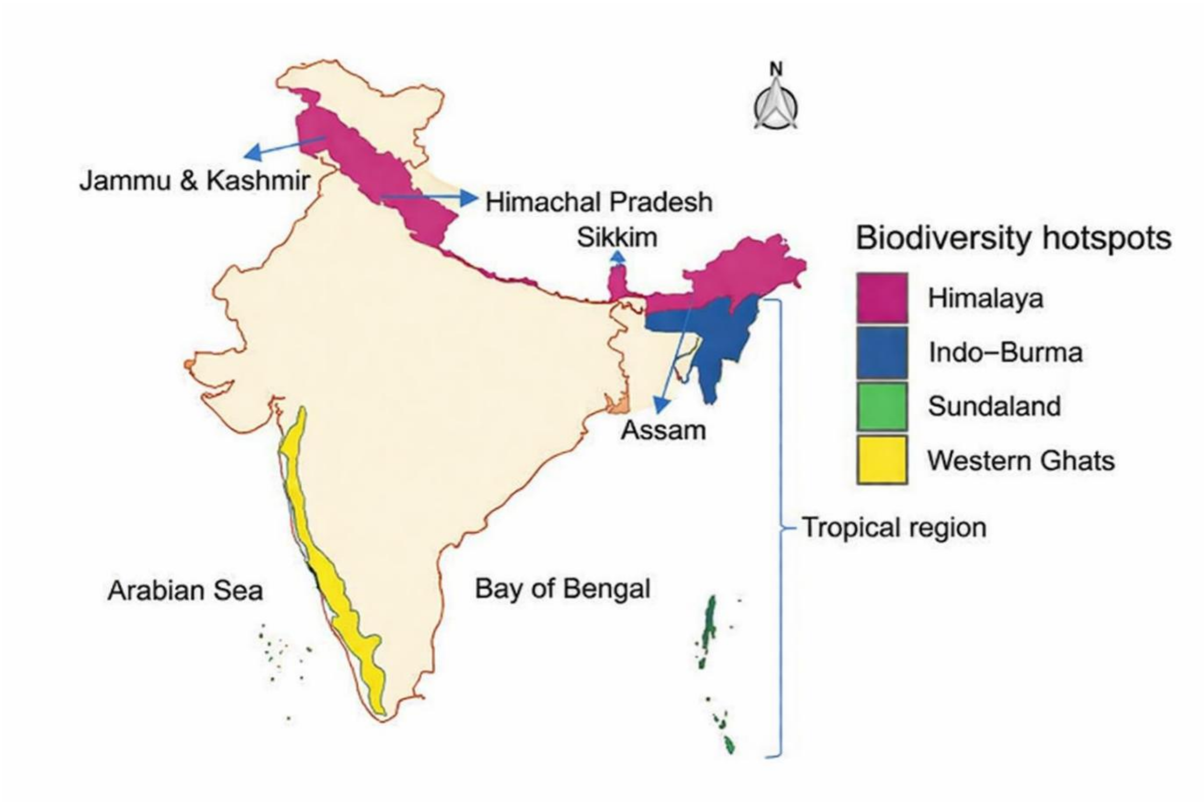

FIGURE 1: India's Biodiversity Hotspots

2.1 Himalayan Region:

Characterized by alpine and temperate vegetation, the Himalayas support numerous plants widely used in Ayurveda, Unani, and Tibetan medicine.

Aconitum (*Aconitum heterophyllum*, *Aconitum ferox*): Contains alkaloids such as aconitine and atisine. Administered in highly diluted, purified form for fever, diarrhea, and respiratory problems (caution: highly toxic if not processed properly).

Podophyllum hexandrum (Indian Podophyllum): Contains podophyllotoxin. A key source for anticancer drugs like etoposide and teniposide; also employed in treating warts and certain skin conditions.

Nardostachys jatamansi (Jatamansi): Contains sesquiterpenes such as jatamansone and nardostachone. Functions as a nervine tonic; traditionally used for insomnia, epilepsy, anxiety, and improving memory.

2.2 Indo-Burma Region (Northeast India & Andaman–Nicobar Islands):

Recognized as a global biodiversity hotspot, this region harbors rare and valuable medicinal species.

Taxus wallichiana (Himalayan Yew): Contains paclitaxel (Taxol). A powerful anticancer agent widely used in chemotherapy for ovarian, breast, and lung cancers.

Coptis teeta (Mishmi Teeta): Contains berberine (an isoquinoline alkaloid). Traditionally applied for diarrhea, dysentery, eye infections, and fever; also valued for its antimicrobial activity.

III. CHALLENGES FACING HERBAL MEDICINE

3.1 Limited Scientific Validation:

A major challenge facing herbal medicine is the shortage of rigorous scientific evaluation. Although herbs have been central to traditional systems such as Ayurveda, Unani, and Traditional Chinese Medicine for centuries, much of their use is supported by cultural experience and anecdotal records rather than standardized clinical research. Modern medicine requires strong evidence from randomized controlled trials, pharmacological studies, and toxicology tests to confirm both efficacy and safety. Clinical validation of herbs often remains limited because large-scale trials are costly, patent protection is difficult, and plant composition varies by source. This lack of robust data makes many healthcare professionals hesitant to recommend herbal remedies alongside conventional drugs.

3.2 Variability in Quality:

The safety and effectiveness of herbal products can fluctuate considerably due to differences in cultivation, harvesting, and processing. Environmental factors such as soil quality and climate influence the levels of bioactive compounds (e.g., Korean ginseng has a different potency profile compared to American ginseng). Harvesting time and storage methods can affect medicinal quality—plants harvested too early or stored poorly may lose therapeutic value. Preparation techniques (drying, boiling, fermenting, or using alcohol vs. water extracts) also alter chemical composition. Such inconsistencies make it difficult to guarantee uniform therapeutic outcomes, unlike synthetic medicines, which are chemically stable and standardized.

3.3 Regulatory Gaps:

Pharmaceutical drugs undergo strict regulation under agencies like the U.S. FDA or India's CDSCO, requiring multi-phase safety and efficacy testing before approval. Herbal medicines, however, are often categorized as supplements or traditional remedies, subject to fewer restrictions. In many countries, herbal products can be marketed without pre-market approval if they avoid strong medical claims. This lighter regulation creates risks of adulteration, contamination, or mislabeling. Instances of heavy metal contamination or the addition of undisclosed synthetic drugs in herbal formulations have been reported, which undermines consumer trust.

3.4 Multi-Target Mechanisms:

Unlike synthetic drugs, which are usually designed to act on a single receptor, enzyme, or protein, herbal medicines contain a wide spectrum of bioactive compounds that can affect multiple biological pathways simultaneously. For example, curcumin in turmeric impacts inflammation, oxidative stress, and immune signaling rather than one specific target. This "multi-target" nature can be advantageous in treating complex conditions such as cancer, diabetes, or neurodegenerative disorders. However, it complicates research, since identifying the key therapeutic compound(s) and establishing consistent dosage standards is difficult.

IV. BIOTECHNOLOGICAL APPROACHES IN HERBAL DRUG PRODUCTION

Biotechnology provides cutting-edge tools that strengthen the credibility, safety, and effectiveness of herbal medicine. At its core, biotechnology is an interdisciplinary science that applies biological systems, living organisms, or their components to develop innovative products, processes, and technologies. It integrates knowledge from biology, genetics, molecular biology, biochemistry, and engineering to solve practical challenges and improve human health and well-being.

In the context of herbal medicine, biotechnological approaches—such as genomics, transcriptomics, and metabolomics—have transformed research by enabling the precise identification, characterization, and analysis of bioactive compounds in medicinal plants. These tools not only help uncover therapeutic molecules but also enhance standardization, quality control, and scientific validation, thereby bridging the gap between traditional knowledge and modern medicine.

4.1 Genomics in Herbal Research:

Genomics focuses on studying the complete DNA sequence of plants, providing insights into genes responsible for the biosynthesis of bioactive compounds.

Applications:

- Identification of metabolic pathways producing therapeutic molecules
- Development of molecular markers for medicinal plant breeding and conservation
- Discovery of genetic variations that influence the concentration of active compounds

Examples:

- In *Artemisia annua*, genomics helped identify genes involved in the production of artemisinin, a potent antimalarial drug
- In *Withania somnifera* (Ashwagandha), genomic studies have mapped genes regulating withanolide synthesis, crucial for anticancer and adaptogenic effects

4.2 Transcriptomics for Pathway Discovery:

Transcriptomics involves analyzing RNA transcripts to determine which genes are expressed under specific conditions, shedding light on how medicinal compounds are regulated in plants.

Applications:

- Identifying genes activated during stress that enhance metabolite production
- Revealing tissue-specific expression patterns linked to medicinal properties
- Assisting in metabolic engineering for higher yields of bioactive molecules

Examples:

- In *Taxus* spp. (yew tree), transcriptome analysis uncovered genes controlling the biosynthesis of paclitaxel (Taxol), a frontline anticancer drug
- In *Catharanthus roseus* (periwinkle), transcriptomics identified regulatory genes for vincristine and vinblastine, used in chemotherapy

4.3 Metabolomics for Compound Profiling:

Metabolomics examines the complete set of metabolites in plants, offering a chemical fingerprint of bioactive compounds.

Applications:

- Detecting and quantifying phytochemicals to ensure consistency and safety in herbal formulations
- Comparing wild vs. cultivated species to optimize cultivation practices
- Identifying novel metabolites with therapeutic potential

Examples:

- Metabolomic profiling of *Curcuma longa* (turmeric) has been used to study variations in curcumin content across different varieties and growth conditions

- In *Glycyrrhiza glabra* (licorice), metabolomics has helped standardize glycyrrhizin levels, widely used for its anti-inflammatory and antiviral effects

4.4 Integrative Impact:

Together, genomics, transcriptomics, and metabolomics provide a systems biology approach that:

- Enhances the scientific validation of traditional remedies
- Improves standardization and quality control in herbal formulations
- Supports biotechnological production of rare or endangered medicinal compounds through metabolic engineering or synthetic biology

V. PHARMACOGENOMICS IN HERBAL MEDICINE

The concept of personalized medicine (also called precision medicine or individualized therapy) refers to tailoring medical treatment to the unique characteristics of each patient rather than using a "one-size-fits-all" approach. Personalized medicine considers a person's genetic makeup, environment, lifestyle, and clinical data to design prevention, diagnosis, and treatment strategies that are most effective for them.

Pharmacogenomics, a branch of personalized medicine, explores how an individual's genetic profile affects their response to therapeutic interventions, including both synthetic drugs and herbal medicines. This field helps in understanding why some people experience strong benefits from certain treatments while others show minimal response or even adverse effects. In the context of herbal medicine, pharmacogenomics can identify genetic variations that influence the absorption, metabolism, and efficacy of plant-derived compounds. For example, polymorphisms in cytochrome P450 enzymes may alter how compounds like curcumin, ginsenosides, or alkaloids are metabolized in different individuals. By integrating pharmacogenomics with herbal medicine research, therapies can be tailored for maximum safety and effectiveness, paving the way for evidence-based, personalized herbal treatments.

Pharmacogenomics plays a crucial role in herbal drug production by linking genetic variations with the way individuals respond to plant-derived compounds. Since herbal medicines often contain multiple bioactive molecules that act on diverse biological pathways, genetic polymorphisms in drug-metabolizing enzymes, transporters, and receptors can greatly influence their absorption, metabolism, and therapeutic outcomes. Understanding these genetic influences helps in designing standardized herbal formulations with improved efficacy and reduced adverse reactions. In production, pharmacogenomic insights can also guide the selection of plant varieties rich in specific bioactive compounds, support biotechnological approaches like metabolic engineering, and enable the development of personalized herbal therapeutics tailored to genetic profiles.

VI. BIOTECHNOLOGICAL TECHNIQUES FOR STANDARDIZATION AND QUALITY CONTROL OF HERBAL PRODUCTS

Biotechnology provides essential tools for the standardization and quality control of herbal medicines, ensuring their safety, efficacy, and consistency.

DNA Barcoding: Employs short, specific DNA regions such as rbcL and matK as molecular markers to accurately identify plant species and prevent adulteration—for example, distinguishing authentic *Panax ginseng* from substitutes in commercial supplements.

Identification of Contaminants: Molecular techniques detect harmful substances like heavy metals, pesticides, or microbial pathogens; PCR, for instance, can identify *E. coli* contamination in herbal powders.

Quantification of Bioactive Compounds: High-Performance Liquid Chromatography (HPLC) and Mass Spectrometry (MS) allow precise measurement of active constituents, ensuring consistent dosage and therapeutic effect, as in the standardization of curcumin in *Curcuma longa* supplements.

Chemometrics: Integrates metabolomics data with statistical analysis, providing chemical fingerprints for batch-to-batch comparison and authenticity verification—for example, profiling polyphenols in green tea.

Good Manufacturing Practices (GMP): Supported by biotechnological methods, GMP guides the cultivation, harvesting, processing, and packaging of medicinal plants, ensuring compliance with international quality standards. A practical example is GMP-certified *Withania somnifera* (Ashwagandha) capsules exported globally.

Additionally, bioactive compounds in plants such as *Senna auriculata* flowers are quantified through a combination of drying, grinding, extraction, chromatographic separation, and analytical identification, demonstrating how biotechnology enhances precision and reliability in herbal medicine production.

VII. BIOFORTIFICATION OF MEDICINAL PLANTS

Biotechnological methods, including genetic engineering and selective plant breeding, can enhance the nutritional and therapeutic value of medicinal plants through biofortification. This approach aims to increase the levels of essential nutrients, vitamins, minerals, or bioactive compounds, thereby creating more potent and nutritious herbal supplements. The process typically begins with the identification of target nutrients or compounds followed by the selection of suitable plant species. Depending on the goal, either conventional breeding or genetic modification is employed to enhance the desired traits. The modified plants are then subjected to rigorous testing and field trials to evaluate nutrient accumulation, growth performance, and safety. Once validated, the plants move into up-scale production, followed by promotion and marketing to ensure the biofortified herbal products reach consumers effectively.

VIII. BIOASSAYS AND CELL-BASED ASSAYS FOR HERBAL PRODUCTS

Biotechnology also enables bioassays and cell-based assays to evaluate the pharmacological activity and efficacy of herbal extracts.

Selection of Test Organism: The first critical step is the selection of the test organism, which determines the relevance of the assay. Criteria include sensitivity to the test compound, ease of maintenance, and well-characterized physiology. Examples include microbial bioassays using *E. coli* or *S. aureus* for antimicrobial activity, mammalian cell lines like HeLa or HepG2 for cytotoxicity, antioxidant, or anti-inflammatory studies, and whole-organism models such as zebrafish or *Drosophila* embryos for developmental investigations.

Preparation of Herbal Extract: The herbal extract is prepared in a standardized manner to ensure reproducibility. Plant material—leaves, roots, seeds, or flowers—is collected, dried, powdered, and extracted using appropriate solvents such as water, ethanol, methanol, or acetone. Extraction techniques include maceration, Soxhlet extraction, or ultrasonication, followed by filtration, concentration using a rotary evaporator, and storage under controlled conditions.

Dose Selection: Dose selection is crucial to achieve measurable biological responses without causing non-specific toxicity. Typically, a wide concentration range is tested (e.g., 1–100 µg/mL), and potency is quantified using IC50 or EC50 values.

Controls: Positive and negative controls are included to validate results: a known bioactive compound (e.g., doxorubicin for cytotoxicity assays or ampicillin for antimicrobial assays) serves as a positive control, while solvent or medium alone acts as a negative control.

Exposure and Response Measurement: The test organism or cells are then exposed to the extract under controlled conditions, taking into account temperature, pH, oxygen, light, and incubation time. The biological response is measured using suitable assays: cytotoxicity can be assessed via MTT, LDH release, or Trypan Blue exclusion; proliferation via BrdU incorporation or colony formation; gene or protein expression via qRT-PCR or Western blot; and microbial activity through zone of inhibition or colony-forming unit (CFU) counts. Whole-organism assays may examine survival, behavior, or developmental abnormalities.

Data Analysis: Data analysis involves quantifying effects, plotting dose-response curves, calculating IC50 or EC50, and performing statistical tests such as t-tests or ANOVA. Comparisons with positive and negative controls ensure that observed effects are due to the herbal extract. Software tools like GraphPad Prism, SPSS, or Excel are commonly used for curve fitting and statistical evaluation.

IX. TISSUE CULTURE AND SECONDARY METABOLITE PRODUCTION

Tissue culture refers to the in vitro aseptic cultivation of plant cells, tissues, or organs under controlled conditions of nutrients, temperature, light, and hormones, with the aim of producing whole plants, plant parts, or bioactive compounds. This technique allows rapid multiplication, the generation of disease-free plants, and controlled synthesis of secondary metabolites by exploiting the totipotency of plant cells, where each cell has the potential to regenerate into a complete plant under suitable conditions.

Several tissue culture approaches are employed to produce plant secondary metabolites, including organ culture, callus culture, and suspension culture.

Organ Culture: Involves cultivating differentiated plant organs such as shoots, roots, or embryos on nutrient media, allowing direct production of organ-specific metabolites. The process includes selecting the organ, surface sterilization, placing it on Murashige and Skoog (MS) medium with appropriate growth regulators (auxins for roots, cytokinins for shoots), incubation under controlled conditions, and harvesting for metabolite extraction. Examples include alkaloid production in *Catharanthus roseus* roots and shikonin from *Lithospermum erythrorhizon* roots.

Callus Culture: Involves the in vitro growth of undifferentiated plant cells on nutrient media. Explants such as leaves, stems, or roots are excised, sterilized, and cultured on MS medium containing auxins and cytokinins to induce callus formation. Callus can be maintained through subculturing every 4–6 weeks, and secondary metabolite production can be enhanced by optimizing conditions like light, temperature, and using elicitors such as methyl jasmonate or salicylic acid. Examples include vincristine and vinblastine from *Catharanthus roseus* callus and flavonoids from *Ginkgo biloba* callus.

Suspension Culture: Derived from callus cultures, suspension culture involves growing plant cells in liquid nutrient media under continuous agitation, providing a homogeneous population suitable for large-scale metabolite production. Friable callus is transferred to liquid MS medium, placed on a shaker, and optimized for pH, temperature, nutrients, and elicitor addition. Cells or culture filtrates are harvested to extract secondary metabolites. Notable examples include shikonin from *Lithospermum* suspension cultures and paclitaxel (Taxol) from *Taxus* suspension cultures.

X. CONCLUSION

The integration of traditional herbal knowledge with modern biotechnological tools offers a promising pathway for the development of safe, effective, and standardized plant-based medicines. Advances in genomics, transcriptomics, metabolomics, and pharmacogenomics provide deeper insights into the metabolic pathways responsible for therapeutic compounds, facilitating drug discovery and the standardization of herbal products. Biotechnological techniques including DNA barcoding, chromatographic analysis, chemometrics, and Good Manufacturing Practices ensure authenticity, quality control, and safety of herbal formulations. Furthermore, plant tissue culture technologies allow sustainable production of valuable secondary metabolites, reducing pressure on endangered medicinal plant species. Bioassays and cell-based assays provide scientific validation of herbal extracts by evaluating their pharmacological activity at the cellular and molecular levels. Such interdisciplinary approaches will play a vital role in advancing herbal therapeutics and strengthening their contribution to future global healthcare systems.

ACKNOWLEDGEMENT

The authors express their sincere gratitude to the institutional facilities and support provided for carrying out this research work.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this paper

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