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Research Article

Bacopa monnieri: A Comprehensive Analysis of Quality Standards, Safety, and Regulatory Compliance

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ABSTRACT

India's diverse topography and climate support a rich repository of medicinal herbs, including Bacopa monnieri, which boasts outstanding therapeutic potential. Traditionally rooted in Ayurvedic medicine, B. monnieri is today gaining global popularity for its reputed neuroprotective, cognitive-enhancing, anticancer, and stress-relieving properties. Despite its increasing demands, numerous challenges persist in maintaining quality, safety, and consistency against the backdrop of natural variability, contamination risk, and regulatory issues, even as pressure mounts from the global marketplace. The present research highlighted the organoleptic, microscopic, physicochemical, chromatographic, and toxicological parameters of B. monnieri, drawing on standard literature and regulatory frameworks such as the Ayurvedic Pharmacopoeia of India, the Indian Pharmacopoeia, and the Indian Standards of Medicinal Plants. This study highlights quality challenges, such as contamination with heavy metals and pesticide residues, which can affect the efficacy and safety of the final herbal product formulation. Bioactive compounds like bacoside and bacopaside are present in B. monnieri as confirmed by chromatographic profiling. This study strongly emphasizes the integration of quality assessment to meet both Good Agricultural and Collection Practices and International Safety Standards. Once these challenges are met positively, dedication will improve marketability and therapeutic reliability. Therefore, promote B. monnieri, further strengthening India's stature as a global leader in herbal medicine.

Introduction

India, with its enormous topography and climate variability, is home to a diverse range of medicinal herbs that serve as the foundation for traditional treatment systems such as Ayurveda. Ayurveda has gradually evolved to incorporate scientific concepts, with an emphasis on safety, toxicity, dose accuracy, clinical efficacy, and quality control. This change has driven advancements in herbal-based nutraceuticals and value-added food supplements, leading to an expansion of the global market for herbal products, including nutritional

supplements, cosmetics, and functional foods. However, increased commercialization has prompted concerns about the quality and sustainability of medicinal plant resources. [1-3]

Regulatory Frameworks Governing Herbal Products in India

The principal regulatory frameworks overseeing the quality of herbal medications and nutraceuticals in India include the 'Indian Pharmacopoeia (IP),' the 'Ayurvedic Pharmacopoeia of India (API),' the 'Food Safety and

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Standards Authority of India (FSSAI),' and 'The World Health Organisation (WHO)' standards. While these agencies set standards for safety, purity, and efficacy, significant regulatory gaps remain. [4,5] Many therapeutic plants lack standardized references, leading to variations in herbal compositions. Furthermore, the diversity of plant elements due to soil conditions, climate, and growth methods causes batch-to-batch variations, making quality control challenging. [6]

Contamination and Quality Concerns in Herbal Production

Contamination is a key risk in the herbal production industry. Heavy metal residues, pesticide contamination, microbiological contaminants, and mycotoxins can all be found in herbal medications and nutraceuticals, posing a risk to the safety and therapeutic efficacy of herbal plants. Regulatory bodies have established contaminant limitations, but ensuring industry-wide compliance necessitates rigorous monitoring and quality assurance methods. The export of Indian herbal goods is further hindered by noncompliance with International Safety and Quality Standards, underscoring the importance of consistent global regulatory rules.^[7,8]

Efforts Toward Sustainable and Standardized Production

To address these issues, regulatory authorities such as the 'National Medicinal Plants Board' (NMPB) have developed 'Good Agricultural and Collection Practices' (GACP), which assure sustainable sourcing and consistent production. However, variable agro-climatic conditions make it impossible to maintain consistent medicinal plant production, which complicates regulatory compliance. Furthermore, a lack of integration between ancient Ayurvedic standards (API) and modern pharmaceutical regulations (IP) complicates manufacturers' efforts to meet both domestic and international requirements.^[9]

The 'Food Safety and Standards Act' and Industry Modernization

The 'Food Safety and Standards Act' was introduced to consolidate food and nutraceutical regulations, promoting self-compliance and modernization of the industry. However, gaps in infrastructure, risk-based regulatory frameworks, and enforcement mechanisms continue to hinder effective implementation. [10] For India's herbal industry to thrive in the global market, it must adopt a science-driven approach that integrates GACP, good manufacturing practices (GMP), post-harvest quality controls, and rigorous safety assessments. This would help mitigate concerns related to ingredient variability and contamination risks, ensuring that herbal products meet both national and international regulatory standards. [11]

Bacopa monnieri: Pharmacological Potential and Modern Applications

B. monnieri has been known for its neuroprotective and cognitive-enhancing activity. Meanwhile, it's very recent applications are aimed at stress relief and perhaps even providing some cancer-fighting compounds. The active ingredients present in B. monnieri are known to possess very good pharmacological properties, being strong anticancer and anti-anxiety agents. Therefore, B. monnieri is considered a possible candidate for investigating alternative mechanisms that stimulate the tumor and alleviate stress. Some major bioactive phytochemicals within B. monnieri, such as bacosides, alkaloids, glycosides, sterols, and flavonoids^[12] and exhibits their pharmacological effects among the foremost ranks of antimetastatic, anti-angiogenic, and anti-proliferation agents in cancer treatment, with these effects mediated through distinct pathways. This broad spectrum of activities makes B. monnieri an attractive candidate for cancer prevention and treatment.[13] In addition, the extracts of B. monnieri trigger the arrest of cancer cell growth, proliferation, and metastasis, thus supporting its direct anti-tumor potentials. [14] Simultaneously, B. monnieri's traditional use has been directed at anxiety and stress alleviation. A series of studies has shown that it decreases certain stress-induced behaviors and cortisol levels in zebrafish, suggesting its viability as a long-term adaptation for managing stress safely. [15] Some methodologies involving a combination of B. monnieri and ashwagandha have displayed substantial reductions in perceived stress and cortisol levels, with improvements in mood and sleep quality, thereby strengthening the proposed role of such preparations in stress management. [16] In the context of Avurvedic medicine, B. monnieri has been used over the centuries either as a cognitive enhancer or to address stress-related disorders. Thus, a blend with modern therapies could yield an integrated approach to the management of stress and cancer. [17] Moreover, the association of B. monnieri with other traditional or synthetic drugs may synergistically support their therapeutic use and abate the adverse outcomes.^[18] Table 1 provides an overview of global market trends, trade statistics, and key importing and exporting countries for B. monnieri, highlighting its increasing commercial significance and international demand.

MATERIALS AND METHODS

Data Compilation and Regulatory Compliance

The data on *B. monnieri* were compiled based on key parameters from standard literature, following the respective regulatory limits. Primary references included:

- Ayurvedic Pharmacopoeia of India (API)
- · ICMR- Indian Standards of Medicinal Plants
- Indian Pharmacopoeia (IP)



Table 1: Global market value, trade, import, and export data of *B. monnieri*

Parameters	Import/Export value(s)	
^a Top Exporting Country	India (93% of global exports, 435 shipments)	
^a Other Major Exporters	China (6%), USA (1%)	
^a Other Major Importers	France (10%), Germany (9%)	
^a Top Importing Country	USA (1,332 shipments, 49% of global imports)	
^a Total Global Shipments	7,580 export-import shipments	
^b Projected Market Value (2029)	USD 553.19 million (CAGR: 9.38%)	
^b Global Market Value (2023)	USD 295.33 million	

^a https://www.volza.com/p/bacopa-monnieri/import/

Organoleptic Evaluation of B. monnieri

The organoleptic properties, including color, fragrance, shape, size, and taste, were evaluated using references such as the API, Indian Standards of Medicinal Plants, and the IP.

Microscopic Analysis of B. monnieri

Microscopic characteristics included transverse and longitudinal sections and powder microscopy. Key diagnostic features were documented and compared with reference standards for validation.

Physicochemical Analysis of B. monnieri

Physicochemical analyses were conducted to assess the physical quality and purity of the plant material. Parameters included:

- Moisture content
- Foreign matter
- Total ash
- · Acid-insoluble ash
- Water-soluble ash

These parameters ensured that the material met quality thresholds recommended by regulatory guidelines.

Qualitative and Quantitative Estimation of *B. monnieri*

Chromatographic techniques were employed for qualitative and quantitative analysis of active constituents:

- Thin layer chromatography (TLC)
- High-performance thin layer chromatography (HPTLC)

These methods facilitated the estimation of key bioactive compounds. This profiling ensured consistency in the active phytochemical content of *B. monnieri*.

Toxicity Indicators of B. monnieri

Safety evaluations were conducted through toxicological analysis, which included testing for

- Heavy metal contamination (e.g., Lead, Cadmium, Mercury, Arsenic)
- · Pesticide residues
- Aflatoxins

All results were compared with regulatory limits to ensure consumer safety and compliance with International Quality Standards.

RESULTS

Organoleptic Evaluations of B. monnieri

An organoleptic evaluation is the evaluation of plant material based on the sensory characteristics such as color, flavor, shape, size, and taste. These include the broad and detailed visible characteristics, involving features such as fracture, texture, and aroma, of the medicinal plant. [19] The evaluation process acts as the primary step in confirming the authenticity of medicinal plants. Trained professionals conduct this assessment by visually examining the plant part, either unaided or with the aid of a magnifying lens. [20] Table 2 provides the appropriate ranges for different attributes of *B. monnieri* in the API and different standard references.

Microscopic Evaluation of B. monnieri

Microscopic identification of herbs is crucial for detecting contaminants, such as fungi, mold, insects, or animal or human waste, as well as for recognizing tissue-specific features. Staining techniques, such as phloroglucinol and concentrated hydrochloric acid for lignin, reveal unique tissue structures. [24] Microscopic evaluation has been conducted, which includes transverse and longitudinal sections (TS/LS), as well as powder microscopy. Stains such as safranin are used to observe components like starch and fixed oils. [25] Table 3 presents certain microscopic features seen in the TS/LS and powdered sample of *B. monnieri*. Fig. 1(a) and 1(b) depicts the unique microscopic characters of *B. monnieri*.

bhttps://www.maximizemarketresearch.com/market-report/bacopa-monnieri-extract-market/216007/#:~:text=Bacopa%20 Monnieri%20Extract%20Market%3A%20Global,and%20Forecast%20(2024%2D2030)&text=Global%20Bacopa%20Monnieri%20 Extract%20Market,reaching%20nearly%20USD%20553.19%20Million.

Table 2: Organoleptic and macroscopic characteristics of B. monnieri

	Table 2. Organoleptic and	a macroscopic characteristics of <i>B.</i>	monneri
Organoleptic analysis of leaf	API ^[21]	IP ^[22]	Indian Standards of Medicinal Plants ^[23]
Shape	Obovate-oblong	n.d.	Obovate-oblong to spathulate
Size	1–2 cm long	n.d.	0.6-2.5 cm length and 3-8 mm width
Color	Green	Green	Faint green
Odor	n.d.	n.d.	n.d.
Taste	Slightly bitter	Slightly bitter	Slightly bitter
Macroscopic analysis			
Leaves	The leaves are simple, arranged in opposite pairs with a decussate pattern. They are green, sessile, and measure about 1–2 cm in length. Their shape ranges from obovate to oblong. The taste is mildly bitter.	The leaves of plants are simple and arranged oppositely in a decussate fashion. They are nearly sessile, smooth (glabrous), and exhibit shapes ranging from obovate-oblong to spathulate. Leaf size varies between 0.6 to 2.5 cm in length.	It is simple and oppositely arranged in a decussate pattern. They are somewhat sessile, smooth, and hairless, with shapes ranging from obovate-oblong to spathulate. The leaf margins are entire (without teeth or lobes), smooth, hairless, obovate-oblong to spathulate, with whole edges, microscopic specks on the bottom surface, faintly visible 1-3 veins, and pale green in colour.
Whole plant The plant has narrow, thin-stemmed, and finely branched stems which are creamish-yellow in colour. The main stem is thin, it is green to purple-green in colour and 1–2 mm in diameter, is fleshy, hairless (glabrous), has nodes and internodes. The leaves are simple leaves, green, opposite in decussate pattern, and sessile. The flowers are small, single (not in groups), at the axils, and consist of pedicels 6 to 30 mm long and are associated with small reduced bracteoles. The fruit is smooth, egg-shaped capsule 5 mm long at most.		Plant is having microscopic spots on the bottom surface, barely 1-3 nerved, and pale green in colour.	The fresh plant is succulent, shrivels upon drying, slightly bitter, and odorless. It comprises crumpled root fragments, branching stems, leaves, flowers, and few fruits. Roots are off-white, wrinkled, and 5 mm thick. Stems are pale yellowishgreen, cylindrical, glabrous, with prominent nodes. Flowers are pale blue or pinkish-white, solitary, axillary, with a gamopetalous corolla and bicarpellary pistil. Fruits are globose capsules (5 mm), enclosed in a persistent calyx. Seeds are minute, oblong, and irregular.

n.d. = No data available.

Physicochemical Parameters of B. monnieri

A physicochemical parameter is a group of measures generally employed to evaluate the effectiveness of diverse medicinal plants. Physicochemical boundaries determinization of very important factors which encompasses moisture content and the determination of the foreign matter, which are very important factors. The determination of ash value discriminates across the various physiological ash and non-physiological ash and shows the silica contents in the plant factors. A determination of water and alcohol extracts delivers an overview of the plant sample and what chemical components could be found. Table 4 shows the acceptable boundaries of the physicochemical features of *B. monnieri*.

Qualitative and Quantitative Estimation of *B. monnieri*

Chromatographic profiling, using TLC-dependent methods, is critical in qualitatively identifying the primary active chemical constituents of medicinal plants. In a scenario of *B. monnieri*, the primary active chemical constituents are

bacopaside and bacoside. Following this chromatographic profiling, a quantitative separation of the primary active constituents is performed, typically using HPLC or HPTLC, which enables the precise determination of their concentrations. This is an important step for assessing any possible adulteration of *B. monnieri* by lower-grade species or duff plant material. [29,30] Table 5 gives the information provided by the literature and its Rf values quantitative range for bacopaside and bacoside, and the method for quantification can be found in numerous references.

Toxicity Indicators of B. monnieri

Toxicity indicators in *B. monnieri* involve characteristics of the plant that go beyond the implications for quality in medicinal plants, as they have the potential for adverse effects on human physiology if consumed. Indicators of toxicity include heavy metal contamination, pesticide residue, and aflatoxins in *B. monnieri*. ^[27] There are problematic sites that may induce mold that is grown on soil that produces aflatoxins, which are known carcinogens. In addition to these, uncertainty with site



Table 3: Microscopic characters of *B. monnieri*

Type of microscopy	$API^{[21]}$	$IP^{[22]}$	Indian Standards of Medicinal Plants ^[23]
TS of leaf			
Epidermis	A thin cuticle covers both the upper and lower epidermal layers.	Both the upper and lower leaf surfaces bear anomocytic stomata.	Comprises upper and lower layers; the upper epidermis has larger cells and, in some areas, a striated cuticle. Both of the upper and lower layer compactly includes the stomata.
Trichomes	Glandular hairs are flat. Subsidiary cells exist on both surfaces.	Present in midrib	Sessile glandular trichomes with multicellular heads are present on both epidermal layers.
Chloroplasts and parenchyma in Lamina	The mesophyll contains a less amount of prismatic calcium oxalate crystals scattered very irregularly. Small vascular veins continuously travel through the mesophyll, each enclosed by a unique bundle sheath.	Mesophyll is isobilateral, composed of spongy cells shows less presence of prismatic crystals of the calcium oxalate.	The mesophyll comprises of spongy parenchyma through which vascular strands extend. The parenchymatous cells contain prismatic crystals along with a very small cluster of crystals of calcium oxalate.
Lamina structure	n.d.	Midrib indistinct.	The transverse section of the midrib is almost cylindrical, featuring a slight dorsal (upper side) elevation.
Vascular bundles and trichomes in midrib	n.d.	n.d.	The midrib houses a centrally positioned conjoint, collateral meristele, which is enclosed by a parenchymatous sheath Narrow collenchymatous bands are situated beneath both epidermal layers of the midrib.
Petiole composition	n.d.	n.d.	n.d.
Powder microscopy of le	eaf		
Stomata	n.d.	n.d.	Diacytic to anomocytic stomata, predominantly present on the lower epidermis.
Polygonal and wavy- walled epidermal cells	n.d.	n.d.	Epidermal cells exhibit sinuous anticlinal walls and, in some areas, a striated cuticle.
Trichomes	n.d.	n.d.	Cup-shaped glandular trichomes holding heads composed of 4 to 8 cells.
Palisade parenchyma	Simple, round, and oval starch grains 4-14 μ in diameter. Xylem vessels with reticulated thickening.	n.d.	Parenchymatous cells encompass prismatic and cluster-shaped calcium oxalate crystals, also with sprinkled starch grains and oil globules entrenched within their structure

n.d. = No data available.

history, and unreliability in irrigation water can elevate pesticide and metal levels.^[31] This presents a major limitation for the herbal industry and trade. Only an excessive level of heavy metals and pesticide residues in *B. monnieri* can lead to the rejection of the entire lot.^[32] Table 6 illustrates some of the indicators of toxicity from a range of standard references.

DISCUSSION

B. monnieri has garnered considerable commercial interest in the areas of herbal medicines, nutraceuticals, and functional foods due to its well-established reputation as a cognitive-enhancing and neuroprotective agent. Its rising popularity, particularly in the context of neurological health, underscores its potential for

therapeutic application. However, the full commercial utilization of *B. monnieri*'s potential will require smart solutions to address barriers related to robust quality assurance, standardization, cultivation, and harvesting practices of the crop.

Despite some regulatory support, an important limitation for the efficacy of *B. monnieri*, is achieving consistency in quality. The potency or medicinal properties of *B. monnieri* can vary significantly from one batch to another due to a multitude of factors, including the agro-climatic environment in which it is grown, agronomic practices, harvesting methods and practices, and post-harvesting practices. The variable bioactive content, which ultimately impacts the efficacy of the product, relates to the primary bioactive agent, bacosides, and can result in inconsistencies

Table 4: Physico chemical parameters of *B. monnieri* and related values

Physico chemical features	PI ^[21] (%)	IP ^[22] (%)	Indian Standards of Medicinal Plants ^[23] (%)
'Foreign matter'	n.m.t. 2	n.m.t. 2	n.d.
'Total ash'	n.m.t. 18.0	n.m.t. 18	n.m.t. 16
'Ethanol soluble extractive'	n.d.	n.m.t. 6	n.l.t. 17
'Alcohol soluble extractive'	n.l.t. 6.	n.d.	n.d.
'Water soluble extractive'	n.l.t. 15.0	n.l.t. 22.0	n.l.t. 18
'Acid insoluble ash'	n.m.t. 6.0	n.m.t. 6.0	n.m.t. 2.5
'Loss on drying'	n.d.	n.m.t. 12.0	

'n.m.t.: Not more than; n.l.t.: Not less than; n.d.= No data available'.

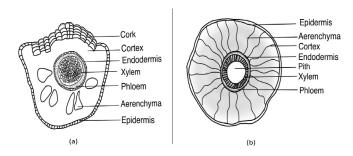


Fig. 1(a): TS of B. monnieri root (b) TS of B. monnieri stem

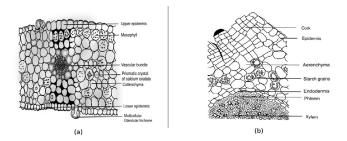


Fig. 1(b): Powdered microscopy of *B. monnieri* root (b) TS of *B. monnieri* leaf

in purity, potency, and efficacy. This challenge can only be addressed with the implementation of appropriate standardization and quality assurance programs. [33] Regulatory bodies, including the 'Indian Pharmacopoeia,' 'Ayurvedic Pharmacopoeia of India,' 'Food Safety and Standards Authority of India,' and 'World Health Organization' have published guidelines and standards for herbal medicines to assure the safety, efficacy and quality of medicinal herbs - including contaminants (heavy metals, pesticide residues, aflatoxins), physicochemical, organoleptic, and phytochemical properties. However, significant limitations in current regulatory practices hinder their widespread effectiveness.

Limitations of Current Regulatory Practices and Standardization Methods

One key challenge is the absence of internationally accepted standards for herbal medicines, including *B. monnieri*. While national requirements exist in the form

of APIs and IP, adherence to international standards is often lacking, for example, international standards developed by the WHO, the European Pharmacopoeia, and the US Pharmacopeia. The inconsistent and misaligned standards create regulatory bottlenecks for manufacturers who want to meet both domestic and international standards. [34,35] Standards often lack reference databases to develop the comprehensive reference materials required for what would be considered accepted standards. Additionally, many species, including B. monnieri, lack fully established reference standards for all bioactive constituents, which heightens the risks of possible adulteration and/or substitution throughout the supply chain. For instance, species adulteration in Curcuma longa (Turmeric) placed sustainability and traceability of herbal materials at the forefront.[33] Additionally, the implementing and enforcement of regulatory guidelines remain varied. The gaps in infrastructure and riskbased regulatory systems, combined with minimal post-marketing surveillance, can diminish the utility of contemporary standards.

Critical Analysis of Existing Research on *B. monnieri*'s efficacy

Many studies have affirmed the cognitive-enhancing and neuroprotective qualities of *B. monnieri*; however, there are contradictions and inconsistencies, which make it difficult to generalize.^[37] Clinical studies vary widely in terms of sample size, dosage regimen, and duration, which in turn affects the replicability and reliability of the study's findings.

For example, while some randomized controlled trials (RCTs) found significant improvements in memory retention and cognitive performance, other studies found minimal to no effects. [38,39] Variability in outcomes may be due to differences in the proportion of bacosides. Some studies have also raised the issue of placebo effects, particularly in studies that use subjective measures of cognition. [38]

Safety assessments have generally determined that B. monnieri is well-tolerated; however, some studies have reported slight gastrointestinal discomfort^[40] and fatigue.^[41] The safety of *B. monnieri* in different



Table 5: Qualitative and quantitative estimation approaches of *B. monnieri*

Method	$API^{[21]}$	IP ^[22]	Indian standards of medicinal plants ^[23]	Common experimental protocol
TLC	n.d.	Bacoside and bacopaside II spot of test and reference were detected under UV light at 254nm.	R _f at 0.48 for bacoside A	Test Sample (IP Method): A silica gel GF254- protected plate was preferred as the stationary phase and a blend of chloroform and methanol in the proportion of 7:3 vol/vol was used as the mobile phase for chromatographic development. As per Gupta et al. (2008): The extract obtained from <i>B. monnieri</i> was prepared using the ethanol and further concentrated. The concentrate was further added onto a silica gel plate and developed using a solvent system of n-butanol, acetic acid, and water in a 4:1:5 proportion. After developing, the spots were revealed by spraying with vanillin-sulphuric acid reagent.
HPTLC	n.d.	n.d.	$R_{\rm f}$ at 0.18–0.22 for bacoside I	Other standard literature: HPTLC densitometry of <i>B. monnieri</i> involves ethanol extraction, silica gel TLC, development in n-butanol:acetic acid:water (4:1:5), vanillin-sulphuric acid visualization, scanning at 620 nm.

n.d.= No data available

Table 6: Toxicity indicators and permissible ranges *B. monnieri*

Table of remedy mandates and permission ranges 2 monnier.			
Parameter	Limits	Reference	
'Lead'	2.5 mg/kg (Food not specified)		
'Copper'	30 mg/kg		
'Arsenic'	1.1 mg/kg	"(Food Safety and Standards: Contaminants, Toxins and Residues) Regulations, 2011-FSSAI*"	
'Cadmium'	1.5 mg/kg	Tomis and residues, regulations, 2011 18811	
'Mercury'	1.0 mg/kg		
Permitted range of usage	Whole plant 5-10 gram (as fresh) Extract 0.5-1 gram	FSSAI, 2017**	

[&]quot;*https://www.fssai.gov.in/upload/uploadfiles/files/Compendium_Contaminants_Regulations_20_08_2020.pdf"

populations and over extended time periods need better, more comprehensive evaluations.^[42]

Conclusion and Future Prospects

The therapeutic value of *B. monnieri* for cognitive enhancement and neurological health has been demonstrated, but its widespread clinical and commercial application is limited due to quality control, standardization, and regulatory issues. The lack of standardized, globally accepted standards and validated reference-based materials is a barrier to consistently producing, manufacturing, and certifying high-quality products. Future research should focus on:

- Developing and validating strong reference standards for bioactive constituents of *B. monnieri*.
- Conducting large-scale, multi-site clinical trials involving the standardized extracts to authorize the effectiveness and safety profile across various populations.
- More research related to establishing the adverse reaction with other botanicals (e.g., Withania somnifera/Ashwagandha) or synthetic drugs.

- Promoting sustainable practices with Good Agricultural and Collection Practices (GACP) to provide support to farmers and ensure consistent bioactive constituents.
 Some of the practical recommendations involved to the stakeholders include:
- It may be beneficial for regulatory bodies to develop a single set of harmonized standards and invest in post-market surveillance.
- The agricultural sector, pesticide producers, and manufacturers should engage in quality assurance programs and work with a third-party certifier to establish consumer confidence.
- Agricultural producers, regulatory agencies, and scientific institutions should work collaboratively to address knowledge gaps and ensure that agricultural producers can utilize *B. monnieri* as a sustainable therapeutic approach.

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