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A Review on Standardization and Validation of Marketed Herbal Formulation

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Abstract: In traditional healthcare systems for centuries Herbal medicines have been widely used for the prevention of various diseases. natural origin shows fewer side effects in neurological disorders such as depression and anxiety. herbal products for therapeutic efficacy depend largely on standardization and scientific validation. Some processing methods may affect the quality like harvesting time, environmental conditions. herbal formulations for standardization of involves the assessment of physicochemical parameters, organoleptic characteristics, phytochemical screening, and using modern analytical techniques, chromatographic fingerprinting such as High-Performance High Performance Liquid Chromatography (HPLC), Thin Layer Chromatography (HPTLC), and Gas Chromatography–Mass Spectrometry (GC–MS). To provide scientific evidence pharmacological and toxicological evaluations are involve for the therapeutic potential of herbal formulations. herbal products are available Several marketed compositions such as *Nardostachys jatamansi*, *Bacopa monnieri*, *Lavandula angustifolia, Withania somnifera*, etc these have property to prevent depressant, anxiety and so many diseases. The review highlights the present important the validation and standardization approaches used for marketed herbal formulations and also in this article summarizes previously studied formulations which was used in the management of depression and anxiety disorders.

Keywords: *Herbal Formulations, Marketed Herbal Products, Depression, Anxiety Disorders, Herbal Drug Evaluation, Medicinal Plants.*

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I. INTRODUCTION

The worldwide for centuries Herbal medicine's important part have been used in traditional healthcare systems. treatment of various diseases Systems like Traditional Chinese Medicine, Unani, Ayurveda rely heavily on plant-based remedies [1]. In recent time, there has been a global significant increase herbal medicines use due to their safety perceived, affordability, as well as natural origin [2]. In developing countries According to the WHO World Health Organization 70–80% nearly of the population depends on herbal medicines for the primary healthcare [3]. Herbal products contain a variety of bioactive phytoconstituents like glycosides, flavonoids, tannins, alkaloids, and terpenoids, to their therapeutic properties [4]. Modern pharmaceutical approaches Marketed herbal formulations have considerable gained popularity for their combination in traditional knowledge [5]. In widely available herbal formulations in form of capsules, cream, tablets, syrups, powders, and liquid extracts. Manufacture herbal formulations by many pharmaceutical companies they have conditions to management such as depression, stress, anxiety, insomnia, and other neurological disorders [6]. Common herbs used in such formulations include Brahmi, Ashwagandha, Shankhpushpi (Convolvulus pluricaulis), and Jatamansi (Nardostachys jatamansi). These combinations of herbal are believed to improve mental health and also, they enhance cognitive function, and to reduce stress-related disorders [7,8,9]. Aim of this comprehensive review is provide overview of the standardization and validation used method in the marketed herbal formulations, which used for the management of depression and anxiety disorders. Focuses and also explore on various, pharmacological evaluation methods, analytical techniques and previously studied marketed herbal products to validation in herbal medicine research.

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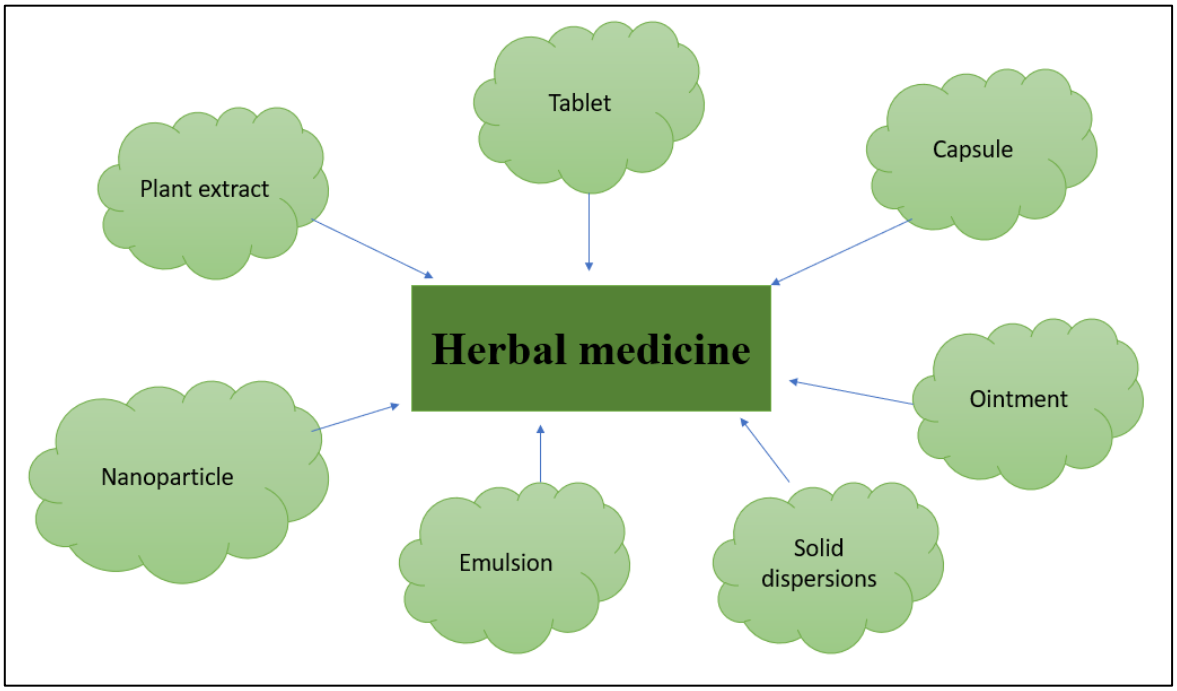

Fig 1 Herbal Medicines

➢ *Standardization and Validation*

The standardization process in herbal drug development defining standards maintaining that ensure product efficacy, as well as quality, safety, and reproducibility [10]. Unlike synthetic pharmaceuticals, where the active ingredients are easily quantifiable and herbal drugs contain complex mixtures of Phyto bioactive compounds. A multi-faceted approach involving modern instrumental techniques is essential for the standardization [11].

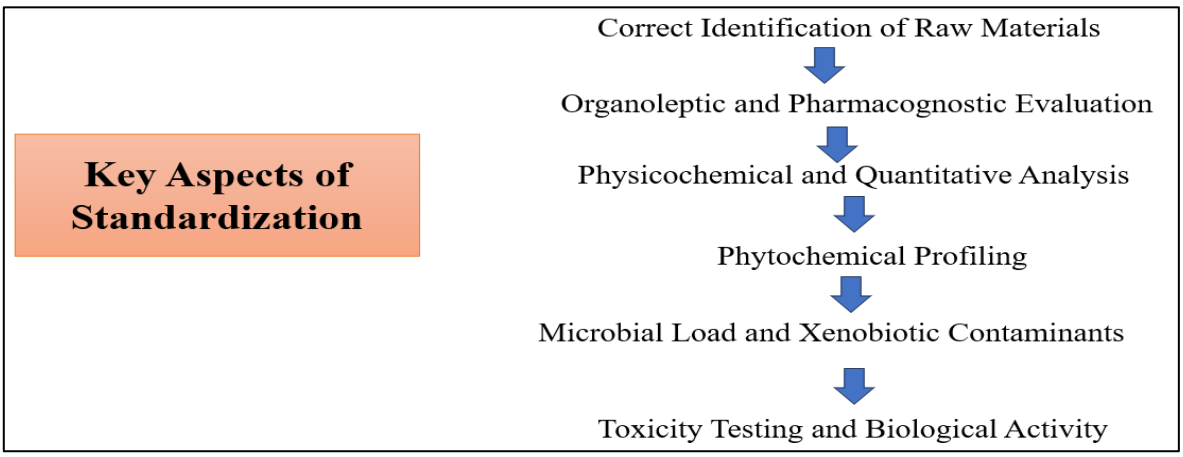

Fig 2 Standardization Key Aspects

➢ *Evaluation Methods for Antidepressant and Anti-Anxiety Activity*

The evaluation of antidepressant and also for anti-anxiety activity are requires a comprehensive and multi-dimensional approach to scientific establish validation. Behavioral assessment of models such as given in table1.

Table 1 Evaluation Parameter Methods for Antidepressant and Anti-Anxiety Activity [12,13,14,15]

S. No.	Category	Test	Parameter Measured
1	Behavioral (Depression)	Forced Swim Test	Immobility time
2	Behavioral (Depression)	Tail Suspension Test	Immobility time
3	Behavioral (Depression)	Sucrose Preference Test	Sucrose intake
4	Behavioral (Anxiety)	Elevated Plus Maze	Time in open arms
5	Behavioral (Anxiety)	Open Field Test	Time in center
6	Behavioral (Anxiety)	Light Dark Box Test	Time in light area

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7	Biochemical	Serotonin, Dopamine, Norepinephrine	Neurotransmitter levels
8	Biochemical	Cortisol / Corticosterone	Stress hormone level
9	Biochemical	Oxidative stress markers (MDA, SOD, GSH)	Oxidative balance
10	Analytical Method	High Performance Liquid Chromatography	Neurochemical quantification
11	Molecular	RT PCR	Gene expression (BDNF, 5-HT receptors)
12	Molecular	Western Blot	Protein levels (BDNF, CREB)
13	Histological	Brain histopathology (H&E staining)	Neuronal integrity
14	Clinical	Hamilton Depression Rating Scale	Depression score
15	Clinical	Hamilton Anxiety Rating Scale	Anxiety score
16	Statistical	ANOVA, Correlation analysis	p-value, correlation coefficient

II. DEPRESSION AND ANXIETY DISORDERS

In the worldwide most common mental health conditions is known as Depression and anxiety disorders, significantly affect the life quality and their productivity, and functioning social of individuals [16]. Global health reports, in millions of people suffer from these Depression and anxiety disorders in each year and for making them major public health concerns [17]. Often These conditions are associated with cognitive impairment, emotional disturbances, and as well as physical symptoms that interfere with daily activities [18,19].

➢ *Depression*

Serious mood disorder is known as Depression characterized by the persistent sadness, as well as loss of interest in activities, and also reduced ability to daily tasks perform [20,21]. It affects all age groups people of and result a combination of psychological, biological, and environmental factors.

- *Symptoms*

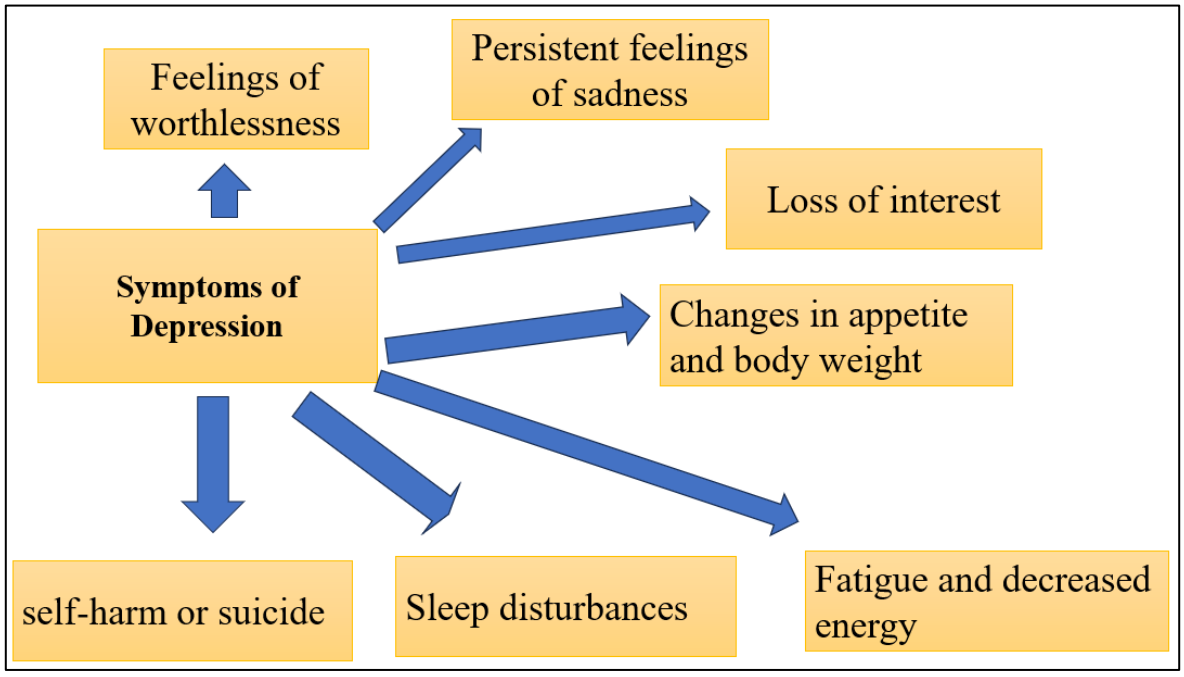

Fig 3 Common Depression Symptoms

Symptoms are severity vary in depending duration on the individual as well as the type of depressive disorder [22].

- *Pathophysiology*

The depression pathophysiology involves multiple neurobiological mechanisms [23]. One of the widely most accepted theories are monoamine hypothesis, which have to suggests that results depression from to decreased levels of the neurotransmitters such as norepinephrine, serotonin, and dopamine in the brain [24]. in the hypothalamic–pituitary–adrenal (HPA) axis Abnormalities, inflammation, oxidative stress increased, and neuroplasticity impaired have also implicated in the depressive disorder's development. predisposition by Genetic and environmental stressors can further contribute to the onset and the progression of depression [25,26,27].

➢ *Anxiety Disorders*

Mental health conditions are group of anxiety disorders which excessive fear, worry, and nervousness that with normal interfere daily functioning [28,29]. While the occasional anxiety is a normal response to stress, as well as anxiety disorders involve in persistent and anxiety excessive that may require medical intervention.

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- *Anxiety disorders Types*

Table 2 Some of the Common Types of Anxiety Disorders Include [30,31,32]:

S. No.	Type of Anxiety Disorder	Description
1	Generalized Anxiety Disorder	Characterized about some excessive worry aspects of daily life such as work, and relationship, health.
2	Panic Disorder	Recurrent also panic attacks unexpected accompanied by their intense fear and also physical symptoms such as rapid heartbeat, trembling, and sweating, breath shortness [33].
3	Social Anxiety Disorder	Intense fear of social situations and feel embarrassed, judged.
4	Phobias	Irrational and persistent fear of the specific objects and heights, flying, animals, or confined spaces.
5	Obsessive-Compulsive Disorder	intrusive and to repetitive thoughts like obsessions of anything's and behaviors compulsive to performed the anxiety reduce [34].
6	Post-Traumatic Stress Disorder	after the exposure Develops traumatic event associated with the flashbacks, nightmares, emotional distress, severe anxiety.

- *Neurochemical Mechanisms*

The anxiety disorders are development associated with the dysregulation of neurotransmitter several systems in the brain. Neurotransmitters like as dopamine, gamma-aminobutyric acid (GABA), serotonin, and norepinephrine for the stress response, and regulating mood, emotional behavior [35,36,37]. Reduced the GABA activity which lead to increased neuronal excitability and also anxiety symptoms. Same as the, imbalances in the serotonin and norepinephrine pathways are to linked pathogenesis of anxiety disorders. Alterations in the brain regions that is the hippocampus, amygdala, and the prefrontal cortex also contribute to the abnormal fear and stress responses.

➢ *Herbal Used for Anti-depressant and Anti-anxiety Therapies*

Depression treatments pharmacological Conventional and for anxiety include benzodiazepines, selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), and monoamine oxidase inhibitors (MAOIs). Although medications these are effective in many cases and also several adverse effects such as:

- Dizziness
- Drowsiness
- Dry mouth and disturbances in gastrointestinal [38]
- Dysfunction of Sexual
- Gain Weight
- Dependence and withdrawal symptoms especially with the benzodiazepines
- Risk of tolerance
- long-term side effects [39]

Because of knowing of these limitations many patients have seek alternative therapies with the fewer adverse effects.

➢ *Previously Studied Marketed Herbal Formulations for Depression and Anxiety*

Several marketed herbal formulations have been investigated for their anti-depressant and anti-anxiety activities.

Table 3 Safety Evaluation of a Pharmacopoeia-Based Herbal Formulation Used for Depression and Anxiety [40,41,42,43]

S. No.	Formulation Name	Plant Name (Botanical Name)	Pharmacopoeia-Based Evaluation	Reference
1	Pharmacopoeia-Based Formulation (PBF)	*Terminalia chebula* Retz.	Microbial load absent; heavy metals (As, Pb, Hg, Cd) below limit of quantification	Fatima et al.
		Emblica officinalis	No aflatoxin contamination (B1, B2, G1, G2) detected	
		Cuscuta reflexa Roxb.	Pesticide residues not detected by LC-MS/MS and GC-MS/MS	
		Rosa damascena Linn.	Microbial pathogens absent; safe for further pharmacological studies	
		Lavandula stoechas	No toxic contaminants detected	
		Polypodium vulgare Linn.	Heavy metals within WHO permissible limits	
2.	Mentat	*Bacopa monnieri, Withania somnifera, Centella asiatica*	Memory enhancer, anxiety, Demonstrated anxiolytic and cognitive enhancing activity	Kean JD,2017
	Brahmi Ghrita			Santhosh, C.,2021

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3.	Ashwagandharishta (Ixoreal Biomed)	*Withania somnifera*	Shows adaptogenic and anti-stress effects	Bachour G,2025
4.	Manasamitra Vataka	Polyherbal Ayurvedic formulation	reduced the daytime sleepiness.	Tubaki BR, 2012
5.	Stresscom	*Nardostachys jatamansi*, *Convolvulus pluricaulis*	Shows anti-anxiety and calming effects	Lyle N,2009
6.	Tagara formulation	*Valeriana wallichii*	Sedative and anxiolytic activity reported	Toolika E,2015
7.	St. John's Wort formulation	*Hypericum perforatum*	Demonstrated antidepressant activity via serotonin modulation	Kholghi, G., 2022
8.	Jatamansi formulation	*Nardostachys jatamansi*	Shows neuroprotective and anti-stress activity	Kamble, S.2025
9.	Sarpagandha formulation	*Rauwolfia serpentina*	Exhibits sedative and tranquilizing effects	Pundarikakshudu K,2015
10.	Shankhpushpi formulation	*Convolvulus pluricaulis*	Neuroprotective and anxiolytic effect	Sharma R, 2022
11.	Passiflora formulation	*Passiflora incarnata*	Significant good sedative and anxiolytic effects on anxiet	Vaibhavi Diliprao Deshmukh,2024
12.	Kava formulation	*Piper methysticum*	Demonstrated anxiolytic activity	Kuchta K, 2020
13.	Ginkgo formulation EGb 761®	*Ginkgo biloba*	Neuroprotective and cognitive enhancing activity	Beck SM,2016
14.	Lavender formulation	*Lavandula angustifolia*	Calming and anxiolytic effects	Yoo, O., 2023
15.	Rhodiola formulation	*Rhodiola rosea*	Adaptogenic and antidepressant activity	Ivanova Stojcheva E,2022
16.	Saffron Extract Capsules	*Crocus sativus*	Antidepressant activity via serotonin modulation	Lopresti AL,2014
17.	CalmAid	*Lavandula angustifolia (Lavender oil)*	Clinically proven anxiolytic effect	Donelli D, 2019
18.	Nature's Bounty Ginkgo Biloba	*Ginkgo biloba*	Neuroprotective and cognitive enhancing activity	Noor-E-Tabassum,2022
19.	Geriforte Tablets	*Withania somnifera, Phyllanthus emblica, Terminalia chebula*	Adaptogenic and anti-stress effects	Ibáñez B,2023
20.	Brahmi Vati	*Bacopa monnieri, Convolvulus pluricaulis, Acorus calamus*	Shows anxiolytic, neuroprotective and cognitive enhancing effects	Jain PK, 2016

➢ *Scientific Validation*

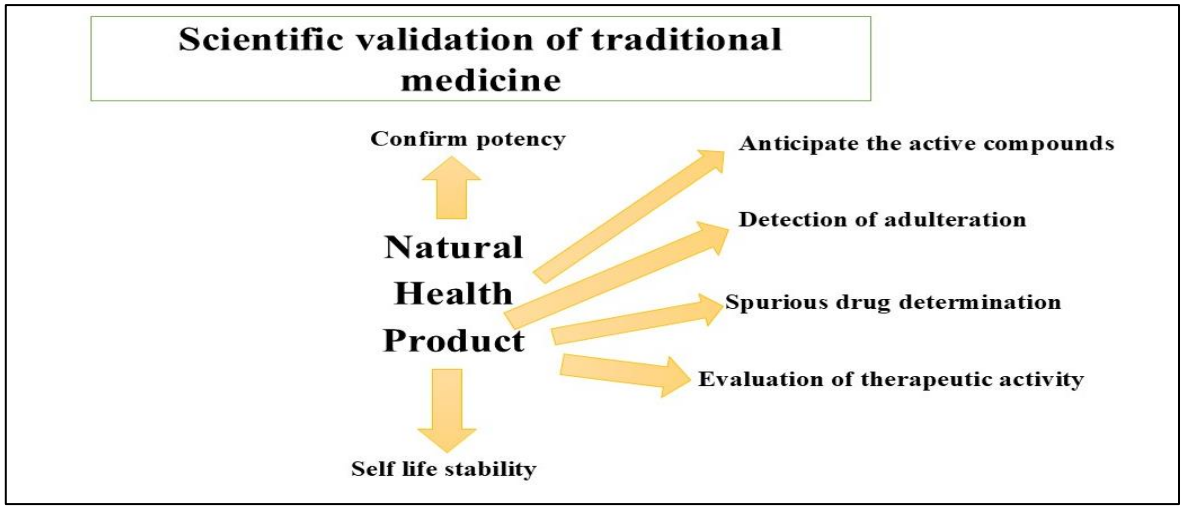

Fig 4 Validation Prospective of the Traditional Medicine which Used for Anxiety and Depression Disorder

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Scientific validation provides an in-depth analysis of the study's findings scientific validation and potential of herbal medicines [44,45]. It emphasizes the promising therapeutic benefits as well as the challenges in clinical translation, and also for the need for robust research to the facilitate the integration of herbal treatments into healthcare mainstream shown in figure3 [46,47].

- *Components of Scientific Validation*

Table 4 Components of Scientific Validation of Herbal Formulations [48,49]

S. No.	Component	Techniques	Purpose
1	Botanical Authentication	DNA barcoding as well as Macroscopic & microscopic evaluation	correct identification of plant species
2	Physicochemical Evaluation	Ash values, extractive values, moisture content, pH determination	quality, Determines purity, and physicochemical characteristics
3	Phytochemical Screening	Qualitative & quantitative analysis such as alkaloids, flavonoids, tannins, etc.	Identifies and estimates bioactive constituents
4	Chromatographic Analysis	HPTLC, HPLC, GC-MS, LC-MS	Provides chemical fingerprinting and ensures batch-to-batch consistency
5	Spectroscopic Analysis	UV-Vis, IR, NMR spectroscopy	Structural identification and confirmation of compounds
6	Biological Evaluation	In vitro (antioxidant, antimicrobial), In vivo (animal models)	Confirms pharmacological activity and therapeutic efficacy
7	Toxicological	sub-acute, Acute, chronic toxicity studies, LD_{50}	Evaluates safety profile for formulation
8	Microbial Contamination Testing	Total microbial count, pathogen detection	Ensures microbiological safety
9	Heavy Metal Analysis	ICP-MS AAS,	Detects toxic metals like arsenic, lead, mercury
10	Pesticide Residue Analysis	Chromatographic methods	Ensures absence of harmful pesticide residues
11	Stability Studies	real-time stability testing and accelerated	Determines shelf-life and storage conditions
12	Method Validation	Accuracy, specificity, precision, LOD, LOQ	Ensures reliability and reproducibility
13	Clinical Validation	Phase I, II, III clinical trials	Confirms safety and efficacy in humans

III. FUTURE OUTCOME

Pharmacological studies have significant demonstrated anti-anxiety, anti-depressant, adaptogenic, and neuroprotective activities of the several herbal formulations. These findings support to the potential use of standardized herbal products as complementary for the treatment of depression and anxiety disorders [50]. The reviewed studies indicate that standardization proper and validation to ensuring the safety and therapeutic effectiveness of the marketed herbal formulations. Analytical evaluation methods which can confirmed the presence of the bioactive phytoconstituents and also ensured that contaminants such as pesticides, heavy metals, and microbial pathogens acceptable limits. extensively used to memory enhance and intelligence in Ayurvedic and the Unani medicine systems.

IV. CONCLUSION

Herbal medicines in worldwide have significant gained attention due to their natural origin effect in therapeutic potential, and comparatively fewer side effects. The herbal formulations increasing use to management of neurological disorders such as depression and anxiety that has highlighted to the need for proper quality control and also scientific validation. Standardization use to ensuring in the quality and reliability of herbal formulations. Its evaluation involves of organoleptic characteristics, physicochemical parameters, as well as phytochemical profiling, and chromatographic fingerprinting using the modern analytical techniques such as HPLC, HPTLC, and GC–MS chromatography technique. Herbal formulations Validation through pharmacological and toxicological studies for the further supports their therapeutic effectiveness. Several marketed herbal formulations containing the medicinal plants such as *Withania somnifera*, *Nardostachys jatamansi*, *Bacopa monnieri*, and *Lavandula angustifolia* have been demonstrated the promising anti-depressant and anti-anxiety activities for the experimental and clinical studies.

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