

## 1. INTRODUCTION

### 1.1 Traditional Herbal Medicine: Global Relevance and Modern Applications

Traditional medicine, particularly herbal-based formulations, continues to play a crucial role in maintaining human health, especially in countries with rich traditional knowledge such as India. According to the World Health Organization (WHO), about 60% of the Indian population and nearly 80% of the global population rely on traditional medicines for primary healthcare (WHO, 2002; Wakdikar, 2004). In rural areas, herbal remedies are often the only accessible treatment options, reflecting their deep-rooted significance in human health.

India has a long-standing tradition of using herbal formulations in systems like Unani, Ayurveda, Siddha, and Homeopathy, with a wealth of medicinal plants that remain central to therapeutic practices (Vaidya and Devasagayam, 2007). Historically, many modern pharmaceuticals like Quinine, Digitalis, and Aspirin have their origins in herbal products, underscoring the essential role that traditional medicine plays in drug discovery (Fabricant & Farnsworth, 2001). In recent years, scientific interest in herbal medicine has increased dramatically, driven by the growing recognition of the adverse effects of synthetic drugs and the efficacy of plant-based alternatives (Sen and Chakraborty, 2017). The COVID-19 pandemic further highlighted this trend, as many individuals turned to herbal remedies for preventive and therapeutic support, leading to a surge in research on the efficacy of various plant-based formulations (Ahmad et.al., 2021; Adhikari et.al., 2021; Kanchibhotla et.al., 2022).

The rise in antimicrobial resistance and side effects associated with modern synthetic drugs has led to a renewed focus on natural remedies, particularly in the context of global health challenges (Patwardhan et al., 2005; Saha et al., 2010). Herbal formulations, which use whole plants or parts such as seeds, fruits, roots, leaves, and flowers, offer a holistic approach to disease management, often with fewer side effects and greater accessibility (Farnsworth et al., 1985; WHO, 1998).

However, one of the major obstacles in promoting herbal formulations, especially in developed countries, is the lack of stringent quality control, standardized documentation, and scientific validation of these remedies (Akbar et al., 2014). For instance, many herbal products available in the market do not meet the quality

specifications outlined by regulatory bodies, leading to variations in potency and efficacy. A notable example is the use of St. John's Wort (*Hypericum perforatum*) for depression, where inconsistencies in the concentration of active compounds like hypericin can significantly affect therapeutic outcomes (Linde et al., 2005). Similarly, the quality of *Ginkgo biloba* extracts can vary widely, impacting their effectiveness for cognitive enhancement or dementia treatment (Sierpina et al., 2005). The need for evidence-based approaches has never been greater, as many medicinal plants possess biologically active compounds that remain unexplored for their full therapeutic potential. Rigorous research into these plants, combined with modern analytical techniques such as High-Performance Liquid Chromatography (HPLC) and Mass Spectrometry (MS), could reveal new drugs or enhance the safety and efficacy of traditional formulations (Kunle et al., 2012). Such evidence-based validation not only enhances the credibility of herbal medicine but also fosters greater acceptance among healthcare professionals and patients alike.

India's rich biodiversity, encompassing over 49,000 plant species, with 5,150 of them being endemic, holds tremendous potential for the discovery of new Phytomedicines (Ramakrishnappa, 2003). The integration of traditional knowledge into modern healthcare systems through tools such as the Traditional Knowledge Digital Library (TKDL) not only safeguards intellectual property but also accelerates the development of plant-based medicines (Mashelkar, 2001). The TKDL bridges the gap between traditional knowledge and modern drug discovery, allowing the development of safe and effective formulations with global commercial potential.

Despite the ancient and rich heritage of traditional Indian medicine, it has often faced marginalization, particularly during the colonial period due to where Western medicine was promoted as the sole legitimate form of treatment. In recent years, however, this narrative has shifted. There is now a growing recognition among modern healthcare practitioners of the benefits of natural remedies, particularly when synthetic drugs fail or produce unwanted side effects (Sen et al., 2017; Gaikwad et al., 2003). This has rekindled interest in polyherbal formulations, especially their potential to address unmet medical needs through synergistic effects of multiple plant compounds (Dubey et al., 2004; Pande et al., 2018).

The present research focuses on assessing the safety, efficacy, and quality of polyherbal formulations using modern scientific tools. By bridging the gap between traditional knowledge and evidence-based medicine, this study aims to contribute to the growing body of research that supports the integration of traditional herbal remedies into contemporary healthcare systems. This is particularly critical as the world faces emerging health threats and the limitations of conventional pharmaceutical approaches become more apparent.

## **1.2 Challenges in Traditional Medicine**

The National Medicinal Plants Board, India, estimated about 77% of the medicinal plants used in the country for several traditional medicinal formulations are from forests and wastelands. The International Union for Conservation of Nature Species Survival Commission estimated that there are 19 extinct, 43 extinct/endangered, 149 endangered, 108 vulnerable, and 256 rare plant species in India (Sen et.al., 2011). Thus, reducing overexploitation, stopping deforestation, cultivating medicinal plant, and using cell cultures and other scientific methods are required to protect the medicinal plants.

Further, the incidence of biopiracy is a major impediment to the advancement of Indian herbal medicine. A survey by a TKDL task force based on 4,896 references revealed that 90 medicinal plants were listed in the US Patent and Trademark Office database, and about 80% of references were related to seven medicinal plants (Kumari, Mustaka, Tamraparna, Garjara, Atasi, Jambira, And Kharbuja) of Indian origin. The task force also revealed that 360 of 762 patents were based on medicinal plants that could be classified as “traditional” (Sen and Chakraborty, 2014). This indicates the potential of Indian traditional knowledge and herbal drugs to address a large number of ailments in the future.

The primary lacunae with Ayurvedic and other traditional herbal products are the lack of drug standardization, information, quality control, and strict monitoring (Joy et.al., 1998). A large number of Ayurvedic formulations are available in spurious, adulterated, or misbranded forms, and several preparations do not follow the traditional proper rules or texts on how to prepare such formulations (Patwardhan et.al., 2005; Rana and Rana, 2014). A report on Ayurvedic medicine has found that about 20% of such medicines purchased through the Internet contained high levels of lead, mercury, and arsenic.

Recently, the US Food and Drug Administration found that several herbal supplements contained currently available drugs like lovastatin (e.g., Mevacor), sildenafil (e.g., Viagra), estrogen, alprazolam (e.g., Xanax), indomethacin (e.g., Indocin), and warfarin (e.g., Coumadin) as adulterants (Dias et.al., 2012; NCCAM, 2013). Herbal manufacturers from India usually follow World Health Organization guidelines for quality control, but the adulteration of formulations remains a major concern for both the domestic and export markets of Indian herbal products. (Patwardhan et.al., 2005; Rana and Rana, 2014).

The majority of Ayurvedic formulations contain crude extracts in mixtures of different ingredients. Some studies have showed that the active principles of such products fail to produce the desired effects when isolated individually (Patwardhan et.al., 2005). This may be due to the synergistic activity of several components present in a formulation. In the absence of pharmacopoeial data on such herbal formulations, it is very difficult to isolate or standardize the active components. Currently, the *Ayurvedic Pharmacopeia* has been compiled on modern lines and is updated often as per requirement (Joy et.al., 1998).

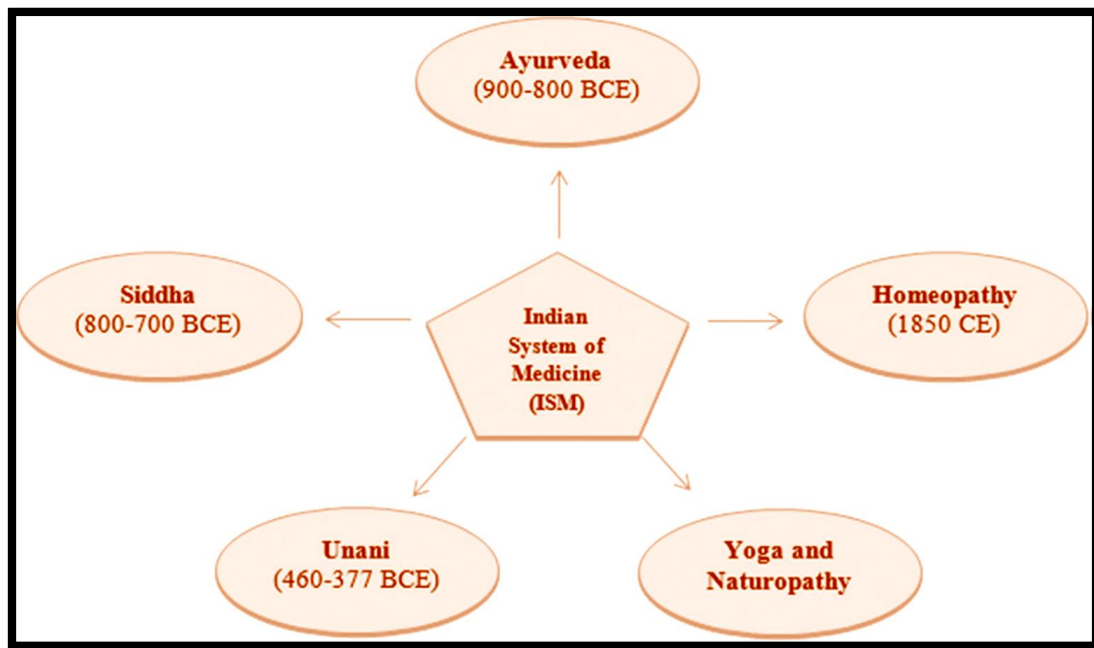
Quality control and drug–herb interaction are other drawbacks, such as the variability in active compound concentrations, presence of contaminants, or lack of regulatory oversight, which can compromise both safety and efficacy. Several herbal products can interact with food, allopathic drugs, or pharmaceuticals, but unfortunately, for the majority of products, such information is lacking. In general, after 1 year of collection, herbs lose their medicinal value; powders prepared from such herbs remain effective for nearly 6 months, while pastes or ointments are effective for 1 year (Rana and Rana, 2014). Several herbs may be responsible for serious adverse effects – for example, creosote bush causes hepatotoxicity, ephedra may be responsible for cardiovascular complications and hepatotoxicity, and kava may induce hepatotoxicity. Several manufacturers do not follow the appropriate methods of preparation and do not use the proper parts of the plant, which may be responsible for toxicity – as in the case of kava-induced toxicity (Rivera et.al., 2013; Sharma et.al., 2008). This situation needs to be addressed properly for the growth of Indian herbal medicine.

In the last 30 years ISMs (Indian system of medicine), especially Ayurveda, have become remarkably popular in European countries. It has been estimated that over 5

million European people have used such traditional medicine in the last few decades. Due to the popularity of traditional medicine, thousands of under-/nonqualified traditional medicinal practitioners/institutions have emerged in Europe, which has led to a serious situation (Patel, 2014). In the last decade, the European Union demanded bibliographic evidence and preclinical safety data before the marketing of traditional medicinal products. Thus, proper standardization of and research and data on products' quantitative and qualitative particulars of constituents, methods of manufacturing, therapeutic uses, contraindications, toxicity profiles, posology, forms, and routes of administration are essential for the promotion of Indian traditional medicine in Europe (Sahoo and Manchikanti, 2013).

### **1.3 Indian systems of medicine**

Concepts and practices of different traditional medicinal systems in India are about several thousand years old. A large proportion of the Indian population still believes in and receives traditional medical care, which is based on the principles of three ancient codified Indian systems of medicine (ISMs): Ayurveda, Siddha, and Unani (Subbarayappa, 2001; Borins, 1987; Ministry of AYUSH, 2010). The practice of medicines which are thought to be Indian origin or which have come to India from outside and got absorbed into Indian culture is known as traditional medicine of India, exemplified in **Fig. 1**. India has the exclusive distinction of its own recognized traditional medicine; Ayurveda, Siddha, Unani, Yoga and Naturopathy, and Homoeopathy. Though different chemicals, minerals, and animal products are used in such system to prepare curative agents, but use of plants have been the basis of treatment in these systems. It is estimated that Ayurveda uses 1,200 species of plant, while Siddha and Unani include 900 and 700 species of plant, respectively, in their medicinal preparations (Kannaiyan, 2014). Ayurveda and other ISMs are judicious combinations of modern science and contemporary clinical medicine, which have the potential to cure a number of diseases in better ways and leverage new leads for modern medicine (Qazi, 2006). Currently, more than 1.5 million traditional medical practitioners in India are using medicinal plants for preventive, promotional, and curative purposes (Wakdikar, 2004).



**Fig. 1. Recognized systems of Indian medicinal practice**

### 1.3.1 Folk Medicine

Folk medicine (also known as “tribal” or “indigenous” medicine) also plays an important role in Indian society, mostly in rural/indigenous/ethnic communities. This type of knowledge is usually passed verbally from ancestors of the particular group of people without any written script. It has been estimated that more than 8,000 species of plants are used by the tribal and ethnic communities in India as part of their health care systems ((Government of India Planning Commission, 2000; Devanna et.al., 2014). Approximately 25,000 effective plant-based formulations are used in folk medicine and are commonly used by rural and ethnic communities in India (Wakdikar, 2004).

### 1.3.2 Ayurveda

Ayurveda, perhaps the most ancient (6000 BC) of the different organized traditional medicinal systems, is native to the Indian subcontinent and has been practiced since the beginning of the Indian civilization. The literal meaning of Ayurveda is “The Science of Life;” the combination of two *Sanskrit* words “ayur” (life) and “veda” (science or knowledge) (Prasad. 2002). Ayurveda involves a logical convention of harmonious living, and its beginning can be drawn from ancient information in *Rigveda* and *Atharva veda*. The source of Ayurveda has been lost in ancient relic, yet its ideas and methodologies have been idealized in between 2500 and 500 BCE in India (Mukherjee,

2001). The utilization of natural resources for advancement through generous experimentation and experiences of day-to-day life has been a regular practice of Ayurveda of Indian people.

The fundamental rule of Ayurvedic treatment contains two basic parts. These are to keep the reason for illness and to make the patient more mindful about the reason for the sickness. The central objective of Ayurvedic treatment is “Ayurveda deals with happy and unhappy life. It explains what is appropriate and what is inappropriate in relation to the life, as well as it measures the life expectancy and the quality of life (Singh, 2008; Mukherjee et.al., 2017). It is a holistic arrangement of medical services with the idea, that the human body is a network of seven fundamental tissues (“Rasa,” “Rakta,” “Mansa,” “Meda,” “Asthi,” “Majja,” and “Shukra”) and the waste results of the body, for example, excretion, urine, and sweat, which are derived by the five fundamental components fire, water, air, ether, and earth and three dynamic energies or functional philosophies “vata, pitta, and kapha” (*Tridosha*). Any unevenness or unsettling influence in these fundamental standards of the body causes disease (Lad, 2002; Mukherjee and Wahile, 2006). Preventive and curative measures are the key components of the Ayurvedic system. Major treatment approaches include the use of “aushadhi” (drugs); “anna” (diet); and “vihara”, which includes exercises and a healthy mode of life (Singla, 2012; Ravishankar and Shukla, 2007; Srinivasan, 1995). The *Charak Samhita*, *Sushrut Samhita*, and *Samhitas of Vagbhat*, together referred to as the Brihatrayee, are considered the three key classics in Ayurveda. *Charak Samhita* and *Sushrut Samhita* (100–500 BC) describe over 700 plants, along with their detailed classification, pharmacological, and therapeutic characteristics (Qazi, 2006; Patwardhan, 2004). Ayurveda treats a patient in general and not the sickness alone. This system of drug highlights the uniqueness of every individual with respect to social conservative status, bio-personality, biosynthetic, and physiological conditions, which may prompt a specific kind of ailment. Further, this facilitates investigation with present-day logical methodologies for tending to different human services issues. Ayurvedic preparations are frequently poly-herbal mixtures of plant and/or animal-derived products, metals, and minerals. However, ancient manuscript including modern Ayurvedic Pharmacopoeia shows the dominance of NPs than other derived products (API, 2001a, b, c; AFI, 2000).

### **1.3.3 Siddha**

The Siddha system of medicine, originating in ancient India around 10,000 BCE–4000 BCE, is one of the oldest medicinal practices, particularly prevalent in South India. Developed alongside Ayurveda, it follows Saiva philosophy, emphasizing natural resources for maintaining health. "Siddha" means "attaining excellence" or "holy harmony," and the system is believed to have been established by 18 Siddhars, including Agathiyar and Thirumoolar. The core philosophy centers around the belief that "food is medicine, medicine is food," and health depends on the balance of three humors and seven basic body elements. Disease is seen as the result of imbalance in these components (Piet, 1952; Sathasivampillai et al., 2017). The diagnostic approach involves an eight-fold system, and psychosomatic health is maintained through yoga and the administration of medicines, often involving metals and minerals (Pillai, 1998; Mukherjee and Wahile, 2006).

Although less known to the Western world due to untranslated literature, Siddha is recognized within Tamil communities as a viable alternative medicine (Thass, 2008; Stephen, 2005). It uniquely integrates spiritual, intellectual, and physical health, emphasizing alchemy and urine examination, differentiating it from Ayurveda (Narayanaswamy and Pandit, 1975; Sathasivampillai et al., 2017). Today, Siddha is considered effective for treating most conditions, except emergencies, with herbo-metal and nanoparticle preparations particularly beneficial for chronic diseases (AYUSH, 2010; ISM, 2011; Husain et al., 2010).

### **1.3.4 Unani system of medicine**

The practice of Unani system of medicine stretches all the way back into the misty dawn of time. The Asia-Pacific database on Intangible Cultural Heritage (ICH) by Asia-Pacific Cultural Centre for UNESCO (ACCU) has deemed Unani System of Medicine as one of the oldest and most acceptable systems of medicine. It is practiced in India and all over the world particularly in Egypt, Syria, Iraq, Iran and most parts of South-East Asia (Asia-Pacific Cultural Centre for UNESCO, n.d.). The Unani system of medicine as its name suggests has its origin in Greece. The core philosophy of this system was conceptualized by Hippocrates. After him, Arab and Persian scholars made great contributions and hold a large share in what constitutes the Unani literature today. It was introduced in India by the Mughals and since then has enjoyed popularity

amongst the masses and now forms an integral part of the healthcare delivery system of the country.

The basics of the Unani system of medicine were laid by Hippocrates and later by Galen. In the eleventh century, the Unani system was introduced in India by Arabs and Persians. The fundamental theory of the Unani system is “humoral theory”, which presupposes the presence of four humors – blood, phlegm, yellow bile, and black bile – in the body, and for Unani practitioner’s diagnosis mainly depends on pulse reading, and examination of the urine and stools (Ahmad, 2007). The main therapeutic approaches in this system include dietotherapy, or “Ilaj-bi-ghiza” (use of specific diet); regimental therapy, or “Ilaj-bil-tadbeer” (exercise, change of climate, massage, venesection, leaching, cupping); pharmacotherapy, or “Ilaj-bi-dawa” (use of medicines from herbal, mineral, and animal sources); and surgery, or “Ilaj-Bil-Yad” (Ahmad, 2007; CSIR and Ministry of AYUSH, n.d.). Unani views the human body as made up of seven standards: Mizaj (temperaments), Anza (organs), Quo (resources), Arkan (components), Arawh (spirits), Aklath (humors), and Afal (capacities). These standards oversee prosperity and additionally disease condition (Kalim et.al., 2010; Chopra and Simon, 2004).

The strength of the system is in its holistic and individualistic approach to health promotion, disease prevention and treatment. It offers an effective treatment for various gastrointestinal, respiratory, genitor-urinary, musculoskeletal, neurological, cardiovascular, lifestyle and metabolic disorders (Husain et.al., 2010). Although the government has given great importance to the multi-faceted development of this system of medicine to make full use of its potential in the Indian healthcare delivery, the Unani system of medicine has not gained much recognition within the times.

A number of issues have been at the backdrop of this lag, primary of which has been the lack of quality data on safety and efficacy of Unani drugs required to put the system’s practices at par with contemporary medical systems. The main reason behind this inadequacy of research data is the lack of appropriate and accepted research methods that can be used for evaluating the system’s practice. However, the question, whether an evidence base is required for a system which has been in widespread practice for ages, has puzzled many a mind. This question needs to be analyzed in terms of extended benefits of putting an evidence basis for practice of Unani medicine,

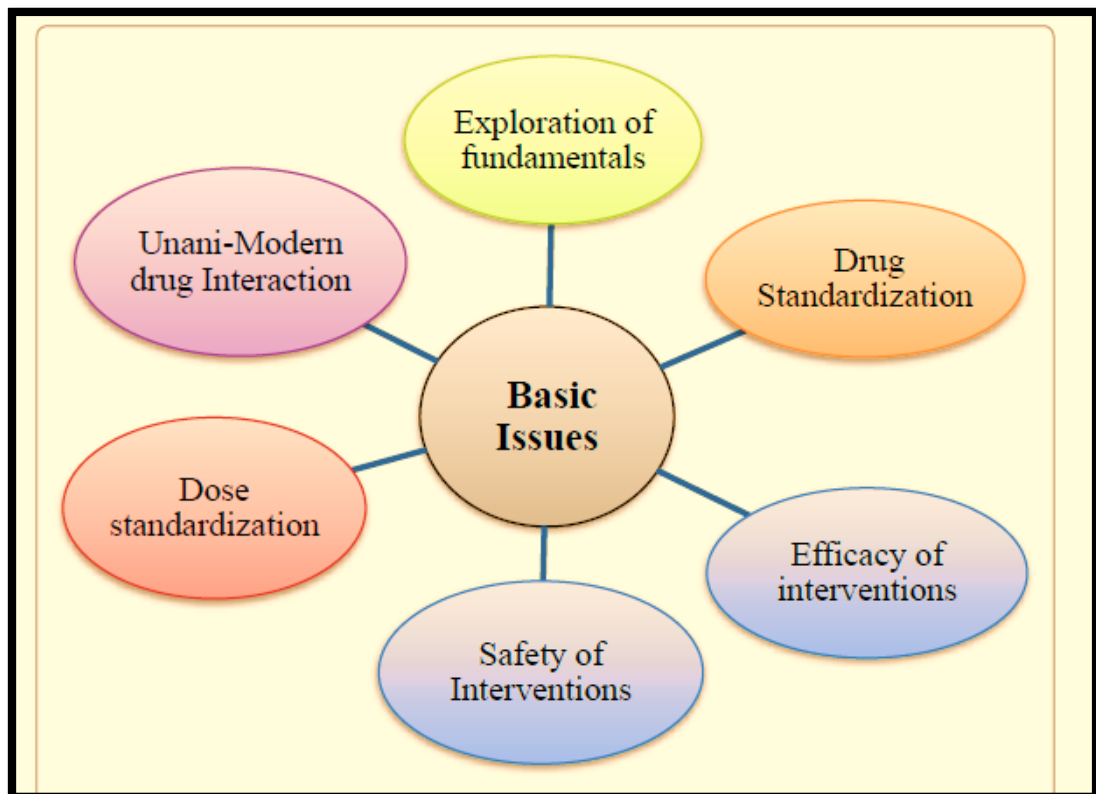
primarily for providing a prospectively better and dependable health care and secondarily for growth of Unani medicine as a contemporary science. Unani System of medicine indeed needs intensive work to bring out an evidence basis to its nosology, primarily to support its concepts and to make a sound scientific basis for its therapeutic interventions. Additionally, it also needs evidence to support its interventions in varied clinical conditions to the extent that their application in a given condition is justified.

The seemingly obvious task of deciphering and devising methods of furnishing this evidence leads us to a new set of questions. How can Unani drugs be standardized using parameters of another health system? Should all formulations used in the system be re-evaluated using biomedical parameters and would this process be affordable? While it is important to substantiate an evidence base for Unani medicine, it is equally important to ensure that the epistemological differences between the two systems are taken into account when developing research protocols. The guiding dictum should be to identify such tools and methods for research in Unani medicine which are sensitive enough to respect the desired rigor of science as well as the original holistic nature of Unani medicine equally (Itrat and Khan, 2016).

#### **1.3.4.1 Unani Medicine: The Amendments Needed**

In the context of recognition and resurgence of Unani system of medicine globally, there are certain issues that need to be critically understood and examined. In our opinion, Unani medicine requires extensive research in the following areas:

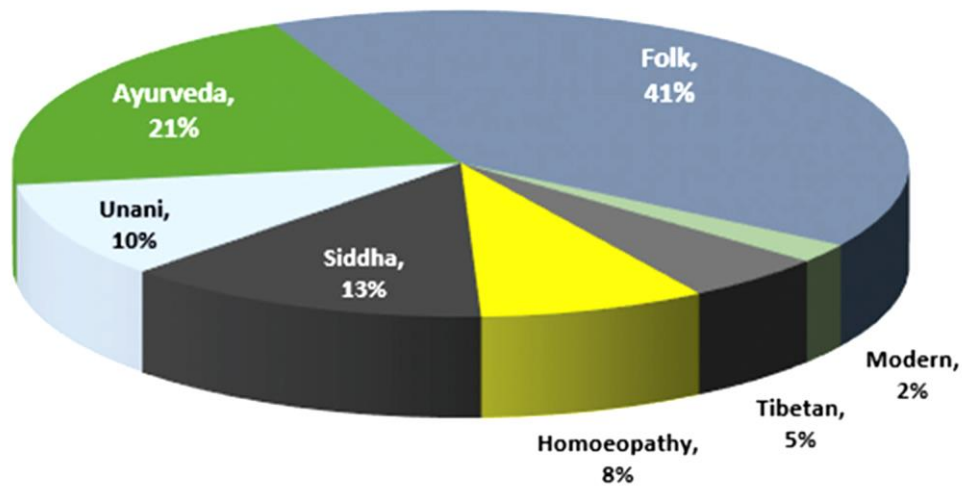
- Revalidation of Unani fundamentals so that they can be inexplicably stated and understood.
- To find out better treatment modalities for existing diseases and for newer diseases.
- To standardize the treatment procedures scientifically.
- To establish dose, duration, indication and side-effect profile of drugs.
- Unani and modern drugs interactions (Fig. 2).



**Fig. 2. Issues that need to be addressed**

#### 1.4 Comparative Analysis of Ayurveda, Siddha, and Unani

Indian traditional medicine has its origin in India that evolved through a continuous process of transformation from its *Vedic* period and a single drug or blends in crude shape are favored over many fold formulations. In spite of the fact that the starting points and advancement times of these traditional medication process are different, however, there is a common background through this foundation, is in their basic standards and practices by utilizing the plants and plant-based preparations in the medicinal services. The extent of utilization of plants in a different system of medications appears in Fig. 3. Moreover, around 85–90% Indian population depends on the traditional system for essential medicinal services (Adhikari and Paul, 2018).



**Fig. 3. Displaying the percentage of plants used in different systems of medicines in India**

This comparative analysis underscores the relative underrepresentation of Unani medicine in modern scientific research compared to Ayurveda and Siddha. While both Ayurveda and Siddha have been widely explored and validated through various studies, Unani medicine, despite its rich historical and therapeutic legacy, remains under-researched, particularly in the realm of standardization and scientific validation (Itrat and Khan, 2016; Teoh, 2016; Mukherjee et.al., 2016; Sen and Chakraborty, 2015). Recognizing this gap, the present study focuses on Unani medicine, aiming to contribute to its standardization and to validate the therapeutic efficacy of its formulations, thereby bridging traditional knowledge with modern scientific practices.

### **1.5 Unani System of Medicine**

Under the shade of traditional medicine systems, the Unani system of medicine is also gaining global acceptance due to the amazing clinical efficiency of the formulations (Ajazuddin, 2010). In Unani system of medicine is mainly based on naturally occurring drugs, mostly herbal in origin. Drugs of animals and mineral origin are also being used (Mohd et.al., 2017). A number of drugs, both single and compound preparations are used widely in Unani Tibb (Unani medicine) in the management of various ailments, and It is a fact that many herbs have been reported with its diverse medicinal effects. The use of herbal medicines has increased remarkably in line with the global trend of people returning to natural therapies. Herbal medicine products may use as a dietary

supplement that people take to improve their health and are sold as tablets, capsules, powders, teas, extracts and fresh or dried plants etc.

Due to the long historical practice and less toxicity of Unani medicines, they are gaining more and more attention all over the world. Even today there is increase acceptability for traditional system of medicine for maintaining human health quality. To full fill this necessity, the herbal plant materials are replaced by some unauthentic substituents or adulterants material and also not follow the proper guideline for the preparation of formulation etc. So, the safety and quality of crude medicinal drugs and finished herbal products have become a foremost concern for health authorities, pharmaceuticals and the public (Jitubhai, 2011). To prevent this adulteration, unethical practice, some sort of uniformity in the manufacture of Unani medicine, the proper standardization process to be needed. The present study deals with various techniques engaged in characterization and standardization of Unani polyherbal formulations.

### **1.5.1 Single and Compound Drugs in Unani Medicine**

Unani medicine, rooted in the ancient Greco-Arabic healing tradition, utilizes a broad spectrum of medicinal substances, categorized into single drugs and compound drugs (formulations). Both categories derive from natural sources—plants, minerals, and animals—and form the core of Unani pharmacology. The therapeutic approach in Unani medicine emphasizes restoring the balance of the body's humors and maintaining health through individualized care, using these diverse medicinal substances.

### **1.5.2 Single drugs in Unani medicine**

Single drugs, known as *Mufradat* in Unani terminology, are derived from a single natural source—whether herbal, mineral, or animal. These drugs are used in their pure form, often with minimal processing, to preserve and harness their innate medicinal properties. For example, herbal single drugs such as *Zanjabeel* (ginger) are employed for digestive ailments, while mineral-based drugs like *Marmar* (marble) and *Sang Jarahat* (lapis lazuli) are utilized in treating bone diseases and wounds. Animal-based single drugs such as *Luban* (frankincense) and *Mahi* (fish) contribute to treating chronic diseases, correcting nutritional deficiencies, and serving as general tonics for vitality (NFUM Pt.- VI, 2011; UPI, Pt.-I, Vol.-I, 2007; Mohd et al., 2019).

Single drugs are essential in classical Unani treatment, where they are selected based on the patient's temperament (*Mizaj*) and the nature of the illness. The simplicity of using single drugs enables targeted treatments, which form the foundation of individualized care in Unani medicine.

### **1.5.3 Compound drugs (Formulations) in Unani medicine**

Compound drugs, known as *Murakkabat*, consist of a combination of two or more ingredients, which can be derived from herbal, mineral, or animal sources (Mohd et al., 2019). These formulations are designed to enhance the therapeutic efficacy of individual ingredients through synergistic effects. Compound drugs are further classified into several categories based on their composition:

#### **1.5.3.1 Polyherbal Formulations**

Exclusively composed of plant-based ingredients, polyherbal formulations are a hallmark of Unani medicine. Examples include *Jawārish Kamooni* and *Habb-e-Asgandh*, which are commonly used for digestive and musculoskeletal disorders (Aslam et al., 2016; UPI, Pt.-II, Vol.-I, 2009; NFUM Pt.-VI, 2011; Mohd et al., 2019).

#### **1.5.3.2 Herbo-Mineral Formulations**

These combine herbs with minerals to enhance their potency. A well-known example is *Kushta* preparations, where herbs are blended with calcined minerals like zinc or gold, commonly used for treating chronic ailments such as arthritis and neurological disorders (Ahmad et al., 2020; Dar et.al., 2016; Said, 1970).

#### **1.5.3.3 Herbo-Animal Formulations**

These formulations incorporate animal-derived substances along with herbs to create powerful therapeutic agents. For instance, *Jawārish Jalinoos* and *Sufoof-e-Jalinus* are herbo-animal formulations used as digestive tonics and systemic remedies (NFUM Part-VI). Animal-based components are traditionally known for their role in enhancing the vitality and strength of the patient, especially in conditions requiring rejuvenation and fortification (Mohd et al., 2019).

### 1.5.3.4 Herbo-Mineral-Animal Formulations

These sophisticated preparations combine herbal, mineral, and animal ingredients to address severe or chronic conditions. By integrating the therapeutic properties of all three sources, these formulations offer a comprehensive approach to rebalancing the body's humors and restoring health. These formulations are particularly valuable in addressing complex health issues where single or simpler formulations may not be sufficient (Mohd et al., 2019; NFUM Pt.-VI).

Unani compound formulations highlight the holistic approach of this system, where multiple natural substances are combined to enhance efficacy and provide a multi-faceted treatment for various ailments.

### 1.5.4 Need of standardization of Unani medicine

Unani system of medicine is claim that mostly it is effective and safe, use to cure wide range of ailments, with the help of single drugs and compound formulations of *Adwiya Nabātiyya* (Plant origin), *Adwiya Haywāniya* (animal origin) and *Adwiya Ma'daniyya* (Mineral Origin), but mainly herbs are used. Unani compound preparations are commonly used in four forms viz. Solid, Semi Solid, Liquid and Vapours. Solid dosage forms are pill (Ḥabb), tablet (Qurs), powder (Safūf), Kushta etc., Semi Solid dosage forms are various type Jawārish, Ma'jūn, La'ūq, Iṭrīfal, khamūra Marham etc., Liquid dosage forms are decoction ('Arq), Syrup (Sharbat), drops(Qaṭūr) etc., and Vapours dosage forms are fumigation(Bakhūr), steam inhalation(Inkibāb), Lakhlakha, perfumes etc. (Afzal et.al., 2004; Ministry of AYUSH, 2016).

It is well known fact that Unani drugs have been used since a long. In older times, Unani practitioners used to treat the patient on an individual basis with the single drugs and also formulate the compound formulation of medicine as need of the patients. They also mentioned a lot from their experience regarding the identification of crude drugs, their authentication methods and about their clinical efficacy but despite these the documentation of standardization on Unani drugs is negligible.

Traditional system of medicine including Unani system of medicine is popular worldwide and these drugs are being used by all community of the people, so there is increase the general acceptability of the use of herbal medicine in today medical practice. The increase in the demand of the drugs leads the shortage of crude drugs. To

fill this necessity, the herbal plant material is substituted by some adulterants and inferior products, also not follow the proper guideline for the preparation of formulation etc. which is responsible to wide range of abuse and adulteration of the products leading to ‘consumer and manufacturer’ disappointment and in some fatal concerns. To prevent this practice there should be some sort of uniformity in the manufacture of Unani medicines is needed to ensure quality control and quality assurance of the Unani drugs. The World Health Organization (WHO) has appreciated the importance of medicinal plants for public health care in developing nations and has evolved guidelines to support the member states in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation, safety and efficacy (WHO, 2005).

Now, today the Unani medicinal products are manufactured on a large scale in mechanical units. Where manufacturers come across many problems such as non-availability of good quality raw materials and proper methodology for standardization, etc., there is also lacking availability of SOP (Standard Operational Procedure) for manufacturing units on large scale production (Afaq et.al., 2012). Thus, to ensure to develop the quality of Unani drugs, the standardization of the single and compound drugs on modern analytical parameter is the basic requirement of Unani system of medicine now days.

### **1.6 Assessment of the Diversity and Traditional Knowledge of Unani Medicinal Plants in Northwest Gujarat**

Building upon the general overview of traditional systems of medicine provided earlier, this section specifically focuses on the Unani system of medicine and its application in the Northwest region of Gujarat. The World Health Organization (WHO) recognizes Unani medicine as a complementary healthcare system. Its primary sources of drugs include plant, animal, and mineral origins (Mishra et al., 2016), with the Unani pharmacopoeia offering a rich selection of natural drugs, predominantly herbal, supplemented by materials of animal, mineral, and marine origins.

Northwest Gujarat, known for its rich but underexplored biodiversity, presents an opportunity to assess and document medicinal plant species used in Unani practices. This region remains largely untapped for its natural resources, making it ideal for a detailed exploration of the plant species that form the backbone of the Unani

pharmacopoeia. The objective of this section is to document and catalog traditional medicinal plants in the area, focusing on those relied upon by rural populations that continue to use Unani practices for their healthcare needs.

### **1.6.1 Batrisu Vasanu-a folk polyherbal formulation**

Traditional polyherbal formulations, integral to Unani medicine, are often transmitted across generations based on practitioners' experiential knowledge. Among these, *Batrisu Vasanu* is notable as a widely used folk formulation in both Unani and Ayurvedic systems. While its therapeutic roles have been investigated in Ayurveda (Charola et al., 2022), its authenticity, applications, and quality control within Unani medicine remain underexplored. Recognizing this gap, the present study focuses on assessing the traditional knowledge and medicinal uses of *Batrisu Vasanu*, aiming to authenticate and evaluate its quality within the Unani framework.

As the study's geographical focus transitioned from Northwest to Central Gujarat, encompassing Vadodara and Ahmedabad, it became evident that Unani practices are more prevalent here. During field surveys and interviews with *Hakims*, *Batrisu Vasanu* emerged as a key polyherbal formulation widely utilized in both Unani and Ayurvedic traditions. Its inclusion underscores the study's aim to bridge traditional practices with scientific validation, addressing the need for standardization and quality assurance in these regions.

India's rich heritage of plant-based treatments underpins the use of various herbs and spices to address postpartum challenges—a time traditionally considered crucial for maternal recovery. Pregnancy is seen as a "hot state" within humoral theories, with labor leading to a "cold" state postpartum (Anonymous, 1993). Therefore, supporting the mother through targeted nutrition and herbal remedies during this period is critical (Jain et al., 2011). The World Health Organization (2006) emphasizes understanding these cultural practices, with the first 40 days postpartum often considered essential for enhanced maternal care.

*Batrisu Vasanu*, composed of 32 herbs and spices, is a traditional formulation in Gujarat, believed to support lactation and maternal health. It is commonly consumed during the early postpartum period, though the authenticity of its botanical composition in commercial products is questionable. This study thus seeks to address these gaps by

examining *Batrisu Vasanu's* composition, preparation, and use within Gujarati culture. Through this analysis, we aim to highlight its ethnomedicinal value as both a galactagogue and a broader nutraceutical, emphasizing the need for quality control and authentication in marketed formulations.

## **1.7 Polyherbal Formulations**

Polyherbal medicines, which contain two or more herbal ingredients are often more effective than single drugs because of their complementary and/or potentiating activities. The combination of two or more herbal extracts brings about increased therapeutic efficiency, enhanced pharmacological actions, faster relief, and reduced adverse effects as compared to conventional medicine due to a lower dose of administration (Nachimuthu et.al., 2021; Aslam et.al., 2016; Raslin and Rajkumar, 2017; Abbas et.al., 2021). Polyherbal medicines are now widely preferred and used around the world because of their high effectiveness, ready availability, low toxicity, and environmentally friendly nature, and it reduces the time of treatment or the individual cost of anti-inflammatory and antimicrobial drugs, resulting in lower prescription costs (Dev et.al., 2019; Abbas et.al., 2021). The concept of polyherbal combination has been well established and has achieved remarkable success in allopathic medicine, providing patients with new hope (Mussarat et.al., 2021).

### **1.7.1 Advantages of polyherbal formulation over single herb**

Ayurvedic and herbal medicinal products contain a combination of botanicals; each of these contains a number of chemical compounds that may give the anticipated activity in combination. The increasing interest in the use of plant-based formulations is leading to a fast-growing market for Ayurvedic (Bhope et.al., 2011). Herbal medicines are in widespread use and although many believe herbal medicines are safe, they are often used in combination and are drawn from plant sources with their own variability in species, growing conditions, and biologically active constituents. A major hypothetical advantage of botanicals over conventional single-component drugs is the presence of multiple active compounds that together can provide a potentiating effect that may not be achievable by any single compound. Polyherbal formulations have plant-based pharmacological agents which may exert synergistic, potentiate, agonistic antagonistic actions by virtue of its associated diverse active principles themselves.

These pharmacological principles work together in a dynamic way to produce maximum therapeutic efficacy with minimum side effects (Benzie and Wachtel-Galor, 2011). Based on the nature of the interaction, there are two mechanisms on how synergism acts (i.e., pharmacodynamics and pharmacokinetic) (Spinella, 2002). In terms of pharmacokinetic synergism, the ability of herb to facilitate the absorption, distribution, metabolism and elimination of the other herbs is focused. Pharmacodynamics synergism on the other hand, studies the synergistic effect when active constituents with similar therapeutic activity are targeted to a similar receptor or physiological system. Other than that, it is believed that multiplicity of factors and complications cause diseases in most of the cases, leading to both visible and invisible symptoms. Here, combination of herbals may act on multiple targets at the same time to provide a thorough relief (Chorgade, 2007). Due to synergism, polyherbalism offers some great benefits which lacks in single herbal formulation. It is evident that better therapeutic effect can be reached with a single multi-constituent formulation. For this, a lower dose of the herbal preparation would be needed to achieve desirable pharmacological action, thus reducing the risk of deleterious side-effects. Besides, PHFs bring to improved convenience for patients by eliminating the need of taking more than one different single herbal formulation at a time, which indirectly leads to better compliance and therapeutic effect. All these benefits have resulted in the popularity of PHF in the market when compared to single herbal formulation (Parasuraman et.al., 2014). Polyherbal formulation also having multiple types of molecules against a disease complication so different molecules cure a disease by different mechanism so provide a complete therapy against a disease condition (Sarwar et.al., 2011).

### **1.7.2 Limitations of polyherbal formulation**

Polyherbal formulations in both Ayurvedic and Unani medicine are valued for their potential synergistic effects, as multiple herbs are thought to work together to enhance therapeutic outcomes. However, the combination of various plant constituents can lead to chemical incompatibilities, resulting in stability issues and variations in potency (Kavitha et al., 2013; Parveen et.al., 2020). Despite the establishment of the Drugs and Cosmetics Act in India, regulatory measures for these traditional formulations remain less stringent, with limited requirements for toxicity studies and clinical validation. Ayurvedic and Unani formulations may be manufactured and even exported without

mandatory clinical trials or rigorous standardization of active ingredients, which can compromise their quality and safety (Rastogi et al., 2012; Rai et.al., 2020; Ramaiah et al., 2013). This lack of regulation can lead to inconsistencies in efficacy, and adverse interactions with other drugs, potentially impacting patient safety (Mukherjee et.al., 2015). For wider acceptance and safer application, stricter quality control, safety evaluations, and evidence-based validation are needed in both traditional systems.

### **1.7.3 Synergistic Effect on Polyherbal Formulations**

The concept of synergy in polyherbal formulations is central to traditional systems like Unani medicine, where combining multiple herbs is believed to enhance therapeutic efficacy. The synergistic effect occurs when the combination of plant constituents produces a more potent result than the sum of the individual components (Karole et.al., 2019). This interaction can increase bioavailability, enhance pharmacological activity, and reduce toxicity, making polyherbal formulations more effective in treating a wide range of ailments (Parasuraman et al., 2014). Studies have demonstrated that polyherbal formulations often show superior biological activity compared to single herbs, supporting their widespread use in traditional medicine (Rahim et al., 2018). Despite these benefits, challenges in standardization remain, making it crucial to scientifically validate these formulations for modern therapeutic use (Patwardhan et al., 2005).

### **1.7.4 The need of standardization of Unani formulations**

India is a main center of Unani, Ayurveda, Homoeopathy and other medicinal plants which used on human health science. People are unable to utilize the advantage of the traditional systems of medicine just because of lack of quality control measures. Due to the improved scientific knowledge a situation has arisen to start the research activities such as standardization of traditional medicinal plant and to develop the scientific methods for the manufacture of quality medicinal formulations (Meena et al., 2010). The manufacturing of Unani medicine is maintained by Drugs and Cosmetics Act. Revalidation of Unani formulations are necessary in order to estimate the purity of drugs, minimizes batch-to-batch difference, check efficacy, safety, quality and suitability of the herbal formulations (Choudhary and Sekhon, 2011; Chaudhary *et al.*, 2014). Across globe more than 80% population rely on health care based on polyherbal formulations from traditional medicines and locally available health care practices. Owing to comparatively lesser adverse effect, most of the countries are shifting to

alternative medicines since long term use of allopathic medicines badly affect the immune system. Absence of the requisite standards has produced side effects like hepatotoxicity even to death. In view of the enhanced demand for herbal based medicines it is imperative that quality and consistency of the drugs are ensured for their maximal value. This can be achieved by strictly adhering to the Good Manufacturing practice (GMP). The standardization of drug aims at establishing consistent potency and to control complete range of phytoconstituents (Chaudhari, 1996).

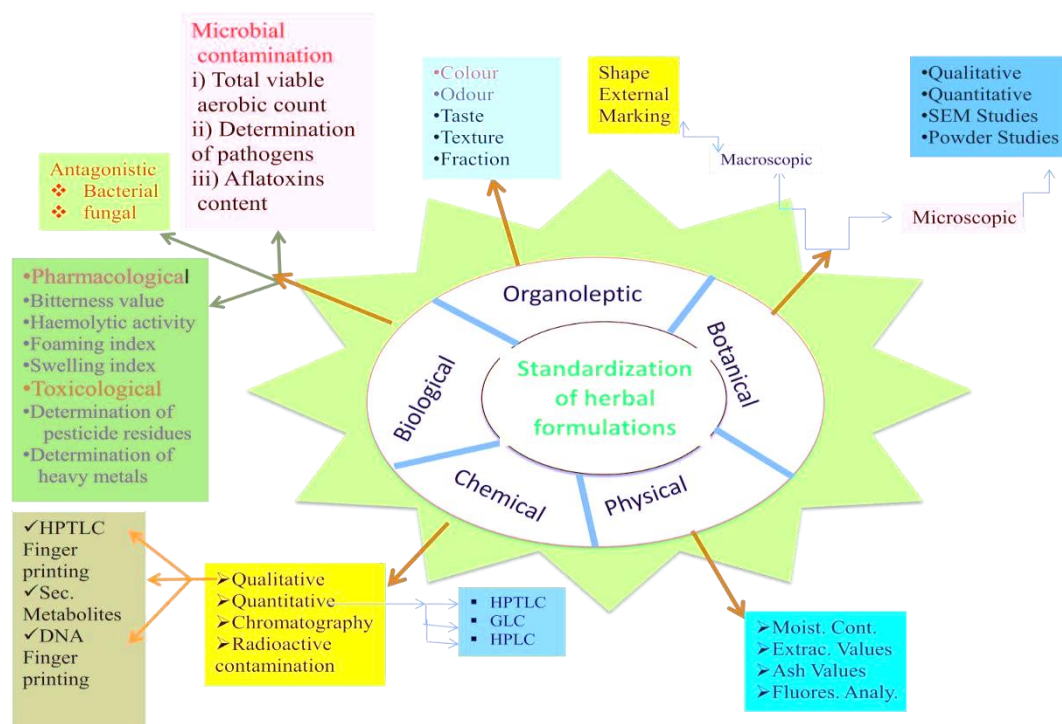
### **1.8 Challenges in standardization**

- (i) Few specific standards are mentioned in the official monographs, leading to ambiguities in quality control.
- (ii) Although standards exist, a range of variations often arise that do not align with those printed in pharmacopoeias.
- (iii) Due to significant geographical variations, minimum content requirements for certain phytoconstituents may not be met, compromising quality.
- (iv) Crude materials may become unfit for use due to infestation or microbial contamination.
- (v) The presence of pesticides or preservatives may exceed tolerance limits, raising safety concerns.
- (vi) Maintaining purity and quality is challenging due to the high demand for herbal formulations of pharmacopoeial value.
- (vii) The collection of plant materials may involve improper practices, leading to contamination or degradation of quality.
- (viii) Authentication processes may be inadequate, increasing the risk of using adulterants or substitutes that compromise the efficacy and safety of the formulations.

#### **1.8.1 Excellence requirement of medicinal plant materials by WHO**

The WHO outlines essential characteristics for assessing the quality of medicinal herbal materials and formulations (WHO guideline, 1999; Figure 4). Key requirements include:

1. **Description of Plant Material:** This includes the scientific and local names, specific plant parts used, collection methods, and processing techniques.
2. **Quality Specifications:** Authenticity must be verified through macroscopic, microscopic, and organoleptic evaluations, alongside chromatographic profiles. Purity limits for foreign matter and ash value determinations are critical.
3. **Assays and Storage:** Active compounds should undergo physical, chemical, or biological assays, with appropriate packaging and storage conditions documented.
4. **Quality Control and Assurance:** Ensuring quality is vital for herbal products intended for the pharmaceutical market, necessitating comprehensive assessments of active phytoconstituents, including their solubility profiles.



**Fig. 4. WHO guidelines for quality control methods for herbal formulations**

### 1.9 Selection and Authentication of Unani Polyherbal Formulations

The present study evaluates five Unani polyherbal formulations: Majoon-E-Najah (MN), Sufoof-E-Najah (SN), Sufoof-E-Chobchini (SC), Formulation 1 (F1), and Formulation 2 (F2). Notably, no prior scientific investigations have been conducted on

these formulations, underscoring the novelty of this research and its contribution to Unani medicine. MN, SN, and SC are well-documented in the Unani Pharmacopoeia of India (UPI) and the National Formulary of Unani Medicine (NFUM), affirming their established therapeutic roles within the Unani system (Anonymous, 2016). Adhering to pharmacopoeial standards is crucial for ensuring consistency, safety, and therapeutic efficacy, as stipulated by regulatory frameworks such as AYUSH (2010). Conversely, F1 and F2 are novel formulations developed by local Unani practitioners and are not documented in classical texts or pharmacopoeias. The authentication of the plant drugs utilized in these formulations followed stringent procedures to ensure their identity, purity, and quality, which is essential for the reliability of subsequent pharmacological and phytochemical analyses.

### 1.9.1 Selected Formulations:

The formulations are as follows:

#### 1.9.1.1 Majoon-E-Najah (MN)

MN Formulation is a semi-solid formulation renowned for its *Musaffi-e-Dam* (blood-purifying) and *Muqawwi-e-Asab* (nervine tonic) properties. Traditionally, it is used for neurological disorders such as *Malikhuliya* (melancholia), *Qulanj* (colic), and *Ikhtenaq-ur-Raham* (hysteria), making it beneficial for conditions related to nervous system imbalances (UPI, Pt. II, Vol. 3, Government of India, 2016).

#### 1.9.1.2 Sufoof-E-Najah (SN)

SN Formulation is a powdered preparation derived from Majoon-E-Najah, formulated without the semi-solid base while retaining the same therapeutic properties. It is employed for similar neurological disorders and acts as a nervine tonic, providing relief in hysteria and melancholia (UPI, Pt. II, Vol. 3, Government of India, 2016).

#### 1.9.1.3 Sufoof-E-Chobchini (SC)

SC Formulation is another powdered polyherbal preparation known for its potent anti-inflammatory and pain-relieving properties. Traditionally, it is used to treat conditions such as *Waj-ul-Mafasil* (joint pain), *Niqras* (gout), *Aatishak* (syphilis), and *Irq-un-Nisa* (sciatica). It is valued for its *Musaffi-e-Dam* (blood-purifying) and *Munaffis-e-Balgham*

(expectorant) actions, as well as its ability to eliminate excess bile (*Daf-e-Safra*) (UPI, Pt. II, Vol. 1, Government of India, 2009).

#### **1.9.1.4 Formulation 1 (F1)**

F1 Formulation targets female infertility and sexual dysfunction, offering multifaceted applications in enhancing female reproductive health. It is utilized as an aphrodisiac, uterotonic, and ovulation-inducing agent. Additionally, it is believed to possess phytoandrogenic properties, contributing to overall reproductive wellness. Furthermore, it shows promise in alleviating stress and insulin resistance, thereby improving fertility outcomes.

#### **1.9.1.5 Formulation 2 (F2)**

F2 Formulation is another novel formulation designed to improve female reproductive health and enhance immunity. Serving as a general tonic, it strengthens immunity while providing aphrodisiac benefits. It is indicated for female infertility and exhibits antidiabetic, antimicrobial, neuroprotective, and antioxidant properties, showcasing its wide-ranging therapeutic potential.

### **1.10 *In vitro* Pharmacological Evaluation of Five Unani Polyherbal Formulations**

The present study evaluates the pharmacological properties of five Unani polyherbal formulations, focusing on their antioxidant, antibacterial, and antifungal activities. Amid rising antimicrobial resistance and oxidative stress-related disorders, this research aims to validate these traditional formulations using standardized assays, bridging Unani knowledge with modern scientific insights.

#### **1.10.1 Antibacterial Activity**

Infectious diseases remain a global health challenge, particularly in developing countries where bacterial infections such as those caused by *Escherichia coli* and *Bacillus megaterium* contribute to high morbidity rates (Alavijeh et al., 2012; Tenaillon et al., 2010). The increasing prevalence of multidrug-resistant strains, including *Staphylococcus aureus* and *Streptococcus pneumoniae*, has intensified the need for novel antimicrobial agents (Livermore, 2009). Resistance mechanisms, such as  $\beta$ -lactamase production and altered binding sites, further complicate treatment with conventional antibiotics (Gould & Lode, 2008; Zhang et al., 2006). Traditional

medicine offers a promising alternative, as herbal formulations have demonstrated antibacterial potential with reduced side effects (Kandasamy et al., 2011; Girish & Satish, 2008). However, despite extensive ethnomedicinal use, only a fraction of plant species has undergone phytochemical or bioactivity screening, highlighting the need for scientific evaluation of natural antimicrobials (Verpoorte, 2000). Present study assesses the antibacterial efficacy of extracts from five Unani polyherbal formulations against *E. coli* and *B. megaterium*, providing a scientific basis for their use as natural antimicrobials (Kaper et al., 2004; Fabricant & Farnsworth, 2001).

### **1.10.2 Antifungal Activity**

Fungal infections caused by *Candida albicans* and *Aspergillus niger* pose significant health risks, particularly among immunocompromised individuals (De-Lucca, 2007; Irkin & Korukluoglu, 2007). The rising incidence of antifungal resistance to conventional treatments such as fluconazole and amphotericin B emphasizes the urgent need for alternative therapeutic options (Gahukar, 2012). Traditional medicinal systems, including Unani and Ayurveda, have long utilized polyherbal formulations to effectively combat fungal diseases, benefiting from their rich phytochemical compositions and potential synergistic effects (Ramasamy & Charles, 2004). Natural compounds from plants, including essential oils and extracts, exhibit promising antifungal properties by targeting fungal cell structures, thus minimizing toxicity risks to human cells (Manna & Abalaka, 2000; Gordon & David, 2001). Present study investigates the antifungal efficacy of five Unani polyherbal formulations against *C. albicans* and *A. niger*, aiming to contribute to the development of safer and more effective plant-based antifungal therapies.

### **1.10.3 Antioxidant Activity**

Antioxidants play a crucial role in protecting the body from oxidative stress, which is linked to various diseases, including cancer, cardiovascular disorders, and neurodegenerative conditions (Halliwell, 2007). Reactive oxygen species (ROS), generated during normal metabolic processes and environmental exposures, can lead to cellular damage if not adequately neutralized by antioxidants (Sies, 1997). Natural antioxidants, particularly those derived from plant sources, have gained attention for

their potential health benefits and ability to scavenge free radicals, thereby mitigating oxidative damage (Gordon, 2001). The DPPH (2,2-diphenyl-1-picrylhydrazyl) assay is a widely used method for evaluating the free radical scavenging capacity of these compounds, providing insights into their antioxidant potential (Blois, 1958). Traditional medicinal systems, including Unani medicine, utilize a variety of herbal formulations rich in phytochemicals that exhibit strong antioxidant properties, enhancing their therapeutic value (Alok et al., 2014). This study evaluates the antioxidant activity of five Unani polyherbal formulations using the DPPH method, contributing to the growing body of evidence supporting their use in promoting health and preventing oxidative stress-related diseases.

### **1.11 Phytochemical Characterization of Selected Unani Polyherbal Formulations**

Phytochemical characterization is essential for standardizing herbal medicines, providing insights into the bioactive constituents responsible for their therapeutic effects (Kaushik et al., 2010). This study examines five selected Unani polyherbal formulations, quantifying their Total Phenolic Content (TPC) and Total Flavonoid Content (TFC) (Cao et al., 1997; Gupta et al., 2023). The quantification of TPC and TFC is crucial, as these compounds are linked to antioxidant, antibacterial, and anti-inflammatory activities, significantly enhancing the formulations' therapeutic efficacy (Yap et al., 2023; Li et al., 2023; Zeb, 2020). Advanced techniques such as Thin Layer Chromatography (TLC), High-Performance Thin Layer Chromatography (HPTLC) fingerprinting, and High-Resolution Liquid Chromatography-Mass Spectrometry Quadrupole Time of Flight (HRLC-MS-QTOF) were utilized to profile and quantify active phytochemicals (Wolfender et al., 2015). HPTLC offers chromatographic fingerprints that are vital for the standardization and quality control of these formulations, ensuring consistency and safety (Kaushik et al., 2010; Patil et al., 2015). Additionally, HRLC-MS-QTOF analysis facilitates the identification and characterization of the phytochemical composition in novel formulations (F1 and F2), supporting validation and regulatory compliance (Wang et al., 2019; Kumar and Madhusudanan, 2020; Kalasariya et al., 2023). This comprehensive approach aims to promote the acceptance of these formulations in Unani therapeutic practices.

### 1.12 Rationale and Scope of the Present Study

The initial aim of this research was to assess the diversity of traditional medicinal knowledge and Unani medicinal plants in northwest Gujarat, a region rich in biodiversity but relatively underexplored. The study sought to document and enumerate medicinal plants used in Unani medicine. However, fieldwork revealed a scarcity of Unani practitioners (Hakims) in this region, limiting the ability to conduct a comprehensive study of traditional practices.

As a result, the research focus shifted to central Gujarat, specifically the districts of Vadodara and Ahmedabad, where traditional and commercial Unani Hakims are more prevalent. During surveys in these areas, it was observed that Hakims commonly used both single-drug and polyherbal Unani formulations, which were widely sold in the market. However, many of these formulations were adulterated or lacked proper authentication and standardization, raising concerns about their quality. This observation sparked a growing interest in Unani polyherbal formulations, leading to the identification of a well-known folk polyherbal formulation, Batrisu Vasanu. Widely used in Unani, Ayurvedic, and folk medicine, this formulation had not been comprehensively studied, making it a valuable subject for further investigation.

Interviews with Hakims and detailed surveys highlighted a broader issue: the significant lack of standardization, authentication, and quality control in many Unani polyherbal formulations. To address this gap, the scope of the research was expanded to include the authentication, pharmacological evaluation, and phytochemical standardization of selected Unani polyherbal formulations, marking the first comprehensive assessment of these aspects.

This research encompasses five selected Unani formulations, including three widely recognized ones recommended by Hakims and two novel formulations developed by traditional in-house Hakims based on their clinical experience. The two novel formulations are unique, with no prior scientific documentation, contributing valuable insights to the field of Unani medicine. The overarching goal of this research is to bridge traditional knowledge with modern scientific practices, particularly within the Unani system of medicine.

## 2. OBJECTIVES OF THE PRESENT STUDY

The objectives of this study are as follows:

1. To document the diversity and traditional knowledge of Unani medicinal plants from Northwest Gujarat.
2. To select, collect, and authenticate the plant sources of Unani drugs for a selected polyherbal formulation.
3. To prepare the selected Unani polyherbal formulations and extract their components using various solvents.
4. To conduct *In vitro* pharmacological screening of selected Unani polyherbal formulations.
5. To perform Phytochemical characterization of selected Unani polyherbal formulations.