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Review

Journey of Herbal Formulation Development

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Abstract

Herbal formulations have gained significant attention worldwide due to their therapeutic potential, safety, and minimal side effects. Various traditional medicine systems, such as Ayurveda, Traditional Chinese Medicine (TCM), and Unani, have contributed to the development of herbal formulations. Modern scientific advancements have further enhanced their efficacy, standardization, and commercialization. This article explores the development of herbal formulations globally, focusing on research trends, current and future prospects. Recent progress in pharmaceutical technology has enabled the creation of innovative herbal drug delivery systems including transfersomes, ethosomes, microspheres, phytosomes, liposomes, polymeric nanoparticles, and nanocapsules that greatly enhance the solubility, stability, bioavailability, and targeted delivery of herbal compounds.

Keywords: Traditional Chinese medicine, formulation, standardization, transferosomes, nanocapsules and targeted delivery.

INTRODUCTION

Herbal plants are most important for mankind for treatment and management of diseases. According to the World Health Organization (WHO), “natural plants are a plant having more bioactive molecules that have been reported their therapeutic benefits, or which are mother sources of Medicinal plants play a crucial role in chemo-pharmaceutical semi-synthesis and are in high demand by pharmaceutical companies due to their valuable bioactive compounds [Huai et al., 2010; Husain et al., 2008; Tiwari et al., 2020].

Traditionally, these plants have been widely used around the world to treat various chronic illnesses. According to multiple reports, even in modern times, an estimated 65–75% of the global population relies on medicinal plants for disease prevention and management [Gupta et al., 2004; Sharma et al., 1998; Bhati et al., 2014]. Herbal plants and their components are integral to several traditional healing systems, including Ayurveda, Unani, Chinese medicine, and homeopathy.

Plant-based formulations are very cost-effective and have fewer adverse effects when used to treat ailments in herbal medicine. The guarantee of herbal product quality is a major concern for maintaining global standards. As a result, standardisation and evaluation are required. The quality and purity of the herbal product must be ensured. Ensuring the quality and purity of herbal products is essential. Standardized herbal formulations enhance the overall quality of plant-based medicines, increasing their acceptance and competitiveness in the global market [Shukla et al., 2019].

Poly-herbal formulation is a great idea that is suited and appropriate for the treatment and management of chronic diseases like cancer. Many studies have been reported with positive findings; however more research is needed to produce promising natural products.

Herbal medicines (HMs) are the backbone of balancing and alternative treatments, which in modern times are gradually gaining worldwide recognition and gradually moving towards integration into healthcare systems [1]. The use of HMs has increased by gender, social class and race in developing countries of the world [2–7].

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The objective of our current study was to develop and standardize the raw materials used in a polyherbal formulation. This was achieved through organoleptic evaluation, powder microscopy, and analysis of physical properties [Jemal et al., 2006; Ferguson et al., 2004; Jo et al., 2004; Mukherjee et al., 2001].

Definition

Herbal medicines (HMs) form the foundation of many complementary and alternative therapies. In recent years, they have gained growing international recognition and are increasingly being integrated into modern healthcare systems [1]. The usage of herbal medicines has risen across different genders, social classes, and ethnic groups, particularly in developing countries [2–7].

Application of Herbal Medicine

- Herbal medicine (HB) includes herbs, plant materials, herbal preparations and herbal finished products containing active ingredients that are plant parts, or ingredients. Other botanical materials, or combinations, and specially used for the prevention and treatment of diseases [8].
- The chemical compounds present in herbal ingredients have shown many benefits in controlling many diseases, including complex diseases/conditions such as HIV/AIDS, cancer, sickle cell disease, malaria and other infectious as well as non-communicable diseases.
- Herbal medicine (HM) encompasses the use of herbs, plant-based materials, herbal preparations, and finished herbal products that contain plant-derived active ingredients. These may consist of entire plants or specific plant parts, as well as other botanical substances or their combinations. Herbal medicines are primarily employed for the prevention and treatment of diseases [13].
- In many rural communities across Africa and Asia, HM continues to serve as the main source of primary healthcare. It also remains deeply rooted in the cultural practices of various societies worldwide. Numerous herbs and traditional herbal formulations have a long-standing history of use for promoting

health. Scientific studies have shown that these herbal medicines contain complex chemical constituents responsible for their pharmacological properties, which account for both their therapeutic effects and potential toxicity [1].

Reasons for improving the use of herbal medicine (HM)

Most reasons can be given for this:

A. Personal preference for HM

- The usefulness of HM is a colossal temporal subculture embedded in the subcultures of many societies. In ancient times, people trusted him as a leading healthcare provider with great success.
- Despite the modernization and spread of traditional health care based on the use of pharmaceuticals.
- Nevertheless, in certain regions, particularly in Africa and Asia, many individuals continue to attribute special healing properties to herbal medicine (HM). For these communities, HM remains the primary choice for initial healthcare and is consistently prioritized as the first line of treatment across various settings.
- viable societies regardless of their economic, academic, and social status.

B. Safety Awareness

- In general, many ordinary consumers are of the opinion that HM is safe and does not pose any danger or effect on appearance.
- While it is true that many HMs are much easier to tolerate than pharmaceutical pills, especially when used long-term to manage chronic diseases [9, 10].
- Studies have shown that in some countries, including South Africa and Ghana, herbalists outnumber traditional physicians, while in India, China, and Vietnam, the number of herbalists is far out.
- Traditional herbalists and doctors are equivalent.

C. Easy access to HM

- Still, in many parts of Africa and Asia, people strongly believe in the distinctive healing power of herbal medicine (HM). In these communities, HM continues to serve as the preferred option for primary healthcare and is regularly relied upon as the first form of treatment in various environments.
- However, in societies where drugs are tightly regulated, HM is the result that is easily obtained at low cost and without a prescription.

D. Low-cost HM

- In certain rural areas, the usage rate of herbal medicine (HM) is often lower when compared to conventional traditional treatments.
- Traditional medicine practitioners (TMPs) who offer services are usually well-established members of the community, staying close to their patients due to the considerable distances to formal healthcare centers.
- Payment arrangements are typically more flexible, with TMPs accepting alternative forms of payment such as clothing, livestock (e.g., chickens, goats), or other goods, rather than cash.
- This is despite the fact that herbal products imported from abroad can be just as expensive as conventional pharmaceutical drugs.

E. Effectiveness of Herbal Medicines in Disease Treatment

- In recent years, research efforts aimed at validating traditional claims and identifying the safety and regulatory needs of herbal substances have significantly increased.
- Scientific studies have been conducted to assess both the safety and therapeutic efficacy of various herbal products.
- Clinical validation has strengthened the credibility and acceptance of many herbal medicines, contributing to their growing recognition and trust.[11]

Global Scenario of Herbal Drug Formulations

- From the ancient time, People are using herbal for safety, efficacy, and cultural acceptability of dosage form of the drug. Plant and plant-based products have utilized with varying success to cure and prevent diseases throughout history. [12]
- Herbal medicines have different dosage form which is to be safe and are formulated in different forms of herbal product.
- Dosage forms such Tablets & capsules provide 2 dose accuracy compared to other dosage forms in herbal treatment.
- Herbal formulations are emerging as key components that play a vital role in the well-being and prosperity of populations across nations.
- Many of modern medicine are produced indirectly from a medicinal plant. [13]

- India is one of the 12 mega biodiversity centers having over 45,000 plant species. Since ancient times, valuable guidance has been provided for the selection, preparation, and use of herbal medicines.In the last five decades the use of herbal medicine has grown to tremendous effect in the market of India and worldwide. [14]

Challenges Concerning with Herbal Medicine

For formulating an herbal drug the basic challenges are being studied.

- ✓ In most of the cases the active principals of a drug are unknown.
- ✓ In the performing herbal formulations selectively analytical methods or reference compounds may not be available commercially.
- ✓ The herbal plant materials are chemically and naturally variable.
- ✓ In the process of harvesting, drying, storage, transporttations, and processing having an effect. The successful productions of quality herbal product and reproducibility of that quality are a major task. [15]
- ✓ The issues related to the financial, ethical, product standardizations, the design of the study and regulatory requirements.
- ✓ The outcome of the herbal treatment largely depends on patient participation.
- ✓ The treatments in herbal medicine compel consistency in the mixture of active components and also the specifications regarding their administrations.
- ✓ The problem associated with herbal drug formulations.
- ✓ Poor agriculture and propagations method.
- ✓ Most of the time inefficient processing techniques leading to low yields and poor quality products.
- ✓ Poor quality control procedures. Lack of current good manufacturing practices.
- ✓ Difficulties in marketing.
- ✓ Lack of trained personnel and equipment. [16]

4. **Need for the herbal drug in Modern science Study**

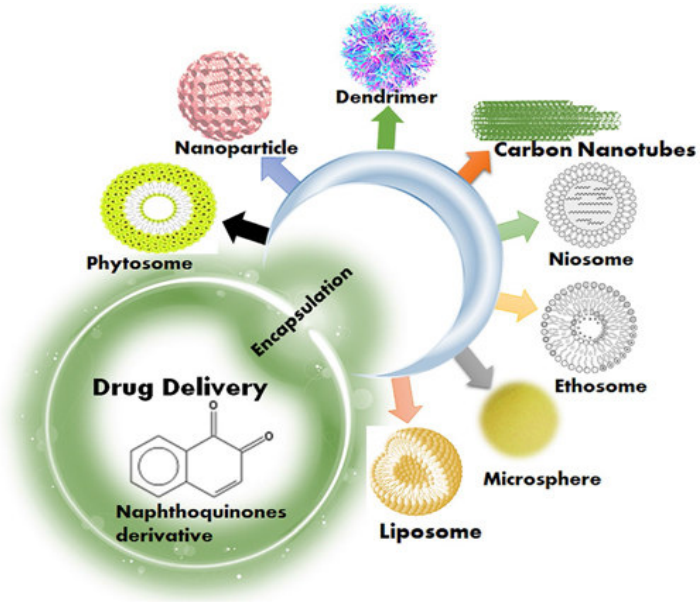
I. The plant has been used for health and medical purpose since last thousands of years. Herbal medicine is an important part of healthcare throughout the world. In many countries including the U.S. herbal medicine are not regulated as extensively as conventional drug therapy. [17]

II. An Herbal medicine has been widely playing an important role as effective remedies for preventions and cure of multiple health conditions for centuries by almost known culture. In developing countries including India, the herbal drug has been playing the vital role in the preventions and cure of disease conditions.

III. As compared to the allopathic drug treatment there is lesser side effect occurs in the treatment of herbal drug dosage forms. As in the form of supplements purpose, the use of the herbal drug is increased and has a great role in the pharmaceutical 0dosage treatment purpose in the science of life. Herbal supplements may contain vitamins, minerals, herbs, or other botanical amino acids and certain other substances. [18]

Novel or Advanced approach of delivery system for herbal medicines

- ➢ Since time immemorial, care has been taken to suggest to the physician the type of medicine most suitable for the patient so that the improvement of symptoms is more rapid and complete. Drugs, among other ingredients, protect, efficacy, and suitability, and the final product is usually recognized as a dosage form or drug delivery system.
- ➢ With the growth of all areas of science and technology, dosage forms have evolved from simple tablets and pills to particularly complex technological and centralized drug delivery systems known as NDDS [19]. In recent years, much interest has been focused on the development of his NDDS of plant constituents [20].



Because of their several ring large sized molecules which cannot be transferred by simple diffusion or their low solubility with oil and other lipids, harshly reducing their control to enter across the plasma membranes of the small intestine [21]. Therefore, the nan dimension NDDSs of plant components have a possible opportunity for increasing the natural development and devastating troubles connected with plant dosage forms. [22]

Recent Advancement in Herbal Remedies Delivery Systems OR Novel drug delivery system



Fig 1: Recent advancement in herbal remedies delivery system[23, 24, 25].

Recent Advancement in Herbal Remedies Delivery Systems OR Novel drug delivery system:
Phytosomes

- With a close resemblance to liposomes, phytosomes are a slice- edge lipid- grounded delivery system that can be exploited to entrap multitudinous phytoconstituents with polyphenolic bases to promote their immersion when delivered.(26)
- The medicine itself is conjugated with lipids to induce vesicles, which promote phytosomal ruse effectiveness indeed further. As a result, the cure demand has been minimised while the medicine's bioavailability has been significantly increased.(27)

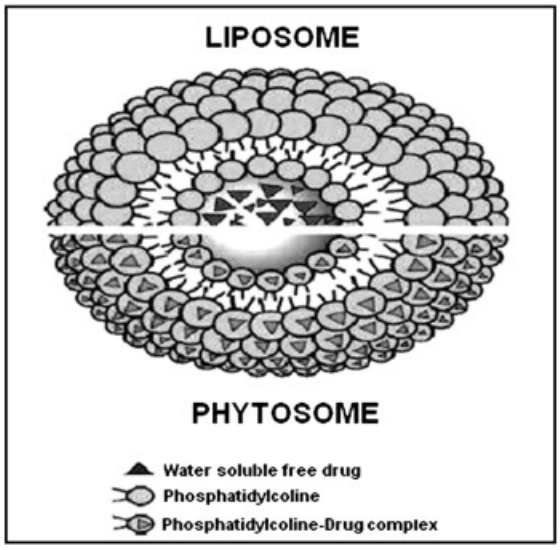
- Phospholipid, aka phosphatidylcholine, is among the essential factors of phytosomes, serves as a vesicle, and has health advantages similar as hepatoprotective action.(28)
- Phytosomes have an optimised stability profile as a result of the chemical relations that have been established between the phosphatidylcholine patch and the botanical excerpt, and due to the enhanced immersion of the active component, indeed the mildest cure can affect in the asked goods. (29**)**

Nanoparticle

- ❖ Nanoparticles (NPs), which generally vary in size from 1 to 1000 nm, can contain active factors that are moreover internal to the patches or face- adsorbed onto the polymeric core.
- ❖ As medicine carriers, they'vethe eventuality to be used for controlled release, to mask medicines and other motes from the terrain, and to enhance bioavailability and remedial indicator. (30)
- ❖ Nanoparticles are largely stable, have a high carrier capacity as a implicit medicine carrier, and can integrate both hydrophilic and hydrophobic motes.
- ❖ They also have the viability of colorful delivery styles, including inhalation and oral administration. also, these carriers can be intended to allow for the matrix- regulated, long- term (sustained) release of the medicines.(31)
- ❖ phytochemicals and herbal excerpts together with the polymeric nanoparticles as an anticancer agent to offer a targeted medicine delivery system that's effective and has minimum to no side goods.

Liposomes

- Liposomes are lipid vesicles with a periphery of 0.1 – 10 m and an waterless core enclosed in phospholipid bilayers. Grounded on size and lipid bilayers, liposomes can be divided into three different orders small unilamellar, large unilamellar, and multilamellar vesicles.(32)
- Liposomes can be synthesised employing lipid motes that are natural, biodegradable,non-toxic, andnon-immunogenic.(33)
- The merit of employing liposomes for parenteral administration is that it prevents gastrointestinal side goods, confined gastrointestinal permeability, and first- pass metabolism.(34)



Solid lipid nanoparticle

- ✓ For controlled and targeted delivery, solid lipid nanoparticles (SLNs) are arising as an volition to colloidal approaches. These are composed of biocompatible and biodegradable accoutrements with a submicron size range (50 – 1000 nm) and can incorporate both lipophilic and hydrophilic drug. (35)
- ✓ Solid lipid nanoparticle have great biocompatibility since utmost lipids are biodegradable. SLNs offer controlled and targeted medicine release; also, medicines that are both lipophilic and hydrophilic can be incorporated; they're also more affordable (less precious than polymeric or surfactant- grounded carriers). (36)
- ➢ The results indicate that solid lipid nanoparticles may be a useful means of recapitulating phytopharmaceuticals to enhance their in vivo performance. (37)

Microemulsions and microspheres

- Due to their increased medicine solubilization, longer shelf life, and rigidity in medication and administration, microemulsions are among the ideal options as new medicine delivery systems.
- Microemulsions are liquid results of oil painting, water, and amphiphile that are thermodynamically stable and optically isotropic and enable drug administration via optical, percutaneous, topical, oral, transdermal, and parenteral routes with controlled or sustained release. Microemulsions differ from conventional mixes as they've low density, and translucency, and are thermodynamically stable.(38)
- By using microemulsion as a delivery medium, a medicine's effectiveness can be increased, lowering the overall cure and adverse goods. also, microemulsions retain the capability to deliver drugs that are both lipophilic and hydrophilic. likewise, because of the thermodynamic stability of microemulsions, they're simple to make and bear no quantum of energy, and the conflation can be controlled or reversed.
- The microemulsion reforms when the temperature, which was unstable at low or high temperatures, is brought back within the stability range.(39)
- Microspheres are principally monolithic spheres or remedial agents circulated throughout the matrix, either as a molecular structure composed of a nonstop phase of one or further miscible polymers, whereby drug patches are distributed on a macroscopic or molecular scale.
- Small, globular patches known as microspheres generally have confines between 1 and 1000 µm. The term ' micro flyspeck' can also be used to describe microspheres. (40).
- Microspheres promote patient compliance by reducing the frequence of dosing. Microsphere morphology enables controlled inflexibility in drug release and deterioration; the remedial goods of microspheres are invariant and sustained, hence a reduction in adverse goods and an increase in bioavailability will crop from effective medicine use.(41)

NANOEMULSIONS

- Nanoemulsion are defined as the oil painting in water conflation with a mean drop having a periphery ranging from 50 to 1000 nm.
- exemplifications of Nanoemulsion are
  1. Tocopherol
  2.Lecithin
- For the medications of the nanoemulsion, we needed veritably highpressure homogenization. operations of nanoemulsions are in utmost food, ornamental and chemical assiduity.(42)
- Nanoemulsion admixture for the treatment of the seditious complaint.
- The studied nanoemulsion factors played the crucial part in saturation enhancing the effect. Compared with Carbopol gel, the skin saturation capability of boswellic acids was significantly increased by Nano-conflation. The exploration concentrated on factory excerpt loaded expression development of a new Nano- emulsion grounded medicine delivery system which may furnish important action and hand by enhancing the bioavailability of herbal medicines.(43)
- Antioxidant Effect of Nanoemulsions Containing Extract of Achyroclinesatureioides(Lam) D.C. Asteraceae
- The protection against lipoperoxidation by the phrasings was also measured in the skin, where the lower conformation of reactive species was observed after treatment with NEE. In conclusion, this study shows the expression effect on the physicochemical parcels of nanoemulsion as well as on the skin retention and antioxidant exertion of quercetin

S. No	Novel drug delivery system	Particle size	Limitations	References
1.	Phytosome	50–few 100 µm	Phospholipids (lecithin) can promote cellular proliferation in the MCF-7 breast cancer cell line. Phytosomes have been observed to rapidly remove phytoconstituents.	[36-37]
2.	Liposome	0.1–10 µm	Low solubility, short half-life, leakage and fusion of encapsulated drugs high production costs, oxidation and hydrolysis of phospholipids.	[35, 50-52]

S. No	Novel drug delivery system	Particle size	Limitations	References
3.	Nanoparticles	1–1000 Nm	Biocompatibility is the major concern with nanoparticles, as is the higher cost of the nanotreatment and the ease of availability.	[33, 53]
4.	Microemulsions	10–300 Nm	Low solubility of compounds with a high melting point employs a large quantity of surfactants to stabilise droplets. Stability can be influenced by the effects of temperature and pH.	[41-44]
5.	Microspheres	1–1000 µm	Less reproducibility, process variables like temperature change, pH change, solvent addition, and evaporation/agitation may have an impact on the stability of the core particles to be encapsulated, resulting in variations in release from one dosage form to another.	[, 44,46]

Current Status and unborn Prospects of Novel Drug Delivery System in India:

- The disquisition of a new medicine delivery system(NDDS) has been ongoing for numerous times but it has gained important traction in recent centuries. The motive for the development of NDDS has been two-fold. First, there are the egregious clinical benefits of these systems, followed by their profitable counteraccusations.
- The NDDS have been developed and are being developed to gain lesser control over a medicine's pharmacokinetics and pharmacodynamics after administration, performing in lozenge forms that are extremely effective, safe, and superior to traditional products.
- Reformulation of old drug in an NDDS constantly revives clinical interest in the medicine, extending its effective request life. In India, the pharma business is worth 20 000 crore, of which 5 is the NDDS request, at Rs. 1000 crore. This difference between the Indian and worldwide requests implies that the NDDS assiduity in India has enormous implicit.(44)
- India serves as an important request for the pharmaceutical assiduity. thus, numerous transnational companies have been anxious to invest and grow preferentially in this sector. The development of new and enhanced procedures in the field of NDDS will produce a high demand for a wide range of excipient operation and development. India is extensively known for its rapid-fire adaption to new excipients and associated technologies.
- As a result, the Indian request for excipients will expand in two ways first, by exporting new organic excipients; and second, by planting new excipients in colorful innovative delivery styles.(1)

SUMMARY

Herbal drug formulations Yesterday, Today, Tomorrow. As the herbal drug is having a great advantage over the last hundreds of year in living science to cure, preventions, treatment. The growing era of human science is having a great impact on herbal drug formulations. The herbal drug formulations have been promoted as beneficial and effective in disease conditions. India has one of the richest plant traditions in the world. Herbal medicine has great applications as supplement purpose as major drug uses in human science nowadays. The herbal drug has enormous and important therapeutic potential which can be explored various beneficial as a dosage form.

A nanoparticle such as phytosomes, liposomes have a great advanced over as the herbal drug formulations since last hundreds of years in life science. The nanoparticles have a report to be as one of the greatest advantages over the allopathic drug formulations in India. These formulations are has been reported to Govind et al Mintage journal of Pharmaceutical & Medical Sciences | 1-5 Vol 8 Issue 1, Jan- Mar 2019 www.mintagejournals.com 4 be one of the important dosage forms in herbal drug formulation in India. Herbal medicines are natural plants and their parts which are being used s medicinal purpose. Herbal medicine is one of the oldest type of medicine in human history. There are plenty of open access journals, knowledge is available on herbal medicine, natural plant, and their products etc. Herbal drugs constitute a major share of all the officially recognized systems of health in India viz. Ayurveda, Yoga, Unani, Siddha, Homeopathy, and Naturopathy, except Allopathic.

CONCLUSION

Drug discovery from the medicinal plant has traditionally been lengthier and more useful than other drug discovery method of drug formulations. The therapeutic as well as having the low side effect of the herbal drug formulations occurs in the science of disease and hence the herbal drug formulations are being good for health treatment, preventions and another beneficial effect in the science. As the herbs are obtained from natural products having and their chemical composition varies depending on several factors and therefore varying from people to people, from energetic decoctions to the use of herbal extracts following western methodologies of mainstream medicine. Traditional medicine has a very long history as compared to another drug system in science it is the sum total of the practices based on the theories, beliefs, and experience of different cultures and times often inexplicable, used in the maintenance of health, as like in the preventions, diagnosis purpose.

CONFLICT OF INTEREST
Authors have no conflict of interest.

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