Current Trends in Pharmaceutical Research, 2023 Vol 10 Issue I
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2582-4783 (Online)

Review Article

AN OVERVIEW OF PHYTOPHARMACEUTICALS

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Abstract

Background: *Phytopharmaceuticals have been used in the treatment of diseases since the beginning of medicine. Today, 80% of the world's population uses medicines derived from plants, directly or indirectly. Since the beginning of time, they have been used to heal illnesses in many civilizations, particularly in India. Many modern medicinal therapies made from plants or plant parts still rely on this age-old wisdom.*

Objective: *The objective of this comprehensive review is to provide updated information about various phytopharmaceuticals derived from plant sources and their importance in Clinical use.*

Methodology: *The classification of Phytopharmaceuticals along with their role in different dimensions has been highlighted through a literature survey. An extensive search for literature was done using a variety of platforms like Pub Med, Google Scholar, Research Gate, Science Direct, etc.*

Conclusion*: The interest and demand for plant-based therapies may increase as a result of the unmet medical needs of this new pharmacological class. Professionally speaking, Phytopharmaceuticals emphasize the revalidation of plant material specifications while taking a balanced strategy that opens prospects for further research and development.*

Keywords: Medicinal plants; Phyto-pharmaceuticals; Drug development; Clinical uses.

Introduction:

Since the dawn of medicine, medicinal plants have been utilized to heal various ailments. Eighty percent of people in the world today take medicines derived from plants, directly or indirectly. Natural products were once used empirically; People are experimenting with them to see if they are beneficial to their health and to learn which herbs can be used to treat certain diseases.

The word "phytopharmaceutical" is derived from the Greek roots "Phyton" (plant) and "Pharmakon" (medicine). This means that the medicine is made from plants. Plant medicines should be considered medicines whose active ingredients are derived exclusively from plants and are made from plant extracts, juices or distillates. Phytotherapy is the belief that certain plants or their components can be used as medicine. Since there are many types of medicinal plants, the word "herb" is often misunderstood. In the herbal medicine market, Phytotherapy over-the-counter, herbal medicine, and traditional herbalism are the three main categories into which plants can be divided. Phytotherapy is a treatment method that uses plant-based medicine as an active therapeutic agent. Herbal products have many medicinal properties, and according to the principles of phytotherapy, these compounds should be considered as sources.

The development of Phytopharmaceuticals that can replace some traditional medicines often requires raw materials and can be produced by pharmaceutical companies in countries through joint ventures. Clinically proven botanical medicine should be of the highest standards. Its effectiveness and safety must be demonstrated by randomized, double-blind, and controlled clinical trials. It is produced and tested in the same way as pharmaceutical products. Herbal medicine has long been considered an

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effective alternative to modern allopathic medicine. However, despite of their growing popularity, only a few herbs have been extensively researched for their medicinal benefits [1].

Classification

Phytopharmaceuticals can be grouped into anthocyanins, carotenoids, lycopene, flavonoids, glucosinolates, isoflavones, limonoids, polyphenols, omega-3 fatty acids, phytoestrogens, Resveratrol, phytosterols, etc. Some of them are as follows [2].

1. **Flavonoids**- Olive oil, beans, cocoa, tea, peanuts, walnuts, spices, green vegetables, onions, and fruits (including grapes, apples, and berries) contain flavonoids, which are polyphenolic compounds. Flavonoids have antibacterial, antifungal, antiviral, and antibacterial properties. Flavonoids are divided into eight subclasses, including flavanols, flavones, flavanones, flavonols, dihydrochalcones, dihydroflavonols, anthocyanins, and isoflavonoids. Flavonols are the most commonly found flavonoids in foods. Quercetin and kaempferol are two important flavonoids in this group. Onions, leeks, broccoli, and blueberries are rich in flavonols. It is said that cell signals from free radicals, inflammation, allergies, platelet aggregation, ulcers, infections, cancer, and liver toxins can be suppressed by flavonoids.

2. **Polyphenols**- The best and most studied class of phytochemicals are polyphenols. To date, 8000 polyphenolic compounds have been identified with antioxidant and pro-oxidant activities depending on their concentrations. Higher doses of polyphenols have been shown to play a role in triggering apoptosis and reducing cell proliferation, migration, and cancer cell invasion while reducing the dose of free radicals in the brain.

Many foods and beverages, such as fruits, vegetables, grains, etc. contain polyphenols, which are natural compounds. Beans and chocolate also contain polyphenols. These chemicals are secondary metabolites produced by plants to protect against UV radiation and bacterial invasion. The lower rate of degenerative diseases is associated with a diet rich in antioxidants.

3. **Isoflavanoid**- Isoflavones are another subclass of phenolic phytonutrients. Legumes produce isoflavones almost exclusively. Soybeans are an important source of isoflavones such as daidzein and genistein. Isoflavones have received much attention for their ability to prevent cancer and osteoporosis. Soy isoflavones have received much attention due to their ability to bind to a family of compounds that bind to estrogen receptors. These are part of a class of phytochemicals called phytoestrogens. Genistein inhibits most cancers, including hormone-dependent and non-hormonal cancers, in vitro, especially colon cancer.

4. **Phytoestrogens**- Nonsteroidal phytoestrogens are a class of phytochemicals that share the structure and biological properties of gonadal estrogens. They provide effective hormone replacement therapy (HRT), are beneficial for the cardiovascular system and reduce menopausal symptoms. They may be a good alternative to the synthetic estrogen receptor modulators currently used in HRT. Phytoestrogens can be classified as lignans, coumarins, isoflavones, flavonoids or stilbenes, depending on their chemical composition. Bean sprouts are rich in coumestrol (the main coumarin), while soybeans are rich in isoflavones. In addition to having estrogenic and antiestrogenic properties, flavonoids may also protect against heart disease and osteoporosis. Flavonoids have a structure similar to estrogen.

5. **Anthocyanins**- The most common class of water-soluble pigments in plants are anthocyanins. They are classified as potential antioxidants because research shows they have therapeutic and anti-inflammatory benefits. Consuming foods rich in anthocyanins reduces the risk of many diseases such as diabetes, dyslipidemia and atherosclerosis (Jaiswal et al. 2019). Fruits, flowers, leaves, roots and

stems of higher plants contain anthocyanins. Plants in the Vaccinium family, such as blueberries, red cabbage, blackberries, cranberries and cherries, are rich in anthocyanins. The three main anthocyanin compounds are pelargonidin, anthocyanins and delphinidin. Organic food dyes called anthocyanins and similar glycosides have been shown to be beneficial to health, especially in the diagnosis and treatment of diabetes.

6. **Phytosterols**- Sterols and stanols of plant origin are called phytosterols. Plant sterols have been used to lower cholesterol for nearly 50 years. They do this by preventing the intestines from absorbing cholesterol. This can lower total cholesterol and low-density lipoprotein (LDL) cholesterol. Fruits, vegetables, nuts, oils, and plant sterols are just a few of the foods that contain them. According to research, the best cholesterol reduction is 2 to 3 grams per day. This indicates that the diet needs to be improved to ensure appropriate plant sterol intake and lower LDL cholesterol.

7. **Carotenoids**- Photosynthetic membranes contain more than 700 pigments called carotenoids, which determine the color of plants and animals. Only 24 of 700 pigments are found in the human diet. The most studied carotenoids are lycopene, zeaxanthin, lutein, alpha-carotene, and beta-carotene. The four most common carotenoids found in foods are lycopene, beta-carotene, lutein, and beta-cryptoxanthin. Lutein and zeaxanthin have been linked to eye problems, while beta-carotene and lycopene have been linked to a reduced risk of heart disease and various cancers. Lutein can prevent uterine cancer, prostate cancer, breast cancer, lung cancer, and lung cancer. They may also help reduce the risk of stomach cancer. It is suggested that the antioxidant properties of carotenoids are mainly responsible for their beneficial effects.

8. **Resveratrol**- In response to disease and stress, plants spontaneously produce resveratrol, a phytoalexin. Research shows that resveratrol has neuroprotective effects and is beneficial to the cardiovascular system when taken in small amounts. These effects are mainly due to its antioxidant properties. The best functions include heart protection, neuroprotection, anti-thrombosis, anti-cancer, anti-infection, and anti-aging. Foods such as fruit especially blueberries, mulberries, strawberries, hops, peanuts, and their derivatives contain plenty of resveratrol.

9. **Terpenoids**- Terpenes, also known as isoprenoids, are phytonutrients commonly found in higher plants, lichens, algae, mosses, liverworts, insects, microbes, and marine organisms. Their effects on plants are due to their need to absorb carbon through the photosynthetic process associated with phytochromes. Animals are adapted to use this substance for the regulation of hormonal activity and growth (vitamin D).

10. **Limonoids**- Citrus fruits are an important source of limonoids, which are terpenoids. These triterpenoids have strong anti-cancer properties and are high in oxygen. Orange peel oil contains d-limonene, a type of monocyclic monoterpene that may prevent cancer. Terpenes in orange oil may prevent cancer.

11. **Omega-3 fatty acid**- Omega-3 fatty acids should be increased in the diet due to their many health benefits. Fish, especially fatty fish such as salmon, rainbow trout, mackerel, herring and sardines, are great sources of long-chain omega-3 fatty acids. The 18-carbon omega-3 fatty acid alpha-linolenic acid is produced by many plants, especially canola, soybean and flax oil. Omega-3 fatty acids have a clear role in the treatment of osteoarthritis. Increasing your intake of omega-3 fatty acids, getting adequate amounts of monounsaturated fatty acids (such as those found in olive oil), and decreasing your intake of omega-6 fatty acids may help people with osteoarthritis better, and sometimes less so. They need non-steroidal antioxidants – anti-inflammatory drugs (NSAIDs). Creating oilseed plants with stearidonic acid, like canola and soybean, is one way to improve the availability of long-chain omega-3 fatty acids. There are just a few plants that naturally contain this omega-3 fatty acid, including echium oil and black currant seed oil.

Table 1: List of some Phytopharmaceuticals and their medicinal importance

List of Phytopharmaceuticals	Plant Scientific Name / Common Name	Economically Important plant part	Medicinal Importance
Ginsenosides	*Panax ginseng/Korean ginseng*	Root	Cognitive Performance
Diosgenin	*Dioscorea deltoidea/Nepal yam*	Leaf, stem, tuber	Antiproliferative
Bilobalide and ginkgolides	*Ginkgo biloba/Maidenhairtree*	Leaves and seeds	Dementia, age-related cognitive impairment
Monoterpenes and sesquiterpenes	*Melissa officinali/Lemon balms*	Leaves	Dementia, cognitive impairment
Artemisinin	*Artemisia annu/Sweet wormwood*	Aerial parts and leaves	Antimalarial
Morphine	*Papaver somniferum/Opiumpoppy*	Latex	Analgesic
Taxanes	*Taxus bacata/Common yew*	Leaves and bark	Anticancer drugs
Digoxin	*Digitalis lanata/ Foxglove*	Leaves	Cardiotonic
Cocaine	*Erythroxylumcoca/Cocoa*	Leaves	CNS stimulant
(L)-dopa	*Mucuna prurien/Cowitch*	Seeds	Parkinsonism
Caffeine	*Coffea arabica,Camellia sinensis/Coffee,tea*	Seeds and leaves	CNS stimulant, decreased tonic immobility
Thymol & carvacrol	*Trachyspermum Ammi/Ajwain*	Flower, seeds, leaf	Antifungal, antioxidant, antimicrobial, antinociceptive, cytotoxic activity
Quinine	*Cinchona ledgeriana/Peruvianbark*	Bark	Antimalarial
Reserpine, Serpentine, Ajmaline, and ajmalicine	*Rauvolfia serpentina/ Snake root*	Roots	Antiarrhythmic
Berberine	*Berberis vulgaris/Common barberry*	Fruit, bark, root, and stem	Antidiarrheal

Role of Phytopharmaceuticals in Treatment

Medicinal plants have been used in the treatment of diseases since the genesis of humanbeing. Today, 80% of the world's population uses medicines derived from plants, directly or indirectly. In the past, p eople experimented with
differentplants, thinking that they would be beneficial to their health, and learned to use special plants to cure ailments. Henri Leclerc introduced the term phytotherapy to medical science, a concept that re

fers to the study of the use of extracts of origin as medicines or health agents. Phytopharmaceuticals i nclude plant species or complex mixtures of plants in natural or medicinal form. The difference is that botanical extracts obtained through a patented extraction process are used in the formulations. Phytop harmaceuticals must meet the same requirements as other medical devices: safety, performance and co nsistency. The role of Phytopharmaceuticals in treatment is given as follows:

1. In the treatment of congestive heart failure

Digitoxin is isolated in a pure state from purple foxglove (*Digitalis purpurea*). It is used as a cardiac glycoside in the treatment of congestive heart failure. These days most of the natural compounds are used as a basis or a model for the chemical synthesis of pharmaceutical substances. For e.g.- salicylic acid is produced by the plant *Filipendula ulmaria* (meadowsweet), and a derivative of salicylic acid, acetylsalicylic acid (produced by willows) have a long history of decreasing pain and fever, but have been synthesized using chemical methods since a century[3].

2. As an antithrombotic agent

The antithrombotic activity of many plant extracts and purified active compounds is demonstrated by the inhibition of activated partial thromboplastin time, prothrombin time, and thrombin time. In vitro studies have also shown that many plant extracts or non-enzymatic bioactive drugs work by inhibiting key components of the coagulation cascade (e.g., thrombin, FXa, and/or TF/FVIIa). Among isolated medicinal herbs, natural flavonoids including myricetin and quercetin [4], kaempferol, isorhamneta kaempferol-3-o- (2″, 4) are potent inhibitors on human thrombin Liglucoside; baicalein, luteolin, apigenin [5] and acacetin cypress; lactones such as senkyunolide I [6]; catechinsepicatechingallate and epigallocatechingallate [7] [8]; tanshinones [9] 15, 16-dihydrotanshinone and such as tanshinone IIA and plant-based β-sitosterol [10]. Some negative products/ingredients may also exhibit dual inhibition of thrombin and/or FXa *in vitro* or *in vivo* (preclinical) conditions, but examples of dual inhibitors of protein coagulation are rare [11] [12]. An example of fibrinogenolytic serine protease (lunathrombase) exhibits anti-coagulant activity through dual inhibition of thrombin and FXa [13]. There may be a high demand for this dual inhibitor in the preparation of herbal antibiotics in the pharmaceutical industry. Some herbal medicines tested in vitro have been shown to have lower anticoagulant potency compared to commercially synthesized direct thrombin inhibitors (e.g. dabigatran and bivalirudin); However, preliminary studies have shown that these drugs can be used effectively [14]. In some cases, purified active compounds have been found to have lower anticoagulant potency than the crude product or purified plant part; this suggest that the active ingredients combine to enhance their antithrombotic activity [15]. Clinical studies are still needed to evaluate the therapeutic effect of this herb.

3. In the treatment of COVID-19 virus

It is a well known fact that the drug discovery process is expensive and time-consuming, the recovery of existing drugs as a treatment option for COVID-19 has been explored, but some molecules have been removed as treatments due to ineffectiveness or serious side effects. . These effects require the search for effective and safe alternative treatments. Keeping this in mind, herbal medicines derived from medicinal plants can be explored as important sources for the development of COVID-19, as their role in the treatment of diseases such as HIV, MERS-CoV, and influenza has been previously reported. Considering this fact, the current study investigated the effects of flavonoids, alkaloids, tannins and glycosides, etc., which have anti-inflammatory properties and can inhibit SARS-CoV-2.

4. In the treatment of Diabetes

Diabetes is a metabolic disease of pandemic presence. Its ever-increasing prevalence is threatening to cause significant damage both to individuals and society as a whole. The precise cause is not always nailed down; however, an underlying genetic predisposition cannot be ruled out. Diabetes is a

persistent systemic disease that is consistently linked with the development of CVDs. The incidence of diabetes and related CVDs has dramatically increased over the past years with an alarming increase in mortality due to CVDs than diabetes.

Table 2: List of Phytopharmaceuticals in the treatment of Diabetes

Serial No.	Medicinal plant (common name)	Active ingredient	Family	Mode of action
1.	*Aloe vera* (aloe) [19]	Phytosterols, polysaccharides	Asphodelaceae	Hypoglycemic effect, stimulate synthesis, and/or release of insulin
2.	*Aralia elata* (Japanese angelica tree) [20]	Elatosides E together with oleanolic acid	Araliaceae	Normalizes serum glucose levels
3.	*Allium sativum* (garlic) [21]	Allicin	Amaryllidaceae	normalizes fasting blood glucose, serum triglycerides, total cholesterol

6. As Phytoradiotherapy

Radiotherapy (RT) is an effective method of cancer treatment, but like any other method of cancer treatment, there are inherent limitations. While technological advances and a growing understanding of its biological effects have improved its results dramatically, the use of RT is still limited to certain patient populations and by normal tissue toxicities. The harmful side effects of treating patients with radiation can offset its therapy benefits, limiting its use in certain cases. Phyto, or plant-based, medicines offer a way to add to radiation treatment, while also protecting patients from its toxic side effects.

Different plant extracts including Green Tea, Bitter Melon, and more display remarkable therapeutic properties. The anti-tumorigenesis properties of these plants would not only enhance a patient's radiation therapy directly by promoting tumor control but also minimize side effects, with their antioxidative properties, that are often a contributing factor to an unsuccessful radiotherapy treatment. For example, *Vincea rosea* and *Pargaum harmala L.* were used effectively against cervical cancers while herbs such as Curcumin and *Stephania Tetranda* were used to battle brain cancers.

Table3: List of phytopharmaceuticals in the treatment of lung cancer [22, 23, 24]

Serial No.	Phytomedicine in the treatment of lung cancer	Description	Result	Supplemental Treatment
1.	*Rhus verniciflua (Lacquer Tree)*	Prolongation of survival in non-small cell lung cancer (NSCLC) patients	Median survival tim e and survival rates increased in patients	Chemotherapy
2.	*Brucea javanica*	Inhibit brain metastasis as a complication of lung cancer	5-month increase in median survival	Radiotherapy
3.	*Cannabis sativa/Cannabidiol (CBD)*	Test the effects of combining radiotherapy and CBD oil treatment	substantially enhanced tumor cell killing was seen	None

Development Process of Phytopharmaceuticals

Phytopharmaceutical drugs are defined as purified and standardized fractions with defined minimum four bioactive or phytochemical compounds (which can be qualitatively and quantitatively assessed) of an extract of a medicinal plant or its part, for internal or external use of human beings or animals for diagnosis, treatment, mitigation, or prevention of any disease or disorder but does not include administration by parenteral route. In Schedule Y of Drugs & Cosmetic Act and Rules thereof, the newly added Appendix I B describes data to be submitted along with the application to conduct clinical trial or import or manufacture of a phytopharmaceutical drug in the country. The regulatory requirements for NDA for the phytopharmaceutical drug include standard requirements for a new drug-safety and pharmacological information, human studies, and confirmatory clinical trials. A schematic flowchart for the development process of phytopharmaceutical drugs is shown in Fig.1.

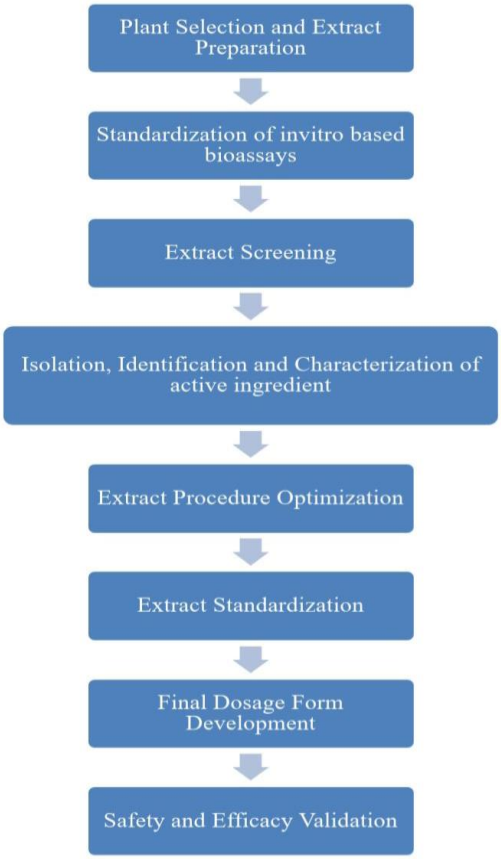

Fig. 1: Development process of Phytopharmaceuticals

The overall process involves the following steps:

1. Data submission by applicant: The information to be submitted by the applicant with respect to the content of herbal medicines, which includes detailed information about plants, products or herbal medicines and their contraindications or side effects. Events recorded in medicine or ethno medicine, documentary information and information on the use of the drug preparation, safety studies, including scientific studies of botanical drugs, pesticides used, and information on product, manufacturer, quantity sold, degree of human exposure, and age are to be submitted [25].

2. Pharmacological Information: According to the information published by the government, there is medical information, including human studies, clinical studies or epidemiological studies, regarding the development of herbal-free health medicines.

3. Identification, Authentication and Extraction: Botanical identification is an important first step in good research. Before proceeding with the chemical preparation, it is necessary to identify the plant followed by preparation of extracts and quantification of the bioactive components [26]. There are many things that needs to take in consideration for the identification and extract preparation such as:

- Classification of plants that provide herbal medicines [27].
- Morphological and anatomical description of plant history provides testing characteristics and additional images to confirm identity and uniqueness.
- Plant origin, habitat and season or harvest time [28].
- Complete list of information about all manufacturers and suppliers, including their names and answers to the following questions: Raw materials, place of growth, different stages of plant growth at harvest, collection time, storage and inspection of powdered plant material for obtaining uniform particle size.
- Quality control is essential for the effectiveness and safety of herbal products. Medicines can be identified because they can describe many things besides their properties, such as purity, content and other chemical, physical or biological properties or manufacturing processes [30]. Keeping the total ash not more than 10% and the foreign matter rate not less than 20% is a way to guarantee the quality of the product.

4. Subsequent Fractioning: The extraction procedure is the first step before extracting any desired natural compounds [31]. The solvent extraction, distillation, pressing, and sublimation are examples of extraction techniques in accordance with the extraction principle. The method of solvent extraction is the most used.

- Starting material is taken into account along with test procedures and quality requirements [32].
- The following pertinent processing information should be provided: additional details on excipients, diluents, stabilizers, and preservatives; solvent selection; extractive values; solvent residue testing; chemical tests; microbiological loads; and heavy metal pollutants. Chromatographic fingerprinting method for phyto- chemical characterization, which makes use of a phytochemical reference marker and a test for the product's primary active ingredients, should be developed [33].

5. Formulation Preparation and Manufacturing: An ayurvedic formulation is a dosage form that includes one or more herbs, or herbs that have been processed in a certain way and in a certain quantity to provide a variety of medicinal, dietary, and cosmetic benefits [34]. Ayurvedic medicines are derived from the ingredients of botanicals through extraction, distillation, expression, fractionation, purification, concentration, or fermentation process. To objectively evaluate conflicting toxicological, epidemiological, and other data is one of the most challenging undertakings [35]. The following information should be included in the formulation of phytopharmaceutical drugs such as-composition, test for identification, percentage of final purified fraction with a specified marker of phytopharmaceutical drug per unit dose, names and percentages of all excipients, stabilizers, and other agents employed, as well as packaging materials [36]. The inactive as well as active

phytopharmaceutical chromatographic fingerprinting profile with phytochemical reference is a quality specification for such products. The production process, along with the environmental controls, the method of manufacturing the dose including limit of acceptance and in-process quality control testing should be included [37]. If the material is packaged; packaging materials, packaging procedures, and a description of the final pack should also be included. There are numerous quality requirements for finished goods; they consist of dosage form-specific assays and chromatographic fingerprint profiles with phytochemical references [39]. If an active constituent is unknown, an analysis for the active constituent or a distinctive marker should be determined.

6. Stability data: Testing for stability is essential for the creation of medications made from plants. Worldwide drug regulatory organizations have established standards based on stability tests. Stabilization information for the phytopharmaceutical medicine in a dosage form or composition should be provided for storage intervals of one month, two months, three months, and six months kept in a non-extreme environment at a range of 40± 2 °C and a relative humidity (RH) of 75± 5% [40].

7. Safety Information: It was decided that all conventional and herbal products wishing to enroll in clinical trials for any therapeutic condition should follow the same procedures as those used by the Department of the Drug Controller General of India for conventional drugs, in accordance with the guidelines for the security and effectiveness of herbal medicines that were created by an expert committee [41]. The details on safety and pharmacological studies must be provided (but only if the phytopharmaceutical drug is intended for use during pregnancy), in addition to animal toxicity and efficacy data, such as 28 to 90 days of repeat-dose oral toxicology on both types of organisms, in-vitro genotoxic data (Ame's examination and Chromosomal abnormality test as per Schedule Y), dermal toxicity tests for topical administration products, and teratogenicity studies.

8. Human studies: To assess the safety (toxicology) and effectiveness of phytopharmaceuticals at par with medications based on synthetic compounds, well-done clinical trials would need to be conducted. Ayurvedic medications that have long history of clinical uses without any adverse effects are exempted from these necessary requirements [42]. An extra prerequisite for traditional medicines is proof of a potential mechanism, which is neither usually understood nor required.

9. Clinical trials: The protocols for any particular or unique safety and effectiveness studies that are suggested expressly for the phytopharmaceutical medicine ought to be submitted for approval in accordance with the applicable regulations and standards [43]. In addition, it is necessary to submit for approval of proposed protocols for human clinical studies necessary to generate or validate information on safety and effectiveness for the phytopharmaceutical dosage form or product [44]. The data to be submitted with application for conducting clinical trial of phytopharmaceutical drugs are shown in Fig.2.

10. Regulatory Information: The following are the essential components of Ayurveda, the Siddha or Unani (ASU) drug regulations in India [45]:

- The Classical ASU medications are made and named in accordance with the formulas mentioned in the reliable textbooks [46]. If only reliable books and published material are cited for the supplied medicine, no manufacturing license is needed for this category [47].

- Under modern phytopharmaceuticals oversight, using advanced extraction with solvent approaches, fractionation, recent formulation creation, and other methods is now permitted for medicines development. A patent or proprietary medicine uses components from authoritative texts, but alongside intellectual assistance, innovation, or invention to manufacture unique products from classical medicine [48]. Once the NDA approval from CDSCO is granted, the

novel phytopharmaceutical medicine will have its commercial position as a new chemical entity-based drug.

11. Marketing and post-marketing surveillance: Post-marketing surveillance (PMS) is the process of finding and gathering information about pharmaceuticals after they are approved for usage in a broad population. One of PMS's most significant responsibilities might be to rigorously assess the efficacy and safety of new medications around the globe, especially for patients with a variety of alternative health issues. The demography of persons who will ultimately use the drug is significantly distinct from the population investigated before the drug is introduced in the preapproval stage. Following approval, applicants are required to provide information once every six months for a period of two years, after which they must submit updates annually [49].

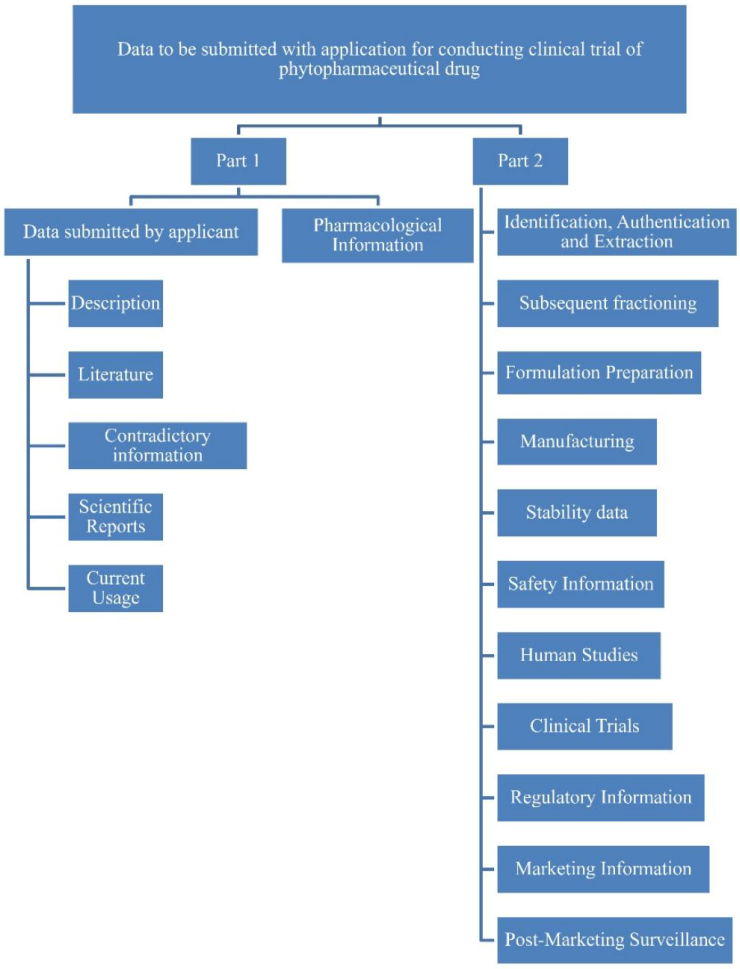

Fig. 2: Data to be submitted with application for conducting clinical trial of phytopharmaceutical drugs

Conclusion:

Globally, there is a growing demand for herbal medicines, which is bolstered by increased studies conducted in laboratories for the pharmacological assessment of the bioactive elements and their potential to treat a range of illnesses. Under the framework of contemporary medicine, focus on development of Phytopharmaceuticals is anticipated to encourage innovations and creation of new

medications derived from botanicals. It would stimulate research and draw funding for academic institutions, researchers, and promote business to produce useful drugs. The aim of the current review was to present an extensive description of the Phytopharmaceuticals and stimulate curiosity among researchers to investigate in-depth biological functions that they may exhibit. Additionally, investigating the chemical components found in different plant species may aid in the discovery of novel therapeutic leads and hence aid in the drug development process.

Acknowledgement

NA

Conflict of Interest

The authors declare no conflicting interests.

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How to cite this article:

Sarkar S, Goswami D, Das T. An Overview of Phytopharmaceuticals, *Curr Trends Pharm Res*, 2023; 10 (1): 56-69.