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Herbal Monograph Preparation

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ABSTRACT
Think of herbal monograph is a "botanical biography".The monograph publication process contains of selection, collection and processing of raw materials, identification tests, quality control (purity and safety testing) of herbal raw materials, safety information such as toxicity tests. herbal monographsinclude information about nomenclature, part used, constituents, range of application, contraindications, side effects, incompatibilities,dosage.
Thecomparativelyanalyses the pharmacopeial review on Herbal drugs Preparation (Tinctures, extract, essential oils, vegetables fatty & Fish oils) see continuous increase in the numberof monographs in different editions of the European Pharmacopoeia. The total number of articles on Herbal drugs included in the last edition. In this edition, drugs from roots and rhizomes prevail followed by herbs and leaves. Largest is the number of drugs containing essential oils,flavonoids and mucilage's.The number of monographs on Herbal drug preparations in articles are for galenical preparations (tinctures, extracts, homoeopathic preparation) monographs for essential oils and articles on vegetable and animal fats, oils and waxes). Amongst galenical preparations, the largest is the number of dry extracts followed by the monographs on tinctures and homoeopathic preparations. According to the content of active substances in pharmacopoeialgalenical preparations, largest is the number of preparations containing alkaloids, followed by essential oil drug preparations, flavonoids and anthraquinone.An important conclusion is the introduction of more accurate and worldly instruments method for examine of active component in herbal drug preparation.In that common use method for examine that is spectrometric, Gas Chromatography (essential oils), & HPLC for other all groups of active substances.
Pharmacopoeia is an essential reference for all individuals and organizations working within pharmaceutical research and development, manufacture and testing around the globe. Herbal pharmacopoeia intends to promote the responsible use of herbal medicines with the highest possible degree of efficacy and safety through the development of standards of identity, purity, and analysis for botanicals including the review of traditional and scientific data regarding their efficacy and safety. The American Herbal Pharmacopoeia (AHP) and those of other nations (e.g., the British pharmacopoeia, the European pharmacopoeia, the pharmacopoeia of the People's Republic of China, the Indian Ayurvedic pharmacopoeia) intend to promote the responsible use of herbal medicines with the highest possible degree of efficacy and safety and disseminate such information through monographs and other publications.

I. INTRODUCTION AND IMPORTANCE OF MEDICINAL PLANTS AND HERBS

Introduction

The Indian Pharmacopoeia is the legally recognised book standard for the quality of the drug substances and preparations included there in for INDIA, according to the drug and cosmetic act of 1940. The Indian Pharmacopoeia Commission created the Indian Pharmacopeia (IPC). On December 9, 2004, the Indian government formed the Formulation of Indian Pharmacopoeia Commission as an independent entity inside the Ministry of Health and Family Welfare (1)

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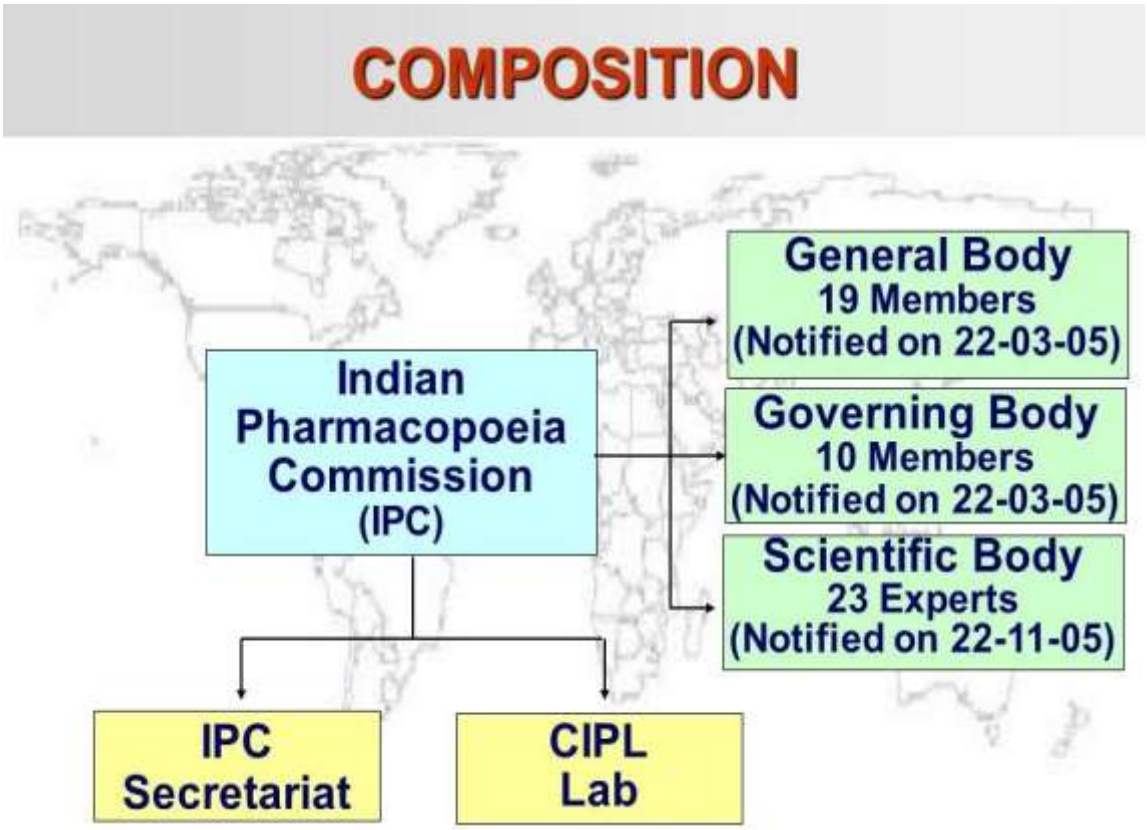

The national pharmacopeia's herbal monographs and other authorities are crucial for the identification of herbal ingredients. A monograph in this context is a document that defines a botanical drug and offers details for proper identification. The herb's basic properties, activity, clinical applications, and suggested dosage are listed in the herbal monograph. (2) A type of alternative and complementary medicine (CAM) known as herbal medicine, phytomedicine, or herbalism employs plants or its unprocessed components to treat disease. It could also involve goods made by animals, fungi, or microbes (3). The study of pharmacognosy and the application of medicinal plants, which form the basis of conventional medical treatment, is known as herbal medicine (also known as herbalism).

Some natural medications have been translated thanks to global pharmacology research.A class of medications known as artemisinin that was discovered in the herb known as Artemisia annuaa herb that was known in Chinese medicine to treat fever.The safety and effectiveness of plants employed in 21st-century herbalism are only partially supported by scientific research, and there are typically no requirements for purity or dosage. The range of herbal medicine frequently encompasses fungi and bee products, in addition toPhytotherapy or phytomedicine are additional names for herbal medicine

Before the introduction of chemical medicines, man relied on the healing properties of medicinal plants. Some people value these plants due to the ancient belief which says plants are created to supply man with food, medical treatment, and other effects. It is thought that about 80% of the 5.2 billion people of the world live in the less developed countries and the World Health Organization estimates that about 80% of these people rely almost exclusively on traditional medicine for their primary healthcare needs. More than 3.3 billion people in the less developed countries regularly use medicinal plants since they represent the "backbone" of traditional medicine. There are about 2000 different ethnic groups in the world, and practically all of them have their own unique traditional medical experiences and expertise. Many indigenous tribes in Iran have a long history of learning how to use therapeutic plants. Each tribe in Iran has its own unique plants

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and customs as a result of the diverse climates and geographical regions that make up the country. Due to its long heritage of cultivating traditional medicinal plants, Alamut is one of Iran's most significant geographical areas. Because the Alamut region and the various villages it includes are remote from other Iranian towns, the locals have relied on traditional medical knowledge and medicinal plants. In this study, we analysed the medicinal plants with most therapeutic usage in the region.(4)

Any plant that has compounds that can be utilised therapeutically or that serve as building blocks for the production of effective pharmaceuticals is considered to be a medicinal plant. This definition enables the distinction between plants that are considered medicinal but have not yet undergone a full scientific investigation and plants whose therapeutic capabilities and ingredients have been established scientifically. Several plants have long been utilised in traditional medicine. Although there may not be enough scientific evidence (such as double-blind trials, for example) to support some of them, some do appear to work. These plants ought to be recognised as therapeutic herbs. Pharmacists refer to these substances as "crude medications of natural or biological origin."To describe entire plants or specific plant sections that have therapeutic characteristics.Over 90% of traditional medicine recipes and treatments use medicinal plants, however this research will focus exclusively on those that have been linked to illness prevention measures. The distinction between therapy and prevention can, in some circumstances, be exceedingly narrow. As an illustration, consider the fact that kidney illness can be avoided by treating minor blood pressure increase. (5)In order to maintain a population's health, general well-being, and way of life, medicinal plants have always been crucial. Plant stems, leaves, flowers, seeds, berries, and roots have been utilised for thousands of years to treat and maintain a variety of pathological illnesses. In beverages, meals, massage treatments, and cosmetic formulae. This book, which is based on scientific findings and original research, provides a thorough and current introduction to medicinal plants from around the world. It describes these plants' enormous therapeutic and economic potential and analyses various aspects of their toxicity to humans as well as their significance for maintaining human health and homeostasis. (6)

IMPORTANCE OF MEDICINAL PLANTS

Alternative medicine is the practise of employing plants for therapeutic purposes (AM). All cultures, particularly Western and Asian, have employed AM. Unfortunately, the majority of people today still hold that a dosage form is necessary for a treatment to be effective (i.e., formulating in tablets, capsules, etc). Even though many tablets and capsules, like paclitaxel, digoxin, and aspirin, are made of plant compounds and are taken on a daily basis. Our forefathers used plants and herbs to flavour and preserve food, alleviate headaches, lessen discomfort, and even prevent diseases like epidemics. Through the ages, human groups have shared knowledge of these plants' therapeutic powers. The biological characteristics of plant species used around the world for a variety of purposes, including the treatment of infectious diseases, are typically due to active chemicals created during secondary metabolism. People are currently being warned by numerous studies about the danger and risk posed by pathogenic germs that have developed a resistance to antibiotics (7).

Different plant species that are utilised in herbalism (or "herbal medicine") are referred to as "medicinal plants." It involves both the study and the use of plants for therapeutic purposes. The Latin term is where the word "herb" comes from. Today, any component of the plant, including the fruit, seed, stem, bark, flower, leaf, stigma, or root, is referred to as a herb. These healing plants are also utilised in some types of spiritual practises, as well as in food, flavonoids, medication, and perfume.

Long before the prehistoric era, people employed plants for medical purposes. There is proof that herbal medicine has been used by Unani Hakims, Indian Vaids, and European and Mediterranean cultures for more than 4000 years. Herbs were used in healing rituals by indigenous cultures in Rome, Egypt, Iran, Africa, and America. Other cultures developed traditional medical systems like Unani, Ayurveda, and Chinese Medicine that systematically used herbal therapies (8).

India's forests are the main source of a huge variety of aromatic and medicinal plants that are mostly harvested as raw materials for the production of pharmaceuticals and perfumery goods. The four main systems of indigenous medicine are Ayurveda, Unani, Siddha, and medications. Ayurveda and Unani Medicine are the most advanced and popular systems in India.

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Around 21,000 plant species have the potential to be used as medical plants, according to the WHO. According to information now available, more than 75 percent of the world's population relies mostly on plants and plant extracts for their medical needs. More than 30% of all plant species have been utilised medicinally at some point.

IMPORTANCEOf SOME HERBS

- Aloe, sandalwood, turmeric, sheetraj hindi, and khare khasak are a few herbs that are frequently used as antiseptics.
- Liquorice, honey, and turmeric are all great first aid for cuts.
- Aloe and barberry are only two of the many herbs that are used as tonics. They might also be nourishing.
- Certain cough syrups contain ginger and cloves. They are renowned for having expectorant qualities.
- Cloves, cardamom, and wild cherries are all expectorants.
- Some medicinal herbs have disinfection properties that kill disease-causing microorganisms.
- Some herbs also possess antibacterial qualities. The growth of bacteria, dangerous organisms, and germs can be inhibited by turmeric. A popular home treatment for cuts and wounds is turmeric.
- Aloe vera is regarded as the King of therapeutic plants in Ayurveda
- Saunf or fennel increases breast milk produce.
- The Queen of therapeutic plants is Tulsi. Tulsa's potent scent helps prevent bacterial development. It empowers you to combat stress.
- Methi is one of the most amazing medicinal plants. It regulates cholesterol levels.
- Fennel is an aromatic plant that helps with health issues. (9)

REGULATION OF GUIDLINES OF US, EUROPE AND INDIA

India

A significant portion of India's legally acknowledged health systems are based on herbal medicinal products. Herbal medicines are governed in India by the IMCC (Central Council of Indian Medicine) Act, the Research Councils (ICMR and CSIR), the Department of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy), and the Drugs and Cosmetics Act 1940 (Amendment). The Drug Controller General of India (DCGI) requirements must be followed in order for herbal treatments and medicinal plants to be incorporated into the modern (Allopathic) system.The Drugs and Cosmetic Act of 1940 sets standards for medications, and the relevant Pharmacopoeias have prescribed specific monographs. With criteria for 52 drugs, the publication of the Herbal Pharmacopoeias is a positive step in this direction. The D and C Act's first schedule lists the authorised texts that must be adhered to in order to licence any herbal product under the two categories : ASU medications and Patent or proprietary medicines. There are a lot of herbal products on the market even though it is challenging to classify them according to the Drugs and Cosmetics Acts and Rules because neither herbal products nor herbal Pharmacopoeias have any legal standing in our country.

United States

The term complementary/alternative Medicines (CAM) is most frequently used to refer to Traditional medical systems in the United States. Use of CAM in addition to conventional care is referred to as "Complementary Medicine." In addition to standard medical treatment, The FDA clarified the different categories of complementary alternative medicine (CAM) products into cosmetic, device, dietary supplement, drug, as well as "new drug" and "new Animal drug," food, and food additive in its draught guidance, "Guidance for Industry on Complementary and Alternative Medicine Products and Regulation by the Food and Drug Administration." Some CAM products are covered by these statutory definitions. Additionally, it was made clear that CAM goods are not immune from regulation under either the FDA Act or the Public Health Service Act. Later, following recommendations from a number of organisations, including The American Herbal Products Association, the proposed guideline was removed (AHPA). (11)

European Union

The European Directive 2001/83/EC, which mandates the marketing of each medicinal product and calls for the issuance of an ad hoc authorization based on the findings of tests and experiments pertaining to quality, safety, and efficacy, covers herbal medicines. The definition of traditional herbal medicine, the streamlined registration process, the provisions for community herbal monographs, the community list of herbal substances and preparations, and the creation of the Committee for Herbal Medicinal Products are the

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main features of Directive 2001/EC (HMPC).European Directive 2004/24/EC on traditional herbal medicinal products was introduced specifically in recognition of the position that it was challenging for businesses to meet the full requirements for a Marketing authorisation, particularly in relation to efficacy, as are required under Directive 2001/83/EC for many herbal medicines. A HMPC has been established by Directive 2004/24/EC, which is a part of the EMA, the European Agency in charge of evaluating medical products, to handle tasks relating to the streamlined registration and authorization of herbal medicinal products. Community herbal monographs are established by CHMP, and they list herbal substances and preparations (12).Evidence of the product's historic use is recognised as proof of its effectiveness. Authorities may still request proof of safety, though. Quality assurance Physical, chemical, and microbiological testing must be mentioned in the product specifications. The bibliographical evidence should demonstrate that the product has been used as a medicine for at least 30 years, 15 of which should have been spent in the European Union. The programme for conventional use If a product has been in the Community for less than 15 years but otherwise qualifies for the directive's streamlined registration process, registration will be submitted to the committee for herbal medicinal products.

HISTORY OF HERBAL DRUGS IN INDIAN PHARMACOPEIA

Apothecaries and growers in England, where there was no regulation on the specification of quality as well as particular quantities used as medicine, bolded Unit 1617 drugs and medicine that were in common usage. The British Pharmacopoeia, which first published in several versions in 1851, was based on the Pharmacopoeia London of 1618. The unification of the pharmacokinetics of London and Dubai was the original goal of the British Pharmacopoeia. The Medical Act of 1858 emphasised the need for a new book with a list of medicines and compounds, instructions for their production, and the actual weight at which they should be combined. It was decided to publish the British Pharmacopoeia as a result. The second edition of the British Pharmacopoeia, which was combined with the renowned pharmacopoeia London 1618 and Dubai Pharmacopoeia 1807, was published in 1885. Editions 3 through 6 were released in 1885, 1898, and 1932, respectively. Respectively. In the years 1874 and 1890, respectively, addenda to the second and third editions were published. The General Medical Council decided in 1947 that the standard interval should be five years, beginning with the seventh grade in 1948. 1953, 1958, 1963 saw the appearance of further education, and 1968 saw its approval. The 2013 edition of the British Pharmacopoeia is divided into six volumes and includes 3,000 monographs on drug substances, excipients, and manufactured medicines. The first United States Pharmacopoeia (USP) was published on December 15th, 1820. After a ten-year hiatus, further education finally started. The 19th edition of USP was released in 1905. The announcement of the USP and N F (National Formulated) merger was made on July 5, 1974. USP covers all medications substances and medication products that only use pharmacopeial ingredients are covered by NF. The first United States Pharmacopoeia (USP) was published on December 15th, 1820.

After a ten-year hiatus, further education finally started. The 19th edition of USP was released in 1905. The announcement of the USP and N F (National Formulated) merger was made on July 5, 1974. USP covers all medications substances and drug products for which NF only covers the ingredients chapter of the pharmacopoeia. Using a DNA-based authentication technique, the adulterants are ruled out. The basic chapter on determining an essential oil's flash point was also included. A revised chapter on thin layer chromatography, including high-performance thin layer chromatography, was included in the Addendum 2016 (Indian Pharmacopoeia, 2014c). A few of the herbs and herbal remedies mentioned in the IP are also utilised in veterinary medicine (Rastogi, Pandey, Prakash, et al., 2015). While including the monographs of herbal pharmaceuticals in IP, specific inclusion and exclusion criteria were observed (2014a, 2014b, 2014c; Guidance Manual for Monographs Development of Herbs and Herbal Products including Phytopharmaceutical Drugs, 2016).

IP 2018's paper is now under review. Amarbel, Anise Oil, Belladonna Dry Extract Tablet, Citronella Oil (Geraniol type), Citronella Oil (Java type), Green Coffee Bean Extract, Horse Chestnut Dry Extract, Milk Thistle Dry Extract, Schisandra Dry Extract, Schisandra Fruit, Sweet Orange Oil, and other new monographs will also be included in IP 2018. As a result, there will be 165 individual monographs for herbal medications. IP 2018 is anticipated to go into effect on January 1,

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2018. The growing practise of including monographs for herbal medications.

CURRENT STATUS OF HERBAL DRUGS IN STANDARD IN INDIAN PHARMACOPEIA

The first of April saw the implementation of the seven-volume, four-volume IP (2014a). The topic of drug needs is handled in Volume III. A separate chapter covers the general requirements for herbs and herbal products. The individual monographs are arranged alphabetically. A new general section on DNA-based proof One of the key traits, especially in light of the standards for herbs and herbal products, was the ability to rule out adulterants. There was also a basic chapter on figuring out an essential oil's flash point. The thin layer chromatography chapter has been updated to include high-performance. The Addendum 2016 contained a rewritten chapter on thin layer chromatography, including high-performance thin layer chromatography (Indian Pharmacopoeia, 2014c). In IP, a number of the plants and herbal treatments are also used in veterinary care (Rastogi, Pandey, Prakash, et al., 2015). As long as they complied with certain inclusion and exclusion criteria, the monographs of herbal medications were included in IP (2014a, 2014b, 2014c; Guidance Manual for Monographs). Information based on well-known usage trends about its safety profile. They should also fit the other requirements for inclusion and be of public interest, commercially available, and have a distinct and well-defined botany.

No longer in use, illegal in India, or deemed inappropriate by the IPC and regulatory body are herbal medicines are not regarded as intellectual property. It has previously been discussed how IP will face both current and future challenges (Prakash et al., 2016). The IP 2014 herbal monographs list is included in the table below, along with its addenda for 2015 and 2016. (13)

CURRENT STATUS OF HERBAL DRUGS IN AYURVEDIC PHARMACOPOEIA

Since the beginning of human civilization and the Vedic era, the Ayurvedic medical method has been used extensively throughout India. Despite the numerous changes that Ayurveda has undergone over the course of its lengthy history, it continues to be the primary source of medical comfort for a sizable portion of the people of the country. The vast majority of Vaidya's are no longer self-contained units gathering and making their own remedies as they once were due to urbanisation and the disappearance of forests. He is now forced to rely on recently established organisations, such as one that gathers and supplies unprocessed pharmaceuticals and another that undertakes the mass manufacturing of drugs in Ayurvedic pharmaceutical facilities operated on a commercial scale.

The Government of India determined that it was necessary to amend the Drugs and Cosmetics Act of 1940 in order to use it to control Ayurvedic, Siddha, and Unani drugs in a limited manner in light of the new trend in Ayurvedic pharmaceuticals. Act

The statute was then amended in 1964 to ensure only a minimal level of control over the manufacture and distribution of these medications, specifically:

• The manufacture should be carried out under specified sanitary circumstances, under the supervision of a Person possessing specified qualification;

• The ingredients used to prepare medications should be genuine and correctly labelled.

• Every container's label should have a true list of all the chemicals, or the formula, that make up the drug.

According to the letter No. 5-5/CCRAS-2006/Tech/APC/Hqrs. Dated 12thMarch 2009, the Ayurvedic Pharmacopoeia Committee (APC), which was established under the former Department of AYUSH, The exercise was started by India's Ministry of Health and Family Welfare based on the current population. Prof. S. S. Handa served as the committee's chair, followed by Dr. S. K. Sharma as vice chair, Dr. G. S. Lavekar as member secretary from February 2009 to February 2010, Dr. Ramesh Babu Devalla as member secretary, and other distinguished specialists in their disciplines. The work was also completed with the approval of PCIM&H's Governing Body and under its supervision (14,15)

Quality Aspects of Herbal Monograph

There are hundreds of different elements in plants, some of which are only present in very little amounts. Rarely do phytochemical research succeed in isolating and identifying all secondary metabolites contained in the plant extract, despite the availability of advanced chemical analysis methods. In addition, plant elements vary greatly depending on a number of variables (see below), which impedes the quality assurance of phytotherapeutic agents. Herbal medicine quality

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assurance and standardisation involve a number of stages. However, a key factor in ensuring the stability and quality of herbal remedies is the source and quality of the raw ingredients Other elements, such as the use of fresh plants, temperature, light exposure, water availability, nutrients, period and time of collection, method of collection, drying, packing, storage and transportation of raw material, age and part of the plant collected, etc., can significantly impact the quality of herbal medicines and, as a result, their therapeutic value. Plants possessing certain plant constitutions that are heat labile must be dried at low temperatures. Enzymatic activities that last for a very long time after plant collection also degrade other active principles. This explains why herbal medication composition is frequently highly variable. Therefore, it is essential to consistently carry out thorough standardisation and quality control of both the raw materials and the herbal preparations themselves. When the active principles are unclear, a marker substance or substances should be chosen for analysis. To determine if these markers actually account for the stated therapeutic effects of herbal medications, these markers have seldom if ever been evaluated. As was previously mentioned, in addition to these variable factors, other factors might affect the quality, safety, and effectiveness of herbal medications, including the extraction method and contamination with microorganisms, heavy metals, pesticides, etc. Because cultivated plants exhibit less variance in their constituents than wild-harvested plants, pharmaceutical corporations prefer employing them.Additionally, and maybe more importantly, when medical plants are created Monitoring the primary secondary metabolism throughout cultivation allows for the most accurate determination of the ideal harvesting time (16,17, 18,19)

Safety Aspect of the Herbal Monograph

There are many claims in the literature that the safety of herbal products or herbal medicines is not given enough thought. Although there is a risk, because herbals are viewed as natural compounds, the possibility is frequently overlooked. It is important to take into account the various categories of herbal products available on the market. On the one hand, there are herbal medicines that have been given approval (HMPs) and have complied with the standards to provide evidence on quality, efficacy, and safety. On the other hand, some products cannot be used as treatments and must not be marketed. On the other hand, some are not allowed to be used as treatments and are not covered by marketing authorizations. As with chemically defined medications, which have been proven in the past to respond to risk concerns with scientific procedures, HMPs are subject to an ambitious and thorough risk management system in the European Union (EU). The approved procedures for pharmacovigilance and risk management favour the approval of herbal preparations as proprietary medicinal medicines for medical use. Herbal items utilised for illness diagnosis, cure, mitigation, treatment, or prevention are typically classified as drugs depending on the specific nation and current legislation. However, some nations, like the United States, market botanical goods as "dietary supplements." Other nations treat herbal preparations like pharmaceuticals, and in order for these items to be registered, clinical efficacy and safety must be established. However, as originally suggested by the WHO Guideline for the assessment of herbal medicines, only a small number of programmes have been established to investigate the safety and effectiveness of herbal medicines. (20)

Although it is possible to conduct clinical studies using herbal medications, only a small number of well-controlled double-blind (placebo-controlled) experiments have been done with these substances.

Regularly Aspects of the Herbal Monograph

The legislative and regulatory process. The availability of herbal medications varies by nation. This is due primarily to cultural factors as well as the fact that scientific research on herbal remedies is scarce. Few herbal preparations have therefore undergone safety and effectiveness testing. In order to support national regulatory agencies, scientific organisations, and producers in this area, the WHO has issued guidelines that outline the fundamental standards for assessing the quality, safety, and effectiveness of herbal medicines. Additionally, the WHO has created a pharmacopoeia. Monographs on herbal remedies and the Principles underlying the evaluation of herbal pharmaceuticals (21)

There are now a number of regulatory models for herbal medicines, including those for prescription medications, over-the-counter medications, traditional medicine, and dietary supplements. So it appears evident that there is a need for regional and/or worldwide regulatory

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structures to control herbal medications. The regulatory frameworks surrounding herbal medications in several selected countries are outlined in the table below. (22)

Stability Testing of Herbal Drugs

Studies on herbal medications' stability that have been published in the literature involve the quantitative monitoring of a particular constituent as an active or analytical marker (s). However, it is not always possible to correlate any changes in the content of a specific or a group of specific Marker(s) in a herbal product during stability studies to equivalent changes in its therapeutic effectiveness. It's because a plant is considered to be the active element in certain of its entries (WHO,2009; CPMP, 2011b). An herbal product's constituents from various chemical classes may encounter numerous intra- or inter-molecular interactions as a result of the heat, humidity, and/or light that were present during the product's production, transportation, and storage. Products that result from potential interactions between several constituent groups have the potential to change a substance's level of activity For instance, hydrophobic and H-bonding interactions between polyphenols and proteins and polysaccharides result in reversible complexes that lower the quantities of free polyphenols. As seen with paeniflorin and glycyrrhizin, tannins' water solubility is improved in the presence of water soluble glycosides through non-covalent interactions (Tanaka, 1999). When tannins are present, alkaloids precipitate (Fear, 1929). When combined with heavy metal ions, polysaccharides, tannins, and lignin's create mono-dentate and bi-dentate complexes. In an alkaline medium, cations combine with polysaccharides to create strong complexes; in other media, weak complexes are formed (Randleman, 1977).Such interactions have the potential to modify the therapeutic profile of a herbal drug by changing its chemical composition during storage. Therefore, it is essential to demonstrate that a drug's overall chemical makeup stays intact throughout its shelf life using chromatographic fingerprints, which are often obtained using advanced analytical techniques. Additionally, herbal medications are frequently created and administered as tablets, capsules (23)

Reference standards and Harmonization Standards

According to their intended use, primary reference standards, secondary Standards, or working standards must go through initial testing. Less pure compounds or extracts are typically insufficient as secondary standards in practical applications since they do not exhibit the same characteristics as the primary standard, and traceability must be guaranteed. Additionally, the words "main standard," "secondary standard," and "working standard" are not consistently employed in practise and are regrettably sometimes used in a misleading manner. The user must make sure that the drug he is using has been sufficiently characterised and is of a quality that can be guaranteed by a re-testing programme. "A system is devised and put into place to guarantee the reference Standards' ongoing suitability for usage.

A retest programme is typically used, accounting for the reference standard's known physicochemical attributes and stability data. The stability of Reference Standards is checked on a regular basis while being stored. This method can avoid any misunderstandings and the requirement to maintain more than one batch of a primary standard. Pharmacopoeial primary reference standards that satisfy all legal requirements for EP and USP monographs are distributed by the EDQM and the USP Convention (EDQM, 2012; United States Pharmacopoeial Convention, 2012). As a result, the standards can be used for their intended purposes (24)

Herbs And Herbal Product such as herbal extract and herbal formulation

Natural products: The name itself suggests that herbal cosmetics are natural and free from all the harmful synthetic chemicals which otherwise may prove to be toxic to the skin. Instead of Traditional synthetic products different plant parts and plant extracts are used in these products, e.g. aloe-vera gel and coconut oil. They also consist of natural nutrients like Vitamin E that keeps skin healthy, glowing and beautiful. For example, Aloevera is a herbal plant species belonging to liliaceae family and is naturally and easily available. There are a rising number of consumers concerned about ingredients such as synthetic chemicals, mineral oils who demand more natural products with traceable and more natural ingredients, free from harmful chemicals and with an emphasis on the properties of botanicals.

Anti-aging Herbs

Rhodiola rosea :- is also referred to as roseroot, arctic root, King's crown, lignum rhodium, and orpin rose. It is a member of the Crassulaceae

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family of plants and is found in frigid climates. Traditional folk medicine used R. Rosea to treat fatigue, depression, anaemia, impotence, gastrointestinal disorders, infections, and nervous system disorders as well as to increase physical endurance, productivity at work, longevity, and resistance to high altitude sickness. Phenolic compounds, which are known to have strong antioxidant properties, are abundant in R. Rosea.

Carrot: It is derived from the apiaceous plant species Daucus carrot. It has been a valuable herb for a long time because of its abundance in vitamin A and other necessary vitamins. As a renewing, regenerating, and anti-aging agent, carrot seed oil is employed. The carotenoids -carotene and -carotene, in lower levels, give the carrot its distinctive and vibrant orange colour. A and -carotenes are partially converted by humans into vitamin A.

Gingko: The leaves and nuts of the Ginkgo biloba (G. Biloba) tree have been used for thousands of years in China and Japan to treat a variety of illnesses, including impotence in men and poor blood circulation, hypertension, poor memory, and depression. It is also establishing a similar reputation as an anti-inflammatory and antioxidant. Ginkgo biloba is a member of the very sized Ginkgoaceae family.

Neem: A botanical relative of mahogany is neem or margosa. It is a member of the Meliaceae family. The Persian language is where Neem Azadirachta indica's Latinized name comes from. Azad is an Indian-origin word meaning "free" and "tree." Neem is a popular remedy for dandruff since it makes components that are antifungal, antibacterial, pain-relieving, and anti- that would treat dandruff.

Dandruff treatment: The most often used herbs in Ayurvedic medicine are naphthalene-containing Neem kapoor, Henna, Hirda, Behada, Amalaki, Magic Nut, Bringaraj, Rosary Pea, Sweet Flag, Cashmere tree, and Mandor.

Henna: Henna is derived from the plant Lawsonia inermis, which belongs to the Lythraceae family. This plant contains the dye molecule Lawsone, which is processed to create henna powder. Gallic acid, glucose, mannitol, lipids, resin (2%), mucilage, and traces of an alkaloid are also present in addition to lawsone. Hennatannic acid and an olive oil-green resin, both soluble in ether and alcohol, are produced by the leaves. Lawsone, which was extracted from L.inermis leaves, has a strong antifungal antibacterial action.

Shikakai: A medicinal plant known as Acacia concinna Linn. (Leguminosae) grows in the tropical rain forests of southern Asia. The fruits of this plant are used as a purgative, expectorant, emetic, and hair-washing agent in addition to promoting hair growth. The powder of Acacia Concinna Linn contains anthraquinone glycosides, saponins, alkaloids, sugar, tannin, and flavanoids.

Hair-care

Amla: The fruit of a tiny, leafy tree that grows all over India and has distinctive properties is known as Amla. Palatable fruit Both its high vitamin C content and the priceless oil that is derived from its seeds and pulp and used as a therapy for hair and scalp issues are highly praised. It treats children's illnesses, hair loss, and eye disorders (25)

Module 2

Content Of Individual Herbal Monograph

Sr.No	HERBAL MONOGRAPH CONTENT
1	**TITLE**
2	**SYNONYM**
3	**VERNACULAR NAME**
4	**IDENTIFICATION PLANT MORPHOLOGY** • Microscopy • Chemical tests • Thin-layer chromatography • High performance liquid chromatography
5	**PURITY TEST** • Foreign matter • Ash contents • Loss on drying • Extractive values

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6	**SAFETY TEST** • Heavy metals • Microbial limits
7	**CHEMICAL CONSTITUENTS**
8	**MEDICINAL USE** • Uses described in folk medicines, not supported by Experimental or clinical data • Biological and pharmacological activities supported by experimental data Clinical studies
9	**SAFETY INFORMATION** • Pre-clinical studies (Toxicology studies) • Others (Adverse reaction, contra-indication, side effect, warning, Precaution)
10	**DOSAGE**
11	**STORAGE**
12	**REFRENCES**

(Table 1) Content of herbal monograph

Identification and Authentication of herbal drugs

Different techniques are frequently employed for discriminating, identification, and authentication reasons. These techniques combine molecular-based, chemical fingerprinting, morphological, and anatomical analysis techniques. The authentication of herbal-related items is handled differently by each of these methods overall, and it also relies on the particular needs. Consequently, a summary of the method's benefits and drawbacks for herb authentication had been provided.

Organoleptic properties

The term "organoleptic qualities" refers to the study of medications utilising the sense organs. It refers to analytical techniques including colour, smell, taste, size, form, and unique traits like touch and texture. It stands to reason that the first time you see the plant or extract, it tends to identify itself. If this isn't enough, the plant or extract may have a distinctive flavour or odour. Morphology, as opposed to Morphography, is the study of a basic drug's form.

Microscopic test and characteristics

This technique enables a more thorough analysis of a medication and can be used to recognise organised medicines by their recognised histological characteristics. It is mostly utilised for the qualitative assessment of whole and powdered forms of organised illegal substances. Every plant has a distinctive tissue feature. A microscope can be used to confirm the specific structural characteristics of medications derived from plants. Different reagents or stains can be employed to differentiate cellular structure for the best outcomes.

Chemicaltests

Chemical assays, quantitative chemical testing, qualitative chemical tests, and instrumental analysis are all part of the chemical evaluation. The solitude Chemical methods of evaluation include purification and the identification of active ingredients. Alkaloids, glycosides, and tannin identification tests are included in qualitative chemical analyses.

TLC FINGERPRINTING OF HERBAL DRUGS

Based on their degree of spectrum similarity, each Peak was first identified as part of the authentication test. hRf information and the start, max, and end Peak heights are included in a tabular form of digital data acquired from Win Cat 4.10 output. Based on the high correlation spectra (rspectra> 0.9), unaligned peaks are moved or

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aligned to the same hRf-values, and their peak height values were organised. In the form of square data matrices. Using the statistical programme Minitab 17, a multivariate statistical analysis was conducted to calculate the hierarchical cluster analysis (HCA) and principal component analysis (PCA) of the matrix data set. The linear association between the biomarker content of samples and their measured biomarker levels was calculated using the partial least squares (PLS) regression method. (26)

UV ANALYSIS OF HERBAL DRUGS

The UV-Vis Spectroscopy is an easy way to characterise, identify, authenticate, stabilise, detect adulteration, and determine the purity of herbs and herbal products. For use in drug development, screening plant extracts for various medications, therapeutic ingredients and their metabolites, absorption, nutritional components, green nanoparticle synthesis, fingerprinting of ultra-diluted drugs, and toxicity studies, there are thousands of research papers available. The UV-Vis spectrum's ability to anticipate a molecule's skeleton and any functional groups that are present in extract form can be used to create isolation and purification techniques.

HPTLC FINGERPRINTING OF HERBAL DRUGS

Although it evolved from the traditional thin-layer chromatography (TLC), high performance thin-layer chromatography (HPTLC) goes well beyond the traditional TLC carried out using HPTLC plates. Indeed, the fundamental separation principles used by HPTLC and TLC are the same. This separation is brought about by the interaction of the sample's constituents with a planar stationary phase, a liquid mobile phase, and a gas phase created in the chromatographic chamber. They both have advantages including visual outcomes, sample analysis in parallel, single plate use, quick results, flexibility, and the potential for multiple detection. There are some technical distinctions between HPTLC and TLC with regard to the plate, solvent usage, amount of time needed for development, and sensitivity. Beyond these contrasts and parallels, HPTLC is a novel idea, with the main emphasis being on reproducibility and separation power. It employs well-defined methodologies with standardised and optimised inputs that successfully pass a validation procedure and produce accurate analytical results with high intra- and inter-laboratory consistency. HPTLC equipment ranges from basic to sophisticated, enabling the creation of traceable digital images and a deeper exploration of the data they contain. Additionally, HPTLC is GMP-friendly (27)

Physicochemical test for herbal drugs

1 Collection of plant materials

The Eclipta alba (L) Hassk and Lippia nodiflora (Linn.) plant specimen for the proposed study was gathered from paddy fields and other irrigated fields in and around Madurai District, Tamil Nadu, India.

2 Preparation of plant material

Tap water was used to clean the collected aerial parts of L. Nodiflora and E. Alba. The plants were divided into little pieces and allowed to air dry for two months at room temperature in the shade. The pulverizer was used to powder the shade-dried materials, which were then sieved up to 80 meshes. For further investigation, it was then homogenised into a fine powder, weighed, and stored in an airtight container. This powdered substance was examined for its physicochemical properties.

3Determination of physicochemical parameters

Physical-chemical constants were computed, including the proportion of total ash content, acid-insoluble ash, water-soluble ash, extractives that are soluble in both water and alcohol, and weight loss during drying. Based on accepted practises 13

4Determination of loss on drying

The sample is heated in an oven below its melting point to calculate loss on drying, which takes into account all volatile stuff, including solvents and water content. If not specified otherwise in the specific monograph, determine the loss on drying on a 1.0 to 2.0 g test specimen.

5 Determinations of total ash value

Put 3 g of the drug's powdered form in a silicon crucible and weigh it precisely. Incinerate the powdered medication by progressively raising the heat until the sample was carbon-free, then chill it and keep it in a desiccator. Calculate the proportion of total ash compared to the sample that was air dried after weighing the ash.

6 Acid – insoluble ash

After 5 minutes of boiling the complete ash produced by the aforementioned technique, add 25 cc of diluted hydrochloric acid. Filter and gather any insoluble material on an ashless filter paper. Then, wash the paper in hot water, light it in a tart crucible, let it cool, and then store it in a desiccator. Calculate the acid-insoluble ash of the crude drug (licorice) based on the air dried drug by weighing the resulting residue. Amounts of total ash and

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acid-insoluble ash in liquorice root that have not been peeled are not to exceed 10% and 2.5%, respectively

Safety Issues of Herbal Medicine.

The safety of herbal medicine has received attention along with the large rise in global consumption. Currently, there are misconceptions and prejudices about how safe herbal therapy is. Therefore, impartial and fair interpretation, as well as publicity, are necessary.

Pharmacology of herbal drugs

Herbal products, botanical products, or phytomedicines are items manufactured from botanicals, or plants, that are used to treat illnesses or preserve health. An herbal supplement is a product made from plants that is only intended for internal use. (28)

Contraindications of herbal drugs

Not recommended for usage in patients with a particular illness state. The reports were divided into 19 illness states, which included gastrointestinal problems, neurological conditions, renal and genitourinary conditions, neoplastic conditions, and conditions affecting the liver, gallbladder, and bile ducts. The most recorded contraindications were for flaxseed (Linum usitatissimum), echinacea (Echinacea purpurea), and pausinystalia yohimbe. For instance, it has been established that flaxseed should not be used by people who have gastrointestinal conditions such acute or chronic diarrhoea, oesophageal stricture, inflammatory bowel disease, hypertriglyceridemia, or prostate cancer (29). Patients with rheumatoid arthritis, systemic lupus erythematosus, leukosis, multiple sclerosis, TB, and HIV infection should not take echinacea (30). Patients with anxiety, bipolar illness, depression, mania, schizophrenia, benign prostatic hypertrophy, and kidney disease were not advised to take yohimbe (31)

Adverse reactions

The possibility of herb-drug interactions has also been raised, most likely as a result of cytochrome P450 enzyme activation or inhibition, which would increase the frequency of adverse drug reactions (ADRs). For instance, consider Ginkgo ginseng. More study is needed to define and assess the therapeutic importance of herb-drug interactions. The potential adverse drug reactions (ADRs) and drug interactions that may arise from the use of herbal remedies, either alone or in combination with other prescription pharmaceuticals, must be understood by healthcare practitioners, patients, regulatory agencies, and suppliers of herbal medicines. (32)

Dosage forms

Drug molecules or plant components are given to the body's action sites through dosage forms. Oral, rectal, Topical, parenteral, respiratory, nasal, ocular, and otic delivery methods are all permitted for the administration of herbal dosage forms [33]. The definition of particular methods for quality control and stability testing will be aided by the categorization of final herbal products into dosage forms. Aerial or underground plant parts, other plant material, or a combination of these, whether in the raw form or as plant preparations, may be included as active ingredients in finished, branded therapeutic goods that are classified as herbal (34) In addition to the active ingredients, herbal medicines may also contain excipients. Pharmaceuticals made from plant materials mixed with chemically identified active ingredients, including chemically identified, isolated plant elements, are not regarded as herbal medicines. (35) The final herbal products or herbal medicinal formulations can be extracted, distilled, expressed, fractionated, purified, concentrated, or fermented using a variety of solvents. Comminuted or powdered herbal medications, tinctures, extracts, essential oils, expressed juices, and processed exudates are some examples of these. [36]

The quality guidelines for packaging and labelling is important to ensure that;

- All medications are shielded from outside factors that can impair their ability to treat patients and jeopardise their health.
- All of the medications are shielded from contamination of any kind.
- Every medication is safeguarded against physical injury, such as leaking and breaking.
- Each medication has the proper dosage, use, and identification labels.
- Specific packaging materials are used to keep all medications safe.

Labelling Care

According to the FDA's requirements, all labels used in the pharmaceutical and healthcare sectors must be properly created and applied to ensure that they remain in place without losing their readability in a variety of settings, including as storage, routine usage, and distribution.

Storage

The GMP rules provide storage recommendations for pharmaceutical products to

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guarantee safe storage for the allotted time and temperature range. As an illustration, the typical storage directions you will find on a medication or drug are “Store in a Dry and Cool Place” or “Don’t keep under direct sunlight.”

Reference standards or analytical markers

An overview of the opportunities and difficulties with markers is provided in the EMA reflection paper on markers used for quantitative and qualitative analysis of herbal medical products (HMPs). The Agency states that markers should fall under the category of secondary plant metabolites (e.g. flavonoids, saponins, terpenes, phenols). Markers from the primary metabolites category, such as carbohydrates, amino acids/proteins, and lipids, may, in exceptional circumstances, be acceptable provided they permit a particular assay.(37)

MODULE :- 3
INDIVIDUAL HERBAL MONOGRAPH PREPARATION
CHERVIL LEVES

(HERB)

(SEEDS).

(FORMULATION)

Synonym :- Anthriscus cereifolium, French Parsely, French Herb, Garden chervil, Sweet cicely, beaked parsley, parsnip, chive, parsley, petroselinum, kohlrabi, tarragon and Daucus.

Types of chervil :- 1) Garden Chervil **2) Root chervil**

3) Wild chervil **4) Bur chervil**

PARTS USED OF CHERVIL :- LEVELS
DISSERTATION OF CHERVIL :-

Salad chervil, garden chervil, and French parsley are other names for chervil (Anthriscus cerefolium). It is a delicate, fern-like herb that has delicate stems and tiny, fern-like leaves. The flavour is slightly anise-flavored with a green and vegetal undertone. The delicate leafy herb chervil normally grows to a height of 30 centimetres, although it can grow as high as 60 centimetres. The frilly, light-green leaves have thin, hollow stems that grow in opposition to them and resemble flat-leaved parsley or carrot greens. When a plant reaches maturity, it will develop a tall flower stalk that will be capped with a little umbel of white edible flowers; however, the leaves will turn bitter. The optimal time to collect the leaves is before the plant blooms. The anise-flavored, extremely aromatic chervil has a sweet, delicate flavour that is sometimes compared to a mild mixture of tarragon and parsley with mint undertones. Salad chervil and turnip-rooted chervil are the two main varieties of chervil that are readily accessible. Similar to how parsley is grown, salad chervil is also grown (Grieve and Grieve, 1971).(38)

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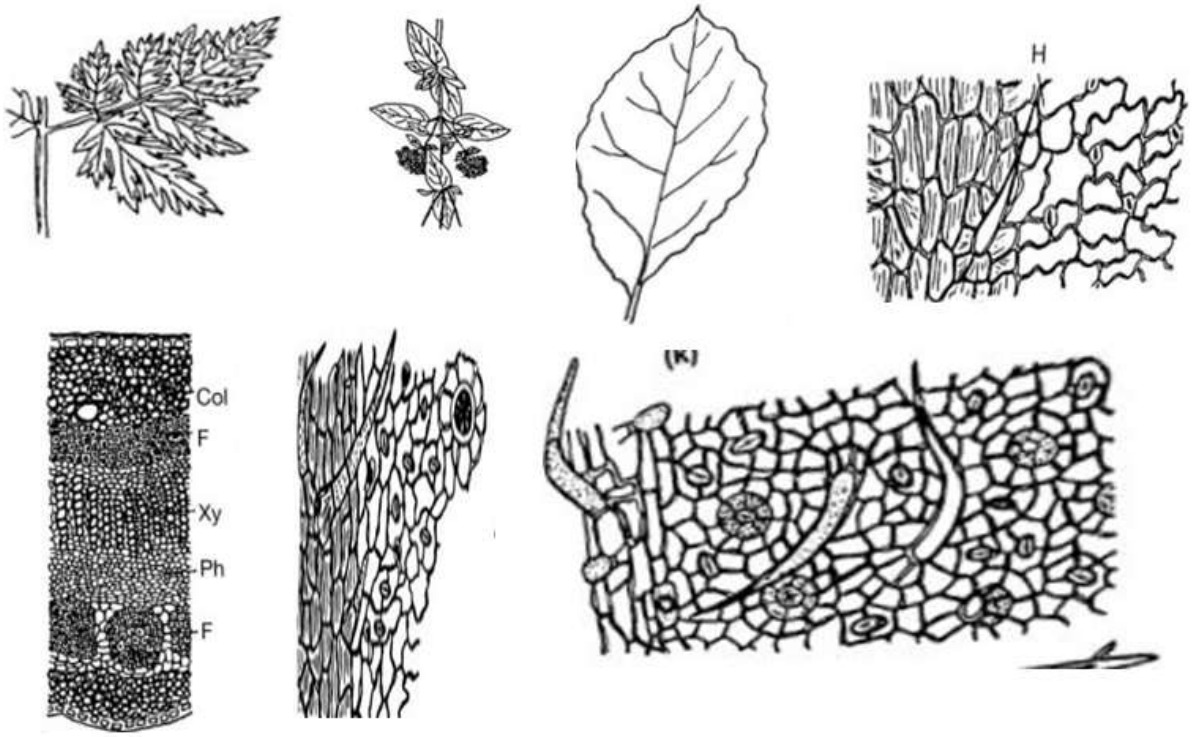
HISTORY OF CHERVIL :-

Another name for chervil is "MYRRHIS." The flammable substance obtained from chervil leaves. In Europe, chervil was taken as a spring tonic to assist the body get rid of pollutants from the previous season. Chervil has been employed as a herb for a variety of therapeutic uses. As a diuretic, digestive aid, expectorant, and skin refresher in the past, chervil has been utilised. Additionally, it reduced gout, kidney stone, and pleurisy symptoms. The most popular use of it is as a treatment for high blood pressure. In cooking, levels and roots are both employed. Chervil is also known as "pluches de cerfeuille" and chervil sprig that has been blanched in French cookbooks. Soups contain this. Traditional remedies for and disturbing dreams include chervil.

In 1st diagram is leaf, 2nd a portion of flowering twing, 3rd cross section of leaf through midrib, 4th leaf, 5th lower epidermis in surface view. Laurel. 5th surface view of lower epidermis. 6th cross section through the midrib of leaf 7th lower epidermis in surface view (39)



USES OF CHERVIL :-

The traditional uses of chervil include expectorant, stimulant, congealed blood dissolver, eczema healer, digestive aid, treatment for high blood pressure, gout, kidney stones, and menstrual irregularities. Since thousands of years ago, spring tonics have been made from the chervil plant's fragile young leaves. Because all the vitamins and

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minerals are present, the combination of chervil, dandelion, and vegetables rejuvenates the body from the shortage in the winter and lack of fresh greens. It is typically used to flavour eggs, fish, chicken, light sauces, and dressings. It also pairs well with mild cheeses and is delicious when added to herb butters.

HERBAL ACTION :- Acting as a natural digestive aid, helps for settle the stomach. Act as a mild stimulant and mood-lifter. Treating menstrual cramps. Treating menstrual cramps. Treating irritation of the eyes. Chervil contains active constituents in the form of volatile oils and antioxidants like flavonoids. Two of the most prominent constituents present in the herb that are methyl chavicol and hendecane

MORPHOLOGY CHARACTERISTICS OF CHERVIL :-

Height: Chervil is a hardy plant that, on average, grows to a height of 12 to 24 inches (25 to 70 cm) and a width of 6 to 12 inches (30 cm), with a focus on 2 fit.The leaves are opposite, compound, bipinnate, and light green in colour. They are further divided into opposite and deeply cut leaflets.

Flowers: Flowers are composed of tiny umbels that develop into compound umbels, are white in colour, delicate, and exquisite.The Chervil has a single, white, thin, and tapering root

Fruits: Fruits are segmented, beaked, and oblong, measuring 0.5-0.75 cm in length.

Seeds: The long, pointed seeds have a noticeable furrow running the length of them. Chervil leaves are almost always used fresh, however they can be stored by freezing them completely or by forming a paste.(40)

PHYSICAL CHARACTERISTICS OF THE PLANT :-

Seeds for chervil are sown in early spring or late fall. It is a biennial herb that measures 0.45 by 0.25 metres. It resists frost and is hardy to zone 7. It blooms from May to June, and from June to July, the seeds ripen. Insects pollinate the hermaphrodite (contains both male and female organs) flowers. The plant reproduces on its own. The plant requires well-drained soil and likes light (sandy), medium (loamy), and heavy (clay) soils (Clapham et al., 1962). Acid, neutral, and basic (alkaline) soils are preferred by the plant. It can grow in complete darkness (deep woodland), partial darkness (light woodland), or no shade at all. It needs soil that is wet. (41)

CONSTITUENTS:- It's also known as "gourmet's parsley." Chervil's volatile oil, flavonoids, and coumarins are its active ingredients. It also contains methyl chavicol (estragole), and hendecane (undecane). Because of its nutritional value, this herb is utilised in cooking. Bioflavonoid is a key active component of wild chervil. Several essential oils that are sold for use in aromatherapy, massage oils, and alternative therapies contain ethyleugenol as one of their main ingredients. 27. Methyleugenol is a fragrance ingredient found in soaps and detergents (0.02-0.2%), creams and lotions (0.01-0.05%), and perfumes (0.3-0.8%)28.

Uses in cooking:- It gives cream-based soups, butter sauces, eggs, or omelettes flavour. To preserve its flavour, it is best added at the conclusion of the cooking process. The herb is best utilised fresh because, unlike most leafy herbs, it does not dry well.(42)

II. CONCLUSION

Bright green chervil (Anthriscus cerefolium) herb can be dried or stored without preservatives. It is used as a garnish because of how fragile it is. When combined with other herbs, it creates a distinctive flavour. The majority of herbal extracts contain chervil, which makes up almost one-third of all botanical herbs. The herb chervil is edible and popular in kitchens all across the world. It is a very well-liked herb with many culinary and therapeutic applications. The plant was viewed as a representation of renewal and fresh life in the past. Large doses of this herb can be ingested without any potential health risks. As a result, it provides a high level of nourishment. The nutritional content of the entire herb is around 100% for health benefits. Since the entire plant is edible, its leaves and roots are the most commonly used parts. Chervil has a wide range of pharmacological effects and is a strong source of vitamins and minerals. Chervil is regarded as a Herb of Immortality in Earth religions and is used as an elixir or incense to communicate with one's soul or the souls of the deceased (as a guide to the new spirit to reach peace and serenity). Is a component of amulets that is also regarded as a magic aid.(43)

REFRENCE: -

[1]. RIPER AUTONOMOUS NAAC & NBA (UG) SIRO- DSIR Raghavendra Institute of Pharmaceutical Education and Research – Autonomous K.R.Palli Cross, Chiyyedu, Anantapuramu, A. P- 515721 2

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Introduction • Indian pharmacopoeia • Ayurvedic pharmacopeia • United states pharmacopeia

[2]. Herbal monographs in national pharmacopoeias and other authorative documents play an important role in the authentication of herbal materials. ♣ In this context a monograph is a document that defines a botanical drug and provides information that allows for its proper identification. ♣ The herbal monographs give a basic description of the herb, and list its chemical constituents, actions, clinical uses and recommended dosage etc. Introduction By Dr. Mostafa Mahmoud Hegazy

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