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Review on Herbs: International Guidelines, Future Insights and Patenting of Herbals

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ABSTRACT:
The demand for herbal products has been rising recently particularly in cosmetic sector. One of the widely used cosmetic product is lip balm served as productive shade for lips. To ensure the safety, efficacy, and quality of these product , several regulatory frameworks have been established including guidelines from the WHO, the European union (EU) and the International council for Harmonisation(ICH). The WHO provides standards on safety and quality control on herbal products . The EU guidelines focus on cosmetic assessments, requiring that all herbal cosmetic products undergo various evaluation to ensure they are free from harmful substances and are effectively used. Further, ICH guidelines promote the standardization of cosmetic practices, ensuring that herbal ingredients meet the quality and safety specifications. Furthermore, patenting also plays a crucial role in protecting the intellectual property (legal rights to protect) of herbal products and research into new sustainable and effective substances. The significance of patenting of herbal cosmetics sector, examining unique challenges and opportunities associated with protection of natural ingredients and formulations.
This review manuscript explores the international guidelines, highlighting their roles in regulating herbal cosmetics ensuring safety.

Keywords: Herbal Cosmeceuticals, ICH guidelines, WHO guidelines, Patenting.

INTRODUCTION:

Herbal cosmeceuticals is a rapidly growing category in the field of cosmetics and personal care products. An herbal cosmetics is also known as “natural cosmetics” as there are no side effects, demand of herbal medicines is growing quickly. Herbal cosmetics are formulated, using different cosmetic ingredients to form base in which one or more herbal ingredients are used to cure various skin ailments. There are is a wide variety of herbal cosmetics, which are manufactured and used every day . The best thing of the herbal cosmetics is that it is purely made of herbs and shrubs and thus is side effects free. The term cosmeceuticals was first used by Raymond reed founder member of U.S society of cosmetic chemist in 1961.later the term was further used by Dr Albert Kligman in the year 1984 to refer the substances that have both cosmetic and therapeutic benefits. Cosmeceuticals are cosmetic -pharmaceutical hybrids intended to enhance health and beauty of the skin. Cosmeceuticals used to improve and nourish the skin appearance and to treat different dermatologic conditions. Cosmeceuticals meant to improve appearance by delivering nutrients necessary for healthy skin. The efficacy of a cosmetic product depends not only on the active

ingredient but also on the delivery system to improve its efficacy. Cosmeceuticals products are most beneficial than cosmetics because it provides beauty as well as therapeutic effect.

Advantages Of Herbal Cosmetics:

Herbal cosmeceuticals offer numerous advantages including:

1. **Natural ingredients**
   Herbal cosmeceuticals often contain natural plant extracts, which can gently applied on skin compared to synthetic chemicals.
   They tend to have fewer side effects.
2. **Rich in antioxidants**
   Many herbs used in cosmeceuticals like green tea, aloe Vera , turmeric are rich in antioxidants, which can protect the skin from free radicals and reduce signs of aging.
3. **Anti-inflammatory properties**
   Herbal ingredients such as chamomile,calendula and licorice have anti-inflammatory that can soothe irritated skin, reduce redness and help with conditions like acne and eczema.
4. **Nourishing and hydrating**
   Herbal cosmeceuticals often contain natural oils and extracts that provides deep hydration and nourishment.ingridents like coconut oil,shea butter, and aloe Vera help moisturize the skin .
5. **Reduced risk of allergic reactions**
   Because they are free from synthetic chemicals, fragrances, and preservatives, herbal cosmeceuticals may reduce the risk of allergic reactions.
6. **Support for Traditional knowledge**
   Herbal cosmeceuticals often draw from traditional medicinal systems like Ayurveda or Traditional Chinese Medicine. These remedies have been used for centuries and provide an alternative to synthetic ingredients.

Disadvantages Of Herbal Cosmeceuticals:

- Herbal drugs have slower effects as compare to allopathic dosage form. Also , it requires long term therapy.
- They are difficult to hide taste and odour.
- Manufacturing process are time consuming and complicated.
- No pharmacopoeia defines specific procedure or ingriedients to be used in any of herbal cosmetics.
- When herbal medicines are consumed with pharmaceutical drugs, the two can interact with each other resulting in injuries to health. It may be the case where a certain part of a plant may be edible and another part may be poisonous.
- Most of the herbs are not easily available.

Uses:

- The use of herbal cosemeceuticals is seen as a more sustainable and eco-friendly in the beauty industry.
- The market for herbal cosemeceuticals has grown rapidly.
- Herbal cosmetics improve various functions of skin by boosting collagen growth and keeping skin healthy.

- Herbal cosmeceuticals are utilized in diverse beauty and wellness products including skincare, oralcare, haircare and aromatherapy to promote natural health and beauty.
- It gives soothing and calming effects.
- It gives hydrating and moisturizing properties.

HERBAL DRUG INDUSTRY - PRESENT SCOPE AND FUTURE PROSPECTS

The herbal drug industry is a rapidly growing sector within the global healthcare and pharmaceutical markets. It involves the production, distribution, and sale of medicines and supplements derived from plants, herbs, and other natural substances. Herbal medicines are used for their therapeutic properties .

Present Scope Of Herbal Industry

World wide there is a growing demand of ayurveda and traditional forms of medicines . In india about 80 % of the rural population use medicinal herbs or indigenous system of medicine . Herb have been known since the era of civilization are high extreme all over the world has a rich source of medicine agent . The popularity of nature product is increasing day by day due to fact that they are comparatively save and less toxic , less side effect , easily available and affordable prices when compare to synthetic drug . The herbal drug industry is very fast growing sector in international market . In India various system of medicines like Ayurveda , siddha , unani , homeopathy ,yoga and naturopathy are been utilized for the health care of people.

India is second largest exporter if medicinal plants in the world after Chinese .Herbal drug industry is very fast growing in international market. In india about 14 well recognized and 8.6 medium scale manufactures of herbal drug are present and about 8000 small scale manufactures are recorded .

There is a wide scope of Indian industry entering in to wild wide business in herbal pharmaceutical field .Indian herbal products are registered in many other countries due to proper standardisation of market products for the safety and efficacy and thus gaining the reability for exporting of products .

The drug and cosmetic act and rules defines GMP for traditional medicinal product in schedule T and every effort should be made by all the manufactures to comply with global standards for capturing world marketing.

Herbal medicines are also entering the field of envt. science , immunology ,medical ,science on innovative ways of application and drug discovery . As india is rich in herbal drugs thereby causing a high incidence of their self medication as these drug sold openly .

Union health ministry working to include Indian system of medication into modern medication system which will be useful and provide evidence based on herbal drug . Industries with annual turrn over of more then 50 cores are Dabur , Zandu , Himalaya etc.

The present scope of the herbal industry is expansive and rapidly evolving, fueled by increasing consumer interest in natural and holistic health solutions.

Here are some key areas highlighting the current scope:

1. Market Growth

- The herbal industry is experiencing significant growth globally, with projections indicating continued expansion due to rising demand for herbal supplements, teas, and skincare products.

2. Diverse Product Offerings

- Nutraceuticals: Herbal supplements and functional foods are increasingly popular for their health benefits.

- Cosmetics and Skincare: Herbal ingredients are being incorporated into beauty products, appealing to consumers looking for natural alternatives.
- Aromatherapy: Essential oils derived from herbs are widely used for stress relief and wellness.

3. Consumer Trends

- Health Consciousness: More consumers are prioritizing preventive health, seeking out herbal products for immunity, stress relief, and overall well-being.
- Sustainability: Growing awareness of environmental issues has led to a preference for sustainably sourced and organic herbal products.

4. Traditional and Modern Integration

- There's an increasing integration of traditional herbal practices with modern scientific research, validating the efficacy of many herbal remedies and leading to new product development.

5. Technological Advancements

- Innovations in extraction and formulation techniques are enhancing product quality and efficacy. E-commerce and digital marketing are also transforming how herbal products reach consumers.

6. Regulatory Landscape

- While regulatory frameworks are tightening, they also encourage transparency and quality assurance, helping to build consumer trust in herbal products.

7. Global Markets

- Emerging markets in Asia, Africa, and Latin America are seeing growth in herbal consumption, driven by traditional uses and increasing global interest in herbal remedies.

8. Research and Development

- Ongoing research into the pharmacological properties of herbs is expanding the understanding of their benefits and leading to new therapeutic applications.

FUTURE PROSPECTS OF HERBAL DRUG INDRUSTY

Herbal based traditional medicine practice remain widespread in developing countries and that of complimentary and alternative is increasing rapidly in developing countries . To ensure quality and safety of herbal medicine there production , use and scale should be officially and legally controlled by established rules and regulation which are not well developed in many countries . therefore herbal products sold is not guaranteed and should be brought under legal control where they are used for medicinal and therapeutic purpose and to ease public about the risk and benefits of herbal medicines.

The future prospects of the herbal industry appear bright, driven by evolving consumer preferences, advancements in research, and growing awareness of health and wellness. Here are some key trends and opportunities that may shape the industry's future:

1. **Increased Demand for Natural Products**

- As consumers become more health-conscious and environmentally aware, the demand for herbal products is expected to rise, particularly for organic and sustainably sourced options.

2. **Expansion of Product Lines**

- Companies are likely to diversify their offerings, developing new herbal supplements, skincare products, and functional foods that cater to specific health concerns and lifestyles.

3. **Integration of Technology**

- Advancements in technology, such as artificial intelligence and blockchain, could enhance supply chain transparency, improve product quality, and enable personalized herbal solutions based on invidu-

al health needs.

4. **Research and Development**

- Ongoing research into the efficacy and safety of herbal products will bolster consumer confidence and lead to innovative formulations. Collaborations between traditional herbal practitioners and modern scientists are likely to grow.

5. **Global Market Expansion**

- Emerging markets, particularly in Asia, Africa, and Latin America, present significant growth opportunities as traditional herbal practices gain recognition and acceptance worldwide.

6. **Regulatory Improvements**

- As regulatory frameworks evolve, there may be more standardized quality control measures, helping to ensure product safety and efficacy while also building consumer trust.

7. **Focus on Preventive Healthcare**

- The shift towards preventive and holistic healthcare approaches will likely enhance the appeal of herbal products, positioning them as integral to wellness routines.

8. **Sustainable Practices**

- There will be a growing emphasis on sustainable sourcing and ethical harvesting of herbs, aligning with global trends towards environmental responsibility.

9. **Education and Awareness**

- Increased consumer education about the benefits and uses of herbs will drive informed purchasing decisions, encouraging more people to explore herbal remedies.

WHO GUIDELINES FOR QUALITY CONTROL IN HERBAL DRUGS.

The World Health Organization(WHO) has established a guidelines for quality control of herbal drugs to ensure their safety ,efficacy and quality .These guidelines are particularly important as the use of herbal drugs .

The WHO guidelines provide framework for the development ,manufacture,and control of herbal medicines.

Goals of WHO Guidelines are

- To strengthen research in evaluation of safety and efficacy of herbal medicines.
- To strengthen and promote use of herbal medicines.

The key aspects include;

1. **Quality control:**

- **Variability in active compounds:** Herbal drugs can exhibit variations in concentration of their active compounds due to factors like growing conditions , harvesting methods and processing techniques
- **Adulteration and Substitution:** Herbal products may be adulterated with synthetic drugs or substituted with different plant species ,posing risk to consumer safety.

2. Sampling and Sample preparation.

The WHO guidelines outline detailed procedures for collection, handling, and processing of samples to ensure the integrity of test sample.

3. Physicochemical Evaluation.

These guidelines recommend a range of physicochemical tests to evaluate the identity, purity and quality of herbal drugs .These include macroscopic and microscopic examination, determination of foregin matter ,ash content and extractive values.

- **Identity**

Macroscopic and microscopic analysis to conform the plant species and its morphological characteristics.

- **Purity**

Evaluation of foregin matter, ash content, extractive values to ensure the absence of contaminants.

- **Quality**

Stability ,potency and consistency of the herbal drug.

4. Biological assays

The WHO guidelines recommend the use of various assays such as in vitro and in vivo tests to evaluate the pharmacological activity, safety ,efficacy of herbal drugs. These assays help to ensure the therapeutic potential and quality of the final herbal drugs.

- In vitro assays: Cell based and enzyme based assays to assess the biological activity of herbal extracts.
- Animal studies: In vivo tests using animal models to evaluate the efficacy, toxicity and pharmacokinetics of herbal drugs.
- Clinical trials: Human clinical trials to assess the safety and effectiveness of herbal drugs in treating specific health conditions.

5. Regulatory considerations.

These guidelines ensure the importance of regulatory frameworks to ensure the quality, safety, and efficacy of herbal drugs .These include for good agricultural and collection practices(GACP), good manufacturing practices(GMP),and post marketing surveillance to monitor the performance and safety of herbal drugs.

- Stability testing is required to determine the shelf life of herbal drugs. These monitor the degradation of active ingredients under various environmental conditions (temp., humidity, light).
- Packaging & labelling – Proper packaging is necessary and labelling should provide clear information on dosage , ingredients ,safety warnings.

These WHO guidelines aim to ensure that herbal medicines meet quality standards and are safe for public consumption.

ICH GUIDELINES FOR QUALITY CONTROL OF HERBAL DRUGS

Definition: ICH is the "international" conference on harmonisation of technical requirements for registration of pharmaceuticals for human use.

- ICH is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.
- ICH's mission is to achieve greater harmonization worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner.

Here are key ICH guidelines that are applicable:

1. ICH Q1A Testing Of New Drugs Substances And Products:

It is a key guideline that provides principles and recommendations for stability testing during the development of new drug substances and drug products. This guideline helps ensure that pharmaceutical products remain effective ,safe and of high quality throughout their shelf life.

Key elements of ICH Q1A:

1. Stability testing purpose:

The primary goal is to assess how environmental factors (e.g. temperature, humidity, light) affect the quality of drug substances and drug products over time. Stability testing ensures that the product remains safe, effective, and required quality throughout the shelf life.

2. **Key factors in stability testing**:
- Temperature - 40 degree C to 45 degree C
- Humidity – 60% or 75%
- Light
- Packaging

3. **Test samples**: Stability testing should include both drug substance (active ingredient) and drug product (final formulation), typically in multiple batches if required.
4. **expiry date and Shelf life** : Based on the stability data, the shelf life of the product is determined, which is the period during which the product expected to remain within its specification limits when stored under defined conditions.
5. **Stability study design**: ICH Q1A outlines the general design and schedule for stability studies, with specific time points (e.g. . ,3 ,6,9,12, months) for testing.
   A study should be conducted in three distinct phases:

- Preclinical phase
- Clinical phase
- Post-approval phase

2. ICH Q1B: Photo Stability Testing Of New Drug Substances And Products

The ICH harmonized guidelines covering the stability testing of new drug substances and products. Forced degradation testing studies are those undertaken to degrade the sample. These studies, which may be undertaken in the development phase normally on drug substances used to evaluate the overall photosensitivity of the material .confirmatory studies are those undertaken to establish photo stability characteristic under standardized conditions.

3. ICH Q1C: Stability Testing For New Dosage Form:

New dosage form

A new dosage form is defined as a drug product that is a different pharmaceutical product type but contains the same active substance as included in the existing drug product approved by regulatory authority.

4. ICH Q1D: Bracketing And Matrixing Designs For Stability Testing Of New Drug Substances And Products

This guideline is to address recommendations on the application of bracketing and matrixing to stability studies conducted by principles outlined in the ICH Q1A(R).

Bracketing

Bracketing is defined as the design of a stability schedule such that only samples on the extremes of certain design factors (e.g., strength, container size) are tested at all times point as in a full design.
E.g.; capsules of different strength made with different fill plug sizes from the same powder blend.

Matrixing

Matrixing is defined as the design of a stability schedule such that a selected subset of the total number of possible samples for all factor combinations would be tested at a specified time point. At a subsequent time point, another subset of samples for all factor combinations would be tested represents the stability of all samples at a given time point. The differences in the samples for the same drug product should be identified as

E.g.; covering different batches, different strengths, different sizes of the same container closure system.

5. ICH Q2 (R1) Validation Of Analytical Procedures:

The objective of validation of an analytical procedure is to demonstrate that it is suitable for its intended purpose. A characteristics applicable to identification, control of impurities, and assay procedures is included:

Types of analytical procedures to be validated:

There are four most common types of analytical procedures they are:

- Identification tests
- Quantitative tests for impurities content
- Limit test for the control of impurities
- Quantitative tests of the active moiety in samples of drug substance or drug product.

Typical validation characteristics considered are listed below:

- Accuracy
- Precision
- Repeatability
- Intermediate precision
- Specificity
- Detection limit
- Quantization limit
- Linearity
- Range

6. ICH: Q3C (R5) Residual Solvents

The objective of this guideline is to recommend acceptable amounts of residual solvents in pharmaceuticals for the safety of the patient. The guideline recommends the use of less toxic solvents and describes levels considered to be toxicologically acceptable for some residual solvents.

7. ICH Q5B: Quality Of Biotechnological Products

This document presents guidance regarding the characterization of the expression for the production of recombinant DNA protein products in eukaryotic and prokaryotic cells. This document describes in assessing the structure of the expression used to produce recombinant DNA.

8. ICH Q7: Good Manufacturing Practice For Active Pharmaceutical Ingredients

In this guide “manufacturing is defined to include all operations of receipt of materials, production, packaging, labelling, relabeling, quality control, release, storage and distribution of API’s and related controls.these controls are inherent responsibilities of the manufacturer and are governed by national laws.

9. ICH Q9: Quality risk management

This guideline provides principles of tools for quality risk management that can be applied to different aspects of pharmaceutical quality. These aspects include development, manufacturing, distribution, and the inspection and submission/review processes throughout the lifecycle of drug substance.

Two primary principles of quality risk management are

- The evaluation of the risk to quality should be based on scientific knowledge and ultimately to the protection of the patient.
- The level of effort, formality, and documentation of the quality risk management process should be equivalent with the risk.

10. ICH Q10: Pharmaceutical quality system

This guideline applies to the systems supporting the development and manufacture of pharmaceutical drug substances and drug products, including biotechnology and biological products, throughout the product lifecycle.

The elements of ICH Q10 should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages.

Pharmaceutical development

- Drug substance development
- Formulation development
- Delivery system development
- Manufacturing process development and scale up
- Analytical method development

Technology transfer

- New product transfers during development through manufacturing
- Transfer within or between manufacturing and testing for marketed products

11. ICH Q11: Development and manufacture of drug substances (chemical/ biotechnological entities)

It addresses aspects of development and manufacture to drug substances, including the presence of steps designed to reduce impurities. In addition, ICH Q11 provides further clarification on the principles and concepts described in ICH guidelines on pharmaceutical development (QS), Quality Risk Management and Pharmaceutical Quality system as they pertain to development and manufacture of the drug substance.

PATENTING OF HERBAL DRUGS :

A Patent application must include one or more claims defining the invention which must be new, inventive and useful. Patents are applied to the inventions of new producers and processed in scientific fields such as pharmacology, biotechnology, electronics, machinery and climates. The term patent usually refers to the right granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof.Patenting herbal drugs is a complex process because it involves balancing traditional knowledge with modern intellectual property rights (IPR). Herbal medicines, often derived from traditional practices, are challenging to patent due to their historical use, difficulty in proving novelty, and the challenges of patenting natural substances.

Key Aspects of Patenting herbal drugs:

1. Patent Eligibility

Novelty: For an herbal drug to be patentable, it must be new or innovative. If the herbal remedy has been traditionally used and documented, it may not meet the novelty requirement.

Inventive Step: The innovation must be non-obvious to someone skilled in the field. For instance, a new formulation, extraction method, or combination of herbs might meet this criterion.
Industrial Applicability: The invention must be capable of being made or used in some kind of industry.

2. Challenges with Traditional Knowledge

Many herbal remedies have been used for centuries, which often places them in the public domain. This can prevent the patenting of such remedies unless a significant modification or improvement is made.There is concern that patenting of herbal drugs based on indigenous knowledge may lead to biopiracy, where companies profit from traditional knowledge without proper compensation to the communities.

3. Patent Types in Herbal Drugs

Process Patents: Protect the specific methods of preparing or extracting the herbal compounds, rather than the plant itself.
Formulation Patents: If a specific formulation combining herbs or using unique concentrations is developed, it may be patented.
Use Patents: The patent may cover the novel use of a known herb or extract for a specific therapeutic purpose, even if the herb itself is not novel.

4. National and International Regulations

Different countries have varying regulations on patenting natural products. Some nations, like India, have strict policies to protect traditional knowledge and prevent exploitation through patents.
International treaties, such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol, aim to ensure fair sharing of benefits from the use of genetic resources, including those used in herbal medicine.

5. Traditional Knowledge Digital Library (TKDL)

In countries like India, traditional herbal knowledge is documented in databases such as the TKDL to prevent its misappropriation. The goal is to ensure that patent offices can access this information to deny patents on knowledge that is already publicly known.
With these rights, the breeder can choose to become the exclusive marketer of the variety, or to license the variety to others. In order to qualify for these exclusive rights, a variety must be new, distinct, uniform, and stable.The breeder must also give the variety an acceptable "denomination", which becomes its generic name and must be used by anyone who markets the variety.

Conclusion:

The herbal industry today presents a dynamic landscape with substantial opportunities for growth, innovation, and consumer engagement. As health and wellness trends continue to evolve, the industry is well-positioned to meet the increasing demand for natural products. The herbal industry is poised for substantial growth and transformation. With a strong focus on natural health solutions, innovation, and sustainability, it has the potential to become a significant player in the global health and wellness market. As consumers continue to seek out holistic alternatives, the future of the herbal industry looks promising**.**
Harmonization achievements in the quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management.

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