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From herb to market: Ensuring quality in herbal drugs & their formulations

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Abstract
The use of herbal products as primary healthcare become prevalent in the world in the last three decades and it is estimated that about 80 percent of the population uses it as a method of treatment and prevention of diseases. Technological facts are generally accepted to be safe because herbal medicines are of natural origin, but the quality, purity and consistency of herbal preparation is a significant issue in determining therapeutic safety and efficacy. This review brings out the different dimensions of quality evaluation of herbal drugs which are macroscopic, microscopic, physical and chemical parameters which aid in authentication and standardization. Such factors that influence the quality of herbal materials as adulteration, improper preparation, incorrect storage and differences in cultivation are described. The significance of Good Manufacturing Practices (GMP) and Good Agricultural and Collection Practices (GACP) according to the WHO guidelines are also outlined in this paper to guarantee the safety and reliability of the product. In addition, several herbal ingredient which can be utilized in making safe and effective herbal cream are discussed. Parameters like pH, Viscosity, Spreadability, and after-feel are vital in terms of product stability and acceptability by the consumer. In general, this review indicate there is a need to have a systematic quality control and standardization of herbal drugs and formulations to combine traditional and modern healthcare practices.

Keywords: Quality control, good manufacturing practices, cosmetic, herbal drug, evaluation parameter

1. Introduction
Plant-based remedies have been integral to traditional healthcare system since ancient times, serving both preventive and therapeutic purposes across many cultures [1]. For centuries, people have used herbal medicines made from a variety of plant sources to promote human health and treat a wide range of condition, including respiratory and digestive issues, chronic pain, and compromised immunity. Alkaloids, flavonoids, terpenes, and polyphenols are a few of the many physiologically active substances found in these preparations that interact with the body to produce therapeutic effects. Herbal remedies have become more popular in recent years as people's concerns about the negative side effects of many allopathic medications have grown [2]. Plant-derived compounds are therefore becoming more well-known as nutraceuticals, cosmetic ingredients, and medicines [3]. The quality control of herbal formulations is still less stringent than that of conventional pharmaceuticals, despite their growing popularity. This leads to problems like adulteration, contamination, substitution, and inconsistent levels of active ingredients [4].

1.1 Introduction to quality aspect
- **Herbal Medicines:** It is the general term used to describe any medicinal products derived from plants or plant material, which are used to treat or prevent disease and promote health [5].
- **Herbal Formulations:** These are liquid, solid or semisolid products made from herbs, with or without excipients, in a specific formulation (e.g. decoction, tablets, ointment) [6].

The term quality, as it pertains to the herbal drug: It is a status of a medicine that is determined by its identity, purity, content, and other chemical, physical, or biological properties or by its manufacturing process. Quality is the result of the sum all the factors that contribute directly or indirectly to the safety, effectiveness, and acceptability of the product.

Pharmacopoeia quality control is based on three key concepts:

a) Plant identification is validated through both macroscopic and microscopic examination. However, plant diseases or environmental pressure can alter their physical appearance, making correct identification difficult.

b) **Purity:** It is crucial for the safety of herbal medicines. It includes determining ash content, the presence of foreign matter, and heavy metal levels.

c) **Content:** Do the active ingredients fall within the specified ranges? Since the active ingredients in the majority of herbal medications are unknown [7].

1.2 Factors affecting quality of herbs

1. **Drug adulteration:** Adulteration is the deliberate or intentional substitution or addition of any other spurious, inferior, defective, spoiled, useless, or other parts or the same or different plants, as well as any other harmful or therapeutic substances or drugs that do not meet official standards.
2. **Inadequate preparation:** The inability to eliminate undesirable components or structure.eg. The ginger rhizome's cork. It is very Important to follow the correct drying conditions. Inadequate drying might give rise to accidental adulteration. E.g. It digitalis leaves are dried at more than 65 degree Celsius, glycoside are hydrolyzed by enzyme action [8].
3. **Improper Storage:** Active ingredient is lost through deterioration especially during storage process. It may cause formation of inactive metabolite and in extreme cases formation of toxic metabolites. Physical factor such as humidity and air (oxygen) may result in deterioration directly or indirectly.
4. **Replacing with exhausted drug:** In this exhausted drug is mix with authentic plant material such as clove, coriander or funnel with species from which active ingredients have already been removed. Such combination tends to result in compromise quality, Since depleted portion has been used to get contents like essential oil.
5. **Herbal ingredient authentication:** Authentication of herbal ingredients require the specific identification of herbal materials through analysis of their microscopic and macroscopic feature. Such properties are to be compared to known reference samples.
6. **Diversity within and between species:** Plants often have a lot of variation both intra and inter-specifically. Their can be considerable difference in their primary and secondary metabolites, leading to change in concentration of each component. This natural variability make it difficult to standardize herbal products.
7. **Cultivation Practices:** This involves the condition in which plants are grown, Such as soil. The concentration of active ingredient in herbal drug may be influenced by quality, climate and farming methods.
8. **Harvesting Time:** The timing of harvesting is important in determining concentration of active constituents various section of the same plant can have different concentration of bioactive compounds, which may result in poor therapeutic effects [9].

1.3 Needs for Quality Evaluation of Herbal Drugs and Formulations: Increasing concern over the adverse effects, toxicity and restrictions of conventional synthetic drug has led to inclination towards herbal medicine. As the market for plant-base products grow, and it is necessary to introduce strict quality control parameters. The regulatory bodies are very crucial in protecting the health of the consumers by making sure that herbal medicinal products are of the required standards. However, the quality assessment of a herbal medicine faces several challenges, including:

1. Reliance on wild source and this result in seasonal and environmental changes in phytochemical composition.
2. Regional regulatory imbalance lead to inconsistency in the herbal products and raw materials standards.
3. Replacement and adulteration compromise the integrity of a products and their therapeutic efficacy.
4. Lack of certification procedures to check the authenticity and quality of the raw plant material.
5. Lack of adequately trained staff in phytochemical analysis, quality control, and assurance.
6. Weak investment in research and development of herbal medicinal products.
7. The lack of proper facilities to conduct toxicological and safety testing which hinder comprehensive assessment of herbal preparation.

This issues demonstrate the necessity of improved regulatory systems, proven analysis techniques and standardize practices to guarantee the uniformity of herbal medicine.

2. Evaluation of Herbal Drugs

2.1 Macroscopical (Organoleptic) Evaluation: The first stage in the analysis and identification of medicinal plant materials is macroscopical analysis. This approach is based on organoleptic evaluation, which uses the crude drug's sensory characteristics-such as colour, taste, odour, size, and texture-to verify its identity. It is qualitative evaluation [11].

Examples:

a) Colour:- (Cinnamon Bark -Brown)
b) Odour:- (Jatamansi - Aromatic)
c) Taste:- (Capsicum - Pungent)
d) Size:- (Digitalis—10-30 cm long and 4-10 cm wide)
e) Shape:- (Nux vomica- Disc shaped)
f) Texture:- (Cascara barks- Fractured surface) [12].
g) Microscopical evaluation:
h) Palisade ratio
i) Vein islet number
j) Vein termination
k) Stomata
l) Stomatal index.
m) Trichomes.

A) Palisade ratio: The average number of palisade cells beneath each epidermal cell is known as the palisade ratio. e.g. Digitalis lanata (2.5-6.5), Atropa belladonna (6-10) [13].

B) Vein-islet number: The average number of vein islets per square millimeter of leaf surface halfway between the margin and midrib is known as the vein-islet number. Vein-islet number is used to identify different drug species. E.g. Indian and Alexandrian senna can be identified by their different vein islet numbers, which are 22 and 27, respectively.

C) Vein Termination: It is described as "no" of veinlet termination per square millimeter of leaf surface halfway between the margin and midrib [14].

D) Stomata: On the aerial portions of plants, stomata are tiny epidermal openings. A central pore, two kidney-shaped cella (guard cells), and a variable number of subsidiary cells make up stomata. The shapes and configuration of the surrounding cells differentiate the various types of stomata. Diacytic (cross-celled) Paracytic (parallel-celled) Anomocytic (irregular-celled) Anisoytic (unequal-celled) [15].

E) Stomata Number: The average number of stomata per square millimeter of the epidermis. For instance, the upper epidermis of Atropa belladonna is 07 - 10, while the lower epidermis is 77 - 115.

F) Stomatal Index: The stomatal index is calculated as the percentage of the total number of epidermal cells, including the stoma, which is counted as one cell.
Stomatal Index = S / E+S 100
Where: S= Total numbers of stomata in a given area of leaf.
E= Number of epidermal cells (including trichomes) in the same area of leaf [16].

G) Trichomes: Trichomes are unicellular or multicellular appendages that are an extension of the above-ground epidermal cells in plants. They can have a variety of morphologies and are widely distributed on the surface of various organs and tissues in different plants. Based on various traits and functions, trichomes are typically classified as single-celled or multicellular, branched or unbranched, and glandular or non-glandular [17].

2.2 Physical Evaluation

a) Moisture content: This refers to the air-dried percentage of active chemical components in crude drugs. Therefore, it is necessary to ascertain a drug's moisture content. Drug moisture content should be kept to a minimum to avoid crude drug degradation from microbial contamination or chemical changes. A medication is heated to a constant weight in an oven at 105 degree Celsius to determine its moisture content. The e.g. Aloe should have a moisture content of no more than 10% w/w [18].

b) Viscosity: A liquid's viscosity is a measure of its composition and remains constant at a specific temperature. As a result, it is employed to standardize liquid medications. E.g. At least 64 centistokes of liquid paraffin-kinematic viscosity.

c) Volatile oil content: Pharmaceutical significance of aromatic drug is because of their odorous principal. The volatile oil content of these crude drugs is used to standardize them.

Table 1: Volatile oil content of herbal drug.

S. No.	Drugs	Volatile oil content%w/w
1.	Clove	>15.0
2.	Fresh lemon peel	>205
3.	Fennel	>1.4

d) Melting point: The melting point of pure chemicals or phytochemicals is extremely constant and sharp. Crude drugs derived from plants to animals are described with a specific range of melting points because they contain mixed chemicals [13].

Table 2: Melting point of various herbal drugs.

S. No.	Drugs	Melting point
1.	Colophony	75-85
2.	Cocoa butter	30-33
3.	Bees wax	52-65

2.3 Chemical Evaluation

A method for the analysis of the constituents can be developed using the chemical nature of the constituents. It also includes phytochemical analysis of the crude as well as chemical testing and assays. It involves various chemical test for Alkaloids, tannins, resins, volatile oils, and waxes.

Table 3: Qualitative Phytochemical Screening Tests for Major Chemical Constituents

S. No.	Constituent	Chemical Test	Reagent Used
1	Alkaloids	Mayer's Test	Mayer's reagent (Potassium mercuric iodide)
		Wagner's Test	Wagner's reagent (Iodine in potassium iodide)
		Dragendorff's Test	Dragendorff's reagent (potassium bismuth iodide)
		Hager's Test	Hager's reagent (Saturated picric acid)
2	Carbohydrates	Molisch's Test	Alcoholic naphthol+conc.H_2SO_4
		Benedict's Test	Benedict's reagent
		Fehling's Test	Fehling's A & Fehling's B solution
3	Flavonoids	Alkaline Reagent Test	Sodium hydroxide solution
		Lead Acetate Test	Lead acetate solution [19].
4	Tannins	Ferric Chloride Test	5% Ferric chloride solution
		Lead Acetate Test	10% Lead acetate solution
		Gelatin Test	1% Gelatin solution+NaCl
5	Glycosides	Keller-Killiani Test	Glacial acetic acid+ $FeCl_3$ + Conc.H_2SO_4
		Borntrager's Test	Benzene + Ammonia
6	Proteins / Amino Acids	Biuret Test	NaOH + Copper sulfate
		Ninhydrin Test	Ninhydrin solution
7	Phenols	Ferric Chloride Test	5% Ferric chloride solution
		Lead Acetate Test	Lead acetate solution [20].

3. WHO Guidelines For Good Manufacturing Practices

Good Manufacturing Practices(GMP) for herbal products are a comprehensive framework for quality assurance that ensures the safety, efficacy, and consistency of herbal medicines by ensuring that they are manufactured, processed, and stored under controlled conditions. Manufacturers protect the public's health by reducing the

possibility of adulteration, variation, and contamination by adhering to GMP [21].

1. Equipment and Facility

a) **Design and Layout:** Sanitary and hygienic standards should be followed when designing manufacturing facilities. To avoid cross-contamination and separate crucial operations, the design should enable unidirectional flow (e.g. Extraction, drying, and packaging) in specific areas.
b) **Equipment Calibration and Validation:** Equipment used in extraction, blending, granulation, drying and packaging requires regular calibration and validation.
c) **Equipment Maintenance and Sanitation:** Records of regular cleaning, inspection and sanitization is required. Irregularities should be promptly rectified and maintenance procedures should be tested to demonstrate their effectiveness.
d) **Personnel and training programs:** GMP principles, hygienic practice, process controls, SOPs equipment operation and in-process quality checks should be all encompassed in routine, systematic training on personnel.
e) **Hygiene practices:** Their should be strict rules on personal hygiene, such as washing hands, wearing should be introduced, protective clothing (gloves, hairnets, gowns).
f) **Cultivation, raw materials sourcing and harvesting GACP (Good Agricultural and Collection Practices):** To provide genetic authenticity, proper cultivation, and harvesting, raw materials are to be obtained in accordance with GACP guidelines.
g) **Contaminant Control:** Measures should be implemented to minimize the chances of contamination in the environment (e.g. microbial load, pesticides, heavy metals, etc) of the raw materials [22].

4. Introduction to Herbal cream

Herbal cream are semisolid dosage form that are used to deal with a number of skin conditions. It improves the condition of skin through the combination of plant extracts and proper bases unlike traditional chemical cosemtics, herbal creams are designed to enhance the looks and also offer therapeutic advantages, traditional medical therapies such as Ayurveda Siddha and Unani. These formulation are helpful in improving cosmetic and long-term skin health by restoring the skin and keeping it safe against various internal and external negative influences. These preparations are usually made using Aloe vera, Amla, Tulsi, Neem, Liquorice root, Green Tea and Cucumber peel, containing bioactive phytochemicals like flavonoids, alkaloids, phenols, and others. Due to the potent antibacterial, antifungal, antioxidant, and anti-inflammatory properties of these compounds, herbal creams are effective in treating minor issues like dryness and acne [23].

Types of herbal cream

a) Oil in water
b) Water in oil

4.1 Advantage

1. **Natural and safer Alternative:** Herbal creams are safer than synthetic chemical-based cosmetics because they are made with plant extracts, essential oils, and naturally derived excipients.
2. **Multifunctional Therapeutic Properties:** Herbs contain bioactive compound that have antibacterial, antifungal, antioxidant, and anti-inflammatory properties.
3. **Ease of Application:** Creams are typically smooth and spreadable making them easy to apply.
4. **Targeted Delivery:** Creams allow for precise delivery of active ingredients to specific areas of the skin, making them effective for treating localized conditions such as, acne.
5. **Moisturizing Properties:** Many creams contain moisturizing agents such as glycerin which help hydrate the skin and improve its texture and appearance [24].

4.2 Commonly used herbal ingredient

A) Liquorice root: The scientific name for liquorice root is Glycyrrhiza glabra, which is part of the Fabaceae family. Extracts form Glycyrrhiza glabra are abundant in natural antioxidants, with glycyrrhizin being the most effective. This extract is known for its skin-whitening, depigmentation, lightening, and anti-aging properties. Liquorice is also referred to as sweet wood. Its hydrophobic extract contains flavonoids and glabridin, which inhibit melanogenesis by blocking tyrosinase activity [25].

Fig 1: Liquorice root

B) Green Tea: Scientific name of green tea is Camellia sinensis. It belongs to family of Theaceae Chemical constituents: Catechins, Polyphenols, Flavonoids, Amino acids, Alkaloid.

Properties

1. Reduces skin inflammation by downregulating NF-kB Pathways.
2. ii) Protects against UV-induced skin damage by neutralizing reactive oxygen species (ROS).
3. iii) Inhibits MMP activity, Preventing collagen degradation.

Fig 2: Green Tea

C)Aloe Vera: Scientific name of aloe vera is Aloe barbadensis miller. It belongs to the family of Asphodelaceae. Aloe vera is a well-known plant celebrated for its healing and protective effects on the skin. It offers significant benefits and acts as a protective agent, effectively treating burns, sunburns, and acne. It contains active compounds such as polysaccharides (acemannan) and glycoproteins.

Properties of Aloe vera

1. Boost collagen production.
2. Provides skin hydration.
3. It has wound-healing properties.

Fig 3: Aloe vera

D) Neem: Scientific name of neem is Azadirachta indica. It belongs to family of Meliaceae Neem leaves and oil are used in many ointments due to their antiseptic, antiviral, and insecticidal effect.

Uses of neem

1. Treat acne
2. Neem reduces the wrinkle due to its anti-oxidant and vitamin E rich properties.
3. Offers even skin tone [26].

Fig 4: Neem

E) Turmeric: Scientific name of turmeric is Curcuma longa It is member of the Zingiberaceae family. Curcuma longa is derived from its rhizomes. Curcumin, isolated from Curcuma Longa, has beneficial effects on the skin, including anti-inflammatory, antioxidant, and antimicrobial activities.
Uses of turmeric:

1. It is used in wound healing.
2. It is used for treatment of skin infection due to its anti-microbial property.

Fig 5: Turmeric

5. Evaluation of Herbal Cream

1. **Appearance:** The first evaluation of a herbal cream usually it includes a visual examination to note its general physical attributes. This involves recoding the colour, opacity or clarity, and general physical condition of the formulation.
2. **Homogeneity:** Herbal cream is check to ensure the ingredients are uniformly distributed throughout the cream. Phase separation, grittiness, and particulate matter are all looked for in the cream.
3. **Spreadability:** The ease with which a formulation spreads across the skin's surface is determined by its spreadability. The spreadability test for the cream involved placing a small amount of cream between two glass slides, one glass side is then gently moved horizontally over the other, simulating the spreading motion on the skin. A shorter time and smoother movement indicated better spreadability of cream [28].
4. **Viscosity:** The viscosity is measured using a Brookfield viscometer. The test is carried out with spindle number 63 and a rotational speed of 100 rpm at a temperature of 25 degree Celsius.
5. **Determining pH:** A pH meter is used to measure pH. The product's pH is crucial because it affects the skin. After dissolving one gram of herbal cream in one hundred milliliters of distilled water, the mixture is kept for two hours. pH of each formulation is measure.
6. **Grasiness Test:** It involves applying a tiny amount of cream to the skin's surface and spreading it out to create a smear. After that, the smear is examined to see if it appears greasy or oily. Being non-greasy is often the aim of herbal cream formulation.
7. **After feel Test:** The skin is treated with a predetermined amount of cream. After that, the skin's remaining sensation is evaluated. This involves assessing the skin's degree of smoothness and softness. The quality of cream that is left on the skin following observation [29].

6. Conclusion

Effective quality control is essential for herbal medicinal products. As the demand for both traditional and modern herbal remedies grows, especially in India's expanding herbal industry, it becomes crucial to standardize every stage of production. The therapeutic efficacy of herbal

medicines largely relies on the presence and consistency of active components, emphasizing the need for comprehensive quality assessments. This process involves standardized sourcing, appropriate processing, and formulation methods, along with ongoing monitoring of both raw materials and finished products. Furthermore, employing advanced analytical techniques, adhering strictly to Good Manufacturing Practices (GMP), and conducting thorough contamination testing are crucial for ensuring product integrity.

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