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Quality Control and Standardization of Herbal Drugs

[1]Mahindra Prajapati, [2]Pushpak S Girase, [3]Gopal P Rajput

[1]Assistant Professor, Department of Pharmaceutics, School of Pharmacy and Technology Management, SVKM's NMIMS, Shirpur 425405, Maharashtra, India; mahendraniper86@gmail.com

[2]Student, Department of Pharmaceutics, School of Pharmacy and Technology Management, SVKM's NMIMS, Shirpur 425405, Maharashtra, India; pushpaksgirase93@gmail.com

[3]Student, Department of Pharmacology, School of Pharmacy and Technology Management, SVKM's NMIMS, Shirpur 425405, Maharashtra, India; gprajput2558@gmail.com

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ABSTRACT:

The term "herbal drugs" represents plants or plant parts that have been transformed into phytopharmaceuticals by means of simple processes concerning harvesting, drying, and storage. A practical adding to the definition is also to contain other crude products derived from plants, which no longer display any organic structure, such as essential oils, fatty oils, resins, and gums. There is cumulative awareness and general suitability of the use of herbal drugs in today's medical practice. Though, most of these applications are unorthodox, it is though, a recognized statistic is that over 80% of the world population depends on herbal medicines and products for healthy living. This increase in the use of herbal creation has also given rise to various forms of misuse and adulteration of the products leading to customers and manufacturers dissatisfaction and in some instances lethal consequences. The challenge is countless and massive, making the global herbal market unsafe. Evaluation of herbal drug is an significant tool in the formulation of high quality herbal products. This review seeks to inform stakeholders in herbal medicine on the need to establish quality parameters with the help of forward-thinking analytical tools and well clear standardization methods in safeguarding the safety of the comprehensive herbal market. The procedures of good quality assurance and standardization of herbal medicines and products by means of various spectroscopic, chromatographic and electrophoretic methods were also debated. In fact, the research arena of quality control of herbal medicines is really interdisciplinary research. It needs edge of chemistry, pharmacology, medicine and even data to provide a platform for the quality control of traditional herbal medicines and supplementary to discover the novel therapeutics composed of various chemical compounds.

INTRODUCTION:

Herbal formulation standardization is a key factor in evaluating the quality of drugs based on their chemical composition, physical, chemical, phytochemical, standardization and In vitro parameters. Quality assessment of herbal formulation is extremely important in order to justify their acceptance in contemporary system of medicine. One of the major challenges faced by herbal industries is unavailability of robust quality control profiles of herbal formulations. The Department of Ayush of the Government of India has initiated a central scheme for the development of standard operating procedures (SOPs) of the manufacturing process for the development of pharmacopeia standards for Ayurvedic medicinal products. India must explore the medicinal important plants. This can only be achieved by the evaluation and analysis of herbal products using advanced techniques of standardization.

The WHO assembly in several resolutions emphasizes the need to regulate medicinal plant products using modern methods. The WHO supports, recommends, and supports traditional/herbal remedies in natural health care programs due to their low cost, safety, and trust. WHO emphasizes the importance of qualitative and quantitative methods in characterizing samples, quantifying bio-markers/chemical markers and finger print profile.

If the principle active component of the product is known, then it is logical to quantify that compound. If the active ingredient contributing to therapeutic efficacy is known, then botanical preparations are standardized to their compounds. If the active ingredients are unknown, a marker substance specific to the botanical plants is selected for analytical purposes..

Herbal drugs: Herbal drugs are of two types: Single/ crude drug

Multiple herbal formulations

Single /crude drugs:

All mainly whole, fragment or cut plant, plant parts usually dried forms, but sometimes fresh.

It also includes algae, fungi and lichen.

Multiple herbal formulations: Herbal components are used in different ways to create different types of products, such as by extracting, distilling, expressing, dividing, analyzing, and creating new formulations.

QUALITY CONTROL METHODS AS PER WHO GUIDELINES-:

It includes safety in herbal drugs, toxicity in herbals and their interactions.

Safety in herbal drugs: A significant gap in quality, safety, and efficacy would impede the free circulation of herbal medicinal products and may pose a risk to consumers. The intricacy of herbal drug preparation and how to interpret bibliographic information regarding safety and efficacy based on experience gained through long-term usage can best be addressed by including specific knowledge and experience.

The safety and effectiveness of complex bio-products, such as herbal medicines products, is directly related to pharmaceutical details, such as the method of manufacturing and the composition of extracts.

A consideration quality for herbal drugs may require more details on aspects of agricultural products. The choice of seeds, conditions of cultivation and harvesting are important factors in producing reproducible quality for herbal drugs. The ongoing discussion on good agricultural practices (GAP) for medicinal plants needs to be regularly monitored.

Toxicity in herbals and their interactions: In addition to efficacy, the FDA is also responsible for determining the safety of the drug products. Not all botanicals / herbs are harmless. Consider the events of 1991 and 1992 in Brussels Belgium where 30 women treated with Chinese herbal slimming product died from renal failure due to the presence of the bacterium aristocholic acid.

One of the herbs was mislabeled as a non-toxic herb. Therefore, the importance of controlling the proper identification of herbal preparations from the very start.

In addition to the issue of mislabeled plant, some mixtures can be toxic, especially if misused.

It is important to maintain continuous surveillance and actively request information rather than collecting reports. Even this can be considered a national program.

Analytical evaluation technique in herbal drugs: Quality control is typically based on three pharmacopoeias: content, identity, and botanical quality. It is clear that content is the most challenging to evaluate, as the active constituents of most herbal drugs are not known. In some cases, markers can be used, which are chemically defined constituents of interest for control purposes, regardless of whether they are therapeutic or not. To demonstrate identity and purity, factors such as the type of preparation's sensory properties, physical parameters, adulterations, contaminants, moisture content, ash content, and solvent residues must be verified. The correct identification of cured herbal material or botanical quality is of paramount importance in setting quality control criteria for herbal drugs.

Organoleptic or macroscopic evaluation: Organic drug evaluation using sense organs (skin, eyes, tongue, nose and ear), or microscopic drug evaluation using color, smell, taste, size and shape, and unique features (touch, texture, etc.)

Qualitative drug evaluation based on morphological and sensory profiles of whole drugs

The fractured surfaces of cinchona wood, quillia wood, cascara wood, quassia wood, etc. play a significant role in determining the odor of the drug. Examples of this type of assessment include the aromatized odor of the umbelliferous fruit and the sweet taste of liquorice. The odor of drugs depends on the nature and quality of the odorous principles present (volatile oils).

Microscopic evaluation: It involves detailed examination of the drugs and it can be used to identify the organized drugs by their known histological characters. It is mostly used for qualitative evaluation of organized crude drugs in entire and power forms with help of microscopic. Using microscope detecting various cellular tissues, trichomes, stomata, starch granules, calcium oxalate crystals and aleuronic grains are some of important parameters which play important role in identification of certain crude drugs.

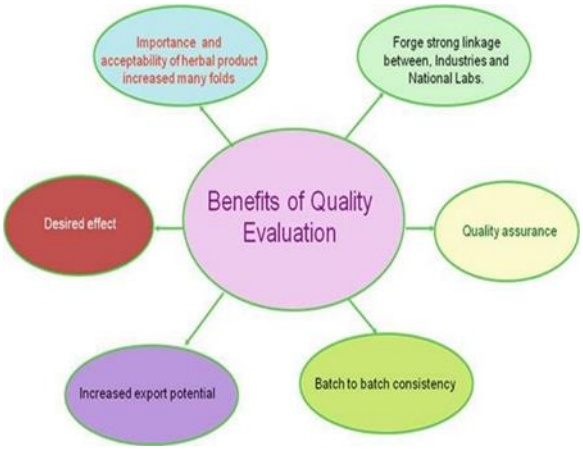

Fig .1 Benefits of Quality Evaluation

METHODS OF STANDARDIZATION:

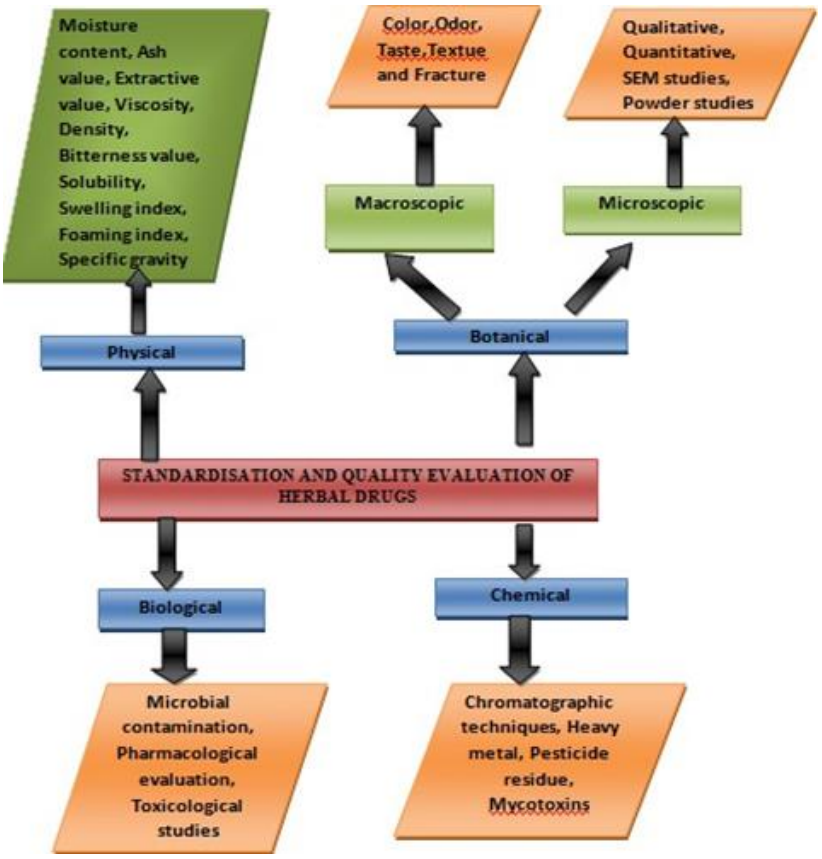

Fig.2 Methods of herbal standardization

Classification of standardization techniques are as follows:

- **A. Physical evaluation**
- **B. Microscopical evaluation**
- **C. Chemical evaluation (pre phytochemical screening)**
- **D. Spectroscopical analysis**

1. PHYSICAL EVALUATION:

Physical evaluation is an essential step in standardizing crude drugs. This approach assists in the assessment of crude drugs with respect to moisture, viscosity and melting point, pH.

Significance - Physical testing also plays a role in determining the quality, quantity and purity of raw drugs.

1.1 Foreign organic matter determination:

External organic matter refers to parts of the organ system of a crude drug that are not included in its definition and description. The maximum amount of foreign organic matter that can be present in a crude drug is defined in the monograph.

If it exceeds the limit, then it is an indication that the quality of the drug has deteriorated. Physical evaluation is very important for standardising crude drugs. It helps in evaluating crude drugs with respect to moisture content and viscosity as well as melting point and pH..

Method:

Weigh 100 –500 g of the drug sample to be examined. Spread it out in a thin layer. F.M.O. should be detected by inspection with eye or by the use of a lens (6x). Separate and weigh it.

Where,

Percentage of foreign organic matter = n × W ×94,100 × 100 / S × M × P

n= number of chart particles in 25 fields. S= number of spores in the same 25 field. W= weight in mg of lycopodium taken.

M= weight in mg of the sample (calculation on the sample dried at 105.c P= number of characteristics particles per mg of the pure foreign matter. 94,000= number of spores per mg of lycopodium

Table 1: Examples of Drugs with Foreign matter

Name of Drugs	**F.O.M.Limit**
Rauwolfia serpentine	Not More Than 2%
Acacia catechu (bark)	Not More Than 2%
Emblica officinalis	Not More Than 3.0%
Curcuma Longa	Not More Than 2.0%
Commiphora wightii	Not More Than 5.0%

1.2 Loss on drying (LOD):

LOD is the weight loss expressed as weight change per day (W/W) and can be calculated as follows:

The following is how crude drugs are expressed on an air dried basis:.

Significance-This test determines water and volatile content in the crude drug.

Method:

Place approximately 10 g of drug in accurately weighed evaporating dish.

Place the above-mentioned amount of drug in tared evaporating dish.

Dry at 105O for 5 hours and weigh. Dry and weigh at 1-hour intervals until difference between 2 consecutive weightings equals 0.25 %. Constant weight is reached when 2 consecutive weightings (after 30 minutes of drying and 30 minutes of cooling in desiccator) show 0.01 % difference.

Table 2: Crude drugs with moisture content analysis

Name of Drugs	**Moisture Content (% w/w)**
Rauwolfia serpentine	Not More Than 12%
Acacia	Not More Than 15%

1.3 Ash value:

The residue remaining after incineration is the ash content of the drug.

Significance- Ash value is an indicator of acceptability and purity for drugs that are improperly collected or stored. High ash value indicates contamination, substitution, and adulteration in raw drug..

E.g., Inorganic salts. Adulterated drug naturally contains inorganic salts. The ash value determines the identity or purity of the drug. There are three ways to determine the ash value. Total ash, Acid insoluble ash, Water soluble ash.

Method:

2 to 3 g of ground drug should be burned in tared silica at a temperature not more than 450oc cool and weighed. Calculate the ash percentage using the air dried drug..

1.3.1 Acid insoluble ash:

It governs quantity of silica present, particularly as sand siliceous earth

Procedure:

Add 25 ml dil. HCL to the ash and boil.

Collect the insoluble material in a crucible and wash with hot water.

Lighten to constant weight. Calculate the % Acid insoluble ash using the air dried drug.

1.3.2 Water soluble ash:

Method:

The ash should be boiled for 5 minutes at a temperature of 450 c. Add 25 ml of water to the boil. In a crucible wash, the insoluble matter is collected and ignited for 15 minutes. The percentage of water-soluble ash is calculated using the air dried drug as a reference. (Take the weight of the non-soluble matter and subtract the ash weight; the difference is the water soluble ash percentage).

Table 3: Examples of Drugs with their Total Ash content

Name Of Drugs	**Total ash (%w/w)**
Acacia Catechu	Not More Than 15%
Rauwolfia Serpentine	Not More Than 8%
Centella Asiatica	Not More Than2.0%
Coriandrium Sativum	Not More Than 6.0%
Menth x Piperita	Not More Than14%

1.4. Determination of Ether Soluble Extractive (Fixed Oil Content):

Ether Soluble Extractive Value is useful for the evaluation of crude drugs like resins, fixed oil, etc.

There are two kinds of ESRs:

1)Volatile ESRs

2) Non Volatile ESRs.

1.5 Refractive index:

Refractive index provides an idea of purity. A ray of light is bent when it passes from a less dense medium to a denser medium. This bending of the light is called refraction. The ratio of the speed of light in a vacuum to its speed in a material is called the second medium refractive index. For a liquid for a specific purity value, the refractive index is constant. This is why it is seen as an important tool for standardization. The refractive index can be influenced by the wave length of incident light, the temperature and the pressure.

Table 4: Examples of drugs showing refractive Index

Drug	**Refractive Index**
Caraway Oil	1.4838-1.4858
Clove Oil	1.527-1.535

1.6 Determination of specific optical rotation:

Polarization depends on the polarization phenomenon. When a plane of polarized light passes through a liquid, the light rotates clockwise (dextro) or anticlockwise (levo rotator).

It can be calculated by using formula:

$D25 = 100 \times \varphi lc$

Where,

φ = Observed rotation in drug at-25°

D = d line of sodium light

l = Length of polarimeter tube.

c = Concentration of substance in percent w/v.

1.7 Determination of pH:

The pH value can be expressed as the negative of the concentration of hydrogen ion to the base of 10. The pH value can be determined by the glass electrode and the appropriate pH meter. Most of the extracts have a pH value between 5 and 7, which can be considered a quality indicator.

For example: Andrographis Paniculata 7.33.

1.8 Volatile oil content

The volatile principal of a drug is referred to as a volatile oil. Such crude drugs are classified according to their volatile content..

1.9 Viscosity

The viscosity of a liquid is a constant value for that specific liquid at a specific temperature and is a measure of its composition, which is why it plays an important role in the standardization of liquid drugs.

Significance- It gives knowledge about conformation of drug and stability.

1.10 Microbial contamination

The primary sources of bacteria and mold contamination in medicinal plants are soil and the atmosphere. The extent of E. coli and mold contamination is contingent upon the harvesting and production processes. The presence of the substance aflatoxin in medicinal plants can lead to serious adverse reactions if consumed in conjunction with crude drugs, therefore it should be either completely removed or not present at all.

2. MICROSCOPICAL EVALUATION:

Significance- This method allows for a thorough analysis of the drug and is used as a tool for determining the standard drug. It is considered as a key element for qualitative analysis of organized crude drugs.

Determination of leaf constant:

2.1.1 Stomatal number

It is typical number of stomata per square mm of the epidermis of the leaf.

e.g., Digitalis perpuria: 25-50

2.1.2 Stomatal index

The Stomatal index is the ratio of the number of stomata formed by the total number of epidermal cells each stoma being calculated as one cell.

Stomatal index= S / E+S×100

Where:

S= Total number of stomata in a specified area of leaf

E= Number of epidermal cells in the similar area of leaf.

e.g. Digitalis perpuria: 1.3-3.5

2.1.3 Vein islet number:

Vein-islet number refers to the average number of veiniets per square millimeter of leaf surface between the midrib and the margin. Vein-islet numbers are used to differentiate different drug types.

For example, the number of veinislets per square millimeter is 27 for an Alexandrian senna, and 22 for an Indian senna..

2.1.4 Vein islet number of various drugs:

Datura metal 19-22

Datura stramonium 12-16

Datura fastuosa 18-24

Cannabis sativa 20-30

Bacopa monniera 6-13

Azadirachta indica 10-18Vein termination number.

2.1.5 Palisade ratio:

It is defined as usual no. of palisade cells below each epidermal cell.

E.g., Cassia angustifollia 5.5-10.5 Cassia acutifollia 4.5 - 9.5 Digitalis perpuria: 3.7 - 4.2

2.1.6 Trichomes

The extended extension of leaf called as trichomes and they are also known as plant hairs.

Types of trichomes

1. **Covering trichomes**

a. Unicellular trichomes e.g., Nuxvomica, cannabis

b. Multicellular-unbranched trichomes

(i) Uniseriate-e.g., Datura

(ii) Biseriate-e.g., Calendula officinalis (iii)Multiseriate- e.g., Male fern

c. Multicellular branched trichomes- e.g., Verbascum Thapsus

2. **Glandular trichome**

a. Unicellular glandular trichome- e.g., Vasaka

b. Multicellular glandular trichome- e.g., Digitalis purpurea

3. **Hydathode trichome** – e.g., Piper betal

3. CHEMICAL EVALUATION (PREPHYTOCHEMICALSCREENING):

Many crude drugs have specific chemical compounds and their biological or pharmacologic activity is dependent on these chemical compounds. Chemical evaluation of crude drugs useful to determine specific drug or test their purity.

Table 5: Detection of Phytoconstituents

Detection of alkaloids The Extracts were dissolved alone in dilute Hydrochloric acid and filtered.				
Sr No.	Name Of Test	Procedure	Observation	Inference
1.	**Mayer's Test**	Filtrates + Mayer's reagent (Potassium Mercuric Iodide)	Yellow precipitate	Presence of alkaloids
2.	**Wagner's Test**	Filtrates + Wagner's reagent (Iodine in Potassium Iodide)	Brown/reddish precipitate	Presence of alkaloids
3.	**Dragendroff's Test**	Filtrates + Dragendroff's reagent (Solution of Potassium Bismuth Iodide)	Red precipitate	Presence of alkaloids
4.	**Hager's Test**	Filtrates + Hager's reagent (Saturated picric acid solution)	Yellow precipitate	Presence of alkaloids

Detection of carbohydrates Extracts + 5 ml distilled water and filtered and the filtrates were used for following tests.				
Sr No.	Name of Test	Procedure	Observation	Inference
1.	**Molisch's Test**	Filtrates + 2 drops of alcoholic α -naphthol solution	Formation of the violet ring at the junction	Presence of Carbohydrates
2.	**Benedict's Test**	Filtrates + Benedict's reagent (Heat)	Orange red precipitate	Reducing sugars
3.	**Fehling's Test**	Filtrates + dil. HCl, neutralized with alkali and heated with Fehling's A & B solutions	Red precipitate	Reducing sugars

Detection of Glycosides				
Sr No.	Name of Test	Procedure	Observation	Inference
1.	**Modified Bontrager's Test**	Extracts + Ferric Chloride and immersed in boiling water for about 5 minutes cooled and add equal volumes of benzene	Benzene layer + ammonia sol Give pink-color	Presence of anthraquinone glycosides
2.	**Legal's Test**	Extracts + sodium nitroprusside in pyridine and sodium hydroxide.	Pink color	Cardiac glycoside
3.	**Froth Test**	Extracts + distilled water to 20ml and shaken for 15 minutes	Formation of 1 cm layer of foam	Presence of saponin
4.	**Foam Test**	0.5 gm of Extract + shaken with 2 ml of water	If foam produced persists for ten minutes	Presence of saponin

Detection of phytosterols				
Sr No.	Name of Test	Procedure	Observation	Inference
1.	**Salkowski's Test**	Extracts + chloroform and filtered and filtrates + few drops of Conc. Sulphuric- acid shaken	Appearance of golden yellow	Presence of triterpenes.
2.	**Liebermann Burchard test**	Extracts + chloroform and filtered filtrates + few drops of acetic anhydride, boiled and cooled + Conc. H_2SO_4	brown ring at the junction	Presence of phytosterols

Detection of Phenols				
Sr No.	Name of Test	Procedure	Observation	Inference
1.	**Ferric Chloride Test**	Extracts + 3-4 drops of ferric chloride solution	Formation of bluish black	color presence of phenols

Detection of Tannins				
Sr No.	Name of Test	Procedure	Observation	Inference
1.	**Gelatin Test**	Extract + 1% gelatin solution containing sodium chloride	white precipitate	presence of tannins

Detection of Flavonoids				
Sr No.	Name of Test	Procedure	Observation	Inference
1.	**Alkaline Reagent Test**	Extracts were + few drops of sodium hydroxide solution	yellow color which becomes colorless on addition of dilute acid	presence of flavonoids
2.	**Lead acetate Test**	Extract + 0.25% w/v Ninhydrin reagent was added and boiled for few minute	blue color	Presence of amino acids

Detection of proteins and amino acids				
Sr No,	Name of Drugs	Procedure	Observation	Inference
1.	**Xanthoproteic Test**	Extracts + few drops of conc. Nitric acid	Yellow color	Presence of proteins
2.	**Ninhydrin Test**	Extract + 0.25% w/v Ninhydrin reagent was added and boiled for few minutes	Blue color	Presence of amino acids

Detection of Diterpenes				
Sr No.	Name of Test	Procedure	Observation	Inference
1.	**Copper acetate Test**	Extracts dissolved in water + 3-4 drops of copper acetate solution	emerald green colour	Presence of diterpenes

4. SPECTROSCOPICAL ANALYSIS:

4.1 Ultra Violet Spectroscopy

UV spectroscopy plays an important role in the detection of both herbal and synthetic drugs. It provides information on the purity of a substance. The detection capability of UV spectroscopy is dependent on beer-lamberts law, which states that absorbance is inversely proportional to concentration and path length.

Table 6: Examples of drugs with their wavelengths

Drug	**UV range (nm)**
Morphine	284
Aloe -emodin	225,258,279,287,430
Caffeine	243,326
Scopholine	227,250,288,339

4.2 Infrared spectroscopy: .

This is an analytical method for determining functional groups. IR spectrometers can be used to measure IR spectra on plant substances using an automatic recording IR Spectrophotometer. Mulling technique is used to sample the solid sample.

The following are some of the important IR frequencies:

Amines - 3300-3500 kg/m2

Alkanes - 2940-2860 kg/m2

Carboxylic Acid - 3520 kg/m2

Cyanide - 2225 kg/m2

4.3 Mass Spectrometry:

It provides an idea of the molecular mass and the molecular formula. The molecular mass idea is obtained from the molecular ion peak. Hydrogen deficiency index is used to predict the validated molecular formula and the unsaturation number.

4.4 NMR Spectroscopy –

It is spectroscopic technique which stretches clue of no and types of protons existing in specific structure of complex.

4.5 Chromatographic evaluation

4.5.1 Thin Layer Chromatography

Before HPLC and gas chromatography, TLC was the go-to method for herbal analysis. It's a really important tool for separating compounds, and it's a widely used chromatography technique. It's based on adsorption, so in this method, you have a stationary phase of a finely divided solid that's applied on a thin layer of a supporting plate, and a mobile phase of a liquid that's allowed to flow over the plate's surface. You use adsorbing materials like silica gel, alumina, and kieselguhr..

The benefits of TLC are that it offers many folded detection options in analysis of herbal medicinal products. TLC is also relatively straightforward and can be used for several sample analysis. More than 30 spots can be analyzed for each plate..

Table 7: Examples of drugs with their solvent system

Drug	**Adsorbent**	**Solvent system**
Rauwolfia alkaloids	Silica gel 60 F254	Ethyl acetate: Methanol: Water (100:13.5:10)
Colchicum alkaloids	Silica gel 60 F254	Ethyl acetate: Methanol: Water (100:13.5:10)
Founiculum valgare	Silica gel 60	Toluene: Ethyl acetate (93:7)
Tribulus terrestris	Silica gel G	Toluene: Ethyl acetate (8:2)

For TLC fingerprinting the information that can be captured using a high-performance TLC (HPLC) scanner includes information such as chromatogram, Rf values, color of separated bands, absorption spectrum, λ max, and shoulder inflections/s of all resolved bands. All of these, collected with the profiles on derivatization with changed reagents, signify the TLC fingerprint profile of the sample. The resulting data can be used to determine whether a drug is genuine, to eliminate adulterants, and to ensure the purity and uniformity of the drug. To determine the piperine content, a TLC fingerprinting process was carried out on the methanolic extract from Sitopaladi churna to identify piperine. By using Silica Gel G plate and Toluene: Ethyl acetate: Formic acid (5:3.5:0.5 v/v/v) as mobile phase. RF value of piperine was calculated to be 0.69 (shown by peak 7) at wavelength of 342 nm.

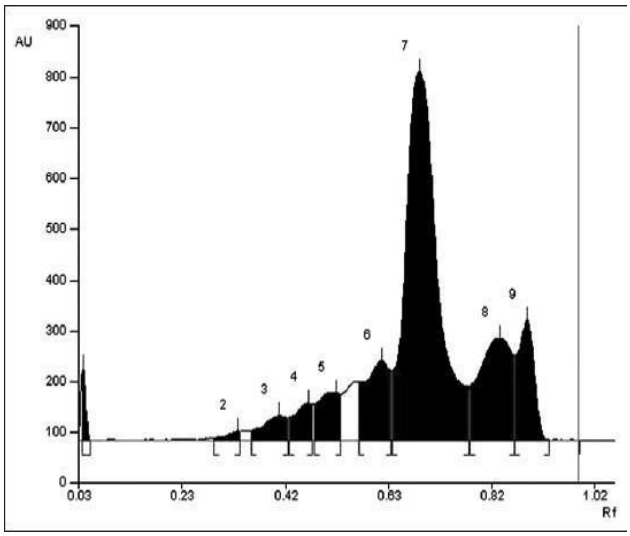

Fig.3 TLC of Sitopaladi churna

4.5.2 HPTLC:

In HPTLC a coating thickness of 100-150 micron is used to reach separation. HPTLC uses open layers of adsorbents on foils to separate component of samples.

Significance of HPTLC: It is used to identify and prevent adulteration of herbal products, as well as to determine the presence of pesticides and mycotoxins, and to ensure the quality of herbs and health food.

In general, HPLC is suitable for the analysis of almost all compounds in herbal medicinal products. The most common column used in the analysis of herbal medicinal products is the reversed-phase column (RP). HPLC is used to isolate and purify herbal compounds. There are two kinds of preparative high-performance liquid chemical analyzers (HPLC): low-pressure (approximately 5 bar) HPLC and high-pressure (approximately 20 bar). High-pressure HPLC is widely used in the pharmaceutical industry as it is an effective purification method and it reduces the time spent on synthesis conditions.

The standard HPLC detector, let's say one wavelength UV detector. This new detector makes it possible to directly HPLC several pharmacologically active ingredients in herbal medicinal products because the ELDS reaction is only dependent on the shape, size and number of herbal medicinal finger prints.

Examples:

i. **HPLC study of Azadirectin**

ii. Mobile Phase: Aceto nitrile: methanol: tri ethyl amine (60:40:1)

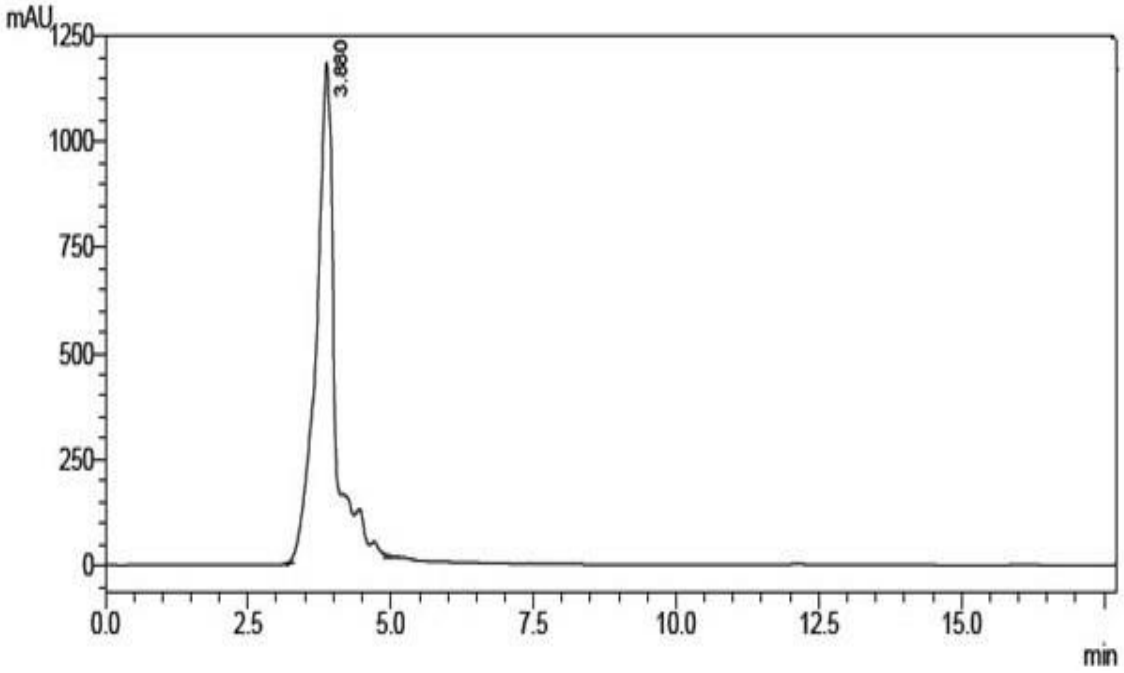

Fig.6 HPLC Spectra of Azadirectin

4.5.3 Gas liquid chromatography & gc-ms:

Significance: GC is an important means for recognition of volatile substances.

Percolating gas stream over stationary phase separates the volatile substances in GLC. The basic separation principle in GLC is partitioning the sample inside and outside the film of liquid dispersed over an inert solid. The nitrogen and helium are most used gases used in GC.[16] Recompenses of these methods are their great sensitivity, stability and high efficiency. Particularly, the hyphenation with MS delivers dependable information for the qualitative analysis of the intricate constituents. The high choosiness of capillary columns allows separation of many volatile compounds concurrently within short times. Though, the most serious drawback of GC is that this method is not suitable for the analysis of samples which are Heat sensitive and non-volatile. The identification and quantification of chemical ingredients present in poly herbal oil preparation (Megni) was done by GC for determination of Eugenol using DB-5 fused silica capillary column and helium as a transporter gas. The retention time(RT) was found to be 8.63 min.sec

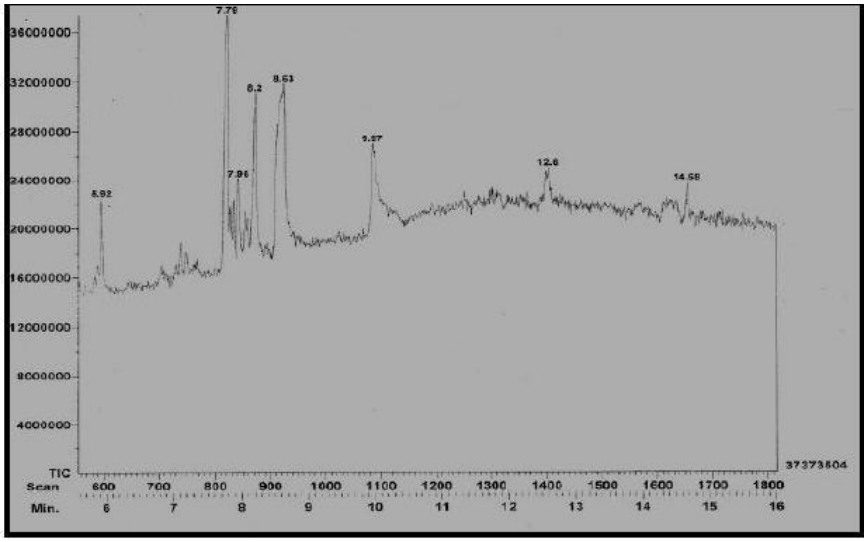

Fig.7 GC chromatogram of Eugenol (Rt = 8.63 min)

Chromatographic fingerprinting:

Chromatographic fingerprinting is the most authoritative method for the quality control of herbal medications. Chromatographic fingerprint of Herbal Medicine is a chromatographic design produced from extract of some mutual chemical components which may be pharmacologically promising or have some chemical features. This chromatographic profile should be contained by the fundamental provenances of - integrity and -fuzziness or - sameness and - differences so as to chemically represent the herbal medicines investigated. This advice that chromatographic fingerprint can successfully establish both ―sameness and ―differences between several samples and the confirmation and identification of herbal medications can be precisely conducted even if the quantity and/or concentration of chemically typical constituents are not very same in different samples of herbal medication. Thus, chromatographic fingerprint should be well-thought-out to estimate the quality of herbal medicines worldwide; seeing multiple constituents present in the herbal medications. This technique can be hired for identification and confirmation as well as for determination of countless adulterants and contaminants and for standardization purpose. In distinction to macroscopic, microscopic and further molecular biological methods this system is not constrained to raw herbs, but can also be useful to pharmaceutical formulations. Chromatographic fingerprinting can be supported out using practices such as thin layer chromatography (TLC), High performance thin layer chromatography (HPTLC), High performance liquid chromatography (HPLC), Gas chromatography (GC) and other hyphened techniques.

DNA fingerprinting: DNA investigation has been proved as an significant tool in herbal drug standardization which is beneficial for the identification of phytochemically indistinguishable sincere drug from adulterated drug. DNA fingerprint genome remnants the same irrespective of the plant part used though the phytochemical constituents will vary with the part of plant used, physiology and atmosphere.

Conclusion:

Plant materials make up the majority of the drug market in both developed and developing countries. They are used in home remedies, OTC drugs and as raw materials in the pharmaceutical industry. Herbal drug quality refers to all the elements that influence the safety, efficacy and acceptance of a product. Today, the field of Herbal Drugs and formulation is developing rapidly. There is still much to learn about standardization of Herbal Drugs.

So, when creating an herbal formulation, it is essential to have a comprehensive understanding of the drug, including all organoleptic properties, phytochemicals, pharmacological properties, and standardization of various parameters through various methods. The challenges of quality control for herbal medicinal products have been largely resolved through the use of chromatographic DNA fingerprinting analysis

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