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Pharmaceutical Manufacturing of CrudeDrugs Kampillaka to Standardization

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Abstract:

The kampillaka is a medicinal plant, it is included in the Sadharana Rasa category. Here is a procedure taken to determine the real quality of kampillaka by detecting adulteration tendencies, by evaluating several components of kampillaka. The mentioned three medications' processes have been standardised to the greatest degree feasible. The quality of the completed product is determined by the quality of the crude pharmaceuticals used. As a result, determining the real quality of crude medications is crucial.

Key word: *Mallotus philippensis*

Intoduction

The pharmaceutical manufacturing of Kampillaka to standardization requires meticulous attention to collection practices, stringent standardization protocols, and comprehensive phytochemical screening methods. By ensuring these steps are carefully executed, pharmaceutical companies can produce high-quality Kampillaka products that are safe, effective, and consistent in their medicinal properties. This approach not only meets regulatory requirements but also enhances the credibility and reliability of Kampillaka as a medicinal herb in modern healthcare practices[1]

Objectives

1. To standardise the quality of crude drug Kampillaka in relation with their pharmaceutical manufacturing.
2. To standardise the method of preparation and final product of the basis of Kampillaka.
3 To examine the manufacturing process of Kampillaka in Pharmaceutical companies
4. To examine the quality maintenance of Kampillaka in Pharmaceutical companies.
5. To examine the parameters of standardisation of Kampillaka.

Selection of Collection Sites:

- Natural Habitat: Choose collection sites that are free from pollutants and contaminants, ensuring Kampillaka plants grow naturally under optimal conditions.
- Cultivation Practices: If Kampillaka is cultivated, adhere to Good Agricultural Practices (GAP) to maintain consistency in growth conditions and active constituent content.[2]

Timing of Collection:

- Harvest Kampillaka plants during the appropriate season and growth stage (e.g., flowering, fruiting) when the concentration of bioactive compounds is highest.
- Ensure plants are harvested at the right maturity to maximize the potency of active constituents.

Collection Techniques:

- Use gentle harvesting methods to minimize damage to Kampillaka plant parts (leaves, stems, fruits) intended for pharmaceutical use.
- Handle harvested material carefully to prevent bruising or contamination.[4]

Processing and Preservation:

- Clean Kampillaka thoroughly immediately after harvesting to remove dirt and other impurities.
- Dry Kampillaka using suitable methods (e.g., shade drying, solar drying) to preserve its bioactive compounds and prevent microbial growth.
- Store dried Kampillaka in cool, dry conditions protected from light in sealed containers to maintain stability until further processing.[5]

Standardization:

Development of Standardization Protocols:

Establish standardized procedures for the collection, processing, and manufacturing of Kampillaka to ensure consistent quality and potency.

- Define parameters such as moisture content, ash value, extractive values, and specific bioactive marker compounds for standardization.[6]

Qualitative Phytochemical Analysis

- Perform preliminary screening using qualitative tests to identify the presence of major phytochemical groups:
  - Alkaloids: Detect using Dragendorff's reagent or Mayer's reagent.
  - Flavonoids: Test with ferric chloride ($FeCl_3$) solution for flavones and flavonols.
  - Tannins: Use ferric chloride test or gelatin precipitation test.
  - Saponins: Foam formation test.
  - Terpenoids: Salkowski test for steroids and triterpenoids.

Quantitative Phytochemical Analysis:

Employ quantitative methods such as:

- High Performance Liquid Chromatography (HPLC): for quantifying specific bioactive compounds like quercetin, kaempferol, or rutin.
- Gas Chromatography-Mass Spectrometry (GC-MS): for identifying and quantifying volatile compounds and fatty acids.

Compound Identification:Marker

- Identify and validate specific marker compounds that serve as indicators of Kampillaka's quality, efficacy, and authenticity.
- Establish standardized methods for quantifying these markers across different batches of Kampillaka products.[9]

Phytochemical parameters

Kampillaka phytochemical parameter typically considered for standardization:

1. .Triterpenoids: These compounds contribute to the medicinal properties of Kampillaka, including anti-inflammatory, antioxidant, and hepatoprotective effects. Standardization involves quantifying specific triterpenoids present, such as betulinic acid and lupeol.
2. Flavonoids: Kampillaka contains flavonoids like quercetin and kaempferol, known for their antioxidant and anti-inflammatory activities. Quantifying these helps ensure the antioxidant capacity and therapeutic potential of the crude drug.
3. Alkaloids: Alkaloids found in Kampillaka, such as nicotine and choline, may have pharmacological effects. Their quantification is essential for assessing the potency and potential side effects of the crude drug.
4. Tannins: Tannins are polyphenolic compounds with antioxidant and anti- inflammatory properties. Their levels in Kampillaka affect its astringent and therapeutic qualities.
5. Saponins: These glycosides contribute to Kampillaka's pharmacological activities, including antimicrobial and anti-inflammatory effects. Standardization involves measuring specific saponins like quillaic acid.
6. Phenolic compounds: Kampillaka contains phenolic compounds such as gallic acid and ellagic acid, which contribute to its antioxidant and anti-cancer properties. Quantifying these helps ensure consistency in medicinal benefits.
7. Fatty acids and essential oils: Kampillaka may contain fatty acids and essential oils with therapeutic properties, such as antimicrobial and anti- inflammatory effects. Their analysis provides insights into the crude drug's bioactivity.
8. Mineral content: Trace minerals in Kampillaka, such as iron, calcium, and magnesium, can influence its therapeutic efficacy and bioavailability.[11]

Standardization of Kampillaka involves establishing specifications for these phytochemical parameters based on scientific research and traditional knowledge. Analytical techniques such as high-performance liquid chromatography (HPLC), gas chromatography-mass spectrometry (GC-MS), and spectrophotometry are used to quantify these constituents accurately. By maintaining consistent levels of key phytochemicals, pharmaceutical manufacturers ensure the quality, safety, and efficacy of Kampillaka-based products for therapeutic use.[12]

Need of standardization

1. Harbal medicine is crucial in order to attain the product's potential quality and stability.
2. The highest grade active ingredient has been employed if the product's quality and

stability are guaranteed. However, the pharmacopoeia does not explicitly specify the standardization principle.

3. The absence of quality standards has been acknowledged as having a negative impact that could be fatal.[13]
4. According to GMP acquisition, particular devices are needed to assess the parameters for standardization. Standardization of herbal medicine is influenced by a number of aspects, including bioefficacy and repeatable therapeutic effects.
5. The primary cause is adulteration of herbal materials, which can occur accidentally or purposely. Examples include improper storage, combining of different ingredients, using the same name for many herbs, or substituting excipient material for a herb.
6. Standardization is a crucial step in testing the bioactivity of herbal extracts used as excipients in the production of allopathic medications. [15]

Advantages of herbal medicine:

- Minimal/low expense
- Strength and effectiveness
- Increase resistance
- Increased defense
- Reduced adverse effects

Chromatography techniques

TLC (Thin layer chromatography)

Prior to the development of instrumental chromatography techniques like as gas chromatography and high-performance liquid chromatography (HPLC), to conduct herbal analysis, thin layer chromatography (TLC) was the technique of choice. drug monographs all employ TLC to analyse their own herbal pharmacopoeias, which are all based on traditional medical texts, such as the Indian Herbal Pharmacopeia. Because the easy TLC separation of herbal medicines using instrumental chromatography changes less over time than other chromatography methods, TLC is more often utilised as an initial screening approach for semi-qualitative evaluations.

Through the use of adsorption and a mobile liquid phase, TLC distributes the solute across the two phases of the reaction. Applied to glass, plastic, or metal, the adsorbent is a thin, homogenous coating of finely powdered drug material. Glass plates are by far the most prevalent kind of dishware out there. Depending on the support and solvent used, partitioning or a combination of partitioning and adsorptions may also be used to produce separation.

Spots with the same Rf value and similar magnitude may be used to identify an unknown sample and a reference sample by chromatographic analysis of the sample plate. Estimation through visual comparison of spot sizes and intensities is often used. TLC provides a wide range of options for identifying herbal medications in analysis. TLC is very easy to use and may be used to the examination of many samples. More than 30 spots of material may be analysedon each plate. The created TLC plates may provide relevant qualitative and quantitative data when analysed using CA MAG video storage and TLC QA-UV techniques.[25]

A number of factors have led to TLC's widespread use: It gives qualitative

and semi-quantitative information about the resolved compounds. It allows for quick Kampillaka fruits and leaves

A chromatographic method for separating non-volatile mixtures is called thin layer chromatography (TLC). A densitogram can be used to measure a spot's blackness; the more material the device detects, the darker the spot.

HPLC (High Performance Liquid Chromatography)

Using the HPLC-MS method, secondary chemicals were annotated in kampillaka fruit extracts, 100% ethanol. Compounds from the ethanolic extracts agreed overall. First, it should be mentioned that several compounds belonging to the previously identified structural categories were not found, which is also a foreseeable situation, may be because of the inadequate data in our LC-MS molecular.[35]

Herbal medicine standardisation has demonstrated DNA analysis to be an important tool for detecting phytochemically similar genuine pharmaceuticals from substituted or tainted ones. It doesn't matter what part of the plant is utilisedor what physiological state it is in since the DNA fingerprint genome stays the same no matter what section of the plant it is in. Additionally, DNA fingerprinting may be used to identify adulterants in processed samples because of the presence of intact genomic DNA specifically in commercial herbal medications.

Crude Drug*(*Kampillaka) Sadharana Rasa

Minerals of common usefulness to mercury have been included in this category. *Kampillaka, gauripasana, navasadara, kaparda, agnijara, girisindura, hingula*, and *mrddarasrnga* are some of the medications[27].

Kampillaka

Table : Nomanclature

Sanskrt.	-	Kampillaka, Kapila; Kambha; Recanaka, Rajanaka
Gana	-	Virecana, Phalinidravya (Caraka), Adhobhagahara, Syamadi (Susruta)
Hindi	-	Kamala; Kabila, Kamila, Kambila, Kapila, Sinduri, Rori (Mirzapur)
Bengali	-	Kamalaguri, Kamila
Marathi	-	Shendri, Kapila
Arabbi	-	Kinbila wars or Wuras
Assam	-	Lochan, Jorat
Punjabi	-	Kamal, Gwalior - Seria, Kamila
Pharsi	-	Kambilay, Kamilah, Kambela, Kambala
Gujarati	-	Kapilo
Telugu	-	Kunkuma, Kampillamu
Orissa	-	Kamalagundi, Kunkumo
Tamil	-	Kapil, Kapila, Kamala
Urdu	-	Kamila
Konkan	-	Komati

Kashmiri	-	Kameelak
Kannada	-	Vasare; Chandrahettu, Kapilathettu
Malayalam	-	Kurmdakku, Kampippala, Kampipalu
English	-	Indian Kamala, Rottlera, Monkeyface Tree
Latin Name	-	Mallotus philippensisMuell-Arg
Family	-	Euphorbiaceae

Synonims of Kampillaka

Kampilla, Karkasa, candra, raktanga, rocana, kampila, reci, rakta curnaka, Kampillak, recana, ranjanaka, rakta samana, vireki, vrana sodhana, recanaka, lohitanga, kampilya, lohita,nadivaso, raktaphala, bahupatra, bahuphalah, pikaksa, rocani, laghupatraka, bahupuspa.[28]

Habitat – "This small evergreen shrub belonging to the Spurge family, is distributed over the whole of India (Orissa, Bengal, Bombay), *Ceylon*, the *East Indies*, *Malay Archipelago*, as far as Australia."

Parts Used –Capsule or fruit glands and hairs
Flowering period: October to November.
Kampillaka fruits: It has a trilobed capsule as its fruit. The Phalaraja (Red - hairy glands that look like particles) is hidden.

Fruiting time: February to March
Its seeds are black and spherical in shape. Phalaraja's red colour secretion will solidify into red colour granule form over ripening fruits, and this phala raja is known as *kabila.*

Kabila Collection Period: Feb. to March from mature fruits.
Purity of Kampillaka: Pure *Kampillaka Phalaraja* will be red in colour and in the shape of fine granules (powder). It's a tasteless and odourless material. This phalaraja is mostly red in colour with a hint of yellow. Small glandular hairs are also present, and certain portions possess fine non-glandular hairs.
According to *Rasa* literature, it resembles brick powder with some gleaming and has no flavour or odour. It may include a few plant tissue particles, and it is sometimes adulterated with sand particles, making it heavier and less lustrous.[55]
Tests for identification of its purity

1. Pick up a little amount of *kampillaka* with moist fingertips and place it on white paper with the same fingers. If a vivid yellow colour mark appears on the kampillaka, it is of the highest grade.
2. If just a little amount of *kampillaka* is passed over the fire then it absolutely burns.
3. If you pour *kampillaka* into water, all of the authentic quality will float to the surface. The foreign stuff will settle at the container's bottom. The kampillaka

that floats on top of the wafer is collected, dried, and used as medicine.

4. *Kampillaka* will not dissolve in cold water if it is pure.
5. When pure *kampillak* is dissolved in either alcohol or water, it forms a crimson liquid.
6. The amount of ash in it should be kept to a minimum.

Preservation: Collected *kampillak* is to be preserved in air tight container.

Expiry Period: 6 Months

Varieties of Kampillaka Phalaraja: *Phalaraja* is generated not just on the fruits of the Kampillaka plant, but also on other areas of the plant. *Kapili raja* is the raja that is gathered from the fruits. Kapila is the raja obtained from various parts of the plant (e.g. branches, etc.) and has a yellowish red colour. This will not have the same therapeutic effect as kapili *(Phala raja).*

Method of Kampillaka Collection:*Kampillaka* mature fruits are gathered in a net, and phalaraja is filtered and collected after rubbing and shaking. Ripe fruits (dried in the shade) are thrashed until the grandular pubescence is removed in a cloth or bag. Fruits are massaged between the palms of hands or kneaded
with the feet on the ground in certain locations. After that, the powder is sifted to remove any fruits or broken bits. It is ready for the market in this condition. By shaking and rubbing the fruits with his hands, *Kampillaka Phalaraja* also gathered in cloth.

Approximately one ser phala raja may be obtained from one man's (amount) *kampillaka* fruits (dry) [61]

The following substances are usually found in adultrated kampillaka:

1. Brick Powder
2. Powder of *Vayuvidanga*
3. Red Colour Soil
4. *Raja* Collected from other parts of *kampillaka* tree.
5. *Mandur curna*
6. Flower Powder of *Kusumbha* (Carthamus Tinctorious)
7. Fruit Powder of Vata (Ficus Bengalensis)

Kampillaka Sodhana: According to *Ayurveda Prakasa*, *Kampillaka Sodhana* is listedbelow.

Ingredients:

1.	*Kamipllaka*	:	1 Part
2.	*Matulunga Rasa*	:	q.s.
3.	Ardraka Rasa	:	q.s.

Procedure:*Kampillaka*that has been washed and dried. After that, it is gatheredin the needed amount.Each dravya *(Matulunga 'Rasa and ardraka rasa)* receives three doses of bhavana for kampillaka, after which the dried and collected *kampillaka* is utilised as a medication known as *suddha kampillaka*.[52]

Kamapillaka: Mallotus Philippensis

Family: Euphorbiaceae

This small evergreen shrub belonging to the Spurge family, is distributed over the whole of India (Uttaranchal, Uttar Pradesh, Orissa, Bengal, Bombay etc.

Parts Used : Glands and hairs from the capsules or fruits.

One of the world's most common little evergreen shrubs or trees, it has ashort, buttressed, bole and is found across India, as well as Australia and Ceylon.

Dioecious, small flowers in spikes; the capsules are globose, 3-lobed, 3-valved, 0.75-1.25 cm diam., densely covered with reddish brown glandular pubescence; the seeds are sub-globose; the bark is thin, grey, and somewhat rough; the leaves are variable, broadly ovate to ovate-oblong or ovate-lanceolate; glabrous above, pubescent with numerous red glands beneath black, smooth; diam.4 mm

Chemical properties

Assays for Na and K such as volumetric/gravimetric/flame photometry and qualitative tests for carbonate and sulphate, and analysis of heavy metals such as arsenic and other elements are all examples of chemical characteristics.

a. Microscopic methods

Light microscopy combined with polarised microscopy is often used to certify minerals. It is a straightforward, low-cost, and extensively utilised technique for mineral authentication.

b. Spectroscopic methods

Near Infrared, UV-Vis spectrophotometer, and Fourier Transform Infrared spectrometers are some of the spectrum approaches used to certify animals. These techniques are used to verify the authenticity of honey.

c. Near Infrared Spectroscopy(NIRS)

Because of its quickness and ability to need little or no sample preparation, Near Infrared Spectroscopy has gained a lot of interest for chemical quality and process control. The near infrared portion of the electromagnetic spectrum is used in NIRS (from about 800nm to 2500nm).

d. Atomic Absorption Spectrometry(AAS)

The absorption of light by elements is the basis for AAS. For the quantification of inorganic minerals in plant medications/poly herbal formulations, mineral/metal pharmaceuticals, and animal drugs, the AAS technique is used. The graphite furnace technique may be used to estimate at the ppm level and even lower levels.

e. X-ray Diffraction Analysis(XRD)

The X-ray diffraction pattern of a pure material is similar to its fingerprint. Powder diffraction is an excellent approach for characterising and identifying polycrystalline phases. Powder diffraction is primarily used to identify components in a sample using a search/match process. Furthermore, the regions under the peak are proportional to the quantity of each phase in the sample.

f. X-ray Fluorescence Analysis (XRF)

It is known as X-ray fluorescence when a material is activated by high- energy X-rays or gamma radiation and emits X-rays that are unique from the original substance (XRF). Research in geochemistry, forensic science, and archaeologyregularly uses the phenomena for elemental and chemical investigation, particularly in the study of metals.[41]

Standard

A standard is a numerical number that quantifies a parameter and thereby indicates the material's quality and purity. The numerical value of the parameter used to create the standard, represented in different metric units. The factor that is accountable for the desired quality and purity of the material is closely tied to the criterion or parameter that is considered for setting the standard. As a result, the acceptability of a substance is almost usually determined by establishing a standard. The quality and purity of a synthetic medication is determined by the majority of physiologically active chemical ingredients present, which are capable of generating the therapeutic action in the anticipated liquid. As a result, the quantity of a certain chemical compound is used as a criterion for standardising a synthetic medication.

However, this is not always the case with natural medications. Natural medicines are obtained from plants, animals, and minerals. The vast majority of medications are produced from plants. Natural medications have a more complicated chemical structure and composition than manufactured pharmaceuticals. Plant components such as the root, stem, flower, leaf, bark, and the whole plant are utilised as medicine. A crude drug's therapeutic properties are attributable to biologically active components. Different environmental and ecological conditions have a significant impact on the formation of these chemical compounds.

Ayurveda does not necessarily credit a crude drug's medicinal effect to a single chemical constituent. Furthermore, the varied therapeutic dose forms are unconcerned with pure active ingredient separation. An Ayurvedia dosage form's therapeutic impact is multimodal, meaning that the primary therapeutic effect is always accompanied by certain supporting effects.

The purity, chemical composition, potency, rate of absorption, metabolic transformation, and elimination of a medication combination determine its effectiveness. For retaining purity, increasing potency, and facilitating metabolic transformation and excretion, several pre and therapeutic processing techniques for varied doses are recommended.[42]

Standardisation - A Multidimensional Approach

Because practically all crude pharmaceuticals are of natural origin, drug standardisation is a difficult process. The therapeutic effectiveness of a natural medication is the sum of its chemical ingredients' effects. As a result, quantityand purity relate to the drug's whole profile rather than any of its characteristics. To standardise a crude medication, a multidimensional strategy is required. The entire profile of crude drug res was then determined

All features of crude drug must be addressed in depth for the purposes of the above. This multimodal approach should analyse every feature of the crude medicine,

including its name, organoleptic properties, geographical source, botanical source, morphological, anatomical, physical, chemical, and biological properties, as well as pertinent references from classical books. The drug's morphological, chemical, physical, and therapeutic value, as well as its origin and other organoleptic characteristics, are all noted in the classical sources. In a nutshell, the multidimensional method is the only way to construct a crude drug standard. To see whether the contents of the gathered samples from various locations have the same features with minor qualitative differences.[38]

Survey Revealed that:

Kampillaka is also known as kapile or Kamila in the market.

In the current crude drug trafficking industry, proof of adulteration of Kampillaka in various forms has been discovered. Brick powder, for example, is a common adulteration of Kampillaka.

Kampillaka is available in the market for Rs.150/- to Rs.200/- per kilogramme, with prices varying from one location to the next. Two market samples were collected from different areas after considering all of these factors to determine the amount and nature of adulteration in the kampillaka market supply. At the same time, another sample was taken from the source.

Sample collection: The following three Kampillaka samples were gathered for research.

Sample – I

The colour of *Kampillaka* is reddish. There are also some grey-colored particles. Itwas obtained from a Raw medicine store in Jaipur.

Sample – 2

Kampillaka is a reddish-brown powder with occasional grey particles. It was purchased from a Raw pharmacy store in Hyderabad.

Sample – 3

Kampillaka is reddish in colour and low in weight. Devi Ram Sagar,Ambedkar Nagar, Bhatta Bondia, Kichha Udam Singh Nagar, and Uttaranchal are among theplaces where it was gathered.

The quality of the crude pharmaceuticals is of highest significance in thediscipline of Ayurvedic Pharmaceutics.

At the same time as encouraging the use of mineral, animal, and plant items for medicinal purposes, ancient Ayurvedic academics recognised their toxicity in general. No one has recommended taking these medications in their raw form for internal use. Furthermore, these medications are poisonous and difficult to absorb in their raw form. These medications will only be absorbed in micronized reduced form and provide therapeutic effectiveness in living organisms. Our ancient Ayurvedic Scholars have outlined specific processing processes, such as sodhana and marana, that will aid to eliminate impurities and toxicities from crude materials and transform them into medication form, based on these aspects. Different sorts of pharmacological procedures were stated in Ayurvedic classics for the purpose of sodhana and marana

of various medications.[53]

Obtaining and assessing the quality of various crude medications has become a tough issue for Ayurvedic drug manufacturing companies in recent years. The relevance of crude drugs is highlighted even more when such crude pharmaceuticals are used in the creation of medications. Changes in distinct samples of pharmaceuticals at different stages of the pharmaceutical process are noted.

Different results will be documented for all the gathered samples in order to determine the best grade of crude medications, i.e. by performing sodhana Samskara and other processes for all the obtained samples.

Materials and Methods:

The materials utilised, the procedures employed, and the changes made are all dependent on the medications' availability, references, previous experiences, and expert judgments. The majority of pharmacological processes in this research are based on A.F.I., I., and II. All of the samples were obtained from various sources. These samples were put through a series of pharmaceutical processes, including sodhana and others.[58]

The pharmaceutical procedure for the crude pharmaceuticals in question may be separated into two key components, as shown below:

1. Sodhana of crude drugs.
2. Marana of sodhita (purified) samples.

Sodhana of Kampillaka Materials andMethods:

Kampillaka Samples: Three Kampillaka samples were gathered for the research, twoof which were market samples and one from a source.

Sodhana Process:

Ingredients and equipments required:

(1) Kampillaka – Sample - 1, Sample - 2, Sample - 3,500 gm. of each.
(2) Water – Q.S.
(3) Containers – 3
(4) Cloth – 3 Pieces
(5) Khalva Yantra – 3

Procedure: In a container, 500 gms. of Kampillaka (Sample-1) is poured over water and well mixed with hands. The contents are then allowed to settle for around 15 minutes as is. Genuine Kampillaka floats on the water due to its low weight, while the alien stuff settles to the bottom. The floating Kampillaka is then collected, filtered, and dried. Bhavana is provided with Nimburasa, Ardraka Rasa simultaneously 3 days with each drava (total 6 days), and bhavana isadministered everyday for one prahara. After that, Kampillaka is gathered and kept. The same approach is used for Samples 2 and 3[59]

Table : Results

Results	**Sample-1**	**Sample-2**	**Sample-3**
Wt. of asudda Kampillaka	500 gm.	500 gm.	500 gm.

Immersed in water for	15 minutes	15 minutes	15 minutes
Quantity obtained after cleaning.	260 gm.	380gm.	460 gm.
Wt. of Kampillaka used for Bhavana	250 gm.	250 gm.	250 gm.
Bhavana with Nimburasa	3 days	3 days	3 days
Bhavana with Ardrakarasa	3 days	3 days	3 days
Wt. after Bhavana	256 girl.	258 gm.	262 gm.
Colour	Light Red	Light Red	Light Red
Appearance	Powder form	Powder form	Powder form

Observations: *Suddha Kampillaka* produced by sample no. 3 is having all therequired characters..

Physico-Chemical Analytical Study

Materials and Methods

Petrographic Study: A tiny sample (rock or mineral) is ground into a very thin flat chip, which is then mounted on a glass plate using canadabalsam and coated with a glass coating. After that, the slide is examined under a petrological microscope. The visual qualities of minerals aid in their identification, and the texture of the rock is determined by the kind, size, shape, and placement of the mineral grains. The rock is given a name based on its mineral assemblage and provenance.[62]

Determination of Foreign Matter

A weighed 100-500 gramme sample of the substance to be evaluated was distributed in a thin layer over a contrasting background. Inspection with the unassisted eye or the use of a hand lens revealed the foreign substance (6x). We separated and weighed the foreign substance. The proportion of foreign matter was calculated.

Determination of Total ASH

2 gm. of accurately weighted powdered drug was burnt at 450°C 5oC in a tared platinum or silica crucible until clear of biological matter, then cooled andweighed. The percentage of ash is computed using the air-dried medication as a reference.

Determination of Acid - Insoluble Ash:

Boil the weighted ash in 25 mL dilute hydrochloric acid for 5 minutes; collect the insoluble materials in a Gooch crucible or on ashless filter paper, wash with hot water, and ignite until the weight is constant. Calculate the percentage of acid- insoluble ash using air dried medication as a reference.

Determination of Water-Soluble Ash:

Boil the weighted ash in 25 mL water for 5 minutes; collect the insoluble stuff in a Gooch crucible or an ashless filter paper, wash with hot water, and ignite for 15 minutes at 450°C. Subtract the weight of the insoluble stuff from theweight of the ash to get the water-soluble ash. Calculate the proportion of water- soluble ash using the air-dried medication as a reference.

Determination of Water - Soluble Extractive:

In a closed flask, macerate 5g of coarsely powdered air dried medication with 100m1 chloroform water for twenty-four hours, stirring regularly during the first six

hours and leaving to stand for eighteen hours. Filter quickly to avoid solvent loss, evaporate 25m1 of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105° to a consistent weight and weigh. Calculate the percentage of water- soluble extractive using the air-dried medication as a reference.

Determination of Moisture Content (Loss on Drying):

In a tared evaporating plate, place 10 gm of correctly weighed crude medicine (without first drying it). After inserting the above-mentioned quantityof medicine in the tared evaporating dish, dry for 5 hours at I05oC and weigh. Continue drying and weighing every hour or so until the difference between two consecutive weighings is less than 0.25 percent. When two successive weighings after drying for 30 minutes and chilling for 30 minutes in a desiccator show no more than 0.012 changes, the weight is said to be constant.[62]

Limit Test for Iron:

Standard ferric ammonium sulphate solution - Weigh 0.1726 gm ferric ammonium sulphate and dissolve in 10 ml 0.1 N sulphuric acid to make a volume of 1000 ml. This solution contains 0.02 gm. of Fe per mL.

Method:

Use 10 ml of the solution and transfer to a Nessler cylinder, or dissolve the prescribed amount of the material being analysed in 40 nil of water. Mix 2 mL of a 20% w/v solution of iron-free Citric acid with 0.1 mL of Thioglycollic acid, make alkaline with iron-free ammonia solution, dilute to 50 mL with water, and set aside for five minutes. Any colour that is created is not brighter than the normal colour.

Standard colour: In a Nessler cylinder, dilute 2 mL of standard iron solution with 40 mL water. Mix 2 ml iron-free citric acid (20% w/v) and 0.1m1 thioglycollic acid, make alkaline with iron-free ammonia solution, dilute to 50m1 with water, and let to stand for five minutes.

Determination of pH Values:

A pH metre with two electrodes, one made of glass and sensitive to hydrogenation activity, and the other a calomel reference electrode, was used to test the pH. At a temperature of 252°C, the test is performed.

Method:

Immerse the electrodes in the test solution and take a pH reading at the same temperature as the standard solutions

Partial analysis of Calcium Carbonate:

Varatika shell samples were pulverised to a mesh size of (-80). The carbonate content of the powdered samples was determined using a traditional wet chemical quantitative technique.

Calcium Estimation: In around 150 ml of water, dissolve a reasonable amount ofcalcium salt (about 0.05gm Ca). 4 mL 8 N potassium hydroxides, 0.2 gramme Patton and Reeder's indicator (containing ascorbic acid). Titrate to a pure blue end-point with
0.05 M. EDTA.

Table: Physico-Chemical Characters of different Kampillaka (Crudeform)Samples

S. No.	Name of the test	Sample No.1	Sample No.2	Sample No.3
1	Colour	Red (Some Grey Colour Particles)	Red (Some Grey Colour Particles)	Red
2	Appearance	Powder	Powder	Powder
3	Rubbing Over White Paper	Yellow Colour Mark	Yellow Colour Mark	Yellow Colour Mark
4	Moisture content	2.42% w/w	2.76% w/w	2.30% w/w
5	Total Ash	33.88% w/w	23.61% w/w	6.49% w/w
6	Water soluble extractive	3.18% w/w	3.83% w/w	2.83% w/w
7	Dilute Acid soluble extractive	7.55% w/w	8.11%.w/w	7.055% w/w
8	Identification of Iron	+Ve	+Ve	– Ve
9	Foreign Matter	3.02% w/w	1.98% w/w	1.49% w/w
10	Acid Insoluble Matter	92.45% w/w	91.89% w/w	92.95% w/w

Table: Physico-Chemical Characters of different Suddha *Kampillaka Samples*

S. No.	Name of the test	Sample No.1	Sample No.2	Sample No.3
1	Colour	Dark Red	Redish Grey	Red
2	Appearance	Powder form	Powder form	Powder form
3	Moisture Content	8.048% w/w	12.79% w/w	4.72% w/w
4	Total Ash	14.13% w/w	22.07% w/w	6.87% w/w
5	Water Soluble Extractive	16.34% w/w	3.99% w/w	4.1% w/w
6	Dilute Acid Soluble	17.33% w/w	9.91% w/w	10.20% w/w

7	Foreign Matter	0.035% w/w	3.52% w/w	1.99% w/w
8	Acid Insoluble Matter	82.67% w/w	90.09% w/w	89.80% w/w

Discussion

Raw materials (ingredients) for the formulations include drugs or therapeutic substances derived from plants, animals, and minerals. The meaning of the standard, the need for standardisation of crude drugs, the various factors to be considered while doing standardisation of crude drugs, such as collection of information from Ayurvedic drug manufacturing industries, complexity of crude drugs, volume of work involved, a multi-dimensional approach, guide lines to be followed in the use of these standards, complexity of the formulations, and so on,can all be found in the standardisation of crude drugs chapter. Lack of research data, specificity vs. sensitivity; technology ruggedness, focused testing, end-product analysis based on crude pharmaceuticals utilised, usage of reference crude drug samples, the involvement of the producer, good manufacturing procedures

The problems of replacements if they are utilised for the production of various medicines are explored in the chapter on standardisation of crude pharmaceuticals, as well as the need of using authentic raw medications for the manufacture of Ayurvedic medicines. The selection of raw drug identification in relation to pharmaceutical manufacture is based on the following criteria. According to the literature review, the crude pharmaceuticals utilised in the manufacture of Ayurvedic medicines are ofplant, mineral, and animal origin.

The quality of the completed product is determined by the quality of the crude pharmaceuticals used. As a result, in Ayurvedic Pharmaceutics, determining the real quality of crude medications is crucial. Then it was recommended that certain medications should be chosen for research. The pharmacological activity of authentic raw drug quality and the demand for such pharmaceuticals are also discussed. There are also details on the raw drug's origin, source, and collecting technique, as well as market trends. Each drug's origins is described in great detail. The design of Monograph was described in the chapter on parameter selection.

According to the fluctuation in the proportion of iron computed as Fe, Ash, Sample No.3 Kampillaka has all of the needed attributes. The bar diagram depicts the variance in moisture content, total ash, water soluble extractive, dilute acid soluble extractive, foreign matter, and acid insoluble matter of crude kampillaka samples.

1. Moisture Content

2. Total ash

3. Water soluble extractive

4. Dilute acid soluble extractive

5. Foreign Matter

6. Acid Insoluble Matter

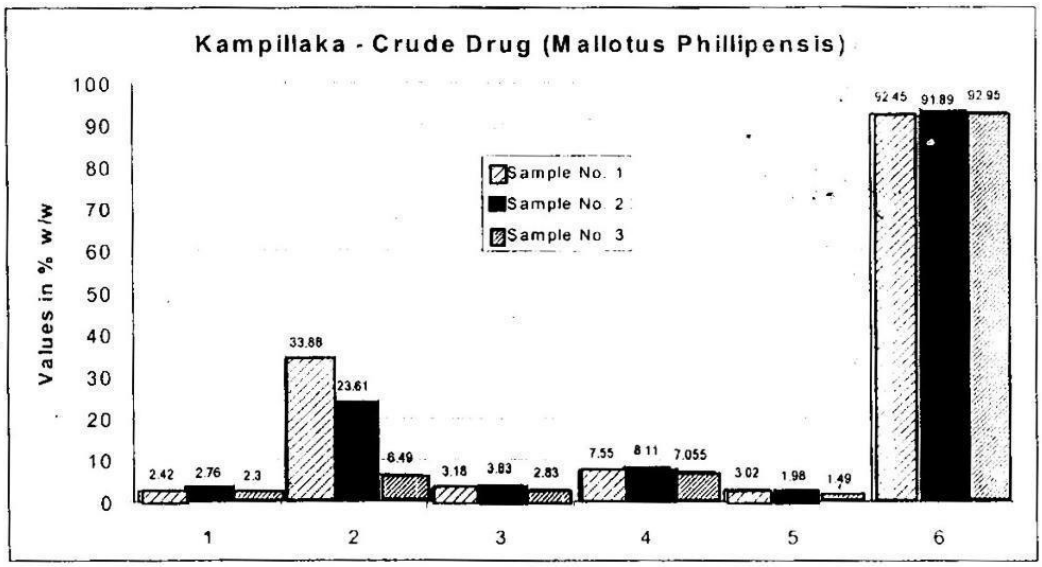

Figure : Kampillaka-Crude Drug (Mallotus Phillipensis)

The bar diagram depicts the variance in % moisture content, total ash, water soluble extractive, dilute acid soluble extractive, foreign matter, and acid insoluble matter of three purified samples of kampillaka.

1. Moisture Content

2. Total Ash

3. Water soluble extractive

4. Dilute Acid soluble extractive

5. Foreign Matter

6. Acid Insoluble Matter

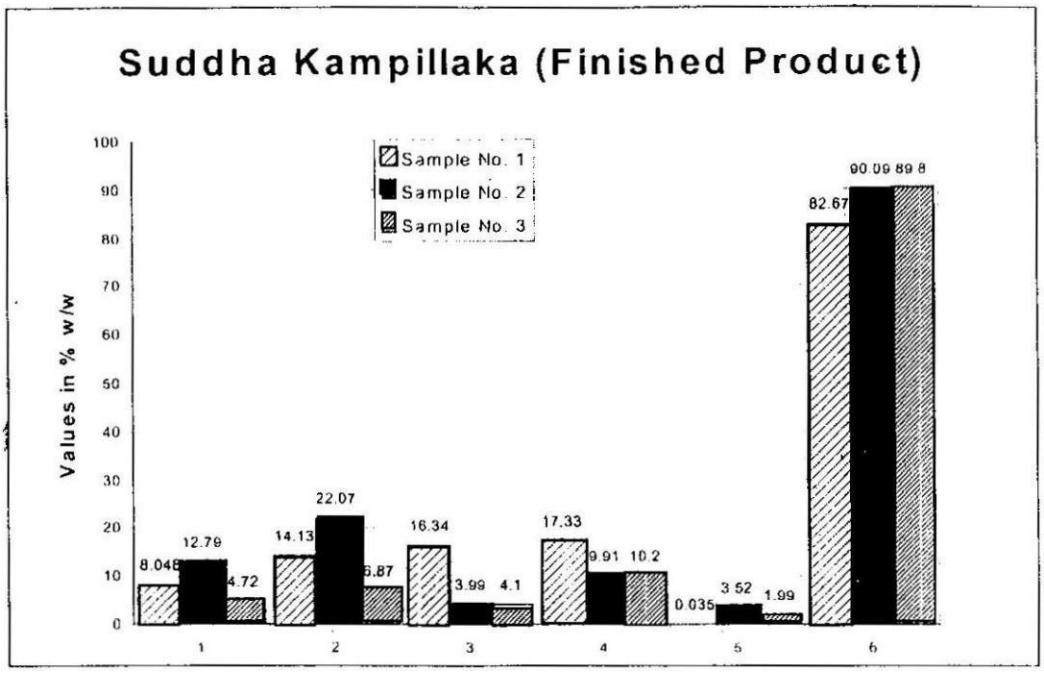

Figure : Suddha Kampillaka (Finished Product)

The Sample No.3 is regarded the finest quality since it has all of the above-mentionedcharacteristics of kampillaka.

Because it is simple and straightforward to identify crude medications using organoleptic properties, the organoleptic characters of top grade chosen crude drugs are also described in the following Monographs.

The current research focuses on the process of collecting certain crude medications, as well as identification using Ayurvedic literature and contemporary characteristics. Identification of replacements, adulteration, and distinction of such raw pharmaceuticals from genuine quality are all part of this research. Differentiation is accomplished by identifying parameters and other characteristics of the medicine. Drugs were also compared using photos. There include details on the raw drug identification, as well as test reports, observations, tabulations, and data from the research.

Conclusion

A significant number of methods to authenticate crude drugs have been addressed here. A simple method like organoleptic characteristics may hold good to authenticate certain drugs but some may require highly sophisticated techniques too, based on the

adulterants and similarity in the chemical constituents. So, it is in the hands of the researchers to choose the right method suitable for the drug of interest which would match the reference standard. Even before choosing the methods the raw materials should be confirmed with traditional practitioners. In addition, while utilizing chemical methods and other analytical tools it is mandatory to stick on to the latest validated techniques that suit the study. One needs to understand what type of raw material / formulation one is dealing with and the type of preparation to be evaluated. In spite of all these factors, the microbial contamination, pesticide residue and heavy metal analysis should be considered before processing the raw material for drug preparation. This is regarding the safety issue of drugs. This type of analysis is required when evaluating the authenticity of botanicals because these extraneous contaminants can cause undesired physiological effects. To conclude, more basic research should be carried out and many individuals should be trained with these authentication techniques to address this issue prevailing in crude drugs.

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