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A Study on Evaluation of Some Herbal Medicinal Products Microbial Qualities

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Abstract - In today's modern medical practise, there is a growing understanding and universal acceptance of the utilisation of herbal medications. It is a well-known truth that more than 80 percent of the world's population relies on herbal medications and products for healthy living, despite the fact that the majority of these applications are unconventional. There has been a rise in the overuse and adulteration of herbal products as a result of this popularity. This has resulted in frustration on the part of consumers and manufacturers alike, and in extreme circumstances, even death. Because of the immensity and breadth of the problem, the international market for herbal products is now unreliable. The purpose of this review is to inform those with an interest in herbal medicine of the need to create quality guidelines for the collection, handling, processing, and manufacture of herbal medicine and to use these parameters in the process of maintaining the safety of the global herbal market. These objectives will be accomplished by shedding light on these matters through this review. The methods of assuring herbal medications and products are of a high grade and complying with industry standards were also highlighted.

Keywords - Herbal medicine, standardization, Microbial Quality, Products.

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1. INTRODUCTION

People of all walks of life and eras have turned to herbal therapy throughout history, making it the oldest kind of treatment in the world still in use today. Humans have relied on the rich diversity of plant resources for food, clothing, housing, and medical treatment of a broad range of maladies since they first learned of their need on the natural world for a wholesome life. Diseases were treated by ancient humans utilising ingredients not normally found in their diet, such as plants, animal parts, and minerals. Their treatment selections were based on gut feelings, personal preference, and past practise. Through trial and error, early humans learned to distinguish between plants with beneficial benefits and those with no effect, and which mixtures or processing techniques yielded the most reliable and beneficial results. Even in prehistoric times, indigenous communities compiled extensive herb libraries with precise knowledge on each plant. Evidence of herbal remedies dating back some 60,000 years have been found at the burial site of a Neanderthal man unearthed in a cave in northern Iraq in 1960. Those artefacts were located in the cave. [1]

In point of fact, the herbal knowledge of indigenous people was a significant contributor to the pharmacopoeia of scientific medicine long into the twenty-first century. The knowledge of pharmaceuticals derived from plants developed over time and was passed down from generation to generation, so providing the groundwork for many different traditional medical systems all over the world. Herbal medicine is still widely practised in some local communities, making up a significant portion of their overall medical practise. Plants with medicinal properties are common in many parts of the world, but they are particularly numerous in tropical regions. It is believed that around one quarter of all contemporary medications is obtained in some way, either directly or indirectly, from higher plants. Therefore, the use of herbal medicine has resulted in the discovery of a number of novel pharmaceuticals as well as non-pharmaceutical compounds. [2]

1.1 Herbal Medicine

To put it simply, a herb is any plant or plant component used for its therapeutic, aromatic, or culinary benefits. Many different chemical substances are synthesised by herbs, which might be thought of as miniature biosynthetic chemical labs. Traditional herbal medicines are made from several parts of plants or crude plant extracts containing many ingredients that frequently interact synergistically together. Use of herbs or herbal

products for their therapeutic or medical purpose is known as herbal medicine or herbalism. They can be derived from any part of the plant, but leaves, roots, bark, seeds, and flowers are the most frequent. They can be ingested, injected, breathed, or administered topically. The presence of "active components" or "active principles," which are chemicals with recognised medical properties, varies widely depending on a wide range of parameters such as plant species, harvest time and season, soil type, herb preparation, etc. [3]

In order for a person to derive the intended benefit from herbal preparations, they will need to consume the necessary dose over the course of a certain amount of time. In spite of the widespread belief that the vast majority of herbal preparations are risk-free for human ingestion, some herbs, like the vast majority of biologically active chemicals, may be poisonous and cause unfavourable side effects.[4]

There is a lack of efficient apparatus to control industrial procedures and quality assurance. Herbal products are available for purchase without a prescription, however consumers may be unaware of the risks associated with using a subpar product. Because of this, having a medication with a well defined and stable composition is one of the most important conditions for the development of a high-quality pharmaceutical.Products derived from plants are notoriously unpredictable and subject to a wide range of influences, making it all the more important to maintain a consistent standard of quality if the sector is to thrive.[5]

1.2 Concept and Scope of Herbal Medicine Quality Control

All medications, whether they are synthetic or derived from plants, should be safe and effective, as a general rule. By "herbal remedies," we mean any drugs derived from plants or plant parts that have undergone little processing beyond harvesting, drying, and storage.This means that they exhibit some degree of adaptability. Differences in growth, location, and harvest time also contribute to this diversity. [6]

In the context of herbal medicine, "standardisation" refers to the process of prescribing a set of standards that ensures quality, effectiveness, safety, and repeatability through a predetermined set of qualitative and quantitative values and criteria.In this context, "standardisation" refers to the process of creating and adopting norms for certain technologies. In order to prescribe a particular herbal medication, it is necessary to establish certain criteria, which may be done through trial and observation. Consequently, standardisation is used in quality assurance. [7]

Herbal medicine quality is frequently affected by a number of factors that do not apply to synthetic pharmaceuticals. Such as:[8]

- Conventional herbal medicines often consist of a number of different ingredients.
- The nature of the driving force(s) is often shrouded in mystery.
- Suitable selective analytical methods or reference substances may not be available for purchase.
- Different plant materials have unique chemical and natural qualities.
- Chemically enhanced varieties and cultivars are real.
- The raw material comes from a variety of sources, and it varies in quality.

Herbal quality is also affected by how the plant is harvested, dried, stored, transported, and processed (for instance, the manner of extraction, the polarity of the extracting solvent, the instability of components, etc.).[9]

1.3 Critical Parameters Influencing Herbal Medicines Quality Control

i. Microscopic evaluation

Quality management of herbal treatments formerly depended exclusively on appearance; however, in recent years, microscopic evaluation has become vital for initial herb identification, for recognising minute particles of crude or powdered plants, and for identifying foreign elements and adulterants. Typically, a simple visual check with reading glasses or a magnifying glass is all that's required to verify that the plant in issue is really the desired species and that the proper area of the plant is being used. In some cases, however, a microscopic inspection is necessary for correctly identifying the species and checking that the correct anatomical part is being studied. [10]

ii. Foreign matter

Nothing else, including other parts of the same plant or other plants, should be used in addition to the part of the plant that is listed on the label when using medicinal herbs. Anything from mould and insects to sand and stones, toxic and harmful foreign materials, and chemical residues should be completely absent. Herbal treatments might potentially include potentially poisonous animal materials, such as insects, and "invisible" microbiological contaminants. [11]

iii. Ash content

Ash is quantified in two ways: first, as total ash, and second, as acid-insoluble ash, which remains after the plant matter has been burned. As a measure of the quantity of material remaining after combustion, total ash incorporates both acid-insoluble ash and ash formed from the plant portion itself. The latter is

what's left behind after you've burned the insoluble materials that remained after boiling the entire ash in diluted hydrochloric acid. The second method quantifies all forms of silica, but mainly sand and siliceous soil. [12]

iv. Heavy metals

Toxicity from metals may occur by accident or on purpose. Heavy metals including mercury, lead, copper, cadmium, and arsenic pose serious health concerns to humans and should be avoided in herbal medicine wherever feasible. These heavy metals may come from a variety of sources, including environmental contamination. We can make an informed prediction about how much of the harmful metal we will really ingest if we know how much of the metal is in the product and how much people are predicted to consume. [13]

1.4 Microbial Pollutants and Aflatoxins

The possibility for microbial contamination in therapeutic plants includes microorganisms including bacteria, fungi, and viruses. It stands to reason that the whole quality of herbal products and preparations is impacted by this microbial background, which in turn is influenced by a wide range of environmental factors. Thus, modern HACCP approaches have made risk assessment of the microbial load of medicinal plants a focal point. [14]

Mold and soil-borne bacteria are a common problem in herbal remedies. While a wide variety of bacteria and fungi make up the microflora found in nature, aerobic spore-forming bacteria are the most common. In the case of Escherichia coli or Salmonella spp., this is particularly true when harvesting, cleaning, drying, handling, and storage procedures are inadequate. Laboratory procedures for analysing possible microbiological contaminations are outlined in both well-known pharmacopoeias and World Health Organization guidelines. [15]

2. METHODOLOGY

The swatches of herbal medicine items utilised in this research were obtained from a variety of herbal medicine firms situated around the city of Pune. Furthermore, the herbal medications known as Pongamia pinnataherbal medicine, Al Mufeed herbal medicine, and Boerhaavia diffusaherbal medicine were purchased from a business that specialised in herbal treatments and was situated in Pune's old market district. These herbal medications were obtained from the spring natural medicine shop in Pune's Mumbai junction neighbourhood. Last but not least, a retail hawker along Solapur road in Pune town was visited to get a herbal cure known as Aegle marmelostraditional medicine. A through H were written on the labels that were applied to the herbal medicines and put in the refrigerator prior to the inspection, as indicated in Table 1.

2.1 Equipment, Materials, and Consumables

The herbal remedies were analysed using high-quality analytical reagents. Throughout the testing, only deionized water was utilised. Glassware was presoaked in weak Nitric acid for 24 hours before being rinsed in deionized water. The atomic absorption spectrometer (AAS) PG 990 was used to analyse the concentration of heavy metals, and the results were printed out. All equipment was checked and adjusted to factory settings before use.

Table 1: Herbal medicine info. NA: not available; FDA

SAMPLE	Herbal MedicinalProduct	NAFDAC Reg.No.[a]	Otherinfo.
A	Boerhaavia diffusa	A1-5578	Mfg. Date:02/03/2017, Exp.Date: 02/03/2018
B	Aegle marmelos	NA	
C	Butea monosperma	A7-2124L	Mfg. Date:09-2015 Exp.Date:09-2019 Batchno.:004
D	Datura metel	A7-2061L	Mfg. Date:11-03-2016 Exp.Date: 11-03-2019.
E	Eclipta alba Medicine	NA	
F	Jatropha curcas	NA	Mfg. Date:16/04/2018. Exp.Date: 16/04/2021
G	Nyctanthes arbor-tristis	NA	Mfg. Date:16/02/2019. Exp.Date: 16/02/2020
H	Phyllanthus Emblica	NA	Mfg. Date:11/01/2017. Exp.Date: 16/01/2019

2.2 The Physicochemical Parameter Determination of Herbal Medicines

i. Determination of temperature

A mercury-in-glass thermometer was used to take the temperature of each sample of herbal medication twice.

ii. Measurement of pH Values

The pH of the herbal medicine samples was measured using a digital pH metre after they were dissolved in water (WJEUIP, model PHS-25). The pH metre was double-checked with buffers 7 and 4 before taking each measurement, ensuring the correctness of the results.

3.3 Phytochemical Determination in Herbal Medicine

In order to carry out the methodology that has previously been outlined by Harborne, Trease and Evans, and Sofowora, the qualitative analysis of phytochemicals found in herbal medicines was carried out in this manner.

i. Flavonoids

A test tube containing 5 ml of the herbal medicine's aqueous solution was treated with two drops of 1% NH3 solution and then with concentrated H2 SO4. The yellow hue is characteristic of flavonoid, whose existence was confirmed by laboratory analysis.

ii. Terpenoid

In a test tube, we combined 5 ml of the herbal medicine sample's aqueous solution with 2 ml of CHCl3. A layer was then formed by adding 3 ml of concentrated H2 SO4 to the mixture. The presence of Terpenoid is indicated by the formation of an interface with a reddish brown hue.

iii. Cardiac glycosides

One drop of ferric chloride solution in 2 millilitres of glacial acetic acid was added to 5 millilitres of aqueous herbal combination. Over this, 1 ml of pure H2 SO4 was added. The presence of a deoxysugar, which is unique to cardenolides, is shown by a brown ring at the interface.

iv. Tannins

Into 5 ml of the herbal medicine samples, we plopped two drops of FeCl3 (0.1%). As a result of the presence of tannins, a brownish-green or blue-black coloration developed.

v. Reducing sugars

Five millilitres of sample was measured and added to a test tube with one millilitre of ethanol. Once they were both at a boil, 1 ml of Fehling solution A and 1 ml of Fehling solution B were each placed in their own test tube. This solution was added to the sample's aqueous solution and incubated for 10 minutes. Success may be seen in the precipitate's progression from yellow to orange to red.

vi. Alkaloids

- **Mayer's test:**A total of 5 ml of the sample was poured into a test tube, and two drops of Mayer's reagent were added to each of the four corners. Alkaloids cause a white, creamy precipitate to develop.
- **Wagner's test:**In a test tube containing a sample that was 5 millilitres in volume, two drops of Wagner's reagent were applied to the walls of the tube. If there is a brown precipitate present, then you can be certain that there is an abundance of alkaloids.
- **Dragendroff's test:**The presence of alkaloids may be determined by warming 5 ml of the sample with 2% H2SO4 for approximately 2 minutes, filtering it, and then adding 3 drops of Dragendroff's reagent. This causes the sample to become a brick red colour, which indicates the presence of alkaloids.

3.4 Samples of Herbal Medication are Digested

In order to analyse heavy metals in herbal remedies, a digestion procedure has become standard practise after it was recommended in the World Health Organization's (WHO) Guidelines for Evaluating the Quality of Herbal Medicines with Respect to Contaminants and Residues (2007). The samples were digested using a mixture of HNO3, HCl, and H2 O2 (30%) in the ratio of 3:1:1. One millilitre of the sample was placed in a 250 millilitre beaker and mixed with five millilitres of a newly prepared acid mixture consisting of concentrated HNO3, concentrated HCl, and 30% H2 O2. After the sample had been thoroughly dissolved, the mixture was cooked on a hot plate at a steady temperature of 150°C until it had turned into a clear solution. Before starting the digestion process, the beaker was washed with deionized water to prevent materials from evaporating. Samples were digested, then diluted with ionised water to a final amount of 50 mL before being analysed by atomic absorption spectroscopy.

4. RESULTS

Herbal medicine in the Pune Local Government region of MaharashtraState was subjected to physicochemical and phytochemical examination, and the results are reported in the Tables below.

Average temperatures of herbal remedies are shown in (Table 2). The average temperature of the herbal remedies that were analysed was 25.00 °C, which is consistent with the temperature of room-temperature aqueous solutions.

The findings of the measurements used to determine the herbal medicines' mean pH value are shown in (Table 3). The pH levels of the herbal remedies ranged anywhere from 1.06 to 11.32, with a mean value of 3.89 representing the entire collection.

Table 2: Herbal Medicine Consumption Temperature Mean in Pune, Maharashtra State.

Sample	Temperature(°C)
A	25.00 ± 0.02
B	25.00 ± 0.02
C	25.00 ± 0.02
D	25.00 ± 0.02
E	25.00 ± 0.02
F	25.00 ± 0.02
G	25.00 ± 0.02
H	25.00 ± 0.02

Table 3: In Pune, Maharashtra State, the average pH of herbal medicines was

Sample	pHValue
A	1.06 ± 0.02
B	1.52 ± 0.02
C	3.64 ± 0.02
D	2.20 ± 0.02
E	11.32 ± 0.02
F	2.54 ± 0.02
G	2.41 ± 0.02
H	3.15 ± 0.02

Table 4: Herbal Medicine's Phytochemical Metric Positive (+) and negative (-) examples are provided.

Sample	Phytochemicals						
	Tannins	Alkaloids	Saponins	Flavonoids	Terpenoid	CardiacGlycoside	Reducingsugars
A	–	+	+	–	+	–	+
B	–	+	–	–	–	+	–
C	+	+	+	–	–	+	+
D	+	+	+	+	–	+	+
E	–	+	+	–	–	+	–
F	+	+	+	+	+	+	+
G	+	+	+	+	+	+	+
H	+	+	+	+	–	+	+

Table 5: Heavy metal concentrations in Pune, Maharashtra State, herbal medicinal products (mg/Kg): mean SD. ND = not detected

Sample	Cd	Cr	Co	Fe	Pb	Ni	Zn
A	ND	4.72 ± 0.06	3.36 ± 0.08	340.49 ± 0.37	ND	10.37 ± 0.03	15.01 ± 0.14
B	ND	ND	0.64 ± 0.02	76.98 ± 0.05	8.25 ± 0.05	4.62 ± 0.02	18.28 ± 0.17
C	ND	ND	2.37 ± 0.11	62.01 ± 0.21	21.45 ± 0.10	10.27 ± 0.25	22.18 ± 0.18
D	ND	ND	3.72 ± 0.15	121.52 ± 0.32	15.36 ± 0.02	9.02 ± 0.08	21.26 ± 0.12
E	ND	ND	3.56 ± 0.14	78.11 ± 0.01	15.28 ± 0.12	10.46 ± 0.08	15.11 ± 0.11
F	ND	3.34 ± 0.02	ND	72.28 ± 0.21	6.34 ± 0.06	15.36 ± 0.14	23.13 ± 0.02
G	ND	22.67 ± 0.04	4.17 ± 0.06	130.82 ± 0.45	13.17 ± 0.01	11.74 ± 0.21	16.81 ± 0.04
H	ND	20.02 ± 0.03	4.51 ± 0.12	51.75 ± 0.16	24.10 ± 0.12	13.18 ± 0.10	17.89 ± 0.15

Table 6: Summarized Heavy Metal Concentrations (mg/Kg) in Pune, MaharashtraState, Herbal Medicinal Products Standard Deviation (SD) = Not Detected (ND) and.

TotalSamples	Cd	Cr	Co	Fe	Pb	Ni	Zn
Mean±SD	ND	11.68 ± 11.08	3.69 ± 1.72	105.42 ± 47.11	16.48 ± 6.69	10.84 ± 3.25	18.63 ± 3.10
Rangevalue	ND	2.25 ± 0.02 – 21.78± 0.01	0.63 ± 0.03 – 4.61 ± 0.12	51.75 ± 0.32 – 220.39 ± 0.37	6.34 ± 0.06 – 24.10 ± 0.12	4.62 ± 0.02 – 14.46 ± 0.34	15.01 ± 0.14 – 3.11 ± 0.02

The results of qualitative phytochemical screening suggest a rich diversity of chemicals with untapped medicinal potential. The samples included a broad range of different phytochemicals, such as Terpenoid, reducing sugar, flavonoids, alkaloids, saponins, tannins, and cardiac glycosides (Table 4). All eight of the herbal treatments examined by the phytochemical test had very high concentrations of at least one of the phytochemicals used in the study. Every single plant remedy was full with alkaloids. Sixty-two percent and seventy-five percent, respectively, of the herbal treatments were found to contain tannins. Flavonoids were found in almost half of the herbal supplements. Although terpenoids were found in 87.5% of the herbal treatments, they were not present in 62.5% of the products. It is possible that the presence of secondary metabolites in herbal medicines is responsible for their effectiveness in treating a broad variety of illnesses. The existence of alkaloids in herbal medicines was tested for in ten different drugs and an ethanol extract; these findings were consistent with the presence of alkaloids in herbal medicines, whereas the results for the other twenty-one medications were not.

Alkaloids are used in medicines to alleviate pain and lower fever due to their antibacterial and analgesic properties. Alkaloids were also found in a number of herbal beverages (antimalarial, antihypertensive, antidiabetic and antiobesity). Apart from (A) Lamgib traditional medicine and (B) Gbogbonise Epajebu, all samples included cardiac glycosides and saponins. These concoctions also used Cleistophoris patens, a plant whose leaf and stem bark were discovered to

contain cardiac glycosides and saponins. found that 90% of the herbal medicines tested included cardiac glycosides, and 20% had saponins. Saponins, like cardiac glycosides, may reduce cholesterol and alleviate heart conditions. In addition, no reducing sugars were found in either sample B or sample E, out of a total of eight different samples of herbal medication. All of the phytochemicals were present in samples F (Koko Fresh) and G (Zee Herbs), but sample D (Super 7) and sample H (Al-Mufeed) were missing only Terpenoid.There is evidence that terpenoids have anti-inflammatory, anti-viral, anti-malarial, cholesterol-synthesis-inhibiting, and anti-bacterial properties. Sample B, the herbal remedy with the lowest concentration of phytochemicals, tested positive for Alkaloids and cardiac glycosides.

5. CONCLUSION

In this analysis, we compare and contrast eight different herbal medicines for their efficacy. Some herbal medicines were found to have pH values outside of the permissible range; for example, Datura metel Herbal Medicine and Phyllanthus Emblica Medicine are both too acidic for human consumption, while Pongamia pinnata is too basic. The investigation also uncovered a number of phytochemicals (such as alkaloids, tannins, terpenoids, flavonoids, reducing sugars, cardiac glycosides, and saponins) that lend credence to the purveyors' claims of health benefits. Phytochemicals in these herbs are responsible for their medicinal effects, including analgesic, antimalarial, antibacterial, antifungal, and antidiuretic effects. Cobalt, Chromium, Iron, Lead, Nickel, and Zinc were all found in the heavy metals study, and some of them were at potentially dangerous concentrations based on guidelines established by pharmacovigilance organisations. There were no harmful levels of cadmium, however, in any of the herbal remedies tested. Some of these herbal medicines may not be safe for human ingestion since they contain dangerously high levels of at least one of the heavy metals that were tested for.

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