QUALITY ASSESSMENT OF SELF-PREPARED MOTHER TINCTURE FROM INDIGENOUS PLANT'S LEAVES STANDARD SAMPLE AS PER H.P.I. PARAMETERS



Submitted to

Madhya Pradesh Medical Science University, Jabalpur, Madhya **Pradesh**

In partial fulfillment of the regulation for the award of Doctor of Medicine in

Homoeopathic Pharmacy

by

Dr. Megha Kaithwal

Session (2021-2022)

Under the guidance of

Prof. (Dr.) Chetna pandey (HOD) DEPARTMENT OF HOMOEOPATHIC PHARMACY

> **Principal & CEO** Dr. S. K. Mishra

GOVT. HOMOEOPATHIC MEDICAL COLLEGE & HOSPITAL

AYUSH Campus, Beside Kaliyasot Dam, MACT Hills, Bhopal- 462003

Annexure: 1

To

The Chairman

Institutional Ethics Committee

Govt. Homoeopathic Medical College & Hospital

AYUSH Campus, beside kaliyasot dam, M.A.C.T Hills Bhopal,

Pin-462003

Madhya Pradesh

(Through Proper Channel)

Subject: Request for approval from the Institutional Ethics Committee to conduct a study for degree of M.D. (Hom.).

Respected Sir/Madam,

As I have proposed to conduct a study titled "QUALITY ASSESSMENT OF SELF PREPARED MOTHER TINCTURE FROM INDIGENOUS PLANT'S LEAVE AS PER H.P.I. PARAMETERS" at Government Homoeopathic Medical College & Hospital, Bhopal, Department of Homoeopathic Pharmacy in course M. D.(HOM.).

I request for an approval from the Institutional Ethics Committee I am here with enclosing the details of the dissertation project work I submit the following undertaking:

- 1. I will start the study after obtaining approval of the Institutional Ethics Committee.
- 2. I will get informed consent from the patients and maintain the confidentiality of the details and essentially obtain an informed consent from the family in case of post mortem studies.
- 3. I will carry out the work without detrimental to regular activities as well as without extra expenditure to the institution or the Government.
- 4. I will not deviate from the area of work for which I have applied for ethical clearance.
- 5. I will inform the Ethics Committee immediately, in the occurrence of any adverse events or serious adverse reactions.
- 6. I will abide by the rules and regulations of the institution.
- 7. I will complete the work within the specified period I have applied for and if any extension of time is required, I shall apply for permission again and continue the work.
- 8. I will submit the summary/report of the study/ project to the Institutional Ethics Committee on completion.
- 9. I will not claim funds from the institution while doing the work or on completion.
- 10. I understand that the members of the Institutional Ethics Committee have the right to monitor the study/project without prior information.

Thanking You.

Date: 00/00/2023 Place: Bhopal		
Signature: Name: Dr. Megha Kaithwal Date: 00/00/2023 Place: Bhopal Forwarded by: Guide: Prof. (Dr.) Chetna Pandey (HOD) College: Govt. Homoeopathic Medical College & Hospital, Address: AYUSH Parisar, Beside Kaliyasot dam, MACT hills, Bhopal Pin		
Date: 00/00/2023 Place: Bhopal Forwarded by: Guide: Prof. (Dr.) Chetna Pandey (HOD) College: Govt. Homoeopathic Medical College & Hospital, Address: AYUSH Parisar, Beside Kaliyasot dam, MACT hills, Bhopal Pin		Yours obediently,
Place: Bhopal Forwarded by: Guide: Prof. (Dr.) Chetna Pandey (HOD) College: Govt. Homoeopathic Medical College & Hospital, Address: AYUSH Parisar, Beside Kaliyasot dam, MACT hills, Bhopal Pin	Signature:	Name: Dr. Megha Kaithwal
Forwarded by: Guide: Prof. (Dr.) Chetna Pandey (HOD) College: Govt. Homoeopathic Medical College & Hospital, Address: AYUSH Parisar, Beside Kaliyasot dam, MACT hills, Bhopal Pin	Date: 00/00/2023	
Guide: Prof. (Dr.) Chetna Pandey (HOD) College: Govt. Homoeopathic Medical College & Hospital, Address: AYUSH Parisar, Beside Kaliyasot dam, MACT hills, Bhopal Pin	Place: Bhopal Forwarded by:	
Address: AYUSH Parisar, Beside Kaliyasot dam, MACT hills, Bhopal Pin		(HOD)
	College: Govt. Homoeopathic Medic	ical College & Hospital,
-462003(M.P.)		Caliyasot dam, MACT hills, Bhopal Pin
	–462003(M.P.)	

DETAILS OF THE SYNOPSIS SUBMITTED BY THE M.D.(HOM.) SCHOLARS FOR CLEARANCE FROM INSTITUTIONAL ETHICS COMMITTEE

Name of the College:	Government Homoeopathic Medical College & Hospital, Bhopal (M.P.)
Department:	Homoeopathic Pharmacy
Name of the Head of the Department:	Prof. Dr. Chetna Pandey (HOD)
(a) College name and address:	Government Homoeopathic Medical College & Hospital, Bhopal, Ayush parisar, Beside Kaliyasot dam, MACT hills, Bhopal 462003.
(b) Designation:	Professor and Head of Department
(c) Mobile No:	9425392477
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Name of the Guide/ Co – Guide:	Prof. Dr. Chetna Pandey (HOD)
(a) College name and address:	Government Homoeopathic Medical College & Hospital, Ayush parisar, Beside Kaliyasot dam, MACT hills Bhopal (M.P.)-462003.
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(c) Mobile No:	9827204815
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Name and address of the postgraduate scholars (in block letters)	Dr. MEGHA KAITHWAL 197 LIG VIKAS NAGAR A.B. ROAD DEWAS (MP) 455001
Date of admission to M.D. (Hom.) Course:	09/04/2022
Name of the Course:	M.D. (HOM.)
Subject:	HOMOEOPATHIC PHARMACY
Title of the topic:	QUALITY ASSESSMENT OF SELF-PREPARED MOTHER TINCTURE FROM INDIGENOUS PLANT'S FRESH LEAVES AS PER H.P.I. PARAMETERS

Introduction:

RESEARCH QUESTION: Review of parameters prescribed for standardization of mother tincture prepared from fresh leaves.

HYPOTHESIS:

Alternate Hypothesis H_a – The Quality of Self-prepared mother tincture from leaves has significant differences with parameters of the H.P.I. Null Hypothesis H_0 – The Quality of Self-prepared mother tincture from leaves has no significant difference with parameters of the H.P.I.

BACKGROUND AND JUSTIFICATION OF THE STUDY:

HOMOEOPATHIC DRUG PREPARED FROM LEAVES -

The word drugs obtain from French word drogue meaning a dry herb. Drug is a beneficial agent prepared pharmaceutically from standardized drug-substance according to the rules and regulations of H.P.I. which is enough capable of affecting the sensations and functions, even the structural change and may be even cause of end of loss of life, if continued for enough time of dose.

The scientific Group of WHO has explained drug as any substance or product that is used to modify or inspect the physiological system or pathological state for the satisfaction of recipients.

Powers of indigenous plants and of such as may be had in a fresh state in the most complete and certain manner by mixing their freshly expressed juice immediately with equal parts of spirits of wine of strength sufficient to burn in lamp. After this has stood a day and a night a close stoppered bottle and deposited the fibrinous and albuminous matters, the clear superincumbent fluid is then to be decanted off for medicinal use. 1 all fermentation of the vegetable juice will be at once checked by the spirits of wine with it and rendered impossible for the future, and the entire medicinal power of the vegetable juice is thus retained (perfect and uninjured) for ever by keeping the preparation in well- crocked bottles and excluded from the sun light. (1)

QUALITY CONTROL OF HOMOEOPATHIC MOTHER TINCTURES:

MOTHER TINCTURE: it is a drug pharmaceutically prepared from medicinal substance of vegetable and animal kingdom, by using alcohol as a vehicle with the help of emersion, maceration, and percolation, it is denote as θ .

Maceration: This method is used in such cases where the drug material requires a lot of time for the extraction of medicinal properties.

Maceration is used for gummy and mucilaginous drug substances.

Percolation: This method is adopted for the extraction of dried drugs, dry vegetable substances and other organic substances. Reduce them to powder form according to one of the grades of fineness as specified in the formula of respective drug monograph. Homeopathic raw material is prone to lot of variation due to several factors, i.e. why homoeopathic drug standardization is very crucial for safety, quality and efficacy of homoeopathic medicine. The identification, purity and quality of homoeopathic drug are determined by reference give in H.P.I. (2)

Standardization: Drug standardization encompasses evaluation of the Homoeopathic drugs in respect of their pharmacognostical, physic-chemical and pharmacological profile in order to study the various qualitative and quantitative characteristics of drug.

Standardization is a system that ensures a predefined amount of quantity, quality and therapeutic effect of ingredients in each dose. Homoeopathic medicine cannot be considered scientifically valid if the drug tested has not been authenticated and characterized in order to ensure reproducibility in the manufacture of the product. (3)

Justification for study:

In aphorism 264 it is mentioned "The true physician must be provided with genuine medicines of unimpaired strength, so that he may be able to rely upon their therapeutic powers; he must be able, himself, to judge of their genuineness." (4)

	In aphorism 265 sixth edition
	It should be a matter of conscience with him to be thoroughly convinced in every case that the patient always takes the right medicine and therefore he must give the patient the correctly chosen medicine prepared, moreover by him. (5)
Aims and Objectives:	Aim: This study aims to review the parameters prescribed for standardization of mother tincture prepared from fresh leaves specifically specific gravity and moisture content.
	Primary Objectives:
	 To determine the specific gravity and moisture content of self prepared mother tincture from fresh leaves.
	■ To chake the quality of self prepared mother tincture.
	Secondary Objective:
	■ To enhance individual skill in homeopathic pharmacy.
	■ To understand about genuineness of drug.
	■ To experience and learn the process of quality assessment.
Duration of the study:	12 months
Study design:	Exploratory experimental study.Comparative study.
Methodology (Material &	Sources of data: Data Collected by comparing quality parameter of leaves with Homoeopathic Pharmacopoeia of India.
Methods)	Number of samples:5 sample of leaves
	Source of Procuring: leaves available in botanical garden.
	Definitions used for study purpose:
	Homoeopathy: Homoeopathy is a medical system founded by the German physician Samuel Hahnemann in 1796. It follows seven fundamental principle and mainly based on "Similia Similibus Curentur" that means likes are cured by likes. In Homoeopathy the substances that cause symptoms of a disease in healthy people can be used to treat similar symptoms in sick people. Homeopathy uses attenuated diluted preparations of medicines from different sources, such as plants, minerals, or animal products, to stimulate the body's own healing response. (6)

Homoeopathic Pharmacy: Homoeopathic pharmacy is a subject concerned with identifying, collecting, preparing, preserving, evaluating and standardizing of Homoeopathic medicines. It also embraces the legal and regulation of dispensing of medicines

Homoeopathic Pharmacopoeia of India: It is an authoritative book by Government of India where official standardized monograph of individual Homoeopathic drugs are published after approval from Homoeopathic Pharmacopoeia Committee. (7)

Vehicles: Homoeopathic vehicles are inert substances that are used as excipients for active therapeutical materials. They are characterized as Solid liquid (Alcohol, distilled water etc.) and Semi-solid (Paraffin, beeswax etc.) depending on their nature. Alcohol is the most commonly used liquid vehicles in preparation and potentization of Homoeopathic medicines. (8)

Homoeopathic medicines: Homoeopathic medicines are materials that has therapeutic value and shows its effectiveness by proving on healthy individuals. It has the properties to cure the similar symptoms it produces on the disease state and they are potentized to different scales of Homoeopathic preparation. The standard medicines are recorded in Homoeopathic Materia Medica. (9)

Official standards: The purity, safety and efficacy standard of drugs based on scientific evidence and testing methods that are appeared in Official Pharmacopoeia.

BENEFITS: 1) The purity of drug can be determined.

2) We will know there is any difference in the drug substance standardization parameters.

LIMITATIONS: Disinfected laboratory

PROCEDURE: 1) The drug substance collected from different sources.

2) Mother tincture is prepared by the process of percolation and maceration.

3) Following test are conducted:

- 1) **Alcohol Content:** it is in the normal range indicates that proportion of the drug and vehicle in the tincture is as per pharmacopoeia and tincture has uniform drug strength.
- 2) **Weight per ml:** weight per ml of the liquids is the weight in gm of one ml of a liquid
- 3) **pH Value:** the ph value of an aqueous solution may be defined as the negative logarithm of the hydrogen ion concentration expressed in gram per litre 7 pH is neutral above it is alkalinity below it is acidity.
- 4) **Total solid**: the total solids means residue obtained when the prescribed amount of the preparation is dried to constant weight under the condition specified next.
- 5) **Thin Layer Chromatography**: Chromatography is most important laboratory technique in which the components of the mixture are separated on an absorbent in order to analyse identify purify and quantify the mixture of the component. (10)
- 6) Lambda Max (λ_{max})
- 7) **Moisture content:** it refers to amount of water present in a substance often expressed as a percentage of total weight.
- 8) **Specific gravity:** specific gravity is a dimensionless ratio that compares the density of substance to density of a reference substance at specific temperature.

REVIEW OF LITERATURE:

Mandal and Mandal book of Homoeopathic

https://www./ronenbeman.com

Medicinal herbs should be collected from their indigenous localities. Wild plants are

most efficacious and have most medicinal properties. If native herbs are available cultivated should never be used. Plants obtain from botanical garden

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3358962/

Healing with medicinal plants is as old as mankind itself. There is substantial proof that man and his hunt for remedies in nature have a long history together, including written records, preserved monuments, and even the original plant medicines. The knowledge of using medicinal plants came about as a result of man's longstanding battles with disease, which taught him to look for pharmaceuticals in the barks, seeds, fruit bodies, and other parts of plants. Modern pharmacology today includes a variety of plant-based medications that have been used for millennia and were known to ancient cultures. Modern science has recognized their active effect. Understanding the evolution of concepts surrounding the use of therapeutic herbs.

https://www.sciencedirect.com/science/article/pii/S26670313210 001 17

Traditional herbal remedies are used to cure a variety of acute and chronic illnesses with little to no hazardous side effects. They have played a significant part in health systems around the world. Numerous health issues, including as hypertension, cancer, diabetes mellitus, wound healing, asthma, pharyngitis, and tuberculosis, can be treated naturally with herbal plants. Because of their numerous pharmacological qualities, plants with high concentrations of bioactive phytomedicine components, such as alkaloids, flavonoids, tannins, and polyphenols, have been utilized to treat diseases. India has long been recognized as a rich source of therapeutic plants, and many herbal medicine methods are regarded as "living traditions." The significant Indian medicinal plants and their current state of medical plant study, however, are not the subject of a collective report.

https://tdtmviournal.biomedcentral.com/articles/10.1186/s4_0794-019-0095-7

Use of coca leaves at high altitudes, but there seems to be a general lack of knowledge among medical professionals and the public regarding coca, its history, and its fascinating and frequently flamboyant origins. The cultural and traditional importance to the Andean people is also not acknowledged. The coca leaves contain a variety of alkaloids, including cocaine, one of which has come to be known as a narcotic, giving rise to the false impression that coca is the same as cocaine. In an effort to clarify the distinctions between the two drugs as well as the causes of this common misunderstanding, this

article compares coca with cocaine. Coca leaves may never be scientifically "proven" to work or not work for travelers at altitude, but at the absolute least, a thorough understanding of coca.

https://www.sciencedirect.com/topics/agriculturalandbiological-sciences/nicotiana-tabacum

Annual cultivation of the significant crop Nicotiana tabacum L. People's ability to survive depends in large part on the harvest. Nematodes that parasitize plants are among the most damaging biotic factors in addition to abiotic limitations. Their control is the most difficult due to their complicated biology, host interactions, and wide host ranges. Plant parasite management has been carried out for decades using fumigant nematicides. However, due to environmental concerns, fumigant nematicides have been outlawed and phased out. Therefore, alternative biopesticides, cultivar resistance, and cultural practices serve as the foundation for nematode management measures. Here, we describe the biology, geographic distribution, degree of harm, and available management strategies for the majority of nematodes associated with tobacco.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3912882/

Gymnema sylvestre (Asclepiadaceae), sometimes known as "gurmar" because of its unique ability to breakdown sugar, is a wellknown plant in the Ayurvedic medical system. Gymnemasaponins, which are triterpene saponins also known as gymnemic acids, and gurmarin, a polypeptide, are the phytoconstituents in plants that have the ability to reduce the appetite for sweets. Along with being used for diuretic, anemia, osteoporosis, hypercholesterolemia, cardiopathy, asthma, constipation, microbial infections, indigestion, and anti- inflammatory conditions, the herb demonstrates a wide range of therapeutic actions that make it an effective natural treatment for diabetes. Due to its favorable effects on blood sugar homeostasis, ability to curb sugar cravings, and ability to encourage pancreatic regeneration, G. sylvestre has promising futures in the treatment of diabetes. Due to its remarkable potential for lowering body weight, blood cholesterol, and triglyceride levels, the plant extract is utilized in dietary supplements.

https://openagriculturejournal.com/VOLUME/10/PAGE/52/FULLTEXT/

Eucalyptus (*Eucapyptus* spp.), an evergreen tall tree native to Australia and Tasmania, has been used since ancient times by the aboriginal population for several purposes. In particular, the species *E. globulus* is widely used in the pulp industry, as well as for the production of eucalyptus oil extracted on a commercial scale in many countries as raw materials in perfumery, cosmetics, food, beverages, aromatherapy and phytotherapy. The 1,8-cineole (eucalyptol), the principal and the most important constituent extracted from eucalyptus leaves, demonstrated an antimicrobial and anti-inflammatory activities. Despite the fact that the healthy effects of eucalyptus have been well established by research, further studies are necessary to investigate

other prime effects of the plant and its possible implication in the treatment of a greater number of pathological conditions.

https://www.mdpi.com/1420-3049/25/3/534

Indigenous populations use plants as an important healthcare resource or remedy for different diseases. Here, isolated extracts from *Justicia* (family Acanthanceae) plant leaves used in Africa as remedy for anemia are characterized by different methods to assess composition and potential nutritional or therapeutic value. Extracts from *Justicia* leaves were obtained by aqueous extraction, with further isolation by centrifuging and high-performance liquid chromatography. Extracts and isolated compounds were characterized by ultraviolet—visible (UV-Vis) spectroscopy and inductively coupled plasma mass spectrometry (ICP-MS).

www.ncbi.nim.nih.gov

Herbs have always been the principal from of medicine in india. Medicinal plants have curative properties due to the presence of different composition, which are fount in secondary plant metabolites in one or more parts of these plants. Ficus religiosa. Commonly known as pepal belonging to the family moraceae is used traditionally as anti ulcer, antibacterial antibiotic, in the treatment of gonorrhea and skin diseases. Ficus religiosa is a Bo tree, which sheltered the buddha as he divined the truths. The present review aims to update information on its phytochemistry and pharmacological activities.

Ficus religious is a large perennial tree, glabrous when young, found throughout the plains of india upto 170m altitude in the Himalayas, largely planted as an avenue and roadside tree especially near temples. It is a popular bodhi tree and has got mythological, religious, and medicinal importance in indian culture since time immemorial. The plants have been used in Indian traditional medicine. For various range of ailments. Traditionally the bark is used as an antibacterial, antiprotozoal, antiviral, astringent, antidiarrhoeal, in the treatment of gonorrhea, ulcer, and the leaves used for skin disease. The leaves reported antivenom activity and regulates the menstrual cycle. In bangladesh it has been used in various diseases such as cancer, inflammation, or infactious diseases. In case of high fever, its tender branches are used as toothbrush. Fruits are used as laxatives. Latex is used as atonic. And fruit powdre is used for asthma.

The pharmacological studies on ficus religiosa with live Ascaria demonstrated a lethal effect at concentrations reduced to 0.05% latex in physiological saline solution. It has been accepted that anthelmintic activity is due to a proteolytic fraction called ficin. It is due to evident from above that methanolic exteacts of ficus religiosa possibly exerted anthelminntic effect because of ficin.

Inclusion	As per H.P.I. Parameters
Criteria:	1. Lambda max (λ _{max})
	2. Total Solid
	3. Alcohol content
	4. pH Value
	5. Weight/ml
	6. TLC
	7. Moisture content
	8. Specific gravity
Exclusion Criteria:	High performance Thin Layer Chromatography (HPTLC)
Observation:	Will be observed and analysed after the completion of study.
Result:	After completion of study.
Conclusions:	Will be analysed after completion of dissertation work.
Appendix:	
References	1. Mandal, P. P., & Mandal, B. (2012). A textbook of homoeopathic
(Vancouver style)	pharmacy (3rd ed.). New Central Book Agency.
	2. https://pinesherbals.com/new-blog/2017/8/10/maceration-vs-
	percolation-an-important-distinction
	3. https://www.wallstreetmojo.com/standardization/
	4. https://organonofmedicine.com/aphorism-264/
	5. https://organonofmedicine.com/aphorism-265/

	6.	https://www.webmd.com/balance/what-is-homeopathy
	7.	https://www.ccrhindia.nic.in/admnis/admin/showimg.aspx?ID=1253
	8.	Homoeopathic pharmacopeia of India vol-I.1971 page 202
	9.	https://health.osu.edu/health/general-health/homeopathy
	10.	pcimh.gov.in/WriteReadData/RTF1984/Homeopathypart1.pdf
	11.	Homoeopathic pharmacopeia of India vol-VI.1990 page 216
Questionnaire (If required):	As pe	er study
Master Chart Performa:	As pe	er study
Statistician Certificates		
Recommendation letter of Institution's head of other Research Institutes associated with the study certificate (If required):		
Signature of the scholar & date:		
Remark of the Guide/Co Guide (Recommended/ not		

Signature of the guide/Co Guide & date:	
Signature of the Head of the Department with date & seal:	_
Signature of the principal of the collage with date and seal	_

RECOMMENDATION OF THE HEAD OF THE DEPARTMENT OF HOMOEOPATHIC PHARMACY

This is to certify that the dissertation/study titled "QUALITY ASSESSMENT OF SELF-PREPARED MOTHER TINCTURE FROM INDIGENOUS PLANT'S FRESH LEAVES AS PER H.P.I. PARAMETERS" by Dr. Megha Kaithwal in course M.D. (Hom.) at Government Homoeopathic Medical College & Hospital, Bhopal will be doneaccording to the regulations of the Institutional Ethics Committee and I recommend it for acceptance.

Date:

Place: Bhopal

Signature

PROF. (Dr.) CHETNA PANDEY

Head of Department

Department of Homoeopathic Pharmacy

Government Homeopathic medical College & hospital, Bhopal (M.P) AYUSH Parisar Beside kaliyasot dam MACT hills Bhopal,462003

RECOMMENDATION OF THE GUIDE

This work "QUALITY ASSESSMENT OF SELF-PREPARED MOTHER TINCTURE FROM INDIGENOUS PLANT'S FRESH LEAVES AS PER H.P.I. PARAMETERS" undertaken by Dr. Megha Kaithwal in course M.D. (Hom.)Homoeopathic Pharmacy at Government Homoeopathic Medical College & Hospital Bhopal M.P., will be under my supervision and I ensure that the scholar willabide by the rules of Institutional Ethics Committee.

Date:

Place: Bhopal

Signature

HOD. (Dr.) Chetna Pandey

Department of Homoeopathic Pharmacy

Government Homeopathic medical College & hospital, Bhopal (M.P) AYUSH Parisar Beside Kaliyasot dam MACT hills Bhopal,462003