UINADS:SFI/2020/KC/1.0

FORMULARY SPECIFICATION

OF

AYUSH KUṬINĪR CŪRAṆAM

THE SIDDHA FORMULARY OF INDIA

सत्यमेव जयते

Government of India
Ministry of AYUSH
Pharmacopoeia Commission for Indian Medicine &Homoeopathy
2020

PDH…….

UINADS: SFI/2020/KC/1.0

On behalf of: : Government of India
Ministry of AYUSH,
AYUSH Bhawan, B-Block,
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FOREWORD

PREFACE

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LEGAL NOTICES

1. In India, there are laws dealing with certain substances which are the subject of the specifications of formulations included in the Siddha Formulary of India. These specifications should be read subject to the restrictions imposed by these laws wherever they are applicable.
2. It is expedient that enquiry be made in each case in order to ensure that the provisions of any law are being complied with.
3. In general, the Drugs and Cosmetics Act, 1940; the Dangerous Drugs Act, 1930; the Poisons Act, 1919; Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; the Narcotic Drugs and Psychotropic Substances Act, 1985 and the Biodiversity Act, 2002; all as amended from time to time, alongwith the Rules framed thereunder, should be consulted to ensure that the provisions of such laws are being complied with.
4. The Class of Formulation and the Formulation itself published herein have been introduced as a *sui generis* provision in wake of outbreak of COVID-19 pandemic and shall not to be generalised or replicated in any other context.
5. Under the Drugs and Cosmetics Act, the Siddha Formulary of India, represented by its Parts is the book of standards for substances included therein and such standards are official. If considered necessary, these standards can be amended and only the Pharmacopoeia Commission for Indian Medicine & Homoeopathy on behalf of Ministry of AYUSH, Government of India is authorised to issue such amendments. Whenever such amendments are issued, the specific Siddha Formulary of India intended thereby would be deemed to have been amended accordingly.

GENERAL NOTICES

Title: The title of the document is "Formulary Specifications of Ayush Kuṭinīr Cūraṇam" with Unique Identification Number for AYUSH Drug Standards (UINADS):SFI/2020/KC/1.0. Wherever the UINADS:SFI/2020/KC/1.0 and/or its subsequent version(s) are referred, it stands for "Formulary Specifications of Ayush Kuṭinīr Cūraṇam" and for the Supplements or Amendments thereto.

UINADS: Unique Identification Number for AYUSH Drug Standards is the specific identity assigned to each Pharmacopoeial monograph or Formulary specification published by PCIM&H. In case of Formulary specification of Formulation, the first fragment of the UINADS is the acronym of the Formulary under concern i.e. Siddha Formulary of India (SFI) in given case. Second fragment separated by a slash (/) and denoted in Arabic numeral, specifies the four-digit calendar year in Christian Era in which this solitary monograph is published for first time. Third fragment separated by a slash (/) denotes the acronym of the Class of Formulation i.e. Kuṭinīr Cūraṇam(KC) in given case. Fourth fragment separated by a slash (/) and denoted in Arabic numeral denotes the serial number assigned to the given specification while last fragment separated by a period (.) and denoted in Arabic numeral denotes the version of the document under concern. With amendments as made time to time, the version number in the UINADS i.e. last Arabic numeral succeeding the period (.) shall go on increasing progressively.

Name of the Formulation: The name given on top of each Formulary Specification is as approved by Competent Authority and will be considered *Official*.

Official: All names of drugs, formulations and processes mentioned in the Formulary will be deemed to be Classical and would be synonymous with the word 'Official' and apply to any statement included in the General Notices, Monographs and Appendices of the Formulary.

Methods of Preparation: The General Method of Preparation has been given immediately preceding the individual Formulation. When there is a statement in the body of a specification of the formulation that a substance will have to be prepared by a certain method, it indicates that the general method is modified to that extent. In some cases, there are more than one methods of preparation and new methods are constantly being evolved. What is intended is that, irrespective of the method of preparation, the resulting substances must comply with Formulary requirements.

Ingredients and Processes: Formulations are to be prepared from individual ingredients that comply with the requirements for those individual ingredients for which monographs are provided in the volumes of Siddha Pharmacopoeia of India (SPI), Part-I. Where Water is used as an ingredient, it should meet the requirements of *water* as specified in the appendix therein, unless specified otherwise. In general, all the ingredients used are required to be free from insects, other foreign matter, from animal excreta, and to show no abnormal odour, colour, sliminess, mould or other evidence of deterioration.

Specification for each Formulation includes its full composition together with special directions for its preparation if any. Such composition and directions are intended for preparation of small quantities for short-term supply and use. When so prepared, no deviation from the stated composition and directions is permitted. However, if such a preparation is manufactured on a large scale with the intention of sale or distribution, deviations from the directions given are permitted, provided that the same ratiois maintained as stated in the specification, with the ingredients complying with its compendial requirements, and also ensuring that the final product complies with all of the requirements stated in the Formulation Composition for the specific formulation.

If a preparation is intended to be stored over a period of time, deterioration due to microbial contamination may be inhibited by the addition to the formulation of a permitted preservative.

In such circumstances, the label should state the name of the preservative and the appropriate storage conditions.

Formulary Specification: Each Specification begins with quoting the source reference followed by the Formulation Composition giving the scientific names of the drugs and respective form of the ingredient intended to be entered to the formulation alongwith a brief account of the Method of Preparation if needed. For drugs of plant origin, the part used has also been specified.

The form and quantity/proportion of each ingredient mentioned in the Formulation composition are as intended to be entered to the formulation after whatever processing intended. It is the onus of manufacturer to ensure addition of exact quantity/proportion of each ingredient to the Formulation and shall not be mistaken with the quantity/proportion of the raw material as such.

Standards: For statutory purposes, unless otherwise specified,the following shall be considered *Official Standards*: Title i.e. Name of Formulation and Formulation Composition.

Capital Letters in the Text: The names of the Pharmacopoeial substances, preparations and other materials in the text are printed in capital initial letters and these infer that materials of Pharmacopoeial quality have been used.

Italics: Italic types are used for Scientific names of the plant drugs and microorganisms, and for some sub-headings and certain notations of the chemical names. Italic types have also been used for words which refer to solvent system in TLC procedure, reagents and substances, processes covered under Appendices. Chemicals and Reagents and Substances of Processes in Appendices have also been printed in Italics.

Powders: Ingredients added to a formulation are often required to be comminuted to various sizes ranging from very coarse to very fine, depending on their use in a formulation. Where they are added to processed formulations, the size of sieve restricting the particle size is given in the monograph, but does not constitute an analytical standard. But where formulations are themselves powders, or where extracts are prepared either as solids (*Sattu*) or liquids/ Kuṭinīr, particle size is an analytical standard and limits are recommended in the monographs, as follows:

Kuṭinīr Cūraṇam: Keeping the traditional practice of '*oṉṟiraṇṭākaiṭittal'* as the size range for such formulations, the standard is as follows: 'All particles shall pass through 710 μm IS Sieve (sieve number 22), and not more than 10 per cent through 355 μm IS Sieve (sieve number 44). The product will be in form of coarse powder from which extemporaneous preparations of Kuṭinīr (decoctions) by patients themselves can be recommended.

The particle sizes are given in terms of sieve sizes using the latest revision of the Bureau of Indian Standards (BIS) sieve sizes, and for the users' convenience, the equivalents or nearest equivalent number of the earlier BIS have also been given in the relevant Appendix.

Weights and Measures: The metric system of weights and measures is employed. Weights are given in multiples or fractions of a gram (g) or of a milligram (mg). Fluid measures are given in multiples of fraction of millilitre (ml). The amount stated is approximate but the quantity actually used must be accurately weighed and must not deviate by more than 10 per cent from the one stated.

When the term ‘drop’ is used, measurement is to be made by means of a tube which delivers 20 drops per gram of distilled water at 15°.

Temperature: Unless otherwise specified, all temperatures refer to centigrade (Celsius) thermometric scale and all measurements are made at 25°.

Solutions: Unless otherwise specified, all solutions are prepared with *Purified Water*.

Filtration: Where it is directed to filter, without further qualification, it is intended that the liquid be filtered through suitable filter paper or equivalent device until the filtrate is clear.

Therapeutic use(s): Therapeutic uses of the Formulation mentioned in this Specification are as approved by the Competent Authority.

Dose(s): The doses mentioned in this Formulary Specification are in the metric systemand are intended merely for general guidance and represent, unless otherwise stated, the average range of quantities per dose which is generally regarded suitable by clinicians for adults only when administered orally. They are not to be regarded as binding upon the prescribers.

The medical practitioner will exercise own judgment and act on own responsibility in respect of the amount of the formulation he/she may prescribe or administer or on the frequency of its administration. If it is usual to administer a medicine by a method other than by mouth, the single dose suitable for that method of administration is mentioned.When, however an unusually large dose appears to have been prescribed, it shall be the duty of the pharmacist or dispenser to satisfy himself/herself that the prescriber’s intention has been correctly interpreted.

Storage: Statement under the heading ‘Storage’ constitutes non-mandatory advice. The substances and preparations are to be stored under conditions that prevent contamination and, as far as possible, deterioration. The container and its closure must not interact physically or chemically with the substance which it holds so as to alter the strength, quality or purity of the substance. If interaction is unavoidable, the alteration must not be so significant as to bring the substance below the prescribed requirements. Precautions that should be taken in relation to the effects of the atmosphere, moisture, heat and light are indicated, where appropriate, in the individual monographs.

Specific directions are given in the monograph with respect to the temperatures at which Pharmacopoeial articles should be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms.

Cold: Any temperature not exceeding 8°and usually between 2° and 8°. A refrigerator provides a cold place in which the temperature is maintained thermostatically between 2° and 8°.

Cool: Any temperature between 8° and 25°. An article for which storage in a cool place is directed may, alternately, be stored in a refrigerator, unless otherwise specified in the individual monograph.

*Room temperature:*The temperature prevailing in a working area

Warm: Any temperature between 30° and 40°

Excessive heat: Any temperature above 40°

Protection from freezing: Where, in addition to the risk of breaking of the container, freezing results in loss of strength or potency or in destructive alteration of the characteristics of an article, the label on the container bears an appropriate instruction to protect from freezing.

Storage under non-specific conditions: Where no specific storage directions or limitations are given in the individual monograph, it is to be understood that the storage conditions include protection from moisture, freezing and excessive heat.

Containers: The container is the device that holds the article. The immediate container is that which is in direct contact with the article at all times. The closure is a part of the container.

The container is designed so that the contents may be taken out for the intended purpose in a convenient manner.

It provides the required degree of protection to the contents from environmental hazards.

The container should not interact physically or chemically with the article placed in it so as to alter the strength, quality or purity of the article beyond the official requirements.

Prior to its being filled, the container should be clean. Special precautions and cleaning procedures may be necessary to ensure that each container is clean and that extraneous matter is not introduced into or onto the container.

Light-resistant Container: A light resistant container protects the contents from the effects of actinic light by virtue of the specific properties of the material of which it is made. Alternatively, a clear and colourless or a translucent container may be made light-resistant by means of an opaque (light-resistant) covering and/or stored in a dark place: in such cases, the label on the container should bear a statement that an opaque covering or storage in dark place is needed until the contents have been used up.

Well-closed Container: A well-closed container protects the contents from extraneous contamination and from loss of contents under normal conditions of handling, shipment, storage and distribution.

Tightly-closed Container: A tightly-closed container protects the contents form contamination by extraneous liquids solids or vapours, and from loss or deterioration of contents from effervescence, deliquescence or evaporation under normal conditions of handling, shipment, storage and distribution.

Single Unit Container: A single unit container is one that is designed to hold a quantity of the drug product intended for administration as a single finished device intended for use promptly after the container is opened. The immediate container and/or outer container or protective packaging is so designed as to reveal evidence of tampering, if any.

Multiple Unit Container: A multiple unit container is a container that permits withdrawals of successive portions of the contents without changing the strength, quality or purity of the remaining portion.

Tamper-evident Container: A tamper-evident container is fitted with a device or mechanism that reveals irreversibly whether the container has been opened.

Labelling: In general, the labelling of drugs and pharmaceuticals is governed by the Drugs and Cosmetics Act, 1940 and Rules thereunder.

INDO-ROMANIC EQUIVALENTS FOR TAMIL ALPHABETS

அ	A	a/*a*
ஆ	Ā	ā/*ā*
இ	I	i
ஈ	Ī	ī
உ	U	u
ஊ	Ū	ū
எ	E	e
ஏ	Ē	ē
ஐ	AI	ai
ஒ	O	o
ஓ	Ō	ō
ஔ	AU	au
ஃ	K̲	k̲

க்	K	k
ங்	Ṅ	ṅ
ச்	C	c
ஞ்	Ñ	ñ
ட்	Ṭ	ṭ
ண்	Ṇ	ṇ
த்	T	t
ந்	N	n
ப்	P	p
ம்	M	m
ய்	Y	y
ர்	R	r
ல்	L	l
வ்	V	v
ழ்	L̲	l̲
ள்	Ḷ	ḷ
ற்	R̲	r̲
ன்	N̲	n̲

ABBREVIATIONS FOR TECHNICAL TERMS AND PLANT PARTS

°C	-	-	°
gram(s)	-	-	g
hour(s)	-	-	h
kilogram(s)	-	-	kg
Kuṭinīr Cūraṇam			K. Cū.
litre(s)	-	-	l
micron	-	-	µ
milligram(s)	-	-	mg
millilitre(s)	-	-	ml
Minute(s)	-	-	min
quantity sufficient	-	-	Q.S.
Fruit			Fr.
Leaf			Lf.
Rhizome			Rz.
Stem Bark			St. Bk.

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Involvement of Dr. Anupam Maurya, Scientific Officer (Phyto-chem.), Dr. (Ms.) Nitin Rai, Scientific Officer (Pharmacognosy), Dr. Sweta Mohan, Scientific Officer (Inorganic chem.) and Sh. Ashish Kumar, Pharmacopoeial Associate (Pub.) is also placed on record.

In last, thanks are due to all those who have directly or indirectly contributed in bringing out this publication.

Sd/-
Dr. D. C. Katoch
Director I/c, PCIM&H

KUṬINĪR CŪRAṆAM

Definition

Certain drugs or combination of drugs are made into coarse powder *oṉṟiraṇṭāka iṭittal* and kept for preparation of Kuṭinīr Cūraṇam.

Method of preparation

Drugs are cleaned and dried. They are coarsely powdered to completely pass through 710 µm IS sieve (sieve number 22) and not more than 10 per cent pass through 355 µm IS sieve (sieve number 44), weighed as per formula, and then mixed well.

Characteristics

The characteristic features aredried and coarsely powdered.

Directions for Preparation of Ayush Kuṭinīr as anInstant Hot Infusion:

Add 3 g of Ayush Kuṭinīr Cūraṇam to 150 ml (approx.1 tea-cup) of boiling water, mix well and allow to rest for 5 min. Strain through muslin cloth/tea strainer.

Note: The specific directions for preparation of Ayush Kuṭinīr are exclusive to the given formulation and shall not be applicable to other classical *Kuṭinīr* formulations.

Mode of administration:

Consume while luke warm.Vellam(jaggery)/ Tirāṭcai(black raisins) and/or Elumiccamcāru(lemon juice) may also be added as per taste, while consuming.

Storage

It should be stored in suitable air-tight container protected from light and moisture.

AYUSH KUṬINĪR CŪRAṆAM

Reference: Ministry of AYUSH's directive No. Z.25023/09/2018-2020-DCC (AYUSH), dated 24.04.2020

Formulation composition:

1.	Tulsi (Tuḷaci SPI)	*Ocimum tenuiflorum*	Lf.	K.Cū.	4 parts
2.	Dalchini (Ilavaṅkapaṭṭai SPI)	*Cinnamomum verum*	St. Bk	K.Cū.	2 parts
3.	Sunthi (Cukku SPI)	*Zingiber officinale*	Rz.	K.Cū.	2 parts
4.	Krishna Marich (Miḷaku SPI)	*Piper nigrum*	Fr.	K.Cū.	1 part

Dose:

3 g once or twice a day in form of instant hot infusion as specified

Directions for Preparation:

Add 3 g of Ayush Kuṭinīr Cūraṇam to 150 ml (approx.1 tea-cup) of boiling water, mix well and allow to rest for 5 min. Strain through muslin cloth / tea strainer.

Note: *The specific directions for preparation of Ayush Kuṭinīr are exclusive to the given formulation and shall not be applicable to other classical Kuṭinīr formulations.*

Mode of administration:

Consume while luke warm. Vellam (jaggery) / Tirāṭcai (black raisins) and/or Elumiccamcāru (lemon juice) may also be added as per taste, while consuming.

Important Therapeutic uses:

Ceripuṇṭākki, Irumal, Iraippu, Uṭaluramākki, Mūkkaṭaippu

Precaution:

Pregnant women should take the formulation under medical supervision.

APPENDIX-1

1A) Ingredient drugs of plant origin (in alphabetical order of official names, followed by part(s) used)

Sl. No.	Official Name	Alternate name appearing in the formulary	Botanical Names	Part Used
1.	Cukku	Sunthi	*Zingiber officinale* Rosc.	Rz.
2.	Ilavaṅkapaṭṭai	Dalchini	*Cinnamomum verum* J. Presl syn. *Cinnamomum zeylanicum* Blume.	St. Bk
3.	Miḷaku	Krishna Marich	*Piper nigrum* L.	Fr.
4.	Tuḷaci	Tulsi	*Ocimum tenuiflorum* L. syn. *Ocimum sanctum* L.	Lf.

1(B) Ingredient drugs of plant origin (in alphabetical order of Scientific name / English equivalent)

Sl. No.	Botanical Names	Official Name	Part Used
1.	*Cinnamomum verum* J. Presl syn. *Cinnamomum zeylanicum* Blume.	Ilavaṅkapaṭṭai	St. Bk
2.	*Ocimum tenuiflorum* L. syn. *Ocimum sanctum* L.	Tuḷaci	Lf.
3.	*Piper nigrum* L.	Miḷaku	Fr.
4.	*Zingiber officinale* Rosc.	Cukku	Rz.

APPENDIX-2

DISEASES/TECHNICAL TERMS AND THEIR ENGLISH EQUIVALENTS

Disease/Technical Terms	English Equivalent
Cerippuṇṭākki	enhancing digestion
Iraippu	dyspnoea
Irumal	cough
Mūkkaṭaippu	cold/catarrah
Uṭaluramākki	health promoting

APPENDIX-3

REFERENCE

F. No. Z 25023 /09/2018-2020-DCC (AYUSH)

Government of India

Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

Dated: 24th April, 2020.

Subject: 'Ayush health promotion product' for commercial manufacturing by Ayurveda, Siddha and Unani drug manufacturers- reg.

Considering the importance of immunity boosting measures in the wake of COVID -19 outbreak, Ministry of AYUSH intends to promote the use of following ready-made Ayush formulation in the interest of health promotion of the masses, which has been endorsed by the Hon'ble Prime Minister during his address to the nation on the Constitution Day, 14th April, 2020. The formulation comprises of-

i)	Tulsi (Ocimum sanctum)	Leaves	4 parts
ii)	Dalchini (Cinnamomum zeylanicum)	Stem bark	2 parts
iii)	Sunthi (Zingiber officinale)	Rhizome	2 parts
iv)	Krishna Marich (Piper nigrum)	Fruit	1 part

2. Method of preparation and use: Take all the ingredients in dry form as per standards laid down in Ayurvedic Pharmacopoeia and make coarse powder. Make sachets or tea bags each of 3 grams of powder or 500 mg. tablet of aqueous extract, to be consumed like tea or hot drink by dissolving in 150 ml of boiled water, once or twice daily. Gud (Jaggery) / Draksha (Resins) and/or Lemon Juice can be added while consuming the formulation.

3. The formulation may be manufactured and sold in generic name as 'Ayush Kwath' or 'Ayush Kudineer' or 'Ayush Joshanda'.

4. State/UT Governments are hereby requested to direct the AYUSH Licensing Authorities to consider granting license/approval for manufacturing of above-mentioned formulation to the interested licensed Ayurveda / Siddha /Unani drug manufacturers in accordance with the provisions of Drugs & Cosmetics Rules, 1945.

Adviser (Ay.) and Head, Drugs Policy Section

To

Principal Secretaries/Secretaries (Health/AYUSH) of all States/UTs.

Copy to:

i) All State/UT Licensing Authorities and Drug Controllers of AYUSH

ii) ASU Drug Manufacturers