

1. TITLE: ZINGIBER OFFICINALE ROSCOE FRESH RHIZOME FOR USE IN TRADITIONAL MEDICINE SPECIFICATION**Last Date of Comments: 27.01.2024**

S.No	Basic Details	Clause/Subclause No.& Attachment	Paragraph No./Figure No./Table No.	Type of Comment	Comments/Suggestions along with Justification for the Proposed Change	Proposed Change/Modified Wordings	Recommendations of the Committee
1.	Name: Monika. N	3.1.2		Editorial	For precise authentication, Detailed macroscopy, microscopy and powder microscopy with pictorial illustration can be included as mentioned in the Indian standard 18094:2022	Detailed macroscopy, microscopy and powder microscopy with pictorial illustration can be included	As suggested by Ayush Division Council, the draft is prepared by referring the Pharmacopeial Publications by PCIMH. Any addition in the pharmacopeia will be included in subsequent revisions of this Indian standard.
		3			To determine its quality and identity, HPTLC fingerprinting data with markers and HPLC quantification of marker are necessary.	HPTLC and HPLC quantification of total zingiberene, total gingerols can be included	-do-
		4.3		Editorial	To validate the quality of the botanical	i. Best before date and	-do-

						ii. QR Code for Authentication can be included in the packaging details	
2.	Name: Dr. R. Ilavarasan	3.1.2		Editorial	Pictorial illustration of specified plant cells can be included after macro and microscopic description for easy understanding and identification of the species. (Reference: Indian Standard 18094: 2022)	Pictorial illustration of specified plant cells can be included for easy understanding as mentioned in the Indian Standard 18094: 2022	same as 1 above
		3		Editorial	To validate the authenticity and quality of the botanical	HPTLC and HPLC quantification of total zingiberene, total gingerols can be included.	-do-
		4.3		Editorial	To validate its Stability data	i. Best before date and ii. QR Code for Authentication can be included in the packaging details	-do-
3.	Name: Suman singh	5.2	table 1	Editorial	Need to add parameter of Assay/ Quantitative analysis.	a) Dried rhizome should contain Essential oil :	Same as 1 above

	Email: research@bakson.net				(As in market these are availability of dried as well as powdered zinger too) so to optimize the quality of that raw material Assay is needed.	Minimum 15 ml/kg of essential oil (anhydrous drug) (Ref- BP/Ph. eur.). b) Dried rhizome should contain Starch Content: NLT 42% (ref. USP) or a) Dried rhizome contains not less than 0.8 per cent w/w of total gingerol, calculated on the dried basis (Ref. IP) by HPLC	
4.	Name: Dr. Mudita Arora Email: dr mudita@bakson.net	5.2	table 1	Editorial	need to add Quantitative analysis (assay) please refer - IP for active content by HPLC	Quantitative analysis : Dried rhizome contains not less than 0.8 percent w/w of total gingerol, calculated on the dried basis.	Same as 1 above
5.	Name: Suman singh Email: research@bakson.net	forward	2	Editorial	Information about the Chemical constituents present in Zingiber rhizomes should be mentioned Information about the possible adulterant in Zinger powder should also be mentioned.	Zingiber officinale contain Volatile oil 1-4%, terpenoids mainly	Same as 1 above

						sesquiterpenoids (α -zingiberene, β -sesquiphellandrene, β -bisabolene, zingiberol and monoterpenoids (camphene, β -phellandrene, cineole, geraniol, curcumene, citral, terpineol, borneol and pungent principles, the gingerols (about 4-7.5 %)).	
		Title		Editorial	The Title is for Fresh rhizome only . but commercially industry is using dried rhizomes too. so the monograph should include Specifications for dried rhizome too	Zingiber officinale Roscoe Fresh or Dried Rhizome for use in Traditional Medicine – Specification	It is to be noted that the Indian Standard for Specifications of Dried Ginger has already been published and may be referred to IS 18094: 2022
		3.1.1 & 3.1.2		Editorial	pictures of raw herb material & Colored Pictures of sections (microscopy) should be included in monograph		Same as in 1 above
		3.1.1	1	Editorial	Pungent taste should be elaborated	Spicy and burning taste	Accepted. Changes shall

							be made in the document
		5.2	table 1	Editorial	<p>The parameters should be divided into sub-sections</p> <p>Physicochemical parameters</p> <p>Foreign matter</p> <p>water / Moisture content</p> <p>Total ash</p> <p>Extractive values (Hydro-alcoholic extract/ alcoholic ext.)</p> <p>Qualitative analysis</p> <p>Qualitative screening (if any specific to plant and differentiation from its adulterant or substitute spp.)</p> <p>Identification by TLC</p> <p>Quantitative analysis (Assay)</p> <p>Heavy metal analysis</p> <p>Pesticide residue</p> <p>Microbial Limits</p> <p>Mycotoxin limits</p> <p>The limits for dried Rhizome can be taken from IP (Indian pharmacopoeia)</p>		<p>The format of the Indian standard for specification of raw herbs were finalized after consultation with different sectional committees and BIS officials. To maintain the uniformity, the given format was adopted. However, the parameters in the Pharmacopeial publications have been included in the draft as per the suggestions of the Ayush Division Council.</p>
6.	Name: Dr. Mudita Arora Email: dr mudita@bakson.net	Title	1	Editorial	The monograph should be for both dried as well as fresh Rhizome	Zingiber officinale Roscoe Fresh or Dried rhizomes for use in Traditional	It is to be noted that the Indian Standard for Specifications of Dried Ginger has already been

						Medicine – Specification	published and may be referred to IS 18094: 2022
	forward	2	Editorial	Chemical constituents need to be added		Zingiber officinale contain Volatile oil 1-4%, sesquiterp enoids (α -zingiberene, β -sesquiphellandrene, β -bisabolene, zingiberol and monoterpenoids (camphene, β -phellandrene, cineole, geraniol, curcumene, citral, terpineol, borneol and pungent principles, the gingerols (about 4-7.5 %).	Same as 1 above
	3.1.1 & 3.1.2		Editorial	Coloured pictures of raw herb material and microscopic charaters should be included in monograph.			-do-
	5.2	table 1	Editorial	The parameters/ tests should be divided into sub sections Limits for dried herb material should be included in table (use		The parameters should be divided into sub sections	The format of the Indian standard for specification of raw herbs were

					<p>Indian pharmacopoeia values for dried material)</p>	<p>Physicochemical parameters Foreign matter Loss on drying and Moisture content Total ash Extractive values (Hydro-alcoholic extract/ alcoholic ext.) Qualitative analysis Qualitative screening (if any specific to plant and differentiation from its adulterant or substitute spp.) Identification by TLC Quantitative analysis (Assay) Heavy metal analysis Pesticide residue Microbial Limits Mycotoxin limits The limits for dried Rhizome</p>	<p>finalized after consultation with different sectional committees and BIS officials. To maintain the uniformity, the given format was adopted. However, the parameters in the Pharmacopeial publications have been included in the draft as per the suggestions of the Ayush Division Council.</p>
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						can be taken from IP (Indian pharmacopoeia)	
		5.2	table 1	Editorial	need to include identification tests (General & TLC) in table (as parameters)	<p>Identification test :</p> <p>1. To 1 g of the pulverized Ginger add 5 mL of dilute acetic acid, prepared by diluting 1 part of glacialacetic acid with 1 part of water, and shake for 15 min. Filter, and add a few drops of ammonium oxalate TS to the filtrate. Acceptance criteria:NMT a slight turbidity is produced. (Ref. USP)</p> <p>2. Sample -50 mg of the residue obtained from Alcohol-Soluble Extractives, Analysis:Disso lve the Sample</p>	Same as 1 above

						<p>in 25 mL of water, and extract this solution with two 15-mL portions of ether. Combine the ether extracts, and evaporate in a porcelain dish. To the residue add 5 mL of sulfuric acid solution (7.5 in 10.0) and 5 mg of vanillin. Allow to stand for 15 min, and add an equal volume of water.</p> <p>Acceptance criteria: The solution turns azure blue. (Ref. USP)</p> <p>3. TLC method of identification (Ref. BP/ Ph. Eur)</p> <p>Test solution: To 1.0 g of the powdered herbal drug add 5 mL of</p>	
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						<p>methanol R. Shake for 15 min and filter. Mobile phase : hexane : ether (40:60 VIV). Detection: spray with a 10 g/L solution of vanillin R in sulfuric acid R and examine in daylight while heating at 100-105 °C for 10 min. or TLC (USP ref) Sample solution:Pulverize 5 g of Ginger. Prepare a 100-mg/mL dispersion of Ginger in methanol. Sonicate for 10 min, and centrifugeor and filterr. Use supernatant or filtrate. Mobile phase:Toluene and ethyl</p>	
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						acetate (3:1) Detection: spray with solution (To 170 mL of ice- cold methanol add 20 mL of glacial acetic acid, 10 mL of sulfuric acid, and 1 mL of anisaldehyde. Mix well.) and examine in daylight while heating at 100- 105 °C for 10 min.	
		B-8.2.1 & B- 8.2.2	1	Editorial	Please Refer IP vol. I (2.2.9) and in secondary test we use MacConkey agar After that Confirmatory is done with Kovac's Reagent.	Add 1 ml to 100ml Macconkey broth. Incubate at 42to 44°C for 24-48 hours.	As the values taken from the PCIMH inputs are used in drafting the standards, the given test methods are also taken from the same.
		B-8.3	1	Editorial	1 gm or 1ml should be changed to 10gm or 10ml	Transfer a quantity of the pretreated preparation being examined containing 10 g or 10 ml of the	-do-

		B-8.3.1	1	Editorial	RVSE broth is used and after incubation subculture on Wilson and Blair's Agar /XLDA media as per IP		-do-
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2. TITLE: STANDARDIZED TERMINOLOGIES FOR CORE CONCEPTS – WC

Last Date of Comments: 27.01.2024

S.No	Basic Details	Clause/ Subclause No.& Attachment	Paragraph No./Figure No./Table No.	Type of Comment	Comments/Suggestions along with Justification for the Proposed Change	Proposed Change/Modified Wordings	Recommendations of the Committee
1.	Dr.V.Jasmine Ranjana	S. No 1	1	Editorial	Endogenous can be considered	Intrinsic or endogenous causes of disease	Accepted
2.	Dr.V.Jasmine Ranjana	S. No 10	1	Editorial	According to Yugi and theraiyar the colour of appu bhotham is padiga niram which is clear white or crystal clear	Colourless can be replaced with crystalline or crystal like	Partially Accepted • The prescribed description quoted in the WHO International Standard Terminologies on Siddha Medicine, 'Crystal clear' term shall be included instead of Crystal-like / Crystalline colour.
3.	Dr.V.Jasmine Ranjana	S No 10	1	Editorial	Softening or softness	Lightning can be replaced with softening or softness	Declined • The prescribed description quoted in the WHO International Standard Terminologies on Siddha Medicine.
4.	Dr.V.Jasmine Ranjana	S No 42	1	Editorial	Figurative can be appropriate than	Perceptible matter can be replaced by figurative matter.	Declined

					perceptible for the term uruva porul.	It can be seen and felt through the senses	Perceptible is more appropriate than the figurative
5.	Dr.V.Jasmine Ranjana	S No 59	1	Editorial	The pancha bootha relation of Motor organs functioning can be mentioned	1.Movements-limb movements 2.excretion-defecation 3.an appropriate word for female genitals functioning can be added	Declined • The prescribed description quoted in the WHO International Standard Terminologies on Siddha Medicine.
6.	Dr.V.Jasmine Ranjana	S No 108	1	Editorial	Attributes of both the patient's attender and the physician are mentioned which indicates the patients disease prognosis.	Attributes of both the patient's attender and the physician are mentioned which indicates the patients disease prognosis.	Accepted

3. TITLE: NIGELLA SATIVA L SEED FOR USE IN TRADITIONAL MEDICINE SPECIFICATION

Last Date of Comments: 25.02.2024

S.No	Basic Details	Clause/Sub clause No.& Attachment	Paragraph No./Figure No./Table No.	Type of Comment	Comments/Suggestions along with Justification for the Proposed Change	Proposed Change/Modified Wordings	Recommendations of the Committee
1.	Monika. N	3	-	Editorial	HPTLC and HPLC Quantification of volatile constituent – Thymoquinone (>0.2	HPTLC and HPLC Quantification of volatile constituent – Thymoquinone (>0.2	Not accepted. Data available in PCIMH Pharmacopeial

					% w/w as per IP 2022), Carvone (more than 60 %), quantification of the compound Reference: Quality standards of Indian Medicinal Plants, ICMR, New Delhi; Volume 1	% w/w as per IP 2022), Carvone (more than 60 %), quantification of the compound can be included Reference: Quality standards of Indian Medicinal Plants, ICMR, New Delhi; Volume 1	Publications have been given in the draft standard. Any addition in the pharmacopeia will be included in subsequent revisions of this Indian standard.
2.	Monika. N	3	-	Editorial	To validate authenticity and precise identification of the botanical due to presence of more substitutes and adulterants	i. DNA barcoding data can be included ii. Detailed macroscopy, microscopy and powder microscopy with pictorial illustrations can be included in the draft Reference: Quality standards of Indian Medicinal Plants, ICMR, New Delhi; Volume 1	Same as 1 above
3.	Monika. N	4.3	-	Editorial	To validate the stability and quality of the botanical	Best before date, QR Code for Authentication can be included in the packaging details	Same as 1 above
4.	Dr. R. Ilavarasan	3	-	Editorial	To validate the authenticity of the botanical	HPTLC and HPLC Quantification of volatile constituent – Thymoquinone (>0.2 % w/w as per IP 2022), Carvone (more than 60	Same as 1 above

						%), quantification of the compound can be included as mentioned in the reference book Quality standards of Indian Medicinal Plants, ICMR, New Delhi; Volume 1 and IP 2022	
5.	Dr. R. Ilavarasan	3	-	Editorial	To prove authenticity and precise identification of the botanical due to presence of more substitutes and adulterants	DNA barcoding data can be included if possible	Same as 1 above
6.	Dr. R. Ilavarasan	4.3	-	Editorial	To validate the stability and authentication of the botanical	i. Best before date and ii. QR Code for Authentication can be included in the packaging details section	Same as 1 above

4. TITLE: STANDARDIZED TERMINOLOGY FOR MATERIALS

Last Date of Comments: 16.02.2024

S.No	Basic Details	Clause/ Subclause No.& Attachment	Paragraph No./Figure No./Table No.	Type of Comment	Comments/Suggestions along with Justification for the Proposed Change	Proposed Change/Modified Wordings	Recommendations of the Committee
1	Name: Monika. N Organisation: N/A Email:	2 N/A		General	The term ID can be included for all the terminologies	Term ID for the each word has to be mentioned.	Declined

	monikanagarajan1@gmail.com Mobile: 7358436244 Comment ID #: AYD_2023-10-298230	S.no 147 N/A		Editorial	Spell mismatch At english transliteration column - the word "Mantukam" has been mentioned but in the tamil, the word "MAnduram " has been mentioned.	As mentioned in the previous column, the correction of the word has to be made as "Manduram".	Accepted. The modification has already been made.
		S.no 151 N/A		Editorial	Incorrect spelling At the column English term (S.no. 151), the word :Reala" was given	The word "Reala" has to be changed to "Realagar"	Accepted. The modification has already been made.
		S.no 156 N/A		Editorial	Typo error In the column English term, (S.no 156), "Deerhorn" has been mentioned which has been corrected.	The word has to be changed to "Deer horn"	Accepted. The modification has already been made.
2	Name: Dr. R. Ilavarasan Organisation: N/A Email: arilavarasan@yahoo.co.in Mobile: 9444873211 Comment ID #: AYD_2023-11-014388	2 N/A		General	The term ID for each word has to be included identification.	Term ID for the each word has to be mentioned.	Declined
		S.no 147 N/A		Editorial	Spell mismatch with tamil word	English transliteration mentioned – Mantukam which has to be changed to Manduram	Accepted. The modification has already been made.
		S.no 151 N/A		Editorial	Incorrect spelling	English term- "Realga" was mentioned which has to be corrected which	Accepted. The modification has already been made.

						seems incomplete word	
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5. TITLE: SMILAX CHINA L SEED FOR USE IN TRADITIONAL MEDICINE SPECIFICATION

Last Date of Comments: 25.02.2024

S.No	Basic Details	Clause/Subclause No.& Attachment	Paragraph No./Figure No./Table No.	Type of Comment	Comments/Suggestions along with Justification for the Proposed Change	Proposed Change/Modified Wordings	Recommendations of the Committee
1.	Monika. N	3	-	Editorial	For precise authentication and to prevent adulteration	i. Detailed microscopy and macroscopy, powder microscopy with pictorial illustrations can be included for precise authentication ii. Plant DNA fingerprinting data can be included.	As suggested by Ayush Division Council, the draft is prepared by referring the Pharmacopeial Publications by PCIMH. Any addition in the pharmacopeia will be included in subsequent revisions of this Indian standard.
2.	Monika. N	3	-	Editorial	To validate authenticity and quality of the botanical	HPTLC fingerprinting with markers and HPLC quantification of any of the major markers like Diosgenin can be studied	Same as 1 above
3.	Monika. N	4.3	-	Editorial	To validate the stability of the botanical.	i. Best before date and ii. QR Code for Authentication can be included in the packaging details	Same as 1 above

4.	Dr. R. Ilavarasan	3	-	Editorial	To validate the authenticity of the botanical	HPTLC and HPLC Quantification of the chief constituent Diosgenin can be included.	Same as 1 above
5.	Dr. R. Ilavarasan	3	-	Editorial	To prevent adulteration, DNA barcoding data can be included if possible	DNA barcoding data can be included if possible	Same as 1 above
6.	Dr. R. Ilavarasan	4.3	-	Editorial	To validate the stability of the product	i. Best before date and ii. QR Code for Authentication can be included in the packaging details	Same as 1 above

6. TITLE: CODE OF PRACTICE FOR MANIKADAI NOOL WRIST

Last date of comments: 16.02.2024

S.No	Basic Details	Clause/Subclause No.& Attachment	Paragraph No./Figure No./Table No.	Type of Comment	Comments/Suggestions along with Justification for the Proposed Change	Proposed Change/Modified Wordings	Recommendations of the Committee
1.	Name: Dr. Rachna Paliwal Organisation: N/A Email: rachna.paliwal@nic.in Mobile: 9830118994 Comment ID #: AYD_2023-12-309567	5.1.4 N/A	N/A	Technical	The width of fingers mentioned can be mistaken for the investigator's fingers	The Total mediolateral width of patient's four fingers	Whole test study mentions the patient's four finger and wrist. It is clearly mentioned in picture.
		6 N/A	N/A	General	Obesity can also be included as special consideration	also include Obesity under special consideration.	It is mentioned in the Table of Annexure A under row 11 FB

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Annexure B: Comments on WC Drafts