

DOCUMENT No.	:	HA/TBC/SPC/OMP/ZO/002	
ISSUE DATE	:	01.07.2020	
<b>REVISION No. &amp; DATE</b>	:	06	02.21.2024
PAGE NUMBERS	••	Page 1 of 4	

## TITLE: GINGER RHIZOME TBC (ORGANIC+FAIR FOR LIFE)

Product name	:	Ginger rhizome TBC (Organic+Fair for Life)	
Common name	:	Ginger	
Botanical name	:	Zingiber officinale Roscoe	
Grade	:	JP Grade: Zingiberis rhizoma	
Country of origin	:	India	
Part used	:	Dried rhizome	and all all and a second
Treatment	:	Heat/Steam treated for microbial reduction	

<b>Botanical Identity</b>		Observation		Method used		
Macroscopic		The rhizome is irregularly compressed and branched; the branches part is slightly curved ovoid or oblong-ovoid, 2-4 cm in length and 1-2 cm in diameter.				
Microscopy	Fire	Powdered Ginger reveals parenchyma cells; these c substances or single cryst fragments of fibers, cork reticulate vessels; starch simple, compound, spher	As per JP XVIII			
TLC	254nm	365nm	Visible	As per		
L1 – Botanical reference stardard solution L2 – Sample solution				JP XVIII <2.03> / Ph. Eur. (2.2.27)		
	L1 L2	L1 L2	L1 L2			
<b>D</b>		Cheeked b	<b>T</b>	und have		
Prepared by:		Checked by:	fissi Cri	ued by:		
Sr. Officer - (	QC	Manager - QC	Mana	Manager – QA		
Date: 02.21.20	24	Date: 02.21.2024	Date:	Date: 02.21.2024		



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PAGE NUMBERS	:	Page 2 of 4	

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S/N	Organoleptic	Observation	Method used
1.	Appearance	Free flowing rhizome particles, mold-free	Quality control methods for medicinal plant materials, WHO, Geneva, 2002,
2.	Color (herb)	Yellow tan	Pg.10-11
3.	Color (infusion)	Cloudy golden	As per in-house method
4.	Odor (infusion)	Characteristic, pungent	As per in-house method
5.	Taste (infusion)	Pungent	As per in-house method

S/N	Physicochemical Analysis	Limits	Method used
6.	Foreign organic matter (% w/w)	Not more than 2.0	As per Ph. Eur. 2.8.2
7.	Loss on drying (% w/w)	Not more than 12.0	As per JP XVIII <5.01>
8.	Total ash content (% w/w)	Not more than 8.0	As per JP XVIII <5.01>
9.	Essential oil (% v/w)	To be reported	As per Ph. Eur. 2.8.12 / JP XVIII <5.01>
		(Not less than 1.0 preferred)	
10.	Bulk density (g/ml)	Between 0.3 – 0.6 (untapped)	As per USP <616> Method I
11.	Particle size		
	Material through #8 mesh (% w/w)	100	
	Material on #12 mesh (% w/w)	Not more than 10.0	As per AOAC 965.22
	Material on # 60 mesh (% w/w)	Not less than 90.0	115 per 110/10 703.22
	Material through #100 mesh (% w/w)	Not more than 1.0	

S/N	Phytochemical Analysis	Limits	Method used
	[6]-gingerol, calculated	Not less than 0.3	As per JP XVIII<2.01> / As per Ph. Eur.
	on the basis of dried material (% w/w)	(Not less than 0.6 preferred)	2.8.12 / As per in-house method

S/N	Contaminants	Limits	Method used
13.	Heavy metals (ppm)		
	Lead (Pb)	Not more than 2.0	
	Cadmium (Cd)	Not more than 0.5	As non USD (222) ICD MS
	Arsenic (As)	Not more than 2.0	As per USP <233>, ICP-MS
	Mercury (Hg)	Not more than 0.2	
14.	Pesticides (ppm)	To comply with USP	As per USP <561>
15.	Aflatoxins (ppb)		
	B1	Not more than 5.0	As per USP <561>-Method-III
	B1+B2+G1+G2	Not more than 20.0	

Prepared by:	Checked by:	Issued by:
Rupp	S Q	GLR.
Sr. Officer - QC	Manager - QC	Manager – QA
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DOCUMENT No.:HA/TBC/SPC/OMP/ZO/002ISSUE DATE:01.07.2020REVISION No. & DATE:0602.21.2024PAGE NUMBERS:Page 3 of 4

#### TITLE: GINGER RHIZOME TBC (ORGANIC+FAIR FOR LIFE)

16.	Alkaloids (ppb)		
	Pyrrolizidine alkaloids	Not more than 400	As per Ph. Eur. (2.8.26)
	Tropane alkaloids (Sum of Atropine and Scopolamine)	Not more than 25	By LC-MS/MS
17.	Microbiological analysis		
	Total plate count (cfu/g)	Not more than 10,000,000	As per USP <61> / Ph. Eur. (2.6.12)
	Yeast and mold (cfu/g)	Not more than 100,000	As per USP <61> / Ph. Eur. (2.6.12)
	Escherichia coli (org/g)	Not more than 100	As per Ph. Eur. (2.6.31) / AOAC 991.14
	Salmonella spp. (org/750g)	Absent	As per USP <62> / Ph. Eur. (2.6.31)

**Packing** –The product is packed in 25 kg single lined polyethylene (100 micron) / polyester (12 micron) bags and then packed in 7 ply, brown corrugated box or as specified by the customer.

**Retest date** – 2 years from date of manufacture.

Recommended storage - Store in well-closed containers, protected from light and moisture at room temperature.

Non-GMO, non-irradiated, non-ETO treated, BSE / TSE free, allergen free.

# **Certifications & Accreditations** For testing facilities: For manufacturing facilities: ISO 22000 **BUREAU VERITAS** Manufacturing Facility NABL For product: USD/ ORGANIC fair trade IN-BIO-147 and Non-EU agriculture Prepared by: Checked by: Issued by: Sold . Sr. Officer - QC Manager - QC Manager - QA Date: 02.21.2024 Date: 02.21.2024 Date: 02.21.2024



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PAGE NUMBERS	:	Page 4 of 4	

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### **Revision History:**

S. No.	Date	Change History	Revision No.
1	01.07.2020	New Document	00
2	01.25.2022	Shelf life changed to Retest date.	01
3	03.14.2022	Part used given as dried rhizome. Analysis of [6]-gingerol and alcohol soluble extractive included. EU Organic and Fair-trade logos added.	02
4	10.26.2022	<ul> <li>Product name updated.</li> <li>Respective Ph. Eur. methods added for TLC, [6]-gingerol, TPC, <i>Salmonella</i>, Yeast &amp; Molds.</li> <li>Loss on drying included.</li> <li>Alcohol soluble extractives deleted.</li> <li>Bulk index NMT 4.0 ml/g changed to Bulk density between 0.3 – 0.6 g/ml.</li> <li>JP method added for essential oil.</li> <li>[6]-gingerol limit changed to NLT 0.3% w/w.</li> <li>Preferred values added for essential oil and [6]-gingerol.</li> <li>Certification updated (FFL included and Fair trade removed).</li> </ul>	03
5.	05.01.2023	Analysis of Pyrrolizidine alkaloids and Tropane alkaloids parameters with NMT limits added.	04
6.	10.06.2023	Date format changed Limits for 'Particle size' changed.	05
7.	02.21.2024	<ol> <li>Title &amp; product name changed to "Ginger rhizome TBC (Organic+Fair for Life)" from "Ginger rhizome, Organic</li> <li>Steam treatment included.</li> </ol>	06

Prepared by:	Checked by:	Issued by:
Rupp	5-2	GLR.
Sr. Officer - QC	Manager - QC	Manager – QA
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