

| DOCUMENT No.                   | :  | HA/TBC/SPC/OMP/ZO/002 |            |
|--------------------------------|----|-----------------------|------------|
| ISSUE DATE                     | :  | 01.07.2020            |            |
| <b>REVISION No. &amp; DATE</b> | :  | 06                    | 02.21.2024 |
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## 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<br>parenchyma cells; these c<br>substances or single cryst<br>fragments of fibers, cork<br>reticulate vessels; starch<br>simple, compound, spher | As per JP XVIII |   |  |  |
| TLC   | 254nm | 365nm  | Visible         | As per                                    |  |  |
| L1 – Botanical<br>reference stardard<br>solution<br>L2 – Sample<br>solution |       |  |                 | JP XVIII <2.03><br>/<br>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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| 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     |
| Date: 02.21.2024 | Date: 02.21.2024 | Date: 02.21.2024 |



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| 16. | Alkaloids (ppb)  |                          |  |
|-----|--|--------------------------|--|
|     | Pyrrolizidine alkaloids                                | Not more than 400        | As per Ph. Eur. (2.8.26)               |
|     | Tropane alkaloids<br>(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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### **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.<br>Analysis of [6]-gingerol and alcohol soluble extractive included. EU Organic and<br>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<br>Limits for 'Particle size' changed.   | 05           |
| 7.     | 02.21.2024 | <ol> <li>Title &amp; product name changed to "Ginger rhizome TBC (Organic+Fair for<br/>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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