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LABORATORY LOCATION:
(PERMANENT LABORATORY)

**INDUSTRIAL BIOTECHNOLOGY RESEARCH CENTRE
SIRIM BERHAD
BLOCK 19, NO.1 PERSIARAN DATO' MENTERI
SEKSYEN 2, P.O BOX 7035
40700 SHAH ALAM, SELANGOR
MALAYSIA**

FIELD OF TESTING: CHEMICAL, MICROBIOLOGY, TOXICITY

This laboratory has demonstrated its technical competence to operate in accordance with MS ISO/IEC 17025:2017 (ISO/IEC 17025:2017).

This laboratory's fulfillment of the requirements of ISO/IEC 17025 means the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations. The management system requirements in ISO/IEC 17025 are written in language relevant to laboratory operations and operate generally in accordance with the principles of ISO 9001 (see Joint ISO-ILAC-IAF Communiqué dated April 2017).

SCOPE OF TESTING: CHEMICAL

Materials/ Products Tested	Type of Test/ Properties Measured/ Range of Measurement	Standard Test Methods/ Equipment/Techniques
Analytical Laboratory Dry Powder, Slurry, Emulsion Or Dilute Suspension (Food Powder, Minerals, Yogurt, Carbon Powder, Cleaning Solution for Contact Lens, Clay Material, Cosmetic Raw Material In Powder Form)	Particle Size Distribution	LWI-238-09 Particle Size Distribution based on Laser Diffraction Technique (Particle Size Laser Analyzer Coulter LS 100Q)

Notes:

1. LWI-238-09: In-house method particle size distribution based on Laser Diffraction Technique
2. LWI: IBRC Laboratory Working Instruction.

Signatories:

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|----|-----------------------------------|--------------------------------|
| 1. | Sarifah Rejab | IKM No.: M/1363/2510/95 |
| 2. | Thavamanithevi Subramaniam | IKM No.: M/4119/6917/14 |

SCOPE OF TESTING: CHEMICAL

Materials/ Products Tested	Type of Test/ Properties Measured/ Range of Measurement	Standard Test Methods/ Equipment/Techniques
<i>Eurycoma longifolia</i> (Tongkat Ali) herbal extract	Chemical marker eurycomanone	SIRIM/MOA 4-11:2019 Annex A Detection of eurycomanone in tongkat ali (<i>Eurycoma longifolia</i> Jack) spray dried aqueous using high-performance liquid chromatography (HPLC)
<i>Zingiber officinale</i> Roscoe (Ginger) herbal extract	Chemical marker 6-gingerol and 6- shogaol	SIRIM/MOA 4-3:2019 Annex A Detection of 6-gingerol and 6- shogaol in halia (<i>Zingiber officinale</i> Roscoe) spray dried aqueous using high-performance liquid chromatography (HPLC)
<i>Ficus deltoidea</i> (Mas Cotek) herbal extract	Chemical marker isovitexin and vitexin	SIRIM/MOA 4-6:2019 Annex A Detection of isovitexin and vitexin in mas cotek (<i>Ficus deltoidea</i> Jack var. <i>kunstleri</i> (King) Corner) spray dried aqueous using high-performance liquid chromatography (HPLC)
<i>Labisia Pumila</i> (Kacip Fatimah) herbal extract	Chemical marker gallic acid	SIRIM/MOA 4-5:2019 Annex A Detection of gallic acid in kacip fatimah (<i>Marantodes pumilum</i> (Blume) Kuntze syn <i>Labisia pumila</i> (Blume) Fern.-Vill.) spray dried aqueous using high-performance liquid chromatography (HPLC)
<i>Hibiscus sabdariffa</i> Linn (Calyx roselle) herbal extract	Chemical marker delphinidin-3-Sambubioside	SIRIM/MOA 4-10:2019 Annex A Detection of delphinidin-3-sambubioside chloride in roselle (<i>Hibiscus sabdariffa</i> L.) spray dried aqueous using high-performance liquid chromatography (HPLC)
Cosmetic Skin Care	Hydroquinone	LWI-238-53-7 Detection of Hydroquinone based on ACM INO 03 (by High Performance Liquid Chromatography)
Birdnest	Sialic acid	LWI-238-53-6 Determination of Sialic Acid Content in Birdnest based on DIONEX Technical Note 41 (by High Performance Liquid Chromatography)
Herbal Extract/ Herbal and Cosmetic Products	Biochemical Antioxidant Assay (DPPH Assay)	LWI-238-34 based on SIRIM/MOA 3:2017 Annex H page 43-48: Determination of Antioxidant Free Radical Scavenging activity (DPPH assay) and Food Chemistry 113 (2009) 1154-1159

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	Biochemical Antioxidant Assay (ABTS Assay)	LWI-238-35 based on SIRIM/MOA 3:2017 Annex G page 37-42: Determination of Antioxidant Free Radical Scavenging activity (ABTS assay) and Food Chemistry 113 (2009) 1154-1159
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Signatories:

- | | | |
|----|--|----------------------------------|
| 1. | Thavamanithevi Subramaniam | IKM No.: M/4119/6917/14 |
| 2. | Dr. Darmawati binti Mohamad Yunos | IKM No.: M/4749/7835/17 |
| 3. | Dr. Nur Ellina binti Azmi | IKM No.: M/4750/7836/17 |
| 4. | Aidawati Mohamed Shabery | IKM No.: M/4532/7511/2016 |
| 5. | Nurul Hammizah binti Hamidon | IKM No.: M/4788/7891/17 |
| 6. | Mohd Zawawi bin Ramlan | IKM No.: M/4789/7892/17 |
| 7. | Raizatul Ainaa binti Gafoor Abdul Rasheed | IKM No.: M/4787/7980/17 |
| 8. | Nurul Farah Athirah binti Shamsuri | IKM No.: M/5297/8663/20 |

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SCOPE OF TESTING: MICROBIOLOGY

Materials/ Products Tested	Type of Test/ Properties Measured/ Range of Measurement	Standard Test Methods/ Equipment/Techniques
Bacteriology Laboratory Cosmetic Products	Aerobic Plate Count Yeast & Mould Count	FDA, BAM 2016, Chapter 23, Part A-H
Sterile and Non sterile Gloves	Aerobic Plate Count Fungi, Yeast & Mould Count	In-House Method Based on INMETRO Nr 332/2012 (National Institute of Metrology, Standardization and Industrial Quality, Brazil)
Traditional Medicine (hard capsules, soft capsules, liquid, pills, powder/granules)	Total Aerobic Microbial Count (TAMC)	British Pharmacopoeia (BP) 2018 Appendix XVIB, Microbial Examination of Non- Sterile Product Appendix XVIF, Microbiological Examination of Herbal Medicine Products for Oral Use and Extracts used in their preparation
Pharmaceutical Drugs	Total Yeast & Mould Count (TYMC)	
	Detection of Specified Organisms: a) Bile Tolerant Gram Negative Bacteria b) Escherichia coli c) Salmonella d) Staphylococcus aureus e) Pseudomonas aeruginosa	

Notes:

1. FDA: Food and Drug Administration
2. BAM: Bacteriological Analytical Manual
3. LWI-238-07-01: Aerobic Plate Count and Yeast & Mould Plate Count (APC-YMC)
4. LWI: IBRC Laboratory Working Instruction.

Signatories:

1. **Mohd Khairul Azwan Ahmad**
2. **Mohd Mahayuddin Hussin**

SCOPE OF TESTING: MICROBIOLOGY

Materials/ Products Tested	Type of Test/ Properties Measured/ Range of Measurement	Standard Test Methods/ Equipment/Techniques
Chemical disinfectants and antiseptics	Quantitative Suspension Test For the Evaluation of Basic Bactericidal Activity	Chemical disinfectants and antiseptics- Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics. Test method and requirements (phase 1). BS EN 1040:2005 (LWI-238-26-01)
Sterile Gloves	Bacterial Endotoxin Test	EP 8.0, Clause 2.6.14 Bacterial Endotoxin USP 85 Bacterial Endotoxin Test (LWI-238-91-01)

Notes:

1. BS EN: British Standard European Norm
2. EP: European Pharmacopoeia
3. USP: United States Pharmacopoeia
4. LWI-238-26-01: Procedure for The Evaluation of Basic Bactericidal Activity of Chemical Disinfectant and Antiseptics
5. LWI-238-91-01: Procedure for Bacterial Endotoxins Test
6. LWI: IBRC Laboratory Working Instruction/

Signatories:

1. **Mohd Khairul Azwan Ahmad**
2. **Mohd Mahayuddin Hussin**
3. **Nurul Akmal Yusof**
4. **Mohd Fairuzuddin Faizan M. Yusoff**

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SCOPE OF TESTING: TOXICOLOGY

Materials/ Products Tested	Type of Test/ Properties Measured/ Range of Measurement	Standard Test Methods/ Equipment/Techniques
Toxicology Laboratory Medical Devices (Gloves, Syringes, Blades, Condoms, Catheters, etc)	In-vitro Cytotoxicity Test	ISO 10993-5:2009, Biological evaluation of medical device – Part 5 (LWI-238-02)
Non-metallic products (Water tanks, Cement/ Concrete Block, Pipe, etc)	Cytotoxicity Test	BS 6920-2.1:2014 BS 6920-2.5:2000+A2:2014 MS 1583-Part 2: Section 1:2003 MS 1583-Part 2: Section 5:2003 (LWI-238-01)
Sludge Waste, Natural Extract, Raw Material, etc	Balb/C 3T3 Neutral Red Uptake Cytotoxicity Test	LWI-238-03 based on ICCVAM
	Acute Oral Toxicity (Acute Toxic Class Method) – Limit Test	LWI-238-24 based on OECD 423
	Acute Oral Toxicity (Up and Down Procedure) – Limit Test	LWI-238-27 based on OECD 425
Cosmetic, Medical devices, Household, Chemical	<i>In Vitro</i> EpiDerm™ Skin Irritation Test (EPI-200-SIT)	EPI-200-SIT Test Kit validated by ECVAM (The European Centre for the Validation of Alternative Methods) and approved under OECD Guidelines for Testing of Chemicals No. 439, July 2015 LWI-238-43 based on OECD 439
	<i>In Vitro</i> EpiOcular™ Eye Irritation Test (OCL-200-EIT)	OCL-200-EIT Test Kit validated by ECVAM (The European Centre for the Validation of Alternative Methods) and approved under OECD Guidelines for Testing of Chemicals No. 492, July 2015 LWI-238-44 based on OECD 492

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SCOPE OF TESTING: TOXICOLOGY

Materials/ Products Tested	Type of Test/ Properties Measured/ Range of Measurement	Standard Test Methods/ Equipment/Techniques
Toxicology Laboratory Medical devices (Gloves, syringes, blades, condoms, catheters, etc)	Systemic Toxicity	ISO 10993-11:2017 (E)-3 rd Edition Part 11 2017-09-15 [Exclude clause 6 Repeated Exposure Systemic Toxicity (Subacute, Subchronic and Chronic Systemic Toxicity)] LWI-238-61
	Primary Skin Irritation	ISO 10993-10:2010 (E)-3 rd Edition 2010-08-01 [Exclude clause 6.5 (Human Skin Irritation Test)] LWI-238-57
	Intracutaneous (Intradermal) Reactivity Test	ISO 10993-10:2010 (E)-3 rd Edition 2010-08-01 [Exclude clause 6.5 (Human Skin Irritation Test)] LWI-238-58
	Guinea Pig Maximization Test (GPMT)	ISO 10993-10:2010 (E)-3 rd Edition 2010-08-01 [Exclude clause 7.2 (Murine Local Lymph Node Assay (LLNA))] LWI-238-59
	Closed-Patch Test (Buehler test)	ISO 10993-10:2010 (E)-3 rd Edition 2010-08-01 [Exclude clause 7.2 (Murine Local Lymph Node Assay (LLNA))] LWI-238-60

Notes:

1. ISO 10993-5:2009 Biological evaluation of medical device: Part 5: Tests for in vitro cytotoxicity.
2. ISO 10993-10:2010 Biological evaluation of medical device: Part 10: Tests for Irritation and Skin Sensitization.
3. ISO 10993-11:2006 Biological evaluation of medical device: Part 11: Tests for Systemic Toxicity.
4. LWI-238-01: Cytotoxicity Test for Non-Metallic Products According to MS 1583/BS 6920.
5. LWI-238-02: Cytotoxicity Test for Medical Devices According to ISO 10993-5.
6. LWI-238-03: In House Balb/C 3T3 Neutral Red Uptake Cytotoxicity Test.
7. LWI-238-24: In-house Acute Oral Toxicity (Acute Toxic Class Method).
8. LWI-238-27: In-house Acute Oral Toxicity (Up and Down Procedure).
9. LWI-238-43: In-house *In Vitro* EpiDerm™ Skin Irritation Test (EPI-200-SIT).
10. LWI-238-44: In-house *In Vitro* EpiOcular™ Eye Irritation Test (OCL-200-EIT).
11. LWI-238-57: In-house Primary Skin Irritation.
12. LWI-238-58: In-house Intracutaneous (Intradermal) Reactivity Test.
13. LWI-238-59: In-house Guinea Pig Maximization Test (GPMT).
14. LWI-238-60: In-house Closed-Patch Test (Buehler test).
15. LWI-238-61: In-house Systemic Toxicity.

16. LWI: IBRC Laboratory Working Instruction.
17. ICCVAM: The Interagency Coordinating Committee on the Validation of Alternative Methods.

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18. ECVAM: The European Centre for the Validation of Alternative Methods.
19. OECD: Organization for Economic Cooperation and Development.
20. BS 6920-2.1:2014 Suitability of Non-Metallic Materials and Products for Use in Contact with Water Intended for Human Consumption with Regard to Their Effect on the Quality of the Water - Part 2: Methods of test: Section 2.1: Samples for Testing.
21. BS 6920-2.5:2000+A2:2014 Suitability of Non-Metallic Materials and Products for Use in Contact with Water Intended for Human Consumption with Regard to Their Effect on the Quality of the Water - Part 2: Methods of test: Section 2.5: The Extraction of Substances that may be of Concern to Public Health.
22. MS 1583: Part 2: Section 1:2003 Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water: Part 2: Methods of test: Section 1: Samples for testing.
23. MS 1583: Part 2: Section 5:2003 Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water: Part 2: Methods of test: Section 5: The extraction of substances that may be of concern to public health.

SCOPE OF TESTING: TOXICOLOGY

Materials/ Products Tested	Type of Test/ Properties Measured/ Range of Measurement	Standard Test Methods/ Equipment/Techniques
Medical devices (Gloves, syringes, blades, Condoms, catheters, etc)	Haemolysis Study of Medical Device	Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood ISO 10993-4 Third edition 2017-04 LWI-238-96
	Neutral red uptake (NRU) cytotoxicity test	Biological evaluation of medical devices- Part 5: Tests for <i>in vitro</i> <i>cytotoxicity</i> ISO 10993-5 Third edition 2009-06-01 LWI-238-97
	Material-mediated pyrogenicity	Biological evaluation of medical devices- Part 11: Tests for systematic toxicity ISO 10993-11 Third edition 2017-09 LWI-238-64
Sludge Waste, Natural Extract, Raw Material, Chemical, Biopesticide, Household etc	Acute Dermal Toxicity: Fixed Dose Procedure	LWI-238-67 based on OECD 402, Acute Dermal Toxicity : Fixed Dose Procedure Adopted 9 October 2017
Pharmaceutical (vaccines/sera/ Immunoglobulins /drug/raw material;)	Abnormal Toxicity	European pharmacopoeia LWI-238-71

Signatories:

1. Dr. Nurul Izza Nordin
2. Suzaini Badrudin
3. Noor Rabihah Aid
4. Syamimi Khalid
5. Juani Mazmin Husin
6. Nurhayati Ariffin
7. Dr. Samsulida Abd. Rahman
8. Norfaeza Bt. Zainudin (nominated)
9. Abdul Hadi Bin Musalli (only in vivo) (nominated)

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SCOPE OF TESTING: TOXICOLOGY

Materials/ Products Tested	Type of Test/ Properties Measured/ Range of Measurement	Standard Test Methods/ Equipment/Techniques
Toxicology Laboratory Cosmetic, Medical devices, Household, Chemical	In Vitro EpiDerm™ Skin Corrosion Test (EPI-200-SCT)	OECD Guidelines for Testing of Chemicals No. 431, 29 July 2016 LWI-238-65

Notes:

1. OECD: Organization for Economic Cooperation and Development.

Signatories:

1. **Dr. Nurul Izza Nordin**
2. **Noor Rabihah Aid**
3. **Juani Mazmin Husin**
4. **Norfaeza Zainudin**
5. **Suzaini Badrudin**
6. **Nurhayati Ariffin**