

Schedule


Issue date: 23 October 2025
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LABORATORY LOCATION/ CENTRAL OFFICE: 	KHTP BIO Analytical Laboratory Sdn. Bhd. Ground Floor, Techno Centre Kulim Hi-Tech Park , 09000, KEDAH MALAYSIA
ACCREDITED SINCE :	11 JUNE 2025
FIELD(S) OF TESTING:	CHEMICAL MICROBIOLOGY Medical Injection Liquid Dialysis Solution Reverse Osmosis Water Water for Injection (WFI) Purified Water

<p>This laboratory has demonstrated its technical competence to operate in accordance with MS ISO/IEC 17025:2017 (ISO/IEC 17025:2017).</p> <p>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).</p>	
CENTRAL LOCATION:	KHTP BIO Analytical Laboratory Sdn. Bhd. Ground Floor, Techno Centre Kulim Hi-Tech Park , 09000, Kedah
FIELD(S) OF TESTING :	CHEMICAL, MICROBIOLOGICAL,

SCOPE OF TESTING : CHEMICAL

Material / Product Tested	Type Of Test / Properties Measured / Range Of Measurement	Standard Test Methods / Equipment / Techniques
Drugs And Pharmaceuticals Herbs And Herbal Products tablets capsules liquid cream balm raw Materials	Cadmium, Lead, Arsenic	In-house Method LTM 7.2.1A-017 using Microwave digestion / GFAAS

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Material / Product Tested	Type Of Test / Properties Measured / Range Of Measurement	Standard Test Methods / Equipment / Techniques
Agricultural Products And Materials animal Feed	Moisture	In-House Method Kbio-TI-0009 based on AOAC Official Method 931.04, 2005
	Ash	In-House Method Kbio-TI-0010 based on AOAC Official Method 923.03, 2005
	Crude fat	AOAC Official Method 2003.06, 2005
	Crude protein	AOAC Official Method 2001.11, 2005
	Carbohydrates	In-House Method Kbio-TI-0013 based on Methods of Analysis for Nutrition Labeling, AOAC International 1993
	Calories/Energy	In-House Method Kbio-TI-0015 based on Methods of Analysis for Nutrition Labeling, AOAC International 1993
Foods Dairy Products fish And Fish Products flour And Confectionary honey And Honey Products infant Food meat, Poultry And Derived Products non-alcoholic Beverages nuts, Fruits, Vegetablesand Derived Products sauces, Herbs, Spices Andcondiments sugar And Sugar Products	Moisture	In-House Method Kbio-TI-0009 based on AOAC Official Method 931.04, 2005
	Ash	In-House Method Kbio-TI-0010 based on AOAC Official Method 923.03, 2005
	Crude fat	In-House Method Kbio-TI-0012 based on AOAC Official Method 2003.06, 2005
	Crude protein	In-House Method Kbio-TI-0011 based on AOAC Official Method 2001.11, 2005
	Carbohydrates	In-House Method Kbio-TI-0013 based on Methods of Analysis for Nutrition Labeling, AOAC International 1993
	Calories/Energy	In-House Method Kbio-TI-0015 based on Methods of Analysis for Nutrition Labeling, AOAC International 1993
Foods Beverages And Fruit Juices	Alcohol	In-House Method Kbio-TI-0022 using GC-FID
Water Mineral Water potable Water surface Water industrial Effluent	pH	APHA 4500-H+B (2012)
	Conductivity	APHA 2510 B (2012)
	Total Suspended Solids	APHA 2540 D (2012)
	Chemical Oxygen Demand	APHA 5220 C
	Biological Oxygen Demand	APHA 5210 B & APHA 4500 -O ,G
	Ammoniacal Nitrogen	APHA 4500-NH3 B, C
Surface Water Industrial Effluent	Oil and Grease	APHA 5520B

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Industrial Hygiene Urine	2, 5 hexanedione	In-House Method Kbio-TI-0020 Based on NIOSH Manual of Analytical Methods (NMAM 8318), Issue 1, 2017, Fifth Edition
	Hippuric acid	In-House Method Kbio-TI-0021 Based on NIOSH Manual of Analytical Methods (NMAM 8301), Issue 3, 2003, Fourth Edition
	Creatinine	In-House Method Kbio-TI-0028 Based on Creatinine Cypress Diagnostics Kit
	Phenol	In-House Method Kbio-TI-0056 based on NIOSH Manual of Analytical Methods (NMAM), Fourth Edition, 1994
Industrial Hygiene Biological Specimen urine blood	Aluminium	In-House Method Kbio-TI-0040 using ICP-MS
	Arsenic	In-House Method Kbio-TI-0040 using ICP-MS
	Antimony	In-House Method Kbio-TI-0040 using ICP-MS
	Cadmium	In-House Method Kbio-TI-0040 using ICP-MS
	Chromium	In-House Method Kbio-TI-0040 using ICP-MS
	Cobalt	In-House Method Kbio-TI-0040 using ICP-MS
	Copper	In-House Method Kbio-TI-0040 using ICP-MS
	Lead	In-House Method Kbio-TI-0040 using ICP-MS
	Manganese	In-House Method Kbio-TI-0040 using ICP-MS
	Mercury	In-House Method Kbio-TI-0040 using ICP-MS
	Nickel	In-House Method Kbio-TI-0040 using ICP-MS
Zinc	In-House Method Kbio-TI-0040 using ICP-MS	
Industrial Hygiene Blood	Lead (Pb)	In-House Method Kbio-TI-0024 Based on Experimental Notes PinAAcle 900T by Perkin Elmer
Medical Devices	1. Ethylene Oxide Sterilization Residues	In-House Method Kbio-TI-0059A based on ISO 10993-7, 2008 and AMD 1 2019-12: Applicability of allowable limits for neonates and infants

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	2. Ethylene Chlorohydrin Sterilization Residues	In-House Method Kbio-TI-0060A based on ISO 10993-7, 2008 and AMD 1 2019-12: Applicability of allowable limits for neonates and infants
Foods Beverages And Fruit Products	Benzoic Acid Sorbic Acid	In-House Method Kbio-TI-0031 using HPLC
	Sugar	ASEAN Manual of Food Analysis, 2011
Foods - Dairy Products - Fish And Fish Products - Honey And Honey Products - Infant Food - Meat, Poultry And Derived Products - Non-alcoholic Beverages - Nuts, Fruits, Vegetables And Derived Products	Total Fat	In-House Method Based on AOAC 963.15, 2005 Acid Hydrolysis-Soxtec 2050
Biological Specimens - Urine	S-Phenylmercapturic Acid (SPMA)	In-House Method Based on: a) NMAM 8236, Issue 1, Fifth Edition, 2014 b) Journal of Chromatography Science Liquid Chromatography-Triple Quadrupole Mass Spectrometry (LC-MS/MS)
	Toluene	In-House Method Based on: a) NMAM 8007, Issue 1, Fifth Edition, 2013 b) NMAM 8002, Issue 2, Fourth Edition, 1994 Headspace-Gas Chromatography-Flame Ionization Detector (HS-GC-FID)
	Methyl Hippuric Acid	In-House Method based on: a) Journal of Chromatography, 182 (1980) 88-93 Biomedical Application b) NMAM 8301, Issue 3, Fourth Edition, 2003 Arc-HPLC

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SCOPE OF TESTING : MICROBIOLOGY

Material / Product Tested	Type Of Test / Properties Measured / Range Of Measurement	Standard Test Methods / Equipment / Techniques
Microbiological Tests On Pharmaceutical And Cosmetics Traditional Herbal Products Cosmetic Toiletries	Total Aerobic Microbial Count	British Pharmacopoeia 2014 Appendix XVI B Pour Plate Technique
	Total Yeast & Mould Count	British Pharmacopoeia 2014 Appendix XVI B Pour Plate Technique
	Bile Tolerant Gram Negative Bacteria - Present/Absent - Semi Quantitative	British Pharmacopoeia 2014 Appendix XVI B Pour Plate Technique
	Escherichia coli - Present/Absent - Semi Quantitative	British Pharmacopoeia 2014 Appendix XVI B Pour Plate Technique
	Salmonella	British Pharmacopoeia 2014 Appendix XVI B Pour Plate Technique
	Pseudomonas aeruginosa	British Pharmacopoeia 2014 Appendix XVI B Pour Plate Technique
	Staphylococcus aureus	British Pharmacopoeia 2014 Appendix XVI B Pour Plate Technique
Medical Devices Medical Devices Medical Solutions - Parenteral Preparation - Ophthalmic - Non- Injectable Preparation	Sterility	USP 41 Microbiological Test <71> Sterility Test
	Bioburden	ISO 11737-1,2018
	Bacteriostasis and Fungistasis	In-house method based on USP 41 Microbiological Test <71> Sterility Test and ISO 11737-2, 2019; Annex A.6.6

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Material / Product Tested	Type Of Test / Properties Measured / Range Of Measurement	Standard Test Methods / Equipment / Techniques
Medical Devices Biological Indicatorspore Strip	Population Count	In-House Method Kbio-TI-0063A based on USP 41 Microbiological Test <55> and ISO 11138 :2017 Part 1 and Part 2 In-House Method Kbio-TI-0063B based on 3M Technical Bulletin-05- 000003
Biological Indicator Spore Strip	Sterility	In-House Method Kbio-TI-0062 on USP 41 Microbiological Test <71> Sterility Test
Medical Injection Liquid dialysis Solution reverse Osmosis Water water For Injection (wfi) purified Water	Bacterial Endotoxins Test by Gel Clot Method	USP 41 Biological Test and Assay <85> Bacterial Endotoxins Test

SCOPE OF TESTING : Medical Injection Liquid Dialysis Solution Reverse Osmosis Water Water for Injection (WFI) Purified Water

Material / Product Tested	Type Of Test / Properties Measured / Range Of Measurement	Standard Test Methods / Equipment / Techniques

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