

As an accredited laboratory, this laboratory is entitled to use the following accreditation symbol.



Valid from 17 May 2023  
to 16 May 2026  
Issued on 17 May 2023



ISO/IEC 17025  
TL 120-01

## Schedule of Accreditation

Accreditation Scheme for Testing / Calibration Laboratories  
Sri Lanka Accreditation Board for Conformity Assessment

Accreditation Number: TL 120-01

**Laboratory of Kelun Lifesciences (Pvt) Ltd,  
Lot No. D4(43-44), Industrial Park-BOI,  
Pallekele,  
Kandy.**

**Scope of Accreditation:** Performing Chemical and Biological testing on parenteral drug products as per the test methods appearing in this schedule.

The Laboratory is accredited for the following tests appear on page 02;

SI NO	Product(s) / Material of test	Specific tests performed	Test Method/ Standard against which tests are performed	Range of testing/ Limits of detection
01	Parenteral drug products (Injection, Infusion)	pH	USP 43, NF-38,2022, chapter 791/ BP 2022 Appendix V L	1-14
		Conductivity	USP 43, NF-38,2022, chapter 644/ BP 2022 Appendix V O	100 µS/cm
		Deliverable Volume	USP 43, NF-38,2022, chapter 698/ BP 2022 Appendix XIX B	1-500 ml
		Particulate matter	USP 43, NF-38,2022, chapter 788/ BP 2022 Appendix XIII	≥ 10 µm ≤ 25 particles/ mL ≤ 25 ≤ 3 particles /ml
02	Glucose infusion BP (5% w/v Glucose 500 ml BP	Identification test	BP 2022, Glucose infusion monograph	Complies/Non complies
		5-Hydroxymethylfurfural and related substances	BP 2022, Glucose infusion monograph	NMT 0.20 at 284 nm
		Assay	BP 2022, Glucose infusion monograph	95.0 % to 105.0 %
		Particulate matter	USP 43, NF-38,2022, chapter 788/ BP 2022 Appendix XIII	≥ 10 µm ≤ 25 particles/ mL
≥ 25µm ≤ 3 particles / mL				
03	Adenosine Injection USP (6mg/2ml Adenosine Injection USP)	Identification	USP 43, NF-38,2022, Adenosine Injection Monograph	Complies/Non complies
		Assay	USP 43, NF-38,2022, Adenosine Injection Monograph	90.0% -110.0%
		Impurities	USP 43, NF-38,2022, Adenosine Injection Monograph	Any individual impurity: NMT 1.0% Total impurities: NMT 1.5%
		Particulate matter	USP 43, NF-38,2022, chapter 788/ BP 2022 Appendix XIII	≥ 10 µm ≤ 25 particles/ mL
≥ 25µm ≤ 3 particles / mL				
04	Metronidazole Intravenous Infusion BP	Identification	BP 2022, Metronidazole Intravenous Infusion monograph	Complies/Non complies

	(0.5% w/v Metronidazole Intravenous Infusion 100ml BP)			
		Assay	BP 2022, Metronidazole Intravenous Infusion monograph	95.0% - 105.0%
		Nitrite	BP 2022, Metronidazole Intravenous Infusion monograph	0-1
		Related substances	BP 2022, Metronidazole Intravenous Infusion monograph	0-0.5%.
		Particulate matter	USP 43, NF-38,2022, chapter 788/ BP 2022 Appendix XIII	$\geq 10 \mu\text{m} \leq 25$ particles/ mL
$\geq 25\mu\text{m} \leq 3$ particles / mL				
05	Sodium chloride Injection BP (0.9% w/v Sodium chloride Injection BP 500ml)	Identification test for Chloride	BP 2022, Sodium chloride Injection monograph	Complies/Non complies
		Identification test for Sodium salt	BP 2022, Sodium chloride Injection monograph	Complies/Non complies
		Assay	BP 2022, Sodium chloride Injection monograph	95.0 % to 105.0 %
		Particulate matter	USP 43, NF-38,2022, chapter 788/ BP 2022 Appendix XIII	$\geq 10 \mu\text{m} \leq 25$ particles/ mL
$\geq 25\mu\text{m} \leq 3$ particles / mL				
06	Sterilized water for Injection BP	Oxidizable substances	BP 2022, Water for Injection BP monograph	Complies/Non complies
		Chlorides	BP 2022, Water for Injection BP monograph	Complies/Non complies
		Nitrates	BP 2022, Water for Injection BP monograph	Complies/Non complies
		Sulfates	BP 2022, Water for Injection BP monograph	Complies/Non complies
		Ammonium	BP 2022, Water for Injection BP monograph	Complies/Non complies
		Calcium and magnesium	BP 2022, Water for Injection BP monograph	Complies/Non complies

		Residue on evaporation	BP 2022, Water for Injection BP monograph	NMT 4 mg
	Water for Injection BP	Acidity and alkalinity	BP 2022, Water for Injection BP monograph	Complies/Non complies
		Particulate matter	USP 43, NF-38,2022, chapter 788/ BP 2022 Appendix XIII	$\geq 10 \mu\text{m} \leq 25$ particles/ mL
				$\geq 25\mu\text{m} \leq 3$ particles / mL
<b>BIOLOGICAL SCOPE</b>				
01	Parenteral drug products (Injection, Infusion)	Sterility testing	USP 43, NF-38,2022, chapter 71/ BP 2022 Appendix XVI	Present or Absent
	Parenteral drug products (Injection, Infusion)	Bacterial Endotoxins	USP 43, NF-38,2022, chapter 85/ BP 2022 Appendix XVI C	0.03-0.25EU/ml Bacterial endotoxins by LAL Chromogenic

Director/CEO  
Sri Lanka Accreditation Board for Conformity Assessment