

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



Valid from 23 November 2023
to 22 November 2026
Issued on 23 November 2023



ISO/IEC 17025
TL 012 - 05

Schedule of Accreditation

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

Accreditation Number: TL 124-01

**Quality Control Laboratory
Celogen Lanka (Pvt) Ltd
Lot No. 7A, Kandy Industrial Park,
BOI, Pallekele, Kandy**

Scope of Accreditation: Performing Chemical & Biological Testing on
Pharmaceutical Products

The laboratory is accredited for the following tests as given in page 02 to 04;

Sl	Product(s) / Material of test	Specific tests performed	Test Method / Standard against which tests are performed	Range of testing/ Limits of detection
Chemical				
01	Tablets Metformin Tablets BP 500mg	Description (For government supply)	Inhouse (Master Formula Record)	White to almost white colored round deep biconvex coated tablets with embossing "DHS" on one side and break line on other side
		Description (For private market)	Inhouse (Master Formula Record)	White to almost white colored round deep biconvex coated tablets with embossing "500" on one side and break line on other side
		Identification	BP 2022, Volume III Metformin Tablets	0% to 100%
		Average Weight	Tablet Weight is Inhouse % Limit is BP 2022, Volume V Appendix XII C Consistency of Formulated Preparation	10mg to 12g
		Uniformity of weight	BP 2022, Volume V Appendix XII C Consistency of Formulated Preparation	10mg to 12g
		Uniformity of dosage unit by mass variation	BP 2022, Volume V Appendix XII C Consistency of Formulated Preparation	Acceptance value where, $L1 \leq 15.0$ or $L2 \leq 25.0$
		Disintegration	BP 2022, Volume III General Monographs Tablets Coated Tablets	0 min to 30 min
		Dissolution	BP 2022, Volume III Metformin Tablets	0% to 115%
		1-Cyanoguanidine	BP 2022, Volume III Metformin Preparation	0.001% to 0.02%
		Assay	BP 2022, Volume III Metformin Tablets	0% to 105%

SI	Product(s) / Material of test	Specific tests performed	Test Method / Standard against which tests are performed	Range of testing/ Limits of detection
Biological				
02	<p>Water Soluble Products</p> <p>Tablets</p> <p>(Acetazolamide, Acyclovir, Amisulpride, Amlodipine Besylate, Ascorbic Acid (Vitamin C) and Zinc Chewable, Atorvastatin, Baclofen, Bisoprolol Fumarate, Bosentan, Cabergoline, Clopidogrel, Clozapine, Dapagliflozin, Deferasirox, Donepezil, Hydrochloride, Ferrous Ascorbate and Folic Acid, Ferrous Fumarate & Folic acid, Ferrous sulphate, Furosemide, Gastro-resistant Aspirin, Gastro-resistant Sodium Valproate, Gliclazide MR, Hydralazine, Hydroxychloroquine Sulfate, Labetalol, Lamotrigine, Levamisole Hydrochloride, Levetiracetam, Lithium Carbonate, Losartan Potassium, Metformin, Methyl dopa, Metoprolol Tartrate, Mycophenolate Mofetil, Nalidixic acid, Oxcarbazepine, Pizotifen, Prolonged release Diltiazem, Prolonged Release Isosorbide Mononitrate, Prolonged Release Metformin, Pyridostigmine, Pyrimethamine, Quetiapine, Risperidone, Sertraline Hydrochloride, Sitagliptin, Sodium Bicarbonate, Sulfadiazine, Ticagrelor, Ursodeoxycholic Acid, Valganciclovir, Vigabatrin, Voriconazole, Warfarin Sodium, Calcium Carbonate, Calcium Lactate, Captopril, Carvedilol, Cetirizine, Zinc Sulphate, Colecalciferol</p>	Total Aerobic Microbial Count	USP 43, NF-38,2022 <1111> Microbiological Test <61> BP 2022, Volume V Appendix XVI D Appendix XVI B	10 CFU/gm to 1000 CFU/gm
		Total Yeast and Mold Count	USP 43, NF-38,2022 <1111> Microbiological Test <61> BP 2022, Volume V Appendix XVI D Appendix XVI B	10 CFU/gm to 100 CFU/gm

Sl	Product(s) / Material of test	Specific tests performed	Test Method / Standard against which tests are performed	Range of testing/ Limits of detection
03	Water Insoluble Non- Fatty Products Hard Gelatin Capsules (Oseltamivir Phosphate, Pancreatin, Penicillamine, Amantadine Hydrochloride, Trientine Hydrochloride, Clindamycin, Gastro-Resistant Omeprazole)	Total Aerobic Microbial Count	USP 43, NF-38,2022 <1111> Microbiological Test <61> BP 2022, Volume V Appendix XVI D Appendix XVI B	10 CFU/gm to 1000 CFU/gm)
		Total Yeast and Mold Count	USP 43, NF-38,2022 <1111> Microbiological Test <61> BP 2022, Volume V Appendix XVI D Appendix XVI B	10 CFU/gm to 100 CFU/gm)
04	Water Insoluble Fatty products- Soft gelatin Capsules Alfacalcidol Capsules, Calcitriol Capsules, Colecalciferol Capsules, Vitamin A And D Capsules, Vitamin A Capsules, Vitamin E Capsules, Biovita Gold, Naïve Fairness, Ovi Codrose, Naïve Rose, Biovita 40 Plus, Biovita Radiant, Biovita Gold Velmi, Kalcin, Biovita Smart, Pregnum F, Naïve Green, Green Coffee Bean, Trichopil, Biovita Hair, Biovita Teens, Nutriphan, Nu-D3 Suppositories Acetaminophen, Diclofenac Sodium, Domperidone	Total Aerobic Microbial Count	USP 43, NF-38,2022 <1111> Microbiological Test <61> BP 2022, Volume V Appendix XVI D Appendix XVI B	10 CFU/gm to 1000 CFU/gm)
		Total Yeast and Mold Count	USP 43, NF-38,2022 <1111> Microbiological Test <61> BP 2022, Volume V Appendix XVI D Appendix XVI B	10 CFU/gm to 100 CFU/gm)

Director /CEO
Sri Lanka Accreditation Board for Conformity Assessment