Valid from 09 April 2025
to 08 April 2029
Issued on 09 April 2025

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

ISO/ IEC 17025
TL 140-01

Schedule of Accreditation

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

Accreditation Number: TL 140 -01

Sands Active (Pvt) Ltd - Analytical Laboratory
No.51, Pathum Piyasa Road,
Croos Watta, Ekala
Ja Ela.

Scope of Accreditation: Performing Chemical & Biological testing on Pharmaceutical Oral Tablets as per the test methods appearing in the schedule.

The Laboratory is accredited for the following tests appear on page 02 to 06 ;

Sl No.	Product(s) / Material of test	Specific tests performed	Test Method / Standard against which tests are performed	Range of testing/ Limits of detection
Biological Testing				
1.	Pharmaceutical Oral Solid Dosage Forms Tablets – Coated & Uncoated Tablets	Microbial Enumeration Tests (Total Aerobic Microbial Count)	GTP/MB/020/00 (With reference to USP-NF 2024 Chapter <61> & <1111> ; BP-2024 Appendix XVI B (Test No. 2); Ph. Eur. (11-Edition) Method 2.6.12 and IP-2022, 2.2.9 (Test No. 1)	Max 10^3 cfu / g
2.		Microbial Enumeration Tests (Total Yeast & Mold Count)	GTP/MB/021/00 (With reference to USP-NF 2024 Chapter <61> & <1111> ; BP-2024 Appendix XVI B (Test No. 2); Ph. Eur. (11-Edition) Method 2.6.12 and IP-2022, 2.2.9 (Test No. 1)	Max 10^2 cfu / g
3.		*Escherichia coli*	GTP/MB/022/00 (With reference to USP-NF-2024 Chapter <62> & <1111> ; BP-2024 Appendix XVI B (Test No. 1); Ph. Eur. (11-Edition) Method 2.6.13 and IP-2022, 2.2.9 (Test No. 2)	Absent / Present
Chemical Testing				
4.	Pharmaceutical Oral Dosage forms Tablets – Coated & Uncoated Tablets	Average Weight	GTP/QC/019/00 (With reference to BP: 2024, Appendix XII C, Method 1, USP-NF: 2024 <2091>, IP: 2022, 2.5.3.)	60mg to 1500mg
5.		Uniformity of Weight	GTP/QC/020/00 (with reference to BP:2024, Appendix XII C, Method 1, USP-NF:2024 <2091>, IP: 2022, 2.5.3)	60mg to 1500mg
6.		Hardness	GTP/QC/007/00 (with reference to USP-NF:2024 <1217>)	50 N to 490 N
7.		Thickness	GTP/QC/008/00	1 mm to 100 mm
8.		Uniformity of Dosage Units (by Weight Variation / by Mass Variation)	GTP/QC/023/00 (with reference to BP:2024, Appendix XII C, Method 1, IP:2022, 2.5.3, USP-NF:2024 <905>)	Acceptance value, L1 ≤15.0

9.	Pharmaceutical Oral Dosage forms Tablets – Coated & Uncoated Tablets	Disintegration Test	GTP/QC/022/00 (with reference to BP: 2024, Appendix XII A., IP:2022, 2.5.1, USP-NF:2024 <701>)	0 seconds to 60 minutes
10.	Pharmaceutical Tablets – Delayed Release Tablets	Disintegration Test	GTP/QC/022/00 (with reference to BP: 2024, Appendix XII A., IP:2022, 2.5.1, USP-NF:2024 <701>)	No dosage unit shows evidence of disintegration, cracking, or softening
11.	Pharmaceutical Tablets – Uncoated Tablets	Friability	GTP/QC/021/00 (with reference to BP: 2024, Appendix XVII G., USP-NF:2024 <1216>, IP:2022, 2.5.5)	Max 1.0%
12.	Pharmaceutical Oral Dosage forms Tablets – Coated & Uncoated Tablets	Identification by Melting Point	BP: 2024, Appendix V A 1	0^0C to 300^0C
13.	Paracetamol Tablets BP 500 mg	Identification by Test with Potassium Dichromate	BP: 2024, Volume: III, monograph	Qualitative test
14.		Identification (by IR)	BP: 2024, Volume: III, monograph & BP:2024: Appendix II A	Qualitative test
15.		Dissolution (by UV)	BP: 2024, Volume: III, monograph & BP:2024: Appendix XII B1, Appendix II B	Min. 70 % + 5%
16.		Assay (by UV)	BP: 2024, Volume: III, monograph	95 % to 105 %
17.		Related Substances (by HPLC) 4-aminophenol	BP: 2024, Volume: III, monograph	Max. 0.1%
18.		Related Substances (by HPLC) 4-chloacetanilide	BP: 2024, Volume: III, monograph	Max. 10 ppm
19.		Related Substances (by HPLC) Any other unknown impurity	BP: 2024, Volume: III, monograph	Max. 0.25%
20.	Metformin Tablets BP 500mg	Identification (by IR)	BP: 2024, Volume: III, monograph & BP:2024: Appendix II A	Qualitative test
21.	Metformin Tablets BP 500mg	Assay (by HPLC)	BP: 2024, Volume: III, monograph	95 % to 105 %

22.	Metformin Tablets BP 500mg	Dissolution (by HPLC)	BP: 2024, Volume: III, monograph & BP:2024: Appendix XII B1, Appendix II B	Max. 75% +5%
23.		Related substances (by HPLC) Impurity A (1-cyanoguanidine)	BP: 2024, Volume: III, monograph	Max. 0.02 %
24.		Related substances (by HPLC) Any individual unknown impurity	BP: 2024, Volume: III, monograph	Max.0.10 %
25.		Related substances (by HPLC) Unknown Impurities	BP: 2024, Volume: III, monograph	Max. 0.5 %
26.	Losartan Potassium Tablets USP 50mg	Dissolution (by UV)	USP-NF:2024 Volume: II, monograph & USP-NF:2024 <711>	Max. 75% +5%
27.		Identification (by HPLC)	USP-NF:2024, Volume: II, monograph	Qualitative test
28.		Assay (By HPLC)	USP-NF:2024, Volume: II, monograph	95.0% to 105 %
29.		Uniformity of Dosage Units (HPLC)	USP-NF:2024, Volume: II, monograph &, USP-NF:2024 <905>	Acceptance value, L1 ≤15.0
30.		Organic Impurities (By HPLC) 1H-Dimer	USP-NF:2024, Volume: II, monograph	Max. 0.5%
31.		Organic Impurities(By HPLC) 2H-Dimer	USP-NF:2024, Volume: II, monograph	Max.0.5%
32.		Organic Impurities(By HPLC) Total Impurities	USP-NF:2024, Volume: II, monograph	Max. 1.0%
33.	Diclofenac Sodium Delayed-Release Tablets USP 50 mg	Dissolution: Acidic Stage: 0.1N HCL	USP-NF:2024 Volume: I, monograph & USP-NF:2024 <711>	Max. 10%
34.	Diclofenac Sodium Delayed-Release Tablets USP 50 mg	Dissolution: Buffer Stage: pH 6.8 phosphate buffer	USP-NF:2024 Volume: I, monograph & USP-NF:2024 <711>	Max. 75% +5%

35.	Diclofenac Sodium Delayed-Release Tablets USP 50 mg	Identification by UV	USP-NF:2024, Volume: I, monograph	Qualitative test
36.		Identification by HPLC	USP-NF:2024, Volume: I, monograph	Qualitative test
37.		Assay (by HPLC)	USP-NF:2024, Volume: I, monograph	90 % to 110 %
38.		Content Uniformity (by HPLC)	USP-NF:2024, Volume: I, monograph & USP-NF:2024<905>	Acceptance value, L1 ≤15.0
39.		Organic Impurities (by HPLC) Diclofenac related compound A	USP-NF:2024, Volume: I, monograph	Max. 0.5%.
40.		Organic Impurities (by HPLC) Any individual unspecified impurity	USP-NF:2024, Volume: I, monograph	Max. 0.5%.
41.		Organic Impurities(by HPLC) Total impurities	USP-NF:2024, Volume: I, monograph	Max. 1.5%.
42.	Atorvastatin Tablets IP 10mg / 20mg	Dissolution (by HPLC)	IP: 2022, Volume: II, monograph & IP:2022, 2.5.2	Max. 70% +5%
43.	Atorvastatin Tablets IP 10mg / 20mg	Identification (by HPLC)	IP: 2022, Volume: II, monograph	Qualitative test
44.	Atorvastatin Tablets IP 10mg / 20mg	Assay (by HPLC)	IP: 2022, Volume: II, monograph	90 % to 110 %
45.	Atorvastatin Tablets IP 10mg / 20mg	Related substances (by HPLC) Any individual impurities	IP: 2022, Volume: II, monograph	1.00%
46.	Atorvastatin Tablets IP 10mg / 20mg	Related substances (by HPLC) Total impurities	IP: 2022, Volume: II, monograph	4.00%
47.	Atorvastatin Tablets IP 10mg	Uniformity of Dosage Units (by HPLC)	IP:2022, 2.5.3	Acceptance value, L1 ≤15.0

Acting Director/CEO
Sri Lanka Accreditation Board for Conformity Assessment