

#### SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

QUALITY ASSURANCE OF VIETNAM
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#### **CALIBRATION**

Valid To: September 30, 2023 Certificate Number: 3633.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following calibrations<sup>1</sup>:

#### I. Chemical Quantities

Parameter/Equipment	Range	CMC <sup>2</sup> (±)	Comments
Atomic Absorption Spectrophotometer (AAS) – Wavelength Accuracy Absorbance	(175 to 900) nm (0 to 3) Abs	0.23 nm F: 0.0015 Abs G: 0.0020 Abs H: 0.00079 Abs	A10-37 annex 10 of the OMCL network guideline:  Qualification of atomic absorption/atomic emission spectrometers; 0.1 % single standard solution; 0.01 % ppm mix standard solution; F= flame, G= graphite, H= Hydride

Parameter/Equipment	Range	CMC <sup>2, 3</sup> (±)	Comments <sup>6</sup>
High Performance Liquid Chromatography (HPLC) – Flowrate	(0.1 to 2.0) mL/min	0.0008 mL/min	A10-24 qualification of high-performance liquid chromatography
Temperature	(20 to 60) °C	0.2 °C	Gravimetric method; UV-VIS, FLD, RID,
Wavelength Accuracy Injection Volume Accuracy	(190 to 770) nm 20 μL	0.3 nm 2.9 %	MS/MS Detector  Ion Chromatography (IC) Standard: Sucrose, Caffeine, holmium oxide solution; Balance: d ≤ 0.0001g Thermometer, d ≤ 0,1 °C
Flame Spectrophotometer	Up to 100 mg/L	0.57 % of reading	A10-80 standard: potassium chlorine solution
Gas Chromatography	(50 to 300) °C	0.24 °C	A10-38 standard: thermometer chemical standards
Kjeldahl Distillation Unit –  Total Nitrogen	Up to 200 mg	0.56 %	A10-20: Titration method; standard: NH <sub>4</sub> <sup>+</sup> 1000 ppm, HCl 0.1 N

Parameter/Equipment	Range	CMC <sup>2, 3</sup> (±)	Comments
Ultraviolet and Visible Spectrophotometer (UV- Vis) –			A10-15, ASTM E925 wavelength accuracy:
Wavelength Accuracy Absorbance	(190 to 1100) nm  ~0.2 Abs ~0.5 Abs ~1.0 Abs ~1.7 Abs ~2.0 Abs	0.4 nm 0.0042 Abs 0.0062 Abs 0.0096 Abs 0.015 Abs 0.018 Abs	Holmium, didymium filter photometric accuracy with certified reference materials: neutral density glass filter, didymium glass filter, potassium dichromate liquid filter
Temperature	(10 to 60) °C	0.12 °C	diemomate nquid mer
Elisa Reader –			A10-16 manufacturer's manual Standards:
Wavelength Accuracy	(300 to 700) nm	0.3 nm	Wavelength accuracy: holmium oxide glass filter
Absorbance Accuracy	~ 0 Abs ~ 0.3 Abs ~0.5 Abs ~1.1 Abs ~1.7 Abs ~2.9 Abs	0.001 Abs 0.005 Abs 0.005 Abs 0.008 Abs 0.010 Abs 0.06 Abs	Photometric accuracy: neutral density glass filter

Parameter/Equipment	Range	CMC <sup>2, 3</sup> (±)	Comments
Dissolution Tester –			A10-17 dissolution. The
Time	(0 to 120) min	0.01 min	United States
Temperature	(20 to 50) °C	0.15 °C	pharmacopeial convention, 2012, p. 5642 – 5649
Rotation Speed	(30 to 200) rpm	0.12 rpm	Standards:
Solubility Testing	(0 to 100) %	5.1 %	certificate prednisone tablets, The United States pharmacopeial
Balance Test	(0 to 90)°	0.17°	convention,11-2015,
Vibration Test	Up to 5 mm/s	0.08 mm/s	CERT1_4-02; temperature datalogger; digital
Paddle/Basket High	(23 to 27) mm	3.0 µm	tachometer, vibration meter, kit for check
Paddle/Basket Shaft Wobble	(0 to 3) mm	0.12 μm	dissolution tester
Disintegration Tester –			
Time	(0 to 120) min	0.01 min	A10-19 disintegration. The
Temperature	(20 to 50) °C	0.15 °C	United States
Oscillation Frequency	(30 to 150) rpm	0.12 rpm	pharmacopeial convention 08/2008
Oscillation Amplitude	Up to 100 mm	0.03 mm	Standards: temperature datalogger; digital tachometer, timer, caliper

Parameter/Equipment	Range	CMC <sup>2, 3</sup> (±)	Comments
Laboratory Test Equipment –			
Time	Up to 24 hr	1.1s	A10-131
Temperature	(-30 to 15) °C (15 to 95) °C (95 to 150) °C (150 to 400) °C	0.29 °C 0.25 °C 0.38 °C 0.62 °C	Standards: temperature datalogger; digital tachometer, timer
Oscillation Frequency	Up to 2000 rpm (2000 to 20 000) rpm	0.63 rpm 2.7 rpm	
pH Meter	(2 to 14) pH	0.013 pH	A10-10 manufacturer's manual; comparison with pH calibration buffer standard solution
Conductivity Meter – Accuracy	Up to 13 mS/cm	0.64 % reading	A10-11 manufacturer's manual; comparison with conductivity standard solutions
Turbidity Meter – Accuracy	Up to 100 NTU (100 to 4000) NTU	1.7 % reading 0.83 % reading	A10-12 manufacturer's manual; comparison with turbidity standard solutions
Salinity Meter – Accuracy	Up to 45x10e-9	1.2 % reading	A10-26 manufacturer's manual; compare with saline standard solutions

Parameter/Equipment	Range	CMC <sup>2, 3</sup> (±)	Comments
Dissolved Oxygen Meter (DO) – Accuracy	(0 to 20) mg/L	0.052 mg/L	A10-22; the Winkler titration method, Standards: KIO <sub>3</sub> , Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub>
Total Dissolved Solids Meter (TDS) – Accuracy	Up to 2000 mg/L (2000 to 3000) mg/L	0.33 % reading 1.2 % reading	A10-21; comparison with TDS standard solutions
Chlorine Meter – Accuracy	(0 to 3.3) mg/l (3.3 to 10) mg/l	0.02 mg/l 0.11 mg/l	A10-28; DPD method; manufacturer's manual; chlorine solution standard
BOD Meters	(270 to 330) mg/L	12 %	A10-27 user manual COA
Potential Titration –			A10-23
Volume of Burette	(0 to 5) mL 10 mL 15 mL 20 mL	0.0013 mL 0.0018 mL 0.0022 mL 0.0025 mL	Gravimetric method
Acid-Base Electrode	(0 to 14) pH	0.013 pH	Comparison with standard solution
Redox Oxidation Electrode	220 mV	5.8 mV	Comparison with standard solution
Silver Electrode	(250 to 350) mV	2.1 mV	Comparison with standard solution

Parameter/Equipment	Range	CMC <sup>2, 3</sup> (±)	Comments
FTIR Spectrophotometers	(3500 to 1800) cm <sup>-1</sup> (1800 to 600) cm <sup>-1</sup> (600 to 539) cm <sup>-1</sup>	1.1 cm <sup>-1</sup> 0.32 cm <sup>-1</sup> 0.09 cm <sup>-1</sup>	A10-76 standard: polystyrene
Hydrometer	(0.600 to 2.000) g/cm <sup>3</sup>	0.0015 g/cm <sup>3</sup>	A10-85 density meter, thermometer
Brix Meter	Up to 75 % Brix	0.32 % Brix	A10-79 sucrose solutions, brix meter
Alcohol Meter	Up to 100 % v/v	0.13 % V/V	A10-86 Standard: alcohol meter standard; liquid water bath; temperature measuring

### II. Dimensional

Parameter/Equipment	Range	CMC <sup>2, 3</sup> (±)	Comments
Microscopy	Eyepiece Unit, mm (0 to 1) mm (Objective 4X)	0.52 %	A10-125 Standard: micrometer
	Eyepiece Unit, mm (0 to 1) mm (Objective 10X)	0.26 %	
	Eyepiece Unit, mm (0 to 1) mm (Objective 40X)	0.38 %	
	Eyepiece Unit, mm (0 to 1) mm (Objective 100X)	0.63 %	

## III. Fluid Quantities

Parameter/Equipment	Range	CMC <sup>2</sup> (±)	Comments
Laboratory Volumetric Glassware –			
Volumetric Flask	(10 to 25) mL (50 to 100) mL (200 to 500) mL 1000 mL 2000 mL	0.019 mL 0.028 mL 0.070 mL 0.15 mL 0.26 mL	A10-02 gravimetric method; balance d =0.01g, d= 0.000 01g
Burette	10 mL 25 mL 50 mL	0.0035 mL 0.0047 mL 0.0079 mL	
Measuring Cylinder	25 mL 50 mL 100 mL 250 mL 500 mL 1000 mL 2000 mL	0.030 mL 0.059 mL 0.059 mL 0.13 mL 0.37 mL 0.74 mL 1.6 mL	
Volumetric Pipette (Bulb Pipette)	1 mL 2 mL 5 mL 10 mL 20 mL 25 mL 50 mL	0.0006 mL 0.0012 mL 0.0014 mL 0.0022 mL 0.0055 mL 0.0058 mL 0.0080 mL	
Graduated Pipette	1 mL 2 mL (5 to 10) mL (20 to 25) mL 50 mL	0.0008 mL 0.0018 mL 0.0034 mL 0.0064 mL 0.014 mL	
Karl – Fisher Titration	(0 to 2) mL (2 to 10) mL (10 to 20) mL	0.0010 mL 0.0015 mL 0.0025 mL	A10-84 gravimetric method; balance d =0.01g, d= 0.001g, d=0.000 1g, d=0.000 01g

Parameter/Equipment	Range	CMC <sup>2</sup> (±)	Comments
Piston Operated Volumetric Apparatus –			
Pipette	1 μL (5 to10) μL (20 to100) μL 500 μL 1000 μL 2500 μL 5000 μL 10 000 μL 20 000 μL	0.015 μL 0.021 μL 0.073 μL 0.10 μL 0.12 μL 3.0 μL 3.0 μL 5.9 μL 12 μL	A10-018 gravimetric method; balance d =0.01g, d= 0.000 01g, d=0.000 001g
Burette	(1 to 50) mL	0.008 mL	
Dispensers	10 mL 25 mL 50 mL	0.12 mL 0.29 mL 0.58 mL	

#### IV. Mechanical

Parameter/Equipment	Range	CMC <sup>2</sup> (±)	Comments
Electronic Balance	(0.001 to 0.01) g (0.01 to 0.1) g (0.1 to 10) g (10 to 22) g (22 to 50) g (50 to 120) g (120 to 320) g (320 to 410) g (410 to 2000) g (2000 to 6200) g (6200 to 30 000) g	0.0012 g 0.000 010 g 0.000 037 g 0.000 059 g 0.000 09 g 0.000 13 g 0.0005 g 0.001 g 0.01 g 0.02 g 1 g	A10-01 Comparison indicator of balance with standard weight; Weights class: E2, F1, M1
Centrifuge, Spin, Systematic Devices Shake	11 4 2000	0.64	A10-13 manufacturer's manual
Non-Contact Type	Up to 2000 rpm (2000 to 20 000) rpm	0.64 rpm 2.0 rpm	Standard: digital tachometer

Parameter/Equipment	Range	CMC <sup>2, 5</sup> (±)	Comments
Pressure – Measuring Equipment			
Gauge Pressure  Barometric Pressure	(0.3 to 7) bar (300 to 1100) mbar	0.0043 bar 4.1 mbar	A10-106 comparison with pressure standard: pressure meter
Moisture Analyzer	Up to 220 g (50 to 150) °C	0.0005 g 1.4 °C	A10-83 standard: weights class E2, F1, digital thermometer
Weights F1, F2, M1, M2	(0.01 to 0.2) g 0.5 g 1 g 2 g 5 g (10 to 50) g 100 g 200 g	0.006 mg 0.009 mg 0.018 mg 0.019 mg 0.022 mg 0.033 mg 0.10 mg 0.16 mg	A10-67 ABBA/ABA method standard: weights class E1, E2, F1, F2 balance d=0.000 01, d=0.0001, d=0.001
Balance Class III, IIII	Up to 8000 g (8000 to 20 000) g (20 000 to 120 000) g	5.8 g 12 g 30 g	A10-127 gravimetric method standard: weights class M1, M2

## V. Thermodynamic

Parameter/Equipment	Range	CMC <sup>2</sup> (±)	Comments
Temperature Chamber (Oven, Incubator, Refrigerator, Freezer)	(-80 to -20) °C (-20 to 4) °C (4 to 105) °C (105 to 180) °C	1.5 °C 0.87 °C 0.30 °C 0.39 °C	A10-03 standard: thermocouple type K, T with datalogger
Furnace	(100 to 350) °C (350 to 950) °C	1.2 °C 1.7 °C	A10-04 standard: thermocouple type K with datalogger

Parameter/Equipment	Range	CMC <sup>2</sup> (±)	Comments
Reactor Block	(105 to 150) °C (150 to 450) °C	0.86 °C 1.4 °C	A10-07 standard: thermocouple type K with datalogger
Autoclave –			
Temperature Pressure	(50 to 140) °C Up to 5 bar	0.37 °C 0.015 bar	A10-05 standard: temperature, pressure datalogger
Liquid Baths	(0 to 20) °C (20 to 60) °C (60 to 100) °C	0.24 °C 0.27 °C 0.58 °C	A10-06 standard: temperature datalogger, thermocouple type K
PCR/RT-PCR	(0 to 100) °C	0.16 °C	A10-145 standard: temperature datalogger
Glass Liquid Thermometer	(-20 to 100) °C (100 to 160)	0.11 °C 0.15 °C	A10-08 comparison with standard thermometer;  Control temperature with liquid bath.
Digital & Analog Temperature Sensor, Probe Thermometer	(-40 to 130) °C (130 to 200) °C (200 to 400) °C (400 to 650) °C	0.07 °C 0.29 °C 0.37 °C 0.67 °C	A10-09 comparison with standards thermometer;  Control temperature with temperature block calibrator
Melting Point Meter	(50 to 150) °C (150 to 300) °C	0.36 °C 0.53 °C	A10-66 Standard: thermometer; Reference substances

Parameter/Equipment	Range	CMC <sup>2</sup> (±)	Comments
Thermo-Hygrometer –			
Temperature	(0 to 15) °C (15 to 50) °C	0.70 °C 0.54 °C	A10-25 comparison with standard thermo-
Humidity	(30 to 90) % RH	2.6 % RH	hygrometer

#### **MECHANICAL**

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory<sup>4</sup> to perform the following test on fume hoods, cleanrooms and bio-safety cabinets.

<u>Test</u>	Test Method(s)
Biosafety Cabinet	A10-14, NSF/ANSI 49 – 2020; EN 12469: 2000; EN 1822-1: 2019
HEPA/ULPA Filter Leak Test, % Testing air flow morphology	Up to 100 %, d= 0.0001 % Observation of the airflow direction clearly according to the design
Noise Test, dBA	$(30 \div 94)  dBA, d=0.1  dBA$
Inflow Velocity Test, m/s Downflow Velocity Test, m/s Lighting Intensity Test lux Testing Filter Performance (hat 0,3 µm), % Ultraviolet Test, µW/cm² Vibration Test, mm Cleanrooms and Associated Controlled Environments – Test Methods	Up to 2 m/s, d= 0.01 m/s Up to 2 m/s, d= 0.01 m/s Up to 4000 lux, d= 0.01 lux Up to 100 % Up to 300 μW/cm², d=1 μW/cm² Up to 2 mm; d= 0.001 mm  A10-111, TCVN 8664: 2011 (ISO 14644: 2005 - Except 4.2.7, 4.2.8)) 009-HD-PST_CR - Procedural standards for certified testing of cleanrooms
Filter Face Airflow Velocity Test, m/s Average Room Airflow Velocity Test, m/s Total Airflow Volume, m³/h Air Change Rate, Times/Hour HEPA/ULPA Filter, Leak Test, % Airflow Direction and Visibility Test	Up to 2 m/s, d= 0.01 m/s Up to 2 m/s, d= 0.01 m/s m <sup>3</sup> /h times/hour Up to 100%, d= 0.0001 % Observation of the airflow direction clearly according to the design of the cleanroom Up to 250 Pa, d= 0.1 Pa Particle (0.3 to 5) $\mu$ m
Differential Pressure Test, Pa Airborne Particle Count Cleanness Classification Test, Particle Recovery Test 100:1 Lighting Level Test, lux Cleanroom Temperature Test, °C Cleanroom Humidity Test, % RH Sound Level Test, dBA Laboratory Fume Hood (as installed, as	d= 0.01 s Up to 4000 lux, d = 0.01 lux (15 to 40) °C, d= 0.1 °C (40 to 90) %RH, d= 0.1 %RH (30 ÷ 94) dBA, d= 0.1 dBA
used)	294-2009-HD-NEBB – Procedural standards for fume hood performance testing
Flow Visualization Test Sound Test, dBA Velocity Test, m/s Light Test, lux Ultraviolet Lighting Test, $\mu$ W/cm <sup>2</sup> Vibration Test	Local and gross smoke visualization are good (30 to 94) dBA, d= 0.1 dBA Up to 2 m/s, d= 0.01 m/s Up to 4000 lux, d = 0.1 lux Up to 300 $\mu$ W/cm <sup>2</sup> , d=1 $\mu$ W/cm <sup>2</sup> Up to 2 mm; d= 0.001 mm

<sup>&</sup>lt;sup>1</sup> This laboratory offers commercial calibration service and field calibration service.

<sup>&</sup>lt;sup>2</sup> Calibration and Measurement Capability Uncertainty (CMC) is the smallest uncertainty of measurement that a laboratory can achieve within its scope of accreditation when performing more or less routine calibrations of nearly ideal measurement standards or nearly ideal measuring equipment. CMCs represent expanded uncertainties expressed at approximately the 95 % level of confidence, usually using a coverage factor of k = 2. The actual measurement uncertainty of a specific calibration performed by the laboratory may be greater than the CMC due to the behavior of the customer's device and to influences from the circumstances of the specific calibration.

<sup>&</sup>lt;sup>3</sup> In statement of CMC, percentages are percentage of reading, unless otherwise indicated.

<sup>&</sup>lt;sup>4</sup> Accreditation is granted for field testing activities at this location only, and only applies to field technicians that are based out of this location.

<sup>&</sup>lt;sup>5</sup> The type of instrument or material being calibrated is defined by the parameter. This indicates the laboratory is capable of calibrating instruments that measure or generate the values in the ranges indicated for the listed measurement parameter.

<sup>&</sup>lt;sup>6</sup> ppm stands for parts in 10<sup>6</sup>.



# **Accredited Laboratory**

A2LA has accredited

## **QUALITY ASSURANCE OF VIETNAM**

Hanoi, VIETNAM

for technical competence in the field of

## Calibration

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017

General requirements for the competence of testing and calibration laboratories. This laboratory also meets R205 – Specific Requirements: Calibration Laboratory Accreditation Program. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system

(refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



Presented this 11th day of November 2021.

Vice President, Accreditation Services For the Accreditation Council Certificate Number 3633.02 Valid to September 30, 2023