



CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

**The National Reference Laboratory for Food and
Safety – Medicine Control Laboratory
Chinggis Avenue 75
Ulaanabaatar, Mongolia 17042**

has been assessed by ANAB
and meets the requirements of international standard

ISO/IEC 17025:2005

while demonstrating technical competence in the field of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of tests to which this accreditation applies.

AT-2017

Certificate Number


ANAB Approval

Certificate Valid: 12/18/2017-12/18/2019
Version No. 003 Issued: 12/18/2017



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005.
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).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

The National Reference Laboratory for Food Safety

Chinggis Avenue 75, Khan-Uul district

Ulaanbaatar 17042, Mongolia

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TESTING

Valid to: **December 18, 2019**

Certificate Number: **AT-2017**

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
pH	USP <791> EP 2.2.3, BP V L, CP VI H, MNP page 543	API, Finished Products	pH Meter
Loss on Drying	USP <731> EP 2.2.32, BP IX D, CP VIII L, MNP page 509	API, Finished Products	Oven, Analytical Balance
Loss on Ignition	USP <733> EP 2.2.14, BP IX A, XI J, CP VIII N, MNP page 509	API, Finished Products, Plant Materials, Herbal Drug	Oven, Analytical Balance
Water Content	USP <921> EP 2.5.12, BP IX C, CP VIII M	API, Finished Products	Dual Karl-Fischer Titrator
Particulate Contamination	USP <788>; <789> EP 2.9.19, 2.9.20, BP XIII CP IX C	Finished Products	Microscopy
Uniformity of Mass	USP <2091> EP 2.9.5, BP XII C2	API, Finished Products	Analytical Balance
Uniformity of Content	USP <905> EP 2.9.6, BP XIIC3, CP X E	API, Finished Products	Spectrophotometer, HPLC
Trace Elements	USP <851> EP 2.2.23, BP II D, CP IV D MNP page 531	API, Finished Products	AAS Apparatus
Melting Point	USP <741> EP 2.2.14, BP V A, CP VI C, MNP page 515	API	Automatic Melting-point

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Viscosity	USP <911> EP 2.2.8, BP V H, CP VI G, MNP page 522	API, Finished Products	Visco-clock, Capillary and Water Bath
Density/Specific Gravity	USP <841> BP V G, CP VI A, MNP page 521	API, Finished Products	Pycnometer, Areometer
Optical Rotation	USP <781> EP 2.2.7, BP V F, CP VI E, MNP page 524	API, Finished Products	Polarimeter
Refractive Index	USP <831> EP 2.2.6, BP V E, CP VI F, MNP page 523	API, Finished Products	Refractometer
Limit Tests	USP <206,221,228,231,232, 233,241,251> EP 2.4.1, 2.4.3, 2.4.4, 2.4.6, 2.4.7, 2.4.8, 2.4.9, 2.4.11, 2.4.12, 2.4.27, BP VII, CP VIIIA, B, G, H, K MNP page 498	All Finished Products, Herbal Drugs	Comparative Test, AAS
Related Substances	USP, EP, BP, CP MNP	API, Finished Products	TLC, HPLC
Friability	USP <1216> EP 2.9.7, BP XVII G, CP X G MNP page 472	Finished Products	Friability Tester, Analytical Balance
Tablet Hardness	USP <1217> EP 2.9.8, BP VII H, MNP page 472	Finished Products	Hardness Tester, Analytical Balance
Disintegration	USP <701> EP 2.9.1, 2.9.2, BP XII A, CP X A, B, MNP page 481	Finished Products	Disintegration Apparatus
Dissolution	USP <711> EP 2.9.3, BP XII B, CP X C, MNP page 474	Finished Products	Dissolution Apparatus
Residual Solvents	USP <467> EP 2.4.24, BP VIII L, CP VIII P, MPN page 486	API, Finished Products	GC
Identification	USP <191> EP 2.3.1, BP VI, CP III, MNP page 490	API, Finished Products	Chemical Reaction

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Identification	USP <201>, <621> EP, BP III A, CP V B, MNP page 538	API, Finished Products	TLC set
Identification	USP <197>, <851> EP 2.2.24, BP II A, CP IV C, MNP page 526	API, Finished Products	FTIR Spectrophotometer
Identification/Assay	USP <197>, <851> EP 2.2.25, BP II B, CP IV A, MNP page 526	API, Finished Products	UV-VIS Spectrophotometer
Identification/Assay	USP <621> EP 2.2.29, BP III D, CP V D, MNP page 542	API, Finished Products	HPLC
Identification/Assay	USP <621> EP 2.2.28, BP III B, CP V E, MNP page 539	API, Finished Products	GC
Assay	USP <726> EP 2.2.31, BP III F, CP V F, MNP page 549	API, Finished Products	Electrophoresis Apparatus
Assay	USP <541> BP VIII, CP A VII A, B, C MNP page 512-515	API, Finished Products	Volumetric Titrator
Clarity of solution	BP 2.2.1, USP<631>, EP 2.2.1, CP IX A MNP page 497	API, Finished products	
Color of solution	EP2.2.2, BP 2.2.2, USP<631>, CP IX B, MNP page 493	API, Finished products	
Minimum fill	EP2.9.17, BP XII C.5, USP <755>, CP X F, MNP page 461	Finished products	Analytical balance, syringe
Visible particles	EP.2.9.20, BP XIII B, CP IX H, MNP page 461	Finished products	
Acid value	EP 2.5.1, BP X B, USP<401>, CP VII H, MNP page 584	API, Finished products	Analytical balance Volumetric titrator
Saponification value	EP 2.5.6, USP<401>, BP X G, CPVII H, MNP page 585	API, Finished products	Analytical balance Volumetric titrator
Ester value	EP 2.5.2, USP<401>, BP X. CP VII H, MNP page 586	API, Finished products	Analytical balance Volumetric titrator

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Peroxide value	EP 2.5.5, USP<401>, CPX F, MNP page	API, Finished products	Analytical balance Volumetric titrator
Iodine value	EP 2.5.4, USP<401>, CPX.E, CP VII H, MNP page	API, Finished products	Analytical balance Volumetric titrator
Determination Nitrogen	USP <461> EP 2.5.9, BP VIII H, CP VII D MNP page 509	API, Finished products	Kjeldahl apparatus
Lead	HCTCL5.4.58	Food and food products	AAS ICE 3300 - Atomic absorption spectrometer
Cadmium	HCTCL5.4.59	Food and food products	AAS ICE 3300 - Atomic absorption spectrometer
Methyl acetate	HCTCL5.4.62	Alcoholic beverage	GC -Gas chromatography
Ethyl acetate	HCTCL5.4.62	Alcoholic beverage	GC -Gas chromatography
Isopropanol	HCTCL5.4.62	Alcoholic beverage	GC -Gas chromatography
n-propanol	HCTCL5.4.62	Alcoholic beverage	GC -Gas chromatography
Isobutanol	HCTCL5.4.62	Alcoholic beverage	GC -Gas chromatography
n-butanol	HCTCL5.4.62	Alcoholic beverage	GC -Gas chromatography
Isoamyl alcohol	HCTCL5.4.62	Alcoholic beverage	GC -Gas chromatography
Acetaldehyde	HCTCL5.4.62	Alcoholic beverage	GC -Gas chromatography
Methanol	HCTCL5.4.62	Alcoholic beverage	GC -Gas chromatography
Benzoic acid	HCTCL5.4.29	Vegetable and fruits conservative products	HPLC ultimate 3000 (DAD) High Performance Liquid Chromatography
Sorbic acid	HCTCL5.4.29	Vegetable and fruits conservative products	HPLC ultimate 3000 (DAD) High Performance Liquid Chromatography
Deltamethrin	HCTCL5.4.39	Vegetable and fruits	GC/MS - ISQ single quadrupole Gas Chromatography- Mass Spectrometry
Fludioxonil	HCTCL5.4.39	Vegetable and fruits	GC/MS - ISQ single quadrupole Gas Chromatography- Mass Spectrometry

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Pirimiphos-metyl	HCTCL.5.4.39	Vegetable and fruits	GC/MS - ISQ single quadrupole Gas Chromatography- Mass Spectrometry
Cypermethrin	HCTCL.5.4.39	Vegetable and fruits	GC/MS - ISQ single quadrupole Gas Chromatography- Mass Spectrometry
Tebuconazole	HCTCL.5.4.39	Vegetable and fruits	GC/MS - ISQ single quadrupole Gas Chromatography- Mass Spectrometry
Triadimefon	HCTCL.5.4.39	Vegetable and fruits	GC/MS - ISQ single quadrupole Gas Chromatography- Mass Spectrometry
Cyproconazole	HCTCL.5.4.39	Vegetable and fruits	GC/MS - ISQ single quadrupole Gas Chromatography- Mass Spectrometry
Fenvalerate	HCTCL.5.4.39	Vegetable and fruits	GC/MS - ISQ single quadrupole Gas Chromatography- Mass Spectrometry
Cyhalothrin	HCTCL.5.4.39	Vegetable and fruits	GC/MS - ISQ single quadrupole Gas Chromatography- Mass Spectrometry
Aflatoxin M1	HCTCL.5.4.06	Food and food products	ELISA-/Enzyme-linked immune sorbent assay
Aflatoxin total	HCTCL.5.4.06	Food and food products	ELISA-/Enzyme-linked immune sorbent assay
Melamine	HCTCL5.4.01	Milk and milk products	ELISA-/Enzyme-linked immune sorbent assay

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Sterility Test	USP <71> EP 2.6.1, BP X VI A, CP XI H, MNP page 611	API, Finished Products	Pipette, Incubator
Microbiological Examination of Non-Sterile Products	USP <61>, <62> EP 2.6.13, BP X VI B, D, F, G, CP XI J, MNP page 591-598	API, Finished Products, Herbal Medicinal Products	Analytical Balance, Incubator
Bacterial Endotoxin Test (LAL)	USP ,85> EP 2.6.14, BP XIV C, CP XI E, MNP page 619	API, Finished Products	Incubator, Shaker, Pipette
Antimicrobial Effectiveness Activity	USP <51>, EP 5.1.3, BP XVI C, MNP page 594	API, Finished Products	Analytical Balance, Incubator, Pipette
Microbiological Assay of Antibiotics	USP <81> EP 2.7.2, BP XIV A, CP XI A, MNP page 598	API, Finished Products	Analytical Balance, Incubator, Zone Reader
Listeria monocytogenes	HMCL 5.4.053; HMCL 5.4.002; HMCL 5.4.014; HMCL 5.4.039	Food and food products	MINI VIDAS automatic analyzer, VITEK 2 compact analyzer, PCR machine-SCIENTZ 96+
Salmonella spp.	HMCL 5.4.052; HMCL 5.4.013; HMCL 5.4.014; HMCL 5.4.037	Food and food products	MINI VIDAS automatic analyzer, VITEK 2 compact analyzer, PCR machine-SCIENTZ 96+
Escherichia coli 0157:H7	HMCL.5.4.008; HMCL.5.4.048; HMCL 5.4.014; HMCL 5.4.036	Food and food products	MINI VIDAS automatic analyzer, VITEK 2 compact analyzer, PCR machine-SCIENTZ 96+

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2017.



Vice President