1. Purpose

The purpose of this document is supplement requirement for drug testing laboratory who request for conformity assessment by technique compliance with ISO/IEC 17025

2. Application

This document shall clearly elaborate how to conduct conformity assessment of drug testing laboratory in accordance with ISO/IEC 17025 exclude bioequivalent testing.

3. References

3.1 ISO/IEC 17025:2017. General Requirements for the Competence of Testing and Calibration Laboratories.

3.2 ISO/IEC 17011:2017. Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies

3.3 ILAC – G18:01/2024: Guideline for the Formulation of Scopes of Accreditation for Laboratories

3.4 R 07 15 001. Policy, requirements and conditions for a medical and public health laboratory accreditation.

3.5 N 07 15 003. Policy and requirements for proficiency testing, inter-laboratory comparison and laboratory's performance assessment in testing.

3.6 WHO good practices for pharmaceutical quality control laboratories. WHO Technical Report Series, No.957, Annex 1. 2010.

3.7 WHO good practices for pharmaceutical microbiological laboratories. WHO Technical Report Series, No.961, Annex 2. 2011.

3.8 WHO guidelines for sampling of pharmaceutical products and related materials. WHO Technical Report Series, No.929, Annex 4. 2005.

3.9 The United States Pharmacopeia / National Formulary (USP/NF) current version.

3.10 British Pharmacopoeia (BP) current version.

3.11 European Pharmacopoeia (EP) current version.

3.12 Notification of Ministry of Public Health, Subject: Drug books, 2556 (B.E), Announce by the Royal Thai Government Gazette, Volume 130, special chapter ง. 10, June 2556 (B.E).

4. Definition and Abbreviation

4.1 Accreditation by technique means accreditation of testing laboratory for parameters/components/analytes e.g., ingredients, impurities, sterility, microbial content etc., in pharmaceutical products and related products by using the same technique, instrument or principle which may carried out by different conditions where appropriate for specific task/parameter. All methods shall be verified before issuing. For example; assay by HPLC technique, GC, Spectrophotometer, Titration, Gravimetric method, Immunochemical method, Sterility test, Dissolution, Microbial limit test etc.

4.2 Pharmaceutical products means dosage forms of pharmaceutical products e.g. Solution, Suspension, Syrup, Gel, Lotion, Tablets, Capsules, Ointment, Cream, Powder etc.

4.3 Related products means raw material and supplements use in pharmaceutical products.

5. Associated document

5.1 G 07 15 016 Guideline for define scope of testing for laboratory accreditation

6. Procedures

6.1 Supplement requirements for drug testing laboratory who request for accreditation by technique

6.1.1 For application of testing by technique, the laboratory shall verify standard method. Additionally, list of methods shall be provided and updated annually to ensure the validity of test method. List of the methods, included new verified method, shall be delivered to BLQS at the time of the assessment or at the request of BLQS.

6.1.2 Competent personnel of laboratory who are authorized to carry out testing shall retained fulfills of necessary evident for their competent covered by matrix or dosage forms of accredited scope.

6.1.3 When sampling is carried out, sampling state must comply with the specific requirements in the ISO/IEC 17025:2017 and WHO guidelines for sampling of pharmaceutical products and related materials, WHO Technical Report Series (current version) or specific requirement of the reference of accredited scope.

6.1.4 In 1 year cycle, Proficiency testing result(s) and/or inter – laboratory comparison by 2 laboratories at least, competency shall evaluated in full range of accredited scope. In case of there are no PT/Inter-lab comparison provider the laboratory must provide traceability of measurement comply with the requirement of ISO/IEC 17025:2017 and specific requirements of reference of accredited scope.

6.1.5 Evident of method verification and metrological traceability of measurand of every matrix / dosage forms, included measurement of uncertainty shall submitted to BLQS when apply for accreditation.

6.1.6 Accredited laboratory who needs to apply for extending scope of accreditation of each technique, all document by clause 6.1.1-6.1.5 is needed for preliminary consideration by the BLQS and the director of BLQS will inform officially approval before submit to accreditation process.

6.1.7 Whenever the evident of the accredited laboratory is not sufficient to demonstrated competency complying with the requirements in some accredited scopes, the BLQS may reduce the scope of accreditation or change the accreditation by items instead.

6.2 Application documents for submit to assessment process

6.2.1 The laboratory shall submit the application to the BLQS with the relevant documents in application form no. 1 (F 07 15 005) including with the sufficient details in matrix/dosage form of all scope of accreditation.

6.2.2 The laboratory shall provide access to the information of independence level e.g. Hard copies, electronic files, software etc., for conformity assessment in every matrix/dosage form, range of activities in the scope of accreditation.

6.3 Qualification of assessor

6.3.1 The assessor shall be officially listed in the BLQS assessor directory and shall be the person who has appropriate knowledge and experience in specific task or field of the conformity assessment at least 7 years. The experience in accordance with ISO/IEC 17025 for on-site assessment within the lasted 7 years shall be 10 times or more, where applicable.

6.3.2 For the assessment programme of each laboratory, each one technical assessor shall be assigned to assessed the laboratory not more than 2 analytical techniques.

6.4 Scope of accreditation

Scope of accreditation by technique for drug testing laboratory e.g. chemical testing, microbiology testing, etc. shall define and state in 3 categories of dosage form as the following;

1) Type of sample (Matrix / Dosage forms) can state as Pharmaceutical Finished Product (Tablet, Capsule), Water for Pharmaceutical Purpose (Water for injection, Distilled Water, Filter Water) etc.
2) Test, can state by parameter or technique used for measurement e.g. Assay by HPLC, Identification by GC-MS/MS, Sterility by Membrane Filtration, Dissolution, Disintegration, Uniformity of Weight etc.
3) Method, can state by name of reference method, reference procedure or reference of technical report by international recognition organization etc.
4) List of active pharmaceutical ingredients of accredited scope.

6.5 Supplementary notes

6.2.1 Appendix 1 General method used for accreditation scope.

6.2.2 Appendix 2 Type of sample / Products.

6.2.3 Appendix 3 Example of accreditation certificate.

7. Data record and Used document

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8. Supplementary notes

Appendix

Appendix 1

General method use for accreditation by technique

1. General method by The United States Pharmacopeia / National Formulary (USP/NF)

1.1 Identification Tests

- <181> IDENTIFICATION – ORGANIC NITROGENOUS BASES
- <191> IDENTIFICATION TESTS – GENERAL
- <193> IDENTIFICATION – TETRACYCLINES
- <197> SPECTROPHOTOMETRIC IDENTIFICATION TESTS
- <201> THIN – LAYER CHROMATOGRAPHIC IDENTIFICATION TESTS

1.2 Limit Tests

- <206> ALUMINUM
- <207> TEST FOR 1,6-ANHYDRO DERIVATIVE FOR ENOXAPARIN SODIUM
- <211> ARSENIC
- <221> CHLORIDE AND SULFATE
- <223> DIMETHYLANILINE
- <226> 4-EPIANHYDROTETRACYCLINE
- <233> ELEMENTAL IMPURITIES - PROCEDURES
- <241> IRON
- <251> LEAD
- <261> MERCURY
- <271> READILY CARBONIZABLE SUBSTANCES TESTS
- <281> RESIDUE ON IGNITION
- <291> SELENIUM

1.3 Other Tests and Assays

- <301> ACID-NEUTRALIZING CAPACITY
- <311> ALGINATES ASSAY
- <341> ANTIMICROBIAL AGENTS-CONTENT
- <345> ASSAY FOR CITRIC ACID/CITRATE AND PHOSPHATE
- <351> ASSAY FOR STEROIDS
- <381> ELASTOMERIC CLOSURES FOR INJECTIONS
- <391> EPINEPHRINE ASSAY

- <401> FATS AND FIXED OILS
- <411> FOLIC ACID ASSAY
- <425> IODOMETRIC ASSAY-ANTIBIOTICS
- <429> LIGHT DIFFRACTION MEASUREMENT OF PARTICLE SIZE
- <431> MEHOXY DETERMINATION
- <441> NIACIN OR NIACINAMIDE ASSAY
- <451> NITRITE TITRATION
- <461> NITROGEN DETERMINATION
- <466> ORDINARY IMPURITIES
- <467> RESIDUAL SOLVENTS
- <471> OXYGEN FLASK COMBUSTION
- <481> RIBOFLAVIN ASSAY
- <501> SALTS OF ORGANIC NITROGENOUS BASES
- <503> ACETIC ACID IN PEPTIDES
- <511> SINGLE-STEROID ASSAY
- <525> SULFUR DIOXIDE
- <531> THIAMINE ASSAY
- <541> TITRIMETRY
- <551> VITAMIN E ASSAY
- <561> ARTICLES OF BOTANICAL ORIGIN
- <563> IDENTIFICATION OF ARTICLES OF BOTNICAL ORIGIN
- <565> BOTANICAL EXTRACTS
- <571> VITAMIN A ASSAY
- <580> VITAMIN C ASSAY
- <581> VITAMIN D ASSAY
- <591> ZINC DETERMINATION

1.4 Physical Tests and Determinations

- <601> INHALATION AND NASAL DRUG PRODUCT: AEROSOLS, SPRAYS AND POWDERS – PERFORMANCE QUALITY TESTS
- <604> LEAK RATE

- <611> ALCOHOL DETERMINATION
- <616> BULK DENSITY AND TAPPED DENSITY OF POWDERS
- <621> CHROMATOGRAPHY
- <631> COLOR AND ACHROMICITY
- <641> COMPLETENESS OF SOLUTION
- <643> TOTAL ORGANIC CARBON
- <645> WATER CONDUCTIVITY
- <651> CONGEALING TEMPERATURE
- <660> CONTAINERS-GLASS
- <661> PLASTIC PACKAGING SYSTEMS AND THEIR MATERIALS OF CONSTRUCTION
- <670> AUXILIARY PACKAGING COMPONENTS
- <671> CONTAINERS-PERFORMANCE TESTING
- <691> COTTON
- <695> CRYSTALLINITY
- <696> CHARACTERIZATION OF CRYSTALLINE SOLIDS BY MICROCALORIMETRY NAD JOLUTION CALORIMETRY
- <698> DELIVERABLE VOLUME
- <699> DENSITY OF SOLIDS
- <701> DISINTEGRATION
- <711> DISSOLUTION
- <721> DISTILLING RANGE
- <724> DRUG RELEASE
- <729> GLOBULE SIZE DISTRIBUTION IN LIPID INJECTABLE EMULSIONS
- <730> PLASMA SPECTROCHEMISTRY
- <731> LOSS ON DRYING
- <733> LOSS ON IGNITION
- <736> MASS SPECTROMETRY
- <741> MELTING RANGE OR TEMPERATURE
- <755> MINIMUM FILL
- <761> NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY

- <771> OPHTHALMIC PRODUCTS – QAULITY TESTS
- <776> OPTICAL MICROSCOPY
- <781> OPTICAL ROTATION
- <785> OSMOLALITY AND OSMOLARITY
- <786> PARTICLE SIZE DISTRIBUTION ESTIMATION BY ANALYTICAL SIEVING
- <788> PARTICULATE MATTER IN INJECTIONS
- <789> PARTICULATE MATTER IN OPHTHALMIC SOLUTIONS
- <791> pH
- <795> PHARMACEUTICAL COMPOUNDING-NONSTERILE PREPARATIONS
- <797> PHARMACEUTICAL COMPOUNDING-STERILE PEPRATIONS
- <801> POLAROGRAPHY
- <811> POWDER FINENESS
- <821> RADIOACTIVITY
- <823> RADIOPHARMACEUTICALS FOR POSITRON EMISSION TOMOGRAPHY-COMPOUNDING
- <831> REFRACTIVE INDEX
- <841> SPECIFIC GRAVITY
- <846> SPECIFIC SURFACE AREA
- <851> SPECTROPHOTOMETRY AND LIGHT-SCATTERING
- <861> SUTURES-DIAMETER
- <871> SUTURES-NEEDLE ATTACHMENT
- <881> TENSILE STRENGTH
- <981> THERMAL ANALYSIS
- <905> UNIFORMITY OF DOSAGE UNITS
- <911> VISCOSITY
- <921> WATER DETERMINATION
- <922> WATER ACTIVITY

1.5 Microbiological Tests

- <51> ANTIMICROBIAL EFFECTIVENESS TESTING
- <55> BIOLOGICAL INDICATORS-RESISTANCE PERFORMANCE TESTS

- <61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS
- <62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: TESTS FOO SPECIFIED MICROORGANISMS
- <63> MYCOPLASMA TESTS
- <71> STERILITY TESTS

1.6 Biological Tests and Assays

- <81> ANTIBIOTICS-MICROBIAL ASSAYS
- <85> BACTERIAL ENDOTOXINS TEST
- <87> BIOLOGICAL REACTIVITY TESTS, IN VITRO
- <88> BIOLOGICAL REACTIVITY TESTS, IN VIVO
- <90> FETAL BOVINE SERUM-QUALITY ATTRIBUTES AND FUNCTIONALITY TESTS
- <91> CALCIUM PANTOTHENATE ASSAY
- <92> GROWTH FACTORS AND CYTOKINES USED IN CELL THERAPY MANUFACTURING
- <111> DESIGN AND ANALYSIS OF BIOLOGICAL ASSAYS
- <115> DEXPANTHENAL ASSAY
- <121> INSULIN ASSAYS
- <130> PROTEIN A QUALITY ATTRIBUTES
- <141> PROTEIN-BIOLOGICAL ADEQUACY TEST
- <151> PYROGEN TEST
- <161> TRANSFUSION AND INFUSION ASSEMBLIES AND SIMILAR MEDICAL DEVICES
- <171> VIAMIN B12 ACTIVITY ASSAY

2. General method by British Pharmacopoeia (BP)

2.1 Appendix V, Determination of

A. Melting Point
B. Freezing Point
C. Distillation Range
D. Boiling Point
E. Refractive Index
F. Optical Rotation and Specific Optical Rotation

G. Weight per Millilitre, Density Relative Density and Apparent Density
H. Viscosity
I. Circular Dichroism
J. Relationship Between Reaction of Solution,
K. Approximate pH and Colour of Certain Indicators
L. Determination of pH values
M. Thermal Analysis
N. Osmolality
O. Conductivity
P. Total Organic Carbon in Water for Pharmaceutical Use
Q. Density of Solid

2.2 Appendix VII, Limit Test for Aluminum, Ammonium, Arsenic, Calcium, Chlorides, Fluorides, Heavy metals, Iron, Lead in Sugar, Magnesium, Manganese and Alkaline-earth Metals, Heavy Metals in Herbal Drugs and Fatty Oils, Nickel in Polyols, Phosphates, Potassium, Sulfates

2.3 Appendix VIII

A. Non-aqueous Titration
B. Amperometric and Potentiometric Titrations
C. Oxygen-flask Combustion
D. Complexometric Titrations
E. Potentiometric Determination of Ionic Concentration using Ion-selective Electrodes
F. Determination of Ethanol
G. Determination of Methanol and Propqn-2-ol
H. Determination of Nitrogen

2.4 Appendix IX, Determination of

- Sulfated Ash
- Sulfur Dioxide
- Water
- Loss on Drying

2.5 Appendix XII

A. Disintegration

B. Dissolution

C. Consistency of Formulated Preparations

2.6 Appendix XIII

Particulate Contamination

2.7 Appendix XIV. Biological Assay and Tests

A. Microbiological Assay of Antibiotics

B. Immunochemical Methods

C. Test for Bacterial Endotoxins

D. Test for Pyrogens

E. Test for Abnormal Toxicity

☞ General method by European Pharmacopoeia (Ph. Eur.)

General method by British Pharmacopoeia

Appendix 2

Type of pharmaceutical products

Dosage form of medicines/drugs, pharmaceutical preparations, pharmaceutical products to be consider for accreditation by technique by Bureau of Laboratory Quality Standards accredit are as following;

1. Liquid form
   - 1.1 Solution
   - 1.2 Suspension
   - 1.3 Emulsion
   - 1.4 Syrup
   - 1.5 Spirits
   - 1.6 Tincture
   - 1.7 Gel
   - 1.8 Lotion
2. Solid form
   - 2.1 Tablets
   - 2.2 Capsules
   - 2.3 Suppositories
   - 2.4 Ointment
   - 2.5 Cream
   - 2.6 Powder

Appendix 3

Template of accreditation certificate

Bureau of Laboratory Quality Standards

Ministry of Public Health

This is to certify that

The laboratory of

Laboratory name.....

Address.....

has been accepted as an

accredited laboratory complying with the ISO/IEC 17025:2017

and the requirement of the Bureau of Laboratory Quality Standards

The laboratory has been accredited

for specific tests listed in the scope within the field of

Drug Testing

(.....)

Director of Bureau of Laboratory Quality Standards

Date of Accreditation: Date ……. Month…….year……

Valid Until: Date ……. Month…..…. year…… Accreditation Number ……../.....

Example of accreditation scope

The laboratory of ..... has been accepted as an accredited laboratory in the field of drug testing for the following scopes.

No.	Type of sample	Test	Method
1	Liquid form - Solution - Suspension - Syrup - Gel - Lotion Solid form - Tablets - Capsules - Powder	Chromatography: HPLC	Current USP/NF <621>
		Chromatography: GC	Current USP/NF <621>
		Spectrophotometry: UV/VIS	Current USP/NF <851>
		pH	Current USP/NF <791>
		Specific Gravity	Current USP/NF <841>
		Uniformity of Dosage Units	Current USP/NF <905>
		Dissolution	Current USP/NF <711>
		Disintegration	Current USP/NF <701>
		Uniformity of weight	Current BP, App.XII C
		Sterility	Current USP/NF <161>
		Microbial Limits Testing	Current USP/NF <61>

List of active pharmaceutical ingredients:

1. Paracetamol
2. Tramadol
3. Aspirin

Accreditation number: xxxx/yy
Issued/Revision No. xx
Date of accreditation: ...month.....year.....
Date Issued/Revised: ..... Month..... Year.....
Valid until: ... month.....year.....

9. History of Change

Revision	Document changes	Prepared /Revised by	Issued date
00	New issued of documents	Mr. Aran Tanunkat	-
01	Added new references to current version	Mr. Aran Tanunkat	4 September 2012
02	- Edited document format complying with document control procedure of BLQS - Edited and added relevant references to current version - Added more details in clause 4 (definition), clause 6 (policy and requirements. - Added the history of changes	Mr. Awiruth Khejonnit	25 October 2019
03	- Edited document format complying with document control procedure of BLQS (SOP 07 00 016, Rev. No: 07, 14 October 2022) - Added more relevant details of certificate and updated history of changes	Mr. Awiruth Khejonnit	10 January 2023
04	- Revised reference of ILAC-G18:01/2024 current version. - Added criteria for accreditation by technique shall be applied for standard method that listed and revised annually. - Identified application form of F 07 15 005 as to the current practice.	Mr. Awiruth Khejonnit	12 March 2024
05	- Updated list of the responsible person to reviewed document	Mr. Awiruth Khejonnit	

Revision	Document changes	Prepared /Revised by	Issued date
	- Clause 6.1.6, revised details of evidence required for application of accreditation. - Appendix 1.3, corrected the acronyms of European Pharmacopeia.		