HOKLAS Supplementary Criteria No. 44

'Chinese Medicine' Test Category – Chemical and Physicochemical Testing to the Hong Kong Chinese Materia Medica (HKCMM) Standards

0 Introduction

(a) This document serves to clarify and supplement the requirements of ISO/IEC 17025:2017 and HKAS Policy Document No. 1 for the accreditation of chemical and physicochemical testing to the Hong Kong Chinese Materia Medica (HKCMM) Standards under the test category of 'Chinese Medicine', including tests for identification (e.g. physicochemical tests, thin layer chromatography, chromatographic fingerprinting, X-ray diffraction analysis, spectroscopic analysis, etc.), contamination (e.g. tests for heavy metals, toxic elements, pesticide residues, mycotoxins and the presence of foreign matter, etc.), ash content, water content, extractives and assay. This document shall be read in conjunction with ISO/IEC 17025:2017, HKAS Policy Document No. 1 and the relevant HKAS and HOKLAS supplementary criteria documents.

(b) For chemical tests under the test category of 'Chinese Medicine' other than those specified in the HKCMM Standards, laboratories shall refer to HOKLAS SC-20. For microscopic identification of Chinese Materia Medica (CMM) based on HKCMM Standards, requirements given in HOKLAS SC-40 shall apply.

(c) Laboratories should note that fulfilling the requirements in this document might not necessarily meet all the requirements of the HKCMM Standards. The HKCMM Standards may have specific requirements for each CMM which shall also be met when conducting the concerned tests.

1 Scope

(No additional explanation)

2 Normative reference

(No additional explanation)

3 Terms and definition

(No additional explanation)

4 General requirements

(No additional explanation)

5 Structural requirements

(a) The technical management of the laboratory shall include at least a member who has in-depth knowledge of and extensive experience in analytical chemistry and chemical / physicochemical testing of Chinese medicine. He/she shall be part of the technical management that is responsible for the technical operation of the laboratory with respect to the relevant tests. Each technical area, e.g. analysis for toxic elements or organics, etc., shall be adequately covered by qualified technical personnel.

6 Resource requirements

6.1 General

(No additional explanation)

6.2 Personnel

(a) Tests shall be performed by staff members who have adequate training in chemical analysis. For tests involving the use of sophisticated analytical instruments such as GC-MS, HPLC, GC-MS/MS, LC-MS/MS, ICP-OES, ICP-MS, etc., testing staff members are normally expected to have completed a post-secondary curriculum in chemistry such as higher diploma in chemistry or chemical technology. Special training shall be given to staff members operating specialised equipment such as high-resolution mass spectrometer, GC-ICP/MS, LC-ICP/MS, etc. The testing staff members for such equipment should possess a degree in chemistry or related disciplines. External training should be provided when techniques involving the use of specialized equipment and requiring special skills and knowledge are being introduced to the laboratory for the first time, unless the existing staff members have already possessed the necessary expertise.

(b) A training programme for each testing staff member shall be documented. The programme shall include training on the analytical techniques involved as well as the test procedures and the quality assurance plans. Records of initial training and continuing competence monitoring,

including all associated raw data, shall be maintained.

(c) Approved signatories

(i) Approved signatories shall either have

(1) at least a Bachelor of Science degree in chemistry or other relevant technical disciplines, or a Bachelor of Pharmacy in Chinese medicine degree, or equivalent, with at least 3 years relevant testing experience; or

(2) an Associate Degree or a Higher Diploma, or equivalent, in chemistry, or other relevant technical disciplines, with at least 5 years relevant testing experience.

Note: Alternatively, appropriate membership of professional bodies is acceptable. Special consideration may be given to persons without the qualifications in Cl. 6.2 (c)(i) but with extensive experience (at least ten years) in the testing area concerned.

(ii) Irrespective of the person's academic qualifications, the nominee shall have at least six months' experience in the areas of testing for which signatory approval is sought.

(iii) In all cases, candidates shall demonstrate to the assessors that his/her technical competence in the test areas under consideration before signatory approval can be granted.

(d) Laboratory personnel responsible for visual assessment of colour difference of test samples, including approved signatories for the visual tests concerned, shall have normal colour vision for colour assessment.

6.3 Facilities and environmental conditions

(a) Acceptable ranges for environmental conditions such as temperature and humidity shall be defined and documented. Cases where environmental conditions fall outside the acceptable ranges shall be recorded and the effects, if any, on test results shall be evaluated. Suitable corrective actions shall be taken to rectify the situation as soon as possible.

(b) Laboratories shall identify instruments that require special environmental conditions. It should be noted that both temperature and humidity fluctuations may affect the performance of some instruments, e.g. analytical balances, microscopes, infrared spectrometers, mass

spectrometers, etc. Laboratories shall ensure that these instruments are placed in an environment that ensures their optimum performance and fitness for the intended use. Voltage stabiliser should be used for instruments sensitive to voltage fluctuation.

(c) When selecting designated areas for special work, laboratories shall consider the previous use of the area and take appropriate measures to ensure that the area is free of contamination. Such laboratory areas include open benches, fume hoods, sample storage area, oven/furnace area, and apparatus soaking/washing area.

(d) Trace analyses are particularly susceptible to contamination. Laboratories shall lay down procedures and the precautions to be taken to prevent contamination or interference on the laboratory activities from the environment. Particular attention should be given to, for example, the presence of dust in the laboratory environment for trace elemental analysis. Precautions shall be taken to avoid the ingress of dust as far as possible. Good housekeeping is essential to minimise contamination by air-borne particulates.

6.4 Equipment

(a) For certain trace analyses, e.g. analysis for toxic elements, it is essential to avoid contamination of test samples and/or standard solutions by labware. Laboratories shall document procedure for washing labware and the type of labware to be used (glass, PTFE, etc.) for particular tests. Attention should also be given to the possible presence of analytes in commercial detergents. Laboratories shall use, if necessary, different washing, storage and segregation procedures for labware used for different analyses such as soaking of labware in acid solution to remove traces of elements for trace elemental analysis. It is also necessary to have a set of labware dedicated for trace elemental analysis to prevent possible cross-contamination. Similarly, dedicated labware is required for incompatible tests. Procedures or precautions for labware cleaning, if given in test standards, shall be followed.

(b) The grade of reagents used (including water) shall be stated in the methods together with guidance on precautions which shall be observed in their preparation or use. The absence of interfering compounds and/or analyte in reagents, especially solvents and acids, used in the test procedures is of particular importance for trace analyses. Laboratories shall ensure that reagents used are suitable for the applications. Critical reagents prepared by the laboratory shall be labelled to identify substance, strength, solvent (other than water), any special precautions and restrictions of use, date of preparation and period of validity. The

person responsible for the preparation of the reagent shall be identifiable from records.

(c) All critical chemicals and consumables having significant effect on the examination results shall be verified to ensure conformity with specified requirements before use.

6.5 Metrological traceability

(a) HOKLAS Supplementary Criteria No. 2 'All Test Categories – Equipment Calibration and Verification' provides HKAS policy on metrological traceability of measurement results. For chemical analyses, it is not uncommon that the calibration procedure forms an integral part of the test procedure and is given in test standards. If this is the case, the calibration procedure given in the test standard shall be followed.

(b) Reference materials used for calibration shall provide the necessary metrological traceability. The requirements given in HOKLAS Supplementary Criteria No. 1 'Acceptability of Chemical Reference Materials and Commercial Chemicals Used for the Calibration of Equipment' shall be followed.

6.6 Externally provided products and services

(No additional explanation)

7 Process requirements

7.1 Review of requests, tenders and contracts

(No additional explanation)

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

(a) Tests for identification of a CMM could include physicochemical tests, thin-layer chromatography, chromatographic fingerprinting, X-ray diffraction analysis, spectroscopic analysis, etc. Tests for safety and quality of a CMM could include tests for heavy metals, toxic elements, pesticide residues, mycotoxins, presence of foreign matter, ash content, water content, determination of extractives and assay. Testing for certain chemical marker compounds e.g. aristolochic acid, ephedrine and aconitines may also be required.

(b) Selection of test methods

(i) Laboratories shall document all methods and procedures, including sampling, selection of representative test portions, sample handling, transport, storage, analysis and recording of results, etc.

(ii) Laboratories shall use methods given in the HKCMM Standards only for compliance testing against the standard. The use of a technique 'more advanced' than that specified in the HKCMM Standards can constitute a deviation.

(iii) For tests which the HKCMM Standards do not provide the test procedures but where only the performance criteria are specified, appropriate standard methods meeting the performance criteria may be used. The laboratories are required to undertake the method verification in accordance with the requirements given in Cl. 7.2.1 (c) of this document. Alternatively, laboratories may develop their own in-house test method and the requirements for method validation given in Cl. 7.2.2 shall apply. The laboratory shall provide evidence that the performances of these methods meet the specified requirements. For compliance testing, it is also essential that the limits of reporting are well below the compliance limits and that the method gives reliable results at the limits.

(c) Verification of methods

(i) Method verification is usually done by comparing the performance data obtained by the laboratory when performing a standard method with those claimed by the same method. If specified in the standard method, the procedure for determination and/or verification of method performance characteristics such as limits of detection and quantitation, precision, recovery, etc. shall be followed. Some standard methods may have already specified the confirmation method required and the identities of organic compounds may be considered as confirmed if these instructions are followed.

(ii) The verification work to be carried out should be appropriate to the purpose of the method, such as identification or quantification of analytes at low and high concentrations. In general, the laboratory shall demonstrate their technical competence in performing the standard method such that the method performance characteristics, such as trueness, precision, limit of detection/quantitation, limit of reporting, measurement uncertainty calculated from the verification data, meet the criteria specified in the standard method for all the matrices and concentrations that the laboratory will apply the method.

Guidelines and requirements given in the HKCMM Standards shall be followed. When the guidelines and requirements are not specified, the procedures given in national or international standards or by reputable professional bodies should be followed. International guidelines on method verification, such as 'How to meet ISO 17025 requirements for method verification' published by Association of Official Analytical Collaboration (AOAC International), may also be applicable.

7.2.2 Validation of methods

(a) Standard test methods shall be strictly adhered to and only be used for the intended concentration ranges and sample matrices. If they are used outside their intended concentration ranges or applied to different sample matrices, validation is required. Laboratories should ensure their competence to perform the test by use of certified reference materials and participation in proficiency testing activities, if available.

(b) Non-standard methods shall be validated and authorised before use. The validated non-standard methods shall be documented and the scope of application, performance characteristics, quality control plan and calibration procedure shall be well defined. Useful guidelines are given in ISO 78-2 'Chemistry – Layouts for standards – Part 2: Methods of chemical analysis' may be useful. The method performance characteristics shall meet the requirements of the HKCMM Standards where relevant.

(c) For chemical tests, some of the method performance characteristics are of particular importance. These include, for example, limits of detection/quantitation, precision and trueness, applicable concentration ranges and sample matrices. It is thus important that laboratory-developed methods should be validated against, amongst others, these characteristics. Laboratories shall define and explain how the limits of detection/quantitation and reporting, if applicable, are derived. These procedures shall be in line with guidelines given by reputable professional bodies and the limits shall not give an unrealistic impression of the method's capability. Reporting limits shall be set at a level at which quantitative results may be obtained with a specified degree of confidence. Limits of detection/quantitation and reporting shall be suitably verified. Examples of guidelines on method validation are IUPAC Technical Report 'Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis', EURACHEM Guide 'The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics', ISO 11843-2 'Capability of detection – Part 2: Methodology in the linear calibration

case' and AOAC Peer-verified Methods Program 'Manual on Policies and Procedures' AOAC International.

(d) Method bias shall be assessed using matrix certified reference materials (CRMs), if available. The CRMs used shall be of the same matrices as the intended sample matrices. The levels of the analytes shall also be within the range of applicability of the method. The procedure given by ISO Guide 33 'Reference materials – Good practice in using reference materials' should be used to assess the trueness of the test method. If suitable matrix CRMs are not available, recovery studies or comparisons with standard reference methods shall be carried out. The recovery studies should be carried out by spiking the analyte into matrix blank or sample blank. The variety of matrices used for method validation should be representative to serve the intended purpose of the method. Additional guideline is given in IUPAC Technical Report 'Harmonized Guidelines for the Use of Recovery Information in Analytical Measurement'.

(e) Interlaboratory comparison is an external means of method validation. It provides independent evidence that the test results obtained by the proposed method are comparable to those obtained by the other laboratories. Where applicable, method bias shall be assessed by interlaboratory comparison.

(f) The performance of a validated method may change due to many reasons. It is therefore necessary to review the performance characteristics of test methods at suitable intervals and perform revalidation if necessary. Such review may also be required when the performance of the method is affected by changes such as changes in equipment, environmental conditions, etc.

(g) The method validation required depends largely on the analytes and matrices of interest. Common CMM matrices include those of plant origin (e.g. CMM of different herbal parts such as root, leave, flower, stem, fruit, seed, etc.), those of mineral origin (e.g. sulphides of mercury and arsenic) and those of animal origin. For methods applicable to general CMM matrices, satisfactory validation data shall be obtained for common matrices. Due consideration shall also be taken for the matrices with potential interferences e.g. high chloride effect on the ICP-MS determination. The test procedure shall document the CMM matrices used in the validation studies. During routine analysis of CMM samples, spike recovery shall be performed on sample types previously not encountered in method validation.

(h) The acceptability of method validation shall be determined based on the

intended use of the test methods. Guidelines stipulated in the HKCMM Standards and this document shall be followed.

(i) Only those analytical techniques that have been validated and have a false compliant rate of < 5% at the level of interest shall be used for screening purposes. In the case of a suspected non-compliant result, the result shall be confirmed by a confirmatory method. The suitability of an acceptable false compliant rate shall be assessed against the purpose of the tests and a more stringent false compliant rate may be required in some cases. Useful guidance for the method validation could be found in 'Guidelines for Validation of Qualitative Binary Chemistry Methods' published by AOAC INTERNATIONAL.

(j) Confirmation of the identity of organic compounds is necessary for non-selective methods such as gas chromatographic methods employing electron capture detector, flame ionisation detector, or thermal conductivity detector, etc. or liquid chromatographic methods employing refractive index detector or evaporative light scattering detector, etc. Procedures and criteria for confirmation of organic compounds shall be documented. The confirmation method shall be able to reliably confirm the identity of the organic compound at the reporting limit. For example, maximum permitted tolerances for relative ion intensities shall be established for mass spectrometric detection in accordance with recognised practices.

7.3 Sampling

(a) Sampling from sample lot or site is not covered by this document. Customers taking their own samples shall be made aware of proper sampling, storage and transportation procedures.

(b) Recommended sampling procedure given in the HKCMM Standards for selecting CMM samples for testing shall be followed. However, it should be noted that the test results should relate to the samples tested only.

7.4 Handling of test or calibration items

(a) Laboratories shall examine and record the condition and appearance of the samples upon receipt. Items to be checked should include, where appropriate, number, amount of sample, colour, form, batch number, etc. Any deviations of test item from specified conditions or the customers' supplied information shall be handled in accordance with Cl. 7.4.3 of ISO/IEC 17025:2017.

(b) Test samples shall be suitably stored as soon as practicable upon receipt. Laboratories shall define the storage conditions for different types of samples, particularly for perishable samples. Guidelines for general storage condition given in the HKCMM Standards should be follow, where applicable. For dried CMM, in order to prevent deterioration and mould growth, they shall be stored under an environment with a low humidity. The environmental conditions for sample storage shall be monitored and recorded to demonstrate that the requirements are fulfilled.

(c) Frequently, it is necessary to split the sample for testing of different properties. It is essential that such sub-samples represent the original samples and that their identities are maintained at all times. Attention should be paid to possible contamination of samples by metals or plasticisers leached from containers, stoppers and grinders into the sub-samples. In choosing containers for sub-samples, the properties of the analyte of interest should be taken into account.

(d) Access to the sample storage shall be controlled and only authorised persons shall have access to the sample storage.

7.5 Technical records

(No additional explanation)

7.6 Evaluation of measurement uncertainty

(a) It is recognised that there is more than one approach for evaluating measurement uncertainty and there is no general consensus on the method to be used in chemical analysis. HKAS accepts approaches for evaluating measurement uncertainty given by reputable professional bodies or standard writing bodies. However, the uncertainty values obtained shall be in line with the definition given in JCGM 200 ‘International vocabulary of metrology - Basic and general concepts and associated terms (VIM)’ and shall include all major components of uncertainty. Reference to the EURACHEM/CITAC Guide CG4 ‘Quantifying Uncertainty in Analytical Measurement’ and ‘VAM Project 3.2.1 Development and Harmonisation of Measurement Uncertainty Principles, Part (d): Protocol for uncertainty evaluation from validation data’ published by LGC, UK, may be useful.

(b) In general, the degree of rigor relates to the level of risk. To properly evaluate safety, substantial property risk or financial risk, or for litigation purpose, a relatively rigorous uncertainty evaluation is required for the associated tests.

(c) Where sampling (or sub-sampling) is to be treated as part of the test, the uncertainty arising from such sampling shall be considered by the laboratory. In other words, it is necessary to analyse the representativeness of the sub-sample (i.e. test portion) as part of the measurement uncertainty evaluation. EURACHEM/CITAC Guide 'Measurement uncertainty arising from sampling: A guide to methods and approaches' produced jointly by Eurachem, EUROLAB, CITAC, Nordtest and the RSC Analytical Methods Committee may be followed.

(d) The uncertainty of physical measurements, the purity of calibration reference materials and their uncertainties, the uncertainties associated with recovery (bias) trials (when recovery factors are applied to results), as well as precision data shall be considered in the evaluation of measurement uncertainty.

(e) Where professional judgement has to be used for significant sources of uncertainty, it shall be based on objective evidence or previous experience. Evaluation of measurement uncertainty containing significant sources evaluated by professional judgement shall not be used for applications demanding the most rigorous evaluation of uncertainty.

Notes:

(1) Measurement uncertainty may be evaluated by rigorously considering individual sources, combined with mathematical combination to produce a measurement uncertainty. This approach is often considered appropriate for more critical work, including for the characterization of reference materials.

(2) Another approach to evaluate measurement uncertainty is based on interlaboratory studies, quality control and method verification/validation data, taking into consideration additional uncertainty sources. Additional sources that need to be considered may include sample homogeneity and stability, calibration/reference material, bias/recovery, equipment uncertainty (where only one item of equipment was used in obtaining the precision data). For evaluating measurement uncertainty of methods and laboratory bias from proficiency testing data, reference such as EUROLAB Technical Report 'Measurement uncertainty revisited: Alternative approaches to uncertainty evaluation' may be useful.

7.7 Ensuring the validity of results

(a) Laboratories shall document their quality control plan and procedures for

each test method and matrix. Common quality control procedures include the analysis of laboratory samples of positive control and negative control (habitually alternatives or commonly confused samples), re-examining of same sample and the comparison of the examination results performed by two independent persons. The plans shall include frequency of performing quality control samples, their acceptance criteria and actions to be taken in cases of acceptance criteria not being met.

(b) The quality control plans and procedures, including acceptance criteria whenever stipulated in the relevant test standards and/or HKCMM Standards shall be followed strictly. If such plans are not given, Cl. 7.7 (b) to 7.7 (d) shall be followed where appropriate.

(i) Blank

Method blank shall be performed at a minimum frequency of one per preparation batch of samples or one per twenty samples, whichever is more frequent. A method blank should consist of blank solvent and all reagents, in the same amounts as the test samples, that are in contact with or added to a sample during the entire analytical procedure. Method blank shall be processed through the entire analytical procedure simultaneously with other test samples within the same preparation batch. Values of method blank above the acceptance limit indicate possible contamination of the batch of samples analysed simultaneously with the blank. Normally, the values of blank should be below the method detection limit.

(ii) Laboratory control sample (LCS)

Laboratory control (positive and/or negative) samples shall be analysed at a minimum frequency of one per twenty samples or one per each batch of samples, whichever is more frequent. LCS should be prepared in a matrix and at a level that are normally encountered. CMM used as controls should only be accepted after strict botanical taxonomy identification. It should be noted that the microscopic features of the test object might show variation by growth period and environment. Therefore, the place of origin, collection time and processing methods should be recorded. The laboratories shall be equipped with LCS relevant to the accreditation scope. The laboratory shall have established that these control samples contain features and properties conforming to the HKCMM Standards.

(iii) Spike

Sample/ matrix spike shall be performed at a minimum frequency of

one per batch of samples or type of matrix or twenty samples, whichever is more frequent. Spiking shall be done before the sample is analysed and should be at the concentration of the analyte present, or the concentration of the mid-range of the calibration curve, or other relevant concentrations. The amount of spike added shall not alter the matrix of the sample significantly and the final concentration shall fall within the calibration range. The spike and the calibration standards used in the same run should be prepared from different stock solutions or by different analysts, if possible.

(iv) Duplicates

Duplicate sample (or duplicate sample spike, if applicable) shall be analysed at a minimum frequency of one per batch of samples or type of matrix or twenty samples, whichever is more frequent.

(c) The calibration curve shall be constructed as specified in the relevant test standards and/or HKCMM Standards. Normally, at least three standards (excluding blank) shall be used to establish a linear calibration graph. The standards used shall cover the range of concentration of the analyte in the test samples. The lowest standard shall be at a level at or below the reporting limit of the test method. Criterion of the correlation coefficient of linear calibration graph shall be defined and implemented. Normally, the correlation coefficient of linear calibration graph shall be at least 0.995. Guidelines given in ISO 11095 ‘Linear calibration using reference materials’ should be consulted, where appropriate. More calibration standards (minimum five) are required for non-linear calibration functions.

(d) Calibration graphs shall be checked regularly using a calibration standard. The frequency of such check depends on the stability of the equipment and a frequency of around 5 per cent is normally considered as adequate, except otherwise specified by the test standards or the stability of the equipment merits a more frequent checking. Acceptance criteria shall be established and shall be commensurate with the required measurement uncertainty.

(e) Control charts shall be used where appropriate to monitor the performance of the laboratory. Control and warning limits of such charts shall be based on statistical principles. Laboratories shall monitor trends indicated in the control charts. Recommendations given in ISO 5725-6 ‘Accuracy (trueness and precision) of measurement methods and results – Part 6: Use in practice of accuracy values’, IUPAC Technical Report ‘Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories’, ISO 7870-2 ‘Control charts – Part 2 Shewhart

control charts', ISO 7870-4 'Control charts – Part 4 Cumulative sum charts' and ISO 7870-6 'Control chart – Part 6 EWMA control charts', may be followed, if appropriate.

(f) Proficiency testing programme

(i) Laboratories shall establish schedules for verifying their performance by analysing matrix CRMs and participating in proficiency testing programmes at intervals commensurate as far as possible with the volume of work undertaken. Participation in proficiency testing programmes or inter-laboratory comparison studies, when proficiency testing programmes are not available, at least once a year for each major test area is required.

(ii) Laboratories shall document procedures for rectifying unsatisfactory performance in proficiency testing programmes. If unsatisfactory results are obtained, the laboratory shall promptly investigate the cause(s), take action to rectify the problem(s) and further demonstrate that it can achieve satisfactory performance for the test/method in question. All findings and action taken in connection with unsatisfactory performance shall be recorded.

7.8 Reporting of results

(a) A description of the samples as received shall normally be given in the test reports. The description shall include, where relevant to the interpretation of test results, a description of the number/set, appearance and amount of samples, type of container and condition when received. Any deviation from the customer's information or abnormality shall be reported.

(b) When test results are below the reporting limits, an indication of the reporting limits shall be given in test reports.

(c) If result to be reported is a numerical value, policy and instructions shall be given on the required number of significant figures and rounding of numbers.

(d) Other information necessary for the proper interpretation of the test results (e.g. quality control results, relevant information provided by the customers, measurement uncertainty, etc.) shall be reported.

(e) The sample preparation procedure shall be given if it is required for the proper interpretation of test results.

(f) Any compliance statement on the identification of the CMM without mentioning of conformity with the specifications of HKCMM Standards shall not be made. The results of organoleptic tests should also be considered when interpreting the identification test results.

(g) The HKCMM Standards refer identification as 'the verification of a CMM by means of microscopic examinations of cross sections and powders, physical and chemical tests and chromatographic analysis'. Ideally and preferably, all tests specified for identification given in the HKCMM Standards should be performed. Statements on the positive identification of CMM can be given under the following two conditions:

(i) the results of microscopic examination of the sample fully conform to the specifications of HKCMM Standards (for details of the requirements, refer to HOKALS SC- 40); and/or

(ii) all tests specified for identification, other than microscopic examination, have been performed and all test results conform to the specifications of HKCMM Standards.

(h) The conformity statement shall state clearly that the sample meets the specifications for the relevant tests specified for identification as given in HKCMM Standards. An example of such statement is as follows:

'The sample was found to conform to the specifications of Cortex Moutan with respect to the following tests specified by the Hong Kong Chinese Materia Medica Standards for identification: microscopic identification, physicochemical identification, thin-layer chromatographic identification and high-performance liquid chromatographic fingerprinting'.

(i) Apart from identification, a statement on the conformity of a CMM sample with other specifications (i.e. the safety and quality specifications) stipulated in the HKCMM Standards may be given. An example of such a statement is as follows:

'The sample was found to conform to the specifications of Cortex Moutan with respect to the following tests specified by the Hong Kong Chinese Materia Medica Standards: heavy metals, toxic elements, pesticide residues and mycotoxins' – if tests for heavy metals, toxic elements, pesticide residues and mycotoxins were performed and all the test results met the requirements of the Standards.

(j) If a customer has claimed that a given sample is a certain CMM and requested a laboratory to perform compliance testing to the safety and

quality specifications stated in the HKCMM Standards for that CMM, and the laboratory has not performed tests specified for identification in the HKCMM Standards on the sample, the laboratory shall explicitly state in the test report that the identity of the sample is solely based on the information provided by the customer. Accordingly, a compliance statement on identification of the CMM sample shall not be made.

Note: For conformity statement on microscopic identification of a CMM based on HKCMM Standards, laboratories shall refer to HOKLAS SC-40.

(k) When stating conformity with a specification or standard, decision rule shall be clearly defined and documented. In determining the decision rule, international guidelines, such as ILAC-G8 'Guidelines on Decision Rules and Statements of Conformity' and EURACHEM/CITAC Guide 'Use of Uncertainty Information in Compliance Assessment' and EUROLAB Technical Report 'Decision rules applied to conformity assessment' may be followed.

7.9 Complaints

(No additional explanation)

7.10 Nonconforming work

(No additional explanation)

7.11 Control of data and information management

(No additional explanation)

8 Management system requirements

(No additional explanation)

Annex
(Informative)

Bibliography

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5 EURACHEM Guide *The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics*

6 ISO 11843-2 *Capability of detection – Part 2: Methodology in the linear calibration case*

7 AOAC Peer-verified Methods Program *'Manual on Policies and Procedures' AOAC International.*

8 ISO Guide 33 *Reference materials – Good practice in using reference materials*

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11 JCGM 200 *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)*

12 EURACHEM/CITAC Guide CG 4 *Quantifying Uncertainty in Analytical Measurement*

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14 EURACHEM/CITAC Guide *Measurement uncertainty arising from sampling: A guide to methods and approaches*

15 EUROLAB Technical Report No. 1/2007: *Measurement uncertainty revisited: Alternative approaches to uncertainty evaluation*

16 ISO 5725-6 *Accuracy (trueness and precision) of measurement methods and results – Part 6: Use in practice of accuracy values*

17 Pure & Appl. Chem., Vol. 67 No. 4 IUPAC Technical Report '*Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories*'

18 ISO 7870-2 *Control charts – Part 2: Shewhart control charts*

19 ISO 7870-4 *Control charts – Part 4: Cumulative sum charts*

20 ISO 7870-6 *Control charts – Part 6: EWMA control charts*

21 ILAC-G8 *Guidelines on Decision Rules and Statements of Conformity*

22 EURACHEM/CITAC Guide *Use of Uncertainty Information in Compliance Assessment*

23 EUROLAB Technical Report No. 01/2017: *Decision rules applied to conformity assessment*

Remark: For dated references in the whole Annex, only the edition cited applies. For undated references cited, the latest edition (including any amendments) applies.