هيئة الدواء المصرية

دليل برنامج

إعتماد هيئة الدواء المصرية للمواد القياسية

الفهرس

برنامج إعتماد هيئة الدواء المصرية للمواد القياسية

أهداف البرنامج

فى إطار حرص هيئة الدواء المصرية على دعم صناعة الدواء والتحديث المستمر لآليات العمل الرقابي بما يتماشي مع أحدث معايير الجودة العالمية والمساهمة فى توفير إحتياجات قطاع الدواء من المواد القياسية يهدف برنامج إعتماد هيئة الدواء المصرية للمواد القياسية إلي توفير الية إعتماد المواد القياسية المطلوبة للعمل الرقابي بمعامل الرقابة الدوائية وتوفيرها بشكل مستمر بما يضمن سرعة إستيفاء متطلبات تحليل العينات الرقابية وبالتالي وصول دواء أمن وفعال للمريض المصري في أقصر مدة ممكنة مع عدم إهدار موارد الشركات العاملة بقطاع الدواء بمصر من العملات الأجنبية .

يشمل البرنامج

إعتماد هيئة الدواء المصرية للمواد القياسية المطلوبة لتحليل العينات الرقابية (مواد فعالة وشوائب) على أن يتم إجراء تقييمها وتحليلها وكذلك التحقق المستمر من جودتها بمعامل هيئة الدواء المصرية والتي يتم توفيرها من خلال :

- موردي المواد القياسية أو وكلائهم.
- الشركات العاملة بمجال الصناعات الصيدلية المحلية والعالمية .
- المعامل الخدمية للجهات الحكومية والخاصة.

مميزات البرنامج

- منح شهادة إعتماد سارية لمدة ثلاثة أعوام للمواد القياسية
- قيد المواد القياسية بقائمة المواد القياسية المعتمدة .

الجدول الزمني للتطبيق المرحلي

المرحلة	الفترة الزمنية	الحالة	النوع
الأولي	بدءا من تطبيق البرنامج	▪ إعتماد المواد القياسية المطلوبة لتحليل مستحضرات صيدلية	إختيارية
الثانية	بعد ثلاثة أشهر من تطبيق البرنامج	▪ إعتماد المواد القياسية المطلوبة لتسجيل مستحضرات صيدلية	إجبارية
الثالثة	بعد ستة أشهر من تطبيق البرنامج	▪ إعتماد المواد القياسية المطلوبة لتسجيل مستحضرات صيدلية ▪ إعتماد المواد القياسية المطلوبة لتحليل مستحضرات صيدلية مسجلة (حاصلة على موافقة متغيرات)	إجبارية
الرابعة	بعد تسعة أشهر من تطبيق البرنامج	▪ إعتماد المواد القياسية المطلوبة لتسجيل مستحضرات صيدلية ▪ إعتماد المواد القياسية المطلوبة لتحليل مستحضرات صيدلية مسجلة (حاصلة على موافقة متغيرات) ▪ إعتماد المواد القياسية المطلوبة لتحليل مستحضرات صيدلية مسجلة (سحب عشوائي) ▪ إعتماد المواد القياسية المطلوبة لتحليل الخامات الدوائية	إجبارية

مجموعات المواد القياسية التي يشملها البرنامج

يتم تطبيق الآلية طبقاً للجدول الزمني المرحلي على المواد القياسية المقدمة للإعتماد والتى تنقسم الى المجموعات التالية :

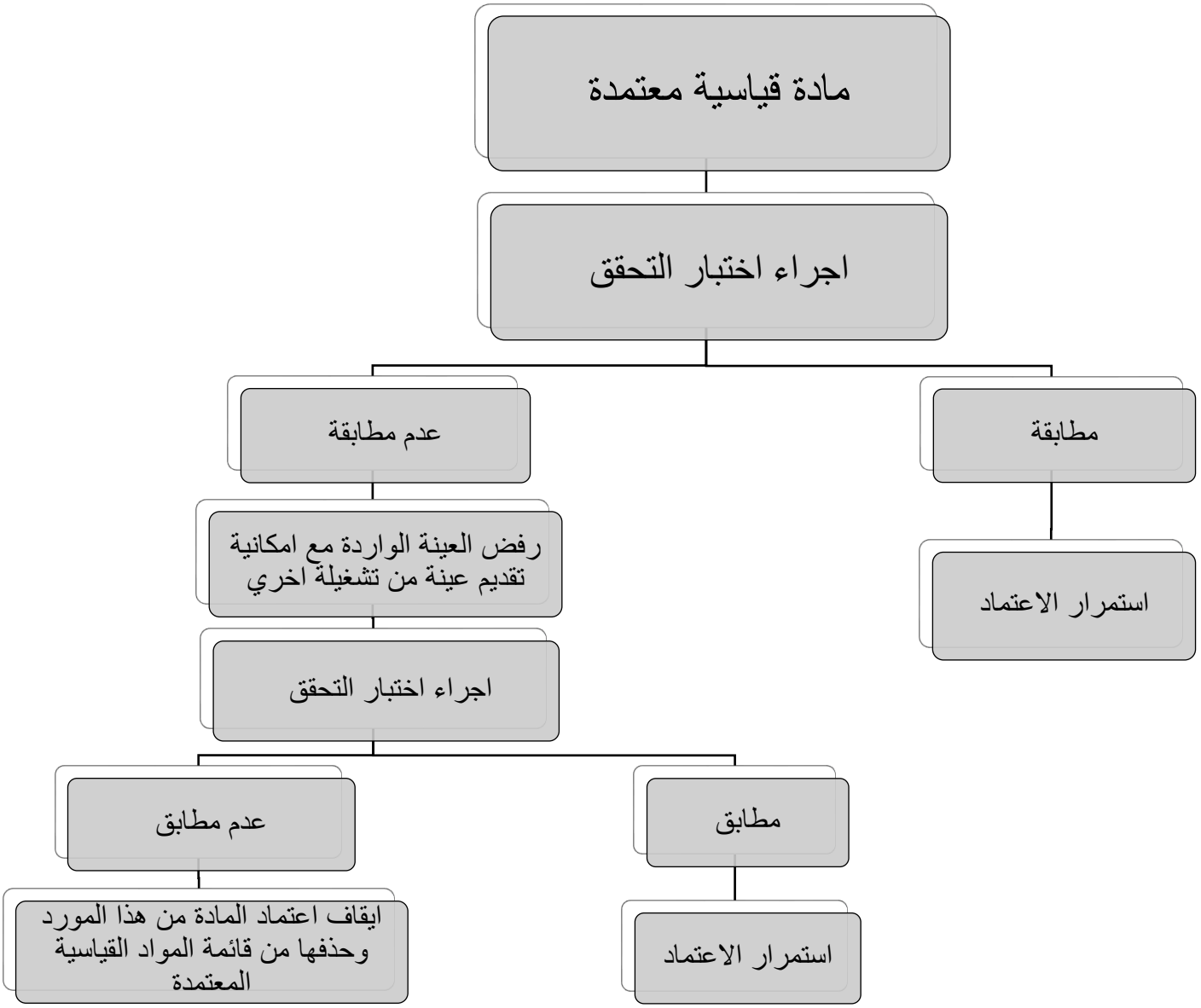
المجموعة الأولى	▪ تشمل المجموعة الاولي المواد القياسية الدستورية, المواد القياسية المعتمدة من المعاهد الوطنية للقياس اوالجهات والمنظمات المعترف بها دوليا ▪ Pharmacopoeia Reference standards, International recognized national metrological institutes or agencies ▪ لا تخضع المواد القياسية التابعة لهذه المجموعة لاي اجراء تقييم اوتحقق ولا تدرج في قائمة المواد القياسية المعتمدة.
المجموعة الثانية	▪ **مواد قياسية معتمدة** من جهة حاصلة علي ISO 17034 ويتم إعتماد هذة المجموعة عن طريق مراجعة المستندات المرفقة واجراء التحقق ان لزم الامر. ▪ **مواد قياسية معتمدة** من جهة مستوفية لمتطلبات ISO 17034 ويتم إعتماد هذة المجموعة عن طريق مراجعة المستندات المرفقة واجراء التحقق.
المجموعة الثالثة	▪ مواد قياسية من مصادر اخرى Working / Secondary Reference Standard ▪ يتم اجراء الاختبارات الخاصة بالاعتماد والتحقق لهذه المجموعة

الآلية التنفيذية

اجراءات ما قبل الإعتماد

الإجراء	الجهة
إرسال بريد اليكتروني بطلب الحصول على الإعتماد	مقدم الطلب
إرسال نموذج التقديم إلكترونيا	الادارة المركزية للرقابة الدوائية
سداد مقابل خدمة طلب تقييم وإعتماد مادة قياسية إستيفاء وإرسال نموذج التقديم إلكترونيا إرسال المستندات المطلوبة إلكترونيا (ملحق 1)	مقدم الطلب
دراسة ومراجعة المستندات والرد على مقدم الطلب وتحديد الكمية المطلوب إرسالها من كل مادة و أى متطلبات تحليل إن لزم الأمرمع تحديد مقابل خدمة تحليل مادة قياسية تحت الإعتماد (عشر ايام)	الادارة المركزية للرقابة الدوائية
سداد مقابل خدمة تحليل مادة قياسية تحت الاعتماد وتسليم العينات (ملحق 2) مرفقا بها المواد القياسية من المجموعة الاولي وأى متطلبات تحليل إن لزم الأمر والمستندات الورقية المطلوبة (ملحق 3) خلال خمسة أيام	مقدم الطلب
التحليل في فترة لا تتجاوز 5 ايام عمل لكل مادة	معامل هيئة الدواء المصرية
إصدار شهادة الإعتماد والقيد بقائمة المواد القياسية المعتمدة وإصدار جدولا مرفقا به أسماء المواد التي تم إعتمادها	**الادارة المركزية للرقابة الدوائية**

اجراءات ما بعد الإعتماد



يتم التحقق من المواد القياسية التابعة للمجموعة الثانية عن طريق مراجعة المرفقات والتحليل ان لزم الامر

يتم اجراء اختبار التحقق للمواد القياسية التابعة للمجموعة الثالثة عند تسليم كل عينة للتحليل الرقابي او مرة كل عام أيهما أقرب.

الشروط العامة والأحكام

1. تلتزم الشركة بالقواعد التنظيمية والضوابط الفنية التي تصدرها الهيئة.
2. عند تسليم عينة لإجراء إختبار التحقق لإستخدامها بغرض التحليل الرقابى يتم ارجاع العينات التي تم التأكد من مطابقتها لمقدم طلب اختبار التحقق ملصق عليها شعار (EDA) ليتم تسليمها للمعمل المختص بالتحليل الرقابى مع المستحضر النهائي.
3. فى حال عدم إلتزام الشركة بالمدة الزمنية المحددة بالآلية التنفيذية لسداد مقابل الخدمة ولتسليم العينات ومتطلبات التحليل يعتبر الطلب كأن لم يكن , ويحق للشركة التقدم بإلتماس لرئيس الإدارة المركزية للرقابة الدوائية لمنح مهلة إضافية وفى حال الرفض تتقدم الشركة بطلب جديد حال الرغبه فى الحصول على الإعتماد.
4. تلتزم الشركة بإخطار الإدارة المركزية للرقابة الدوائية فور حدوث أى تعديلات فى المستندات المقدمة وتقوم لجنة الإعتماد بالرد فى خلال مدة زمنية لا تتجاوز عشرة أيام بالقبول أو تعليق الإعتماد لحين استكمال التعديلات.
5. في حال رفض طلب الإعتماد يكون من حق الشركة إعادة التقدم بطلب جديد بعد تغيير مصدر المادة القياسية المطلوب إعتمادها مع سداد الرسوم المقررة.
6. فى حال رغبة الشركة بتجديد الإعتماد يتم تقديم الطلب خلال فترة زمنية لا تقل عن ثلاثة أشهر من تاريخ التجديد.
7. يلتزم مقدم الطلب بتوفير أي متطلبات للتحليل إن لزم الأمر.
8. يجوز للإدارة المركزية للرقابة الدوائية إجراء تقييم عيني أو افتراضي إن لزم الأمر مع إلتزام مقدم الطلب بتوفير كافة متطلبات التقييم الإفتراضي.
9. يتم إجراء إختبارات التحقق عشوائيا للمواد المعتمدة من هيئة الدواء المصرية.
10. في حالة إعتماد مادة قياسية معايرة (secondary standard) لأحد شركات الأدوية لا يحق إستخدامها سوي للشركة مقدمة الطلب.
11. في حال عدم مطابقة التحقق من عينة لمادة معايرة (secondary standard) أثناء فترة سريان القيد يتم إيقاف إعتماد المادة.

الملحقات

ملحق 1
المستندات المطلوب إرسالها إلكترونيا

المستندات المطلوبة للمجموعة الثانية

- صورة من شهادة ISO 17034:2016 مرفقا بها المدى الخاص بالإعتماد أو صورة من مواصفة مكافئة لل ISO 17034
- مايفيد التمثيل القانوني في حال التعامل مع الوكلاء الرسميين للشركات العالمية أو موردي المواد القياسية.
- شهادات أو تقارير التحليل شاملة البيانات المطلوبة طبقا لل ISO guide 31:

- Title of the Document
- Unique identifier of the RM
- Name and Description of the RM
- Name and Contact Details of the RM Producer
- Intended Use
- Minimum Sample Size/Homogeneity
- Period of Validity
- Storage and Handling Information
- Document Version and Page Numbers
- Property of interest, property value and associated uncertainty) CRM)
- Measurement Methods.
- Meteorological traceability
- Name and function of the RM producer's approving officer.

- **Safety material data sheet**

المستندات المطلوبة للمجموعة الثالثة

- **Certificate of Analysis (CoA) includes:**

- Standard name
- Unique identifier (batch no, code no etc..)
- Reference monographs.
- Retest date /Expiry date

- Results of all required tests according to the reference monographs.
- Storage conditions.
- Instructions of use when necessary
- Intended use when necessary
- Name and function of approving officer.
- Date of certification
- **Safety data sheet.**

في حال المواد القياسية التي ليس لها مرجعية دستورية بالإضافة للمستندات السابقة يتم تقديم :

- Testing Monographs
- Validation studies for methods described in the relevant testing monographs.
- Evidence of characterization of submitted standards (e.g. IR, UV spectra, LC/MS etc…).

ملحق 2

1- أعداد العينات

- **الأعداد لإجراء الإعتماد** (Certification) :
  - عند اعتماد مادة قياسية من الشركة مقدمة الطلب او المورد : ترسل ٢ عبوة
  - عند اعتماد مادة الشوائب : ترسل عدد ٢ عبوة
- **الأعداد لإجراء التحقق** (Verification) **:**
  - عند إجراء التحقق للمادة القياسية المعايرة - standardized working - من الشركة مقدمة الطلب : ترسل ٤ عبوات
  - عند إجراء التحقق للمادة القياسية المعايرة اوالثانوية – working standard- reference standard من المورد : ترسل ٢ عبوة
  - عند إجراء التحقق لمادة الشوائب : ترسل ٢ عبوة

2- بيانات ملصق التعريف علي العبوة (label):

-Standard name.

-Name of manufacturer.

-Identification code i.e. Batch no., Lot no.

-Expiry/Retest date

-Potency (if applicable)

-Water content

-Storage condition

-Weight

-Safety instructions

3- شروط غلق العبوات للمواد القياسية والشوائب (sealing)

يجب ارسال المواد بعبوات تناسب ظروف تخزين المادة مع ضرورة أن تكون العبوات محكمة الغلق بغطاء يناسب لمواصفات كل مادة

ملحق 3

المستندات المطلوب تسليمها ورقيا

- أصل نموذج التقديم موقعا من الممثل القانونى أو المفوض
- أصل خطاب التفويض
- أصل إيصالات سداد مقابل الخدمة

الملحقات

ملحق 4
Assessment checklist for the reference materials producers (RMP)

Requirement	Yes /No
1-Contractual requirements	
Is any request, tender or contract verbal or written; concerning the production of an RM reviewed, following documented policies and procedures established by the RMP?	
Do these policies and procedure ensure the requirements for RMs and their production are adequately defined, documented and understood?	
Do these policies ensure that the RMP has the capability and resources to meet the requirements?	
Does the review include any work that needs to be subcontracted by the RMP?	
Does the RMP maintain records of these reviews, including any changes, records of pertinent discussions with the customer relating to the customer's requirements, and subcontracted work?	
2-Impartiality	
Is the RMP structured and managed so as to safeguard impartiality?	
Does the lab have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work?	
Does the lab identify risks to its impartiality on an on-going basis, which shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel?	
Does the lab have the ability to demonstrate, if a risk to impartiality is identified, and how it eliminates or minimizes such risk?	
Does the lab have top management commitment to impartiality?	
3- Confidentiality	
Is the RMP responsible for and does it treat in an appropriate manner all information obtained, including confidential information unless this information is placed in the public domain or agreed to its disclosure to others or required by law?	
In case the confidential information is required to be disclosed is the individual or the body concerned notified unless prohibited by the law?	
4- Structural requirements	
- Is the RMP a legal entity, or a defined part of a legal entity, that can be held responsible for all its activities related to the production of RMs and does it have a description of its legal status?	

- Does the RMP define its organizational and management structure of, its place in any parent organization and the relations between management, technical operations, support services and subcontractors using organization charts?
c)Does the RMP define the parts of the organization covered by the management system for the production of RM s?
d) Does the RMP specify the responsibility, authority and interrelationships of all personnel who manage perform or verify work affecting the quality of RMs produced?
e) Does the RMP have managerial personnel, supported by technical personnel, with the authority and resources needed to discharge their duties and to identify the occurrence of departures from the management system or the procedures for the production of RMs and to initiate actions to prevent or minimize such departures?
d) Does the RMP have technical management with overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of each operation which forms part of the RM production?
e) Does the RMP appoint personnel that have defined responsibility and authority for ensuring that the requirements for the competence of the lab to produce RMs are met and have direct access to the highest level of management at which decisions are taken on RM production policy or resources?
- Does the RMP management ensure communication internal and external to ensure the effectiveness of the management system and that meeting the customer and other requirements are well communicated?

5-Resources requirements

5 .1 Personnel

-Does the RMP ensure that all personnel involved in RM production are supervised and competent and that they work in accordance with the RMP ’s management system?
-Do personnel, including subcontractors, personnel of external bodies, or other individuals acting on the RMP ’s behalf, comply with the policies and procedures for management of confidential information that are set by the RMP?
-does the RMP shall ensure the competence of all personnel, including technical management personnel, operating under its management system who undertakes activities relating to the production of each particular type of RM.
-are there sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions?
-Does the RMP have procedures for identifying training needs and providing training of personnel?
Is there a training program in place that is relevant to the present and anticipated tasks of the RMP?
Does The RMP maintain records of job descriptions for its personnel involved in RM production activities?

Does the RMP authorize competent personnel to perform particular activities relating to RM production where records of these authorizations, competence, educational and professional qualifications of those personnel shall be kept and provide the evidence of adequate training and competence and include the date on which the authorization and/or competence has been confirmed?	
5.2. Subcontracting - Does the RMP have procedures to ensure: a) The subcontractors' experience and technical competence are sufficient for their assigned tasks? b) Selection of subcontractors on the bas is of their ability to meet the requirements stipulated by the RMP? c) Assessment that all tasks performed by subcontractors comply with the requirements set by the RMP? - Has the RMP ensured not to subcontract: ➢ the production planning? ➢ the selection of subcontractors? ➢ the assignment of property values and their uncertainties? ➢ the authorization of property values and their uncertainties? ➢ The authorization of RM documents? -Does the RMP establish and maintain the evidence of the subcontractor's competence, including records of evaluations and any audits made or supervision of the operations carried out by the subcontractor to ensure their capabilities of performing the subcontracted tasks? - Does the RMP have personnel operating under its management system having sufficient knowledge of the subcontractor's task to evaluate the subcontractor's activity?	
5.3. Provision of equipment, services and supplies - does the RMP have procedures in place for the selection of equipment, services and supplies that affect the quality of the RMs produced? -does the RMP use only equipment, services and supplies that comply with specified requirements to ensure the quality of the RMs it produces? - Does the RMP ensure that equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with the specifications or requirements defined for the RM production activities? - Does the RMP maintain records of purchases of equipment, services and supplies, including records of the selection criteria used, confirmation of acceptance?	
5.4. Facilities and environmental conditions Does the RMP ensure that all laboratory facilities, calibration and testing areas (if applicable), material handling, storage, processing and packaging areas, energy sources, lighting, humidity, temperature, pressure and ventilation are suitable for performing the required activities?	

-Are environmental conditions in which the RM production activities are undertaken monitored controlled and recorded when the environmental conditions could have an adverse effect on the RM? - Are all RM processing and calibration and testing areas, protected, where appropriate, from other environmental factors such as incompatible activities? - Is access to and use of areas controlled as appropriate?	
6-Technical and production requirements **6.1. Production planning** Does the RMP identify and plan those processes that directly affect the quality of RM production, and is this production plan documented and does it address: a) Material l selection including, where appropriate, sampling? b) verification of the identity of the material? c) maintaining suitable environments for all aspects of production? d) Material processing? e) choice of measurement procedures? f) validation of measurement procedures? g) verification and calibration of measuring equipment? h) specification of acceptance criteria for, and assessment of, homogeneity, including sampling? i) specification of acceptance criteria for, and assessment and monitoring of, stability including sampling? j) designing and organizing appropriate characterization, including sampling? k) assessing commutability (where appropriate)? l) assigning property values? m) establishing uncertainty budgets and estimating uncertainties of certified value(s) n) defining acceptance criteria for measurand levels and their uncertainties? o) establishing metrological traceability of measurement result(s) and certified value(s)? p) issuing RM documents? q) ensuring adequate storage facilities and conditions? r) ensuring appropriate label ling and packaging of the RM s? s) ensuring appropriate transport arrangements? t) ensuring post-production stability monitoring?	
6.3. Production control Does the RMP verify that the production plan has been implemented as specified? Are deviations from the plan documented and approved?	
6 .4 Material handling and storage - Does the RMP identify, preserve and separate candidate RMs and RMs from chemicals and other samples, from the time of processing through to their distribution?	

- Does the RMP ensure adequate packaging of all RMs and provide secure storage areas /stock rooms which prevent damage or deterioration of any item or material between characterization and distribution?

Is the condition of all RMs monitored at appropriate intervals throughout the storage period, in order to detect possible deterioration?

Does the RMP control packaging and labeling processes to the extent necessary to ensure conformity with safety and transport requirements?

- Does the RMP take measures to ensure that the integrity of each individual RM unit is maintained until the point when first used?

6 .5 Material processing

Does the RMP establish procedures to ensure that the material has undergone adequate processing for its intended use and address:

a) qualitative analysis for verification of material type and/or identity?

b) synthesis, purification, incubation, and transformation into the final form?

c) homogenization?

d) proper handling

e) measurements for control of material processing?

f) pre -treatment, cleaning or sterilization of processing equipment and sample containers?

g) stabilization of material?

h) packaging of the material?

i) safety precautions?

Is equipment used in material processing operated in accordance with documented procedures?

6.6 Measurement procedures

Are testing and calibration activities consistent with the required accuracy of the property values of the RM, and with any standard specifications relevant to the measurement concerned?

6.7 Measurement equipment

-Does the RMP have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration?

- Does the laboratory verify that equipment conforms to specified requirements before being placed or returned into service?

- Is the equipment used for measurement capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result?

- Is the measuring equipment calibrated when:

the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or calibration of the equipment is required to establish the metrological traceability of the reported results?

-does the laboratory establish a calibration program?

-Is the calibration program reviewed and adjusted as necessary in order to maintain confidence in the status of calibration? - Is all equipment labeled for their calibration status? - Are equipment that are out of use shall be isolated and clearly labeled to be out of service until return to service and verified for proper use. -Are intermediate checks shall be carried out according to a procedure when necessary? Are records retained for equipment which can influence laboratory activities?	
6.8 Data integrity and evaluation Does the RMP ensure that: a) computer software developed software is validated and shown to be adequate for use? b) procedures are established and implemented for protecting the integrity of data? c) equipment and software are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain data integrity? d) appropriate procedures are established and implemented for the prevention of unauthorized access and changes to records, including computer records? Are statistical procedures used verified for their appropriate application?	
6 .9 Metrological traceability of certified values -When producing CRMs, Is the metrological traceability of the certified values established by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference? When metrological traceability to the SI units is not technically possible, ---Does the laboratory demonstrate metrological traceability to an appropriate reference? - Is the evidence of meteorological traceability established when secondary parameters that have a significant influence on the certified value or its uncertainty?	
6 .10 Assessment of homogeneity -Does the RMP carry out an assessment of the homogeneity of any candidate RM in its final packaged form to ensure its fitness for purpose? -When the material is produced in multiple batches, is the equivalence of the batches demonstrated or the homogeneity of each batch evaluated separately? -Are validated measurement procedures selected so that the precision and selectivity are fit for the purpose required? - For certified values, is homogeneity quantified as an uncertainty contribution to the certified value or shall be shown to be a negligible contribution to the uncertainty of the certified value?	
6.11. Assessment and monitoring of stability Does The RMP: a) assess, by experimentation, if necessary, the stability of all relevant properties of an RM under proposed storage conditions and choose pre -treatment, packaging and storage conditions in accordance with the results of the assessment?	

b) assess, by experimentation, if necessary, the stability of all relevant properties of an RM under proposed conditions of transport, and choose transport conditions to maintain stability during transport? c) establish any necessary advice on storage and use of the material to maintain stability at the user ‘s premises? d) select a scheme for monitoring the stability of materials held in long term storage that permits prompt detection of change, taking into account the possible rate of change?	
6.12. Characterization Where the RMP assigns property values, is there characterization of the RM?	
Does the RMP clearly define whether a quantitative or a qualitative property will be characterized?	
Does the RMP select a characterization strategy appropriate for the intended use of the RM?	
Does the RMP specify the characterization study so that the properties of interest are each characterized with appropriate traceability and sufficient reliability?	
Does the lab document a measurement plan that clearly describes the tasks to be performed and communicate this to all personnel responsible for measurements used in characterization?	
Does the lab perform technical evaluation of characterization data and documents to ensure? - The implementation of the measurement plan - Evaluation of the impact of any deviation if present on the characterization data.	
6.13. Assignment of property values and their uncertainties Does the RMP use documented procedures for the assignment of property values?	
Do these procedures include, as appropriate? a) Details of statistical techniques and policies on treatment and investigation of anomalous results, including outliers? b)) The approach used to assign uncertainties to the property values? c) Any other significant factors that may affect the assignment of property values?	
Does the RMP take due account of technical information on test methods and equipment, including reported uncertainty information, and of any evidence of laboratory performance when assigning the property values of interest?	
For Certified Reference Materials “CRM”, does the RMP identify the uncertainty contributions to be included in the assigned uncertainty and considers at minimum uncertainty contributions of each of the following: a) Characterization, including any difference between multiple procedures used for characterization? b) between-unit and within-unit in homogeneity? c) Changes of property values during storage? d) Changes of property values during transport?	

6.14.RM documents and Labels Does the RMP issue and make available an RM certificate for CRMs and product information sheet for other RMs? Does the contents of RM certificates and product information sheets? include the following: a) Title of the document? b) Unique identifier of the RM? c) The name of the RM? d) Name and contact details of the RMP? e) Intended use? f) sample size (whenever applicable)? g) period of validity? h) storage information? i) instructions for handling and use that are sufficient to ensure the integrity of the material? j) Page number and the total number of pages? k) Document version? l) Information on commutability of the material (where appropriate)? And the following additional information a) Description of the CRM? b) Property of interest, property value and associated uncertainty? c) Measurement procedure for operationally defined measurands? d) Metrological traceability of the certified values? e) Name and function of RMP's approving officer?	
Is the RM label securely attached to the product container of an individual RM unit, and designed to remain legible and intact under the defined storage and handling conditions within the lifetime of the RM?	
Does the label identify the material, all information necessary to enable the material to be uniquely distinguished and referenced where appropriate, to its product information sheet or RM certificate?	
Where the physical size of the RM unit limits the amount of information that can be contained on the label, is the information included elsewhere (e.g., in an RM document)? Is a unique identifier given?	
6.15. Distribution services Does the RMP determine the conditions of shipment and ensure that appropriate documentation is provided to allow customs clearance?	
Does the RMP maintain up-to-date records of all RM sales and distribution?	
Does the RMP offer to users' reasonable guidance and technical support related to the RMs it produces?	

Does the RMP employ best efforts to notify users of any change to the property value or uncertainty for any RM within the validity period of the RM certificate or product information sheet?	
Where RMs are subject to resale through a distributor with whom the RMP has a contractual relationship, does the RMP pass on to the authorized distributor all necessary information to ensure that an effective post-distribution service is maintained?	
6.16. Control of quality and technical records Does the RMP establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records?	
Does the RMP ensure that it has recorded such information that might be needed in a future dispute situation?	
Are all records legible and stored and retained in such a way that they are readily retrievable and in facilities that provide a suitable environment to prevent damage, deterioration or loss?	
Do all records have retention time of records been established in accordance with customer or other relevant requirements, and documented?	
When mistakes occur in records, is each mistake be crossed out, not erased, made illegible or deleted, and the correct information entered alongside	
Are all such alterations to records signed or initialed, and dated by the person making the correction? In the case of records stored electronically, has equivalent measures been taken to avoid the loss or change of original information?	
Are all records held securely and, where appropriate, in confidence?	
Does the RMP have procedures to protect electronically held data at all times and to prevent unauthorized access to, or amendment of, such data?	
Does the RMP arrange for all individual measurement observations, appropriate calculations and derived data, calibration records and preparation reports to be retained for a defined period beyond which it is no longer probable that they will be referred to, taking into account the period for which the RM remains valid?	
Have the results of each calibration or measurement (or series of either) carried out by the RMP or by a subcontractor reported in accordance with ISO/IEC 17025?	
6.17. Management of non-conforming work Does the RMP have procedures that are implemented when it establishes that any aspect of its production activities does not conform to its own specified production procedures or the agreed requirements of the customer?	
Do the procedures ensure that? a) Responsibilities and authorities for the management of nonconforming work are designated? b) the actions to be taken when any non-conforming work and/or RMs are identified including root cause analysis and a system that ensures that they are effectively implemented? c) an evaluation of the significance of the non-conforming work is made and identification and implementation of correction and corrective action?	

d) where necessary, work is halted and, if appropriate, issue of the affected RM and its certificates and other appropriate documentation is withheld? e) remedial actions such as customer notifications are taken within a defined time-frame? f) where necessary, best efforts are employed to notify the users of the possible effects, within an appropriate period and, where necessary, non-conforming RMs and/or their certificates and other appropriate documentation already distributed, are recalled? g) the responsibility for authorization of the resumption of work is defined? h) where necessary, an internal audit is conducted to verify the closure and effectiveness of the corrective actions taken?	
Is the decision on recall of RMs taken in a timely manner to limit the use of nonconforming RMs?	
6.18. Complaints Does the RMP have a documented process to receive, evaluate and make decisions on complaints?	
Is a description of the handling process for complaints available to any interested party on request?	
Upon receipt of a complaint, does the RMP confirm whether the complaint relates to conformity assessment activities that it is responsible for and, if so, shall deal with it?	
Is the RMP responsible for all decisions at all levels of the handling process for complaints?	
Are investigation and decision on complaints not result in any discriminatory actions? Does the process for handling complaints include at least the following elements and methods? a) a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it? b) tracking and recording complaints, including actions undertaken to resolve them? c) ensuring that any appropriate action is taken?	
Is the RMP receiving the complaint responsible for gathering and verifying all necessary information to validate the complaint?	
Whenever possible, does the RMP acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome?	
Is the decision to be communicated to the complainant made by, or reviewed and approved by, individual(s) not involved in the original RM activities in question?	
Whenever possible, does the RMP give formal notice of the end of the complaint handling process to the complainant?	
7.Management system requirements Does the RMP define and document its scope of and address the following: ➢ Quality policy? ➢ General management system documentation ➢ control of management system documents ➢ Control of records? ➢ Management review?	

- Internal audit?
- Actions to address risks and opportunities?
- Corrective actions?
- Improvement?
- Feedback from customers?

References

1- ISO 17034: 2016 E “General requirements for the competence of reference material producers”

2- Handling and Use of Non-Compendial Reference Standards in the OMCL Network PA/PH/OMCL (11) 204 R9.

3- https://www.sigmaaldrich.com/EG/en/technical-documents/technical-article/analytical-chemistry/calibration-qualification-and-validation/how-to-choose-the-correct-reference-material-quality-grade.

4- United states pharmacopeia USP <11>

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الروابط الالكترونية لبرنامج الاعتماد

Appointment – حجز موعد سداد مقابل طلب الحصول على الاعتماد

https://form.jotform.com/212552933971056

Appointment - حجز موعد لسداد رسوم تحليل + تسليم متطلبات تحليل

https://form.jotform.com/212553322378050

Annex 1 Submission:

https://forms.office.com/r/VSkb5CLpqS