هيئة الدواء المصرية

دليل برنامج

إعتماد هيئة الدواء المصرية لمعامل مراقبة جودة مستحضرات التجميل

الفهرس

برنامج إعتماد هيئة الدواء المصرية لمعامل مراقبة جودة مستحضرات التجميل

أهداف البرنامج

يهدف البرنامج الي الإرتقاء بمستوى صناعة مستحضرات التجميل والنهوض بمعامل مراقبة جودة مستحضرات التجميل وإستمرارية التأكد من سلامتها و مأمونيتها تزامنا مع إطلاق الهيئة لنظام إدراج مستحضرات التجميل.

يشمل البرنامج

1- إعتماد كافة الإختبارات الخاصة بمأمونية المنتج والغرض من إستخدامه للمجموعات المختلفة وذلك لكافة الأشكال الصيدلية لمستحضرات التجميل و هى :

- إختبارات فيزيائية.
- إختبارات كيميائية.
- إختبارات ميكروبيولوجية.
- إختبارات السمية الحادة.

2- مراجعة شهادات تحليل مستحضرات التجميل المقدمة من المعامل المعتمدة بفئاتها المختلفة وهى:

- معامل مراقبة الجودة بمصانع مستحضرات التجميل المرخصة من هيئة الدواء المصرية.
- معامل مراقبة الجودة بمصانع المستحضرات الصيدلية المرخصة من هيئة الدواء المصرية.
- معامل التحليل الخاصة المرخصة من هيئة الدواء المصرية.
- معامل خدمية تابعة لجهات حكومية.

مميزات البرنامج

منح شهادة إعتماد للإختبارات الخاصة بسلامة و مأمونية المجموعات المختلفة لمستحضرات التجميل سارية لمدة عام و تجدد طبقا للقواعد التنظيمية والضوابط الفنية التى تصدرها الهيئة فيما يخص إختبارات تحليل عينات مستحضرات التجميل.

الآلية التنفيذية

إجراءات ما قبل الإعتماد

الإجراء	جهة التنفيذ
1-سداد مقابل خدمة طلب الحصول على شهادة الإعتماد.	المعمل
2- إستيفاء نموذج التقديم إلكترونيا و إرساله موقعا بالإضافة لمستندات ملحق 1 على الرابط الخاص بذلك.	المعمل
3-الرد على المعمل بالقبول أو الرفض أو إستكمال (ثلاثة أيام).	الإدارة المركزية للرقابة الدوائية
4- سداد مقابل الخدمة(طلب إعتماد الإختبارات الخاصة بمجموعة رئيسية من مستحضرات التجميل) وتسليم أصل المستندات المطلوبة ورقيا بملحق 3 (ثلاثة أيام).	المعمل
5-دراسة الطرق المرسلة و تحديد موعد الزيارة (خمسة عشر يوما) [1].	الإدارة المركزية للرقابة الدوائية
6-زيارة المعمل للتقييم (ثلاثة الى خمسة أيام).	الإدارة المركزية للرقابة الدوائية
7-إرسال تقرير بنتائج التقييم للمعمل (خمسة أيام من تاريخ نهاية الزيارة).	الإدارة المركزية للرقابة الدوائية
8-إرسال المعمل لخطة الإجراءات التصحيحية المطلوبة (خمسة أيام)[2] .	المعمل
9-دراسة الخطة التصحيحية المقدمة و تحديد موعد زيارة أخرى إن لزم الأمر(ثلاثة أيام عمل) [3].	الإدارة المركزية للرقابة الدوائية
10-اعداد التقرير النهائي للإعتماد (عشرة أيام من تاريخ اخر رد وارد من المعمل أو تاريخ إنتهاء آخر زيارة) مع التوصية سواء بالقبول او الرفض.	الإدارة المركزية للرقابة الدوائية
11- إصدار شهادة الإعتماد مرفقا بها جدولا موضحا به الإختبارات الخاصة بالمجموعات المعتمدة من مستحضرات التجميل	الإدارة المركزية للرقابة الدوائية

الآلية التنفيذية

[1] فى حال وجود طلب إستكمال يقوم المعمل بإرساله فى خلال يومين و يتم الرد على المعمل فى خلال يومين.

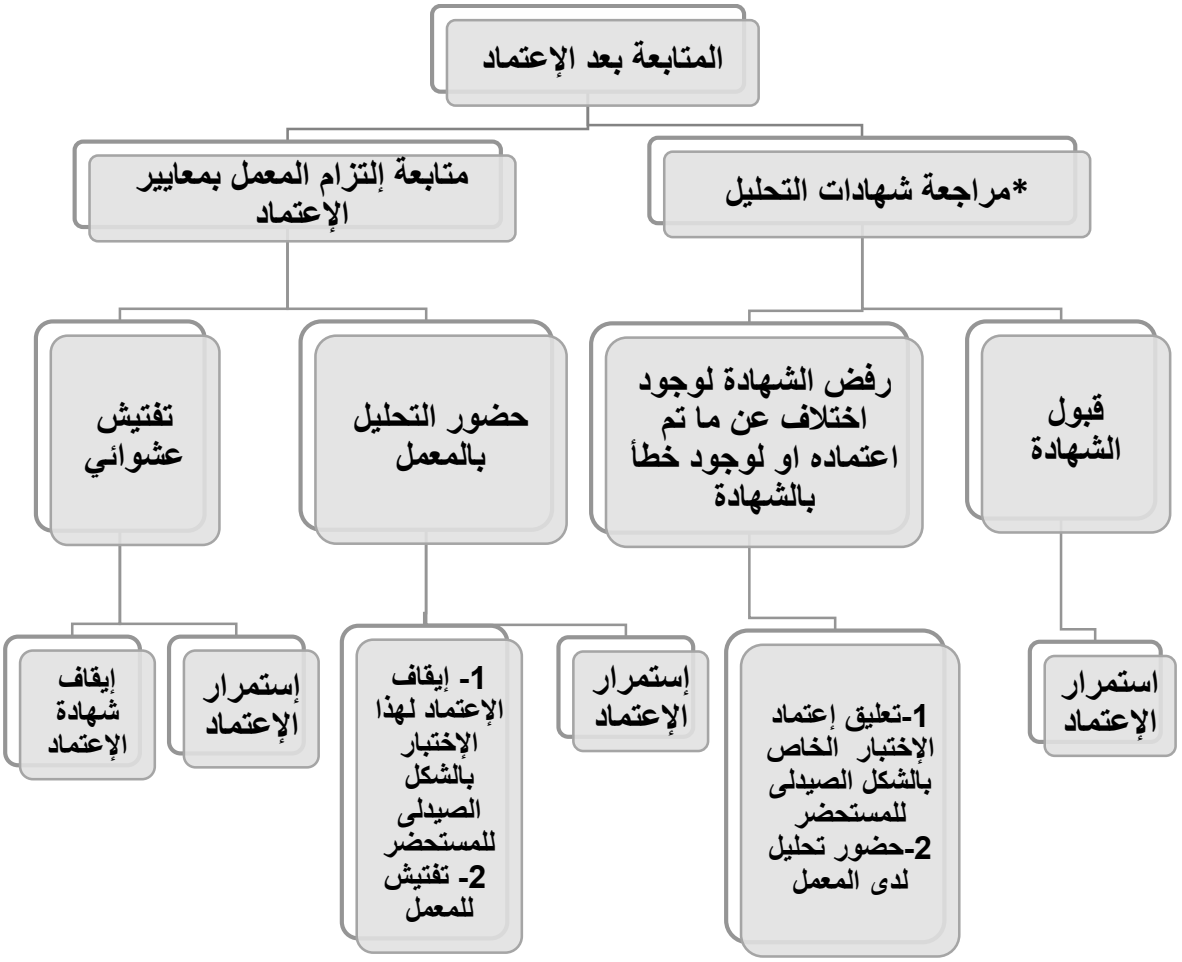
[1] يقوم المعمل بتأكيد موعد الزيارة على الرابط الخاص بذلك فى خلال يومين و فى حال عدم إرسال تأكيد يعتبر ذلك موافقة ضمنية على الموعد المحدد وفى حال وجود طلب إستكمال يقوم المعمل بالرد فى خلال يومين و يتم الرد على المعمل فى خلال يومين.

[2] المدى الزمنى لتصحيح أى بند بالخطة التصحيحية لا يزيدعن شهر.

[3] تقوم الإدارة المركزية بدراسة الإجراءات التصحيحة المقدمة في فترة لا تزيد عن عشرة أيام.

[3] يمنح المعمل مهلة إضافية لإنهاء الإجراءات التصحيحية طبقا للمدد الزمنية الموضحة سابقا و فى حالة عدم إستيفاء المتطلبات يعتبر الطلب كأن لم يكن.

اجراءات ما بعد الإعتماد



*تقوم الشركة بتسليم شهادة تحليل المستحضر لوحدة الإستلام بإدارة التقييم والإعتماد حيث تقوم الإدارة بإعتمادها من وحدة برامج الإعتماد وإصدار التقرير النهائي.

الشروط الأساسية للتقدم للبرنامج

-ضرورة توافر قائمة الأجهزة الأتية طبقا للإختبارات الخاصة بكل مجموعة :

Balance – Oven – water bath with shaker – stirrer – pH meter – hotplate – Atomic absorption spectrophotomer (AAS)/ Inductively Coupled Plasma spectrophotometer (ICP) – SPF analyzer – Gas Chromatography (GC) – UV spectrophotometer.

-فى حال رغبة المعمل بإعتماد إختبار يتطلب توفير جهاز إضافى ، يلتزم المعمل بتوفير الجهاز قبل التقدم بطلب الإعتماد علي أن يتم إعتماد نتائج هذه الإختبارات طبقا EU Cosmetic Regulation (EC) No. 1223/2009

-فى حال التقدم للحصول على إعتماد إختبارات ميكروبيولوجية فلابد من توافر معمل ميكروبيولوجى يضم الأجهزة الأتية:

- Autoclave
- Two Laminar air flow units in controlled room (with air locked double doors)
-Fridge
- Three incubators
-Microscope
-Baths and ovens
- Balance

- فى حال التقدم للحصول على إعتماد إختبارات السمية الحادة فلابد من إرسال ما يفيد توافر كافة الأجهزة و الإمكانيات اللازمة لإجراء الإختبار.

ضوابط التحديث

فى حال رغبة المعمل فى تحديث طرق تحليل بعد الحصول على الإعتماد أو تعديل بأى من المستندات المقدمة للحصول على الإعتماد لابد من إخطار الإدارة المركزية للرقابة الدوائية أولا لتتم الدراسة وإعادة التقييم إن لزم الأمر.

تقوم لجنة الإعتماد بالرد على المعمل فى خلال مدة زمنية لا تتجاوز عشرة أيام.

تجديد الإعتماد

يتم إتباع نفس ذات الإجراءات و يتم تقييم أداء المعمل لتجديد الإعتماد طبقا لنظام النقاط الأتي:-

المعيار	درجة التقييم
إلتزام المعمل بالمدد الزمنية الممنوحة لتنفيذ خطوات الحصول على الإعتماد.	**10**
تعاون ممثلي المعمل مع فريق التقييم أثناء زيارات التقييم وزيارات حضور التحليل لدى المعمل .	**10**
نقاط التقييم التي حصل عليها المعمل طبقا للمعايير المطلوبة خلال مجمل زيارات التقييم عند الحصول على وأثناء سريان شهادة الإعتماد .	**40**
عدم حدوث تعليق مؤقت لإعتماد إختبار شكل صيدلى للمستحضرأو أكثر خلال فترة الإعتماد.	**20**
عدم حدوث إيقاف إعتماد إختبار شكل صيدلى للمستحضرأو أكثرخلال فترة الإعتماد.	**20**
المجموع	**100**

***يمنح معمل مراقبة الجودة 5 نقاط إضافية في حال حصوله على إعتماد طبقا للمواصفة الدولية ISO/IEC 17025:2017 أو مواصفة مكافئة.**

ملحوظة: لا يتم الموافقة علي تجديد الإعتماد في حال حصول المعمل علي نسبة اقل من 75%.

مقابل الخدمة

م	نوع الخدمة	مقابل الخدمة
١	طلب الحصول / التجديد لشهادة الإعتماد.	٥٠٠٠جنيه
٢	طلب إعتماد / تجديد إعتماد الإختبارات الخاصة بمجموعة رئيسية من مستحضرات التجميل.	٢٠٠٠٠جنيه
٣	طلب إعتماد إختبار إضـــافى لمجموعة معتمدة أثناء فترة ســـريان الشهادة.	٥٠٠٠جنيه
٤	إعتماد نتائج التحليل للتشغيلة الواحدة لمستحضر تجميل محلى.	٢٠٠٠جنيه
٥	إعتماد نتائج التحليل للتشغيلة الواحدة لمستحضر تجميل مستورد.	٤٠٠٠جنيه

الشروط العامة والأحكام

1. يلتزم المعمل بالقواعد التنظيمية والضـــوابط الفنية التى تصـــدرها الهيئة فيما يخص اختبارات تحليل عينات مستحضرات التجميل.
2. يلتزم المعمل بتحليل العينات المقدمة بناءا على توجيه الإدارة المركزية للرقابة الدوائية.
3. يلتزم المعمل بالإحتفاظ بالعينات لكل تشـــغيلة تم تحليلها حتى إعتماد شـــهادة التحليل من الإدارة المركزية للرقابة الدوائية.
4. يلتزم المعمل بالاحتفاظ بصورة طبق الأصل من ملف تحليل كل تشغيلة لكل مستحضر لمدة لا تقل عن خمس سنوات.
5. يلتزم المعمل بتوفيركافة الاجهزة اللازمة لإجراء الإختبارات المطلوبة لإستيفاء نطاق الإعتماد.
6. فى حال عدم إلتزام المعمل بالمدد الزمنية المحددة لإنهاء أى إجراء يعتبر الطلب كأن لم يكن, ويحق للمعمل التقدم بإلتماس لرئيس الإدارة المركزية للرقابة الدوائية لمنح مهلة إضـــافية وفى حال الرفض يتقدم المعمل بطلب جديد فى حال الرغبة فى الحصول على الإعتماد.
7. يلتزم المعمل بإخطار الإدارة المركزية للرقابة الدوائية فورحدوث اى تعديلات فى المســتندات المقدمة وتقوم لجنة الاعتماد بالرد فى خلال مدة زمنية لاتتجاوزعشرة ايام بالقبول او تعليق شـهادة الاعتماد لحين استكمال التعديلات.
8. فى حـال رفض طلب الإعتمـاد يكون من حق المعمل التقدم بطلب جديد بعد مرور مدة لا تقل عن ثلاثة أشهرمن تاريخ الرفض مع سداد الرسوم المقررة.
9. يجوز للمعمل اجراء بعض الاختبارات الميكروبيولوجية واختبارات الســـمية الحادة لدى جهات حكومية اومعامل اخرى معتمدة بعد الحصول على موافقة الإدارة المركزية للرقابة الدوائية.
10. يجوزللمعمل التقدم بطلب إعتماد مجموعة جديدة أو إختبارإضـــافى أو أكثرخلال فترة ســـريان الشـــهادة علما بأنه سيتم التجديد لكافة الإختبارات سنويا بالتاريخ المقرر لتجديد الشهادة.
11. فى حال رغبة المعمل بتجديد شـــهادة الإعتماد يتم تقديم الطلب خلال فترة زمنية لا تقل عن ثلاثة أشـــهر قبل تاريخ التجديد.
12. يتم تقييم أداء المعمل سنوياً طبقا لنظام النقاط المعلن لاتخاذ القرار بالموافقة على تجديد الإعتماد من عدمه.

الملحقات

ملحق 1

المستندات المطلوب تقديمها :

1) رخصة سارية للمصنع(في حالة وجود المعمل داخل المصنع)/رخصة معمل خاص.
2) دليل جودة محدث أو مستند مكافئ يحتوي على آخر إصدار من :

الهيكل التنظيمي للمؤسسة التابع لها المعمل(في حالة ان المعمل داخل المصنع) موضح بها موقع المعمل من هذا الهيكل وكذلك المخطط التنظيمي للمعمل (Lab Organogram)

3) الإجراءات والتعليمات والسياسات.
4) قائمة محدثة من الأجهزة والمواد القياسية .
5) تعهد من المعمل بتوافر كافة الأجهزة , الكيماويات والمواد القياسية اللازمة لعمل كافة الإختبارات المطلوب إعتمادها.
6) طرق التحليل المستخدمة و طرق التحقق الخاصة بها.
7) صورة التعاقد في حال إجراء إختبارات في معمل أخر& موافقة مختومة و معتمدة من المسؤول بالمعمل الأخر على القيام بزيارات تقييم له فيما يخص الإختبارات المقدمة للإعتماد.
8) في حال القيام بتحليل بعض الإختبارات في معمل بجهة حكومية يتم تقديم تعهد مختوم وموقع من المعمل المقدم الطلب.
9) صورة إيصال سداد مقابل الخدمة لطلب التقدم للحصول على شهادة الإعتماد.
10) خطابات التفويض.
11) صورة نموذج التقديم موقع من المفوض.

الملحقات

ملحق 2
Assessment checklist

1. Organization and Management	
Clause	**Requirement**
1.1	The laboratory, or the organization of which it is part, should be an entity that is legally authorized to function and can be held legally responsible.
1.2	The laboratory should be organized and operated so as to meet the requirements laid down in these guidelines.
1.3	The laboratory should have managerial and technical personnel with the authorities and resources needed to carry out their duties, to identify the occurrence of departures from the quality management system or from the procedures of performing tests and/or calibrations, validation and verification and to initiate actions to prevent or minimize such departures.
1.4	The lab should have arrangements to ensure that its management and personnel not subject to commercial pressures or conflicts of interest that may adversely affect the quality of their work.
1.5	The lab should have a policy and procedure in place to ensure confidentiality of information contained in marketing authorizations, transfer of results or reports, and to protect data in archives (paper and electronic).
1.6	The lab should define, with the aid of organizational charts, the organization and management structure of the laboratory, its place in any parent organization

and the relationships between management, technical operations, support services and the quality management system.

1.7 The lab should specify the responsibility, authority and interrelationships of all personnel who manage the performance or verify the work which affects the quality of the tests and/or calibrations, validations and verifications.

1.8 The lab should nominate trained substitutes/deputies for key management and specialized scientific personnel.

1.9 The lab should provide adequate supervision of staff, including trainees, by persons familiar with the test and/or calibration, validation and verification methods and procedures, as well as their purpose and the assessment of the results.

1.10 The lab should have management which has overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations

1.11 The lab should designate a member of staff that will ensure compliance with the quality management system and should have direct access to the highest level of management at which decisions are taken on laboratory policies or resources.

1.12 The lab should ensure adequate information flow and guarantee communication and coordination between the staff at all levels.

1.13 The lab should ensure the traceability of the sample from receipt, throughout the stages of testing, to the completion of the analytical test report and maintain a registry with keeping records on all incoming samples and accompanying documents.

1.14 The lab should maintain an up-to-date collection of all specifications and related documents (paper or electronic) used in the laboratory.

1.15 The lab should have appropriate safety procedures.

1.16 The laboratory should maintain a registry with receiving, distributing and supervising the consignment of the samples to the specific units.

2. Quality Management System

Clause	Requirement

2.1 The lab should document the elements of its quality management system in quality manual or equivalent documents, for the organization as a whole and/or for a laboratory within the organization.

2.2 The Quality Manual or equivalent documents should provide (as a minimum) the following policies:

(a) a quality policy statement, including at least the following:

(i) A statement of the laboratory management's intentions with respect to the standard of service it will provide;

(ii) A commitment to establishing, implementing and maintaining an effective QMS.

(iii) The laboratory management's commitment to good professional practice and quality of testing, calibration, validation and verification;

(iv) A requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the documentation concerning quality;

(b) The structure of the laboratory (organizational chart);

(c) The operational and functional activities pertaining to quality, so that the extent and the limits of the responsibilities are clearly defined;

(d) outline of the structure of documentation used in the laboratory quality management system;

(e) The general internal quality management procedures;

(f) References to specific procedures for each test;

(g) Information on the appropriate qualifications, experience and competencies that personnel are required to possess;

(h) Information on initial and on-job training of staff;

(i) A policy for internal and external audit;

(j) A policy for implementing and verifying corrective and preventive actions;

(k) A policy for dealing with complaints;

(l) A policy for performing management reviews of the quality management system;

(m) A policy for selecting, establishing and approving analytical procedures.

(n) A policy for handling of OOS results;

(o) A policy for the employment of appropriate reference substances and reference materials;

(p) A policy to select service providers and suppliers.

2. Standard Operating Procedures	
Clause	**Requirement**
2.3	The laboratory should establish, implement and maintain authorized written SOPs including, but not limited to, administrative and technical operations e.g. (a) personnel matters, including qualifications, training, clothing and hygiene; (b) change control;

(c) internal audit;

(d) dealing with complaints;

(e) implementation and evaluation of corrective and preventive actions;

(f) the purchase and receipt of materials and services;

(g) the procurement, preparation and control of reference substances;

(h) the internal labeling, quarantine and storage of materials;

(i) the qualification of equipment;

(j) the calibration of equipment;

(k) preventive maintenance and verification of instruments and equipment;

(l) sampling, if performed by the laboratory, and visual inspection;

(m) the testing of samples with descriptions of the methods and equipment used;

(n) the evaluation and investigation of atypical and OOS results;

(o) validation of analytical procedures;

(p) cleaning of laboratory facilities, including bench tops, equipment, work stations, clean rooms (aseptic suites) and glassware;

(q) monitoring of environmental conditions, e.g. temperature and humidity;

(r) monitoring storage conditions;

(s) disposal of reagents and solvent samples;

(t) Safety measures.

2.4 The activities of the laboratory should be systematically and periodically audited.

The audits should be carried out by trained and qualified personnel, who are independent of the activity to be audited.

Such audits should be recorded, together with details of any corrective and preventive action taken.

2.5 Management review of quality issues should be regularly undertaken (at least annually), including

(a) Reports on audits or inspections and any follow-up required to correct any deficiencies.

(b) the outcome of investigations carried out as a result of :

-complaints received;

- doubtful (atypical) or aberrant results reported in collaborative trials and/or in inter-laboratory comparison reports;

- Corrective actions applied and preventive actions introduced as a result of these investigations.

3. Documentation Control	
Clause	**Requirement**
3.1	The laboratory should establish and maintain procedures to control and review all documents. A master list identifying the current version status and distribution of documents should be established and readily available.
3.2	The procedures should ensure that: (a)Each document, whether a technical or a quality document, has a unique identifier, version number and date of implementation;

(b)Appropriate, authorized SOPs are available at the relevant locations, e.g. near instruments;

(c)Documents are kept up to date and reviewed as required;

(d)Any invalid document is removed and replaced with the authorized, revised document with immediate effect;

(e)A revised history page includes references to the previous document;

(f)Obsolete documents are retained in the archives to ensure traceability of the evolution of the procedures; any copies are destroyed;

(g)All relevant staff are trained for the new and revised SOPs; and quality documentation.

3.3 The presence of change control system that ensures that:

(a) During the review and revision procedure, documents are prepared by the original initiator, or a person who performs the same function. Documents are reviewed, approved and authorized at the same management level as the original document.

(b) Staffs acknowledged, by a signature, that they are aware of applicable changes and their date of implementation.

4. Records	
Clause	**Requirement**
4.1	The laboratory should establish and maintain procedures for the collection of technical and scientific records

4.2 Records should include all original observations, including calculations and derived data, calibration, validation and verification records and final results of tests.

4.3 Quality and technical/scientific records (including analytical test reports, certificates of analysis and analytical worksheets) should be legible, readily retrievable, stored and retained within a suitable environment.

4.4 Quality Management records should include reports of both internal, external audits, management reviews, complaints and their investigations and records for the implementation and evaluation of CAPA corrective and preventive actions.

5. Data Processing Equipment and Data governance	
Clause	**Requirement**
5.1	When computers are used in the collection, processing, recording, reporting, storage or retrieval of test and/or calibration data, the laboratory should ensure that: (a) Computer software developed by the user should be documented in sufficient detail and appropriately validated or verified as being suitable for use; (b) Procedures are established and implemented for protecting the integrity of data. Such procedures should include measures to ensure: - The integrity and confidentiality of data entry or collection and the storage, transmission and processing of data; -The protection of data from unauthorized access and an audit trail of any amendments should be maintained, especially for the electronic data;

(c) computers and automated equipment are maintained so as to function properly and are provided with the environmental and operating conditions necessary to ensure the integrity of test and calibration data;

(d) Procedures are established and implemented for making, documenting and controlling changes to information stored in computerized systems;

(e) Electronic data should be backed up at appropriate regular intervals according to a documented procedure;

(f) Backed-up data should be suitably archived and stored to be retrievable and to prevent data loss.

6. Personnel	
Clause	**Requirement**
6.1	The laboratory should have appropriate managerial and technical personnel and be suitably qualified and experienced. The laboratory should have sufficient staff to perform its delegated functions and be suitably educated, skilled and trained.
6.2	The technical management should ensure the competence of all personnel who are responsible for: - operating specific equipment, instruments or other devices; - performing tests and/or calibrations, validations or verifications; - performing specific tasks should be appropriately qualified in terms of their education, training and experience, as required; The technical management also has the duty of the evaluation of results as well as signing analytical test reports and certificates of analysis.

6.3 Staff undergoing training should be appropriately supervised and should be assessed on completion of the training including contract staff.

6.4 The laboratory should maintain current job descriptions for all personnel involved in tests and/or calibrations, validations and verifications.

The laboratory should also maintain records of all technical personnel, describing their qualifications, training and experience.

7. Premises

Clause	Requirement
7.1	The laboratory facilities should be of a suitable size and construction and to be designed to suit the functions and operations to be conducted in them.
7.2	The laboratory facilities should have adequate safety equipment located appropriately and measures should be in place to ensure appropriate cleaning. The laboratory should be equipped with adequate instruments and equipment, including work benches, work stations and monitored fume hoods.
7.3	The environmental conditions (lighting, energy sources, temperature, humidity and air pressure) should be appropriate, controlled and suitably monitored.
7.4	Archives should be provided to permit the secure storage and the retrieval of all documents and to which accesses should be restricted.
7.5	Procedures should be in place for the safe removal of types of waste including toxic waste reagents, samples and solvents.
7.6	The lab should have appropriate storage facilities.

7.7 There must be segregation of storage for samples, retained samples, reagents, laboratory accessories, reference substances and reference materials.

The environment of storage areas should be controlled and monitored and with controlled access.

7.8 There should be appropriate safety procedures for the receipt and storage of toxic or flammable reagents.

Segregation of the storage of flammable substances, fuming and concentrated acids and bases, volatile amines and other reagents.

7.9 Gases also should be stored in a dedicated store.

8. Equipment, instruments and other devices	
Clause	**Requirement**
8.1	All equipment should be adapted, located, calibrated, qualified, verified and maintained as required.
8.2	The laboratory should have the required test equipment, instruments and other devices for the correct performance of the tests and/or calibrations, validations and verifications. When laboratory uses equipment outside its permanent control, it shall ensure that documented requirements for this equipment are met.
8.3	All instrumentation, and other devices, must comply with the relevant standards, specifications, and qualification and requirements.

9. Contracts	
Clause	**Requirement**

9.1 The laboratory shall have written procedures for the selection of suppliers of materials, and the provision of services, including maintenance and calibration.

9.2 The laboratory shall have documentary evidence for the evaluation of suppliers of critical consumables and services.

The lab shall maintain an updated list of approved suppliers.

9.3 When the laboratory subcontract tests to a third party, the customer's awareness is must.

9.4 The laboratory shall maintain a registry of all subcontractors that it deals with and a record of the laboratory assessment of the competence of sub-contractors.

9.5 The laboratory take responsibility for all results reported, including those provided by the subcontracting laboratories.

10. Reagents	
Clause	**Requirement**
10.1	The laboratory shall ensure that all reagents and chemicals used in testing are of an appropriate quality and purchased from reputable, approved suppliers.
10.2	In the preparation of reagent solutions in the laboratory: (a) responsibility for this task should be clearly specified in the job description of the person assigned to carry it out; (b) Prescribed procedures should be used which are in accordance with published Pharmacopoeial or other standards where available;

(c) Records should be kept of the preparation and standardization of volumetric solutions.

10.3 All reagents, reagent solutions and volumetric solutions should clearly and with appropriate label.

10.4 In the transportation and subdivision of reagents:

(a) Whenever possible they should be transported in the original containers;

(b) When subdivision is necessary, clean containers should be used and appropriately labeled.

10.5 - All reagent containers should be visually inspected to ensure that the seals are intact and that the reagents are not tampered, both when they are delivered to the store and when they are distributed to the units.

10.6 - Water used as a reagent should be of the appropriate grade for a specific test should be used as described in the pharmacopoeias or in an approved test when available.

- Precautions should be taken to avoid contamination during its supply, storage and distribution.

- The quality of the water should be verified regularly to ensure that the various grades of water meet the appropriate specifications.

10.7 Stocks of reagents should be maintained in a store under the appropriate storage conditions.

10.8 The person in charge of the store is responsible for looking after the storage facilities and their inventory and for noting the expiry date of chemicals and reagents.

Training may be needed in handling chemicals safely and with the necessary care.

11. Reference Substances and Reference Materials	
Clause	**Requirement**
11.1	The laboratory should use appropriate reference substances (RS) and reference materials (RM) whenever possible.
11.2	There should be an appropriate procedure to register and identify RSs.
11.3	All RSs should be identified on receipt which is quoted in the analytical report and work-sheet. RS register should be maintained with the following information available: (a) The identification number of the RS; (b) A precise description of the RS; (c) The source of the RS; (d) The date of receipt; (e) The batch designation or other identification code; (f) The intended use of the RS; (g) The location of the RS, and any special storage conditions; (h) Any further necessary information; (i) Expiry date or retest date; (j) The certificate of analysis.

11.8 A person should be nominated to be responsible for reference substances and reference materials.

11.10 In addition a file should be kept in which all information on the properties of each reference substance is entered including the safety data sheets.

11.11 For reference substances prepared in the laboratory, the file should include the results of all tests and verifications used to establish the reference substances and expiry date or retest date; these should be signed by the responsible analyst.

In case of presence Pharmacopoeial reference substances, they should be regularly checked for validity (current status) from the issuing pharmacopoeia by various means, e.g. web sites or catalogues.

11.12 All reference substances prepared in the laboratory or supplied externally should be checked at regular intervals to ensure that deterioration has not occurred.

11.14 In the case that the result of retesting of a reference substance is noncompliant, a retrospective check of tests performed using this reference substance since its previous examination should be carried out where consideration of possible corrective actions, risk analysis should be applied.

12. Calibration, verification of performance and qualification of equipment, instruments and other devices

Clause	Requirement
12.1	Each item of equipment should be uniquely identified.
12.2	Each item of equipment should be labeled to indicate the status of qualification and the date when re-qualification is next required.

12.3 When installed, the equipment should be subjected to supplier IQ/OQ.

12.4 There must be a detailed plan for the qualification of all equipment and instrumentation.

12.5 Specific procedures should be established for each type of measuring equipment, taking into account the type of equipment, the extent of use and supplier's recommendations .e.g. pH and balances.

12.6 Equipment should be operated only by authorized personnel and instrument manuals and SOPs on the use, maintenance, verification, calibration, qualification should be available.

12.7 Maintenance and qualification and intermediate checks records should be available for each of the instruments.

12.8 Each instrument shall have a usage/maintenance logbook.

12.9 Instrument maintenance procedures should be established.

12.10 "out of service" equipment should be appropriately marked.

12.11 Following service, qualification or maintenance, instrumentation should be appropriately authorized and signed back into use.

13. Traceability

Clause	Requirement
13.1	The results of all analyses should be traceable, where appropriate, ultimately to a primary reference substance.
13.2	The calibration or qualification of instrument procedures should be traceable to a certified reference material and to SI units (metrological traceability).

14. Incoming samples

Clause	Requirement.
14.1	The laboratory shall collaborate with the sample provider to ensure that it obtains sufficient information about samples and objectives of testing and that the required analysis is performed and reported.
14.2	The laboratory should have a sampling plan and an internal procedure for sampling available to all analysts and technicians working in the laboratory. There should be an SOP for sampling and staff members who perform sampling should be appropriately trained and provided with appropriate equipment.
14.3	A standard test request form should be filled out and should accompany each sample submitted to the laboratory provided with the appropriate information.
14.4	The laboratory shall document the review of the request form and document the visual inspection of the sample on receipt.
14.5	The laboratory shall register the sample with an assigned unique registration number and the sample shall be legibly labeled.
14.6	Samples should be appropriately stored and storage areas should be monitored for the environment.
14.7	The examination of a sample should not be started before the relevant test request has been received.
14.8	The sample should be properly stored until all relevant documentation has been received.

14.9 A request for analysis may be accepted verbally only in emergencies. All details should immediately be placed on record pending the receipt of written confirmation.

14.10 Unless a computerized system is used, copies or duplicates of all documentation should accompany each numbered sample when sent to the specific unit.

15. Analytical Worksheets and Laboratory Notebooks

Clause	Requirement
15.1	The information about the sample, test procedure, calculations and the results of testing should be recorded in worksheets or notebooks and should be complemented by the raw data obtained in the analysis.
15.2	The record should provide sufficient information to confirm that the sample was tested in accordance with the requirements or support an OOS result.
15.3	There should be a separate record for each sample.
15.5	The record should provide the following information: (a) the registration number of the sample; (b) page numbering; (c) the date of the test request; (d) the date on which the analysis was started and completed; (e) the name and signature of the analyst; (f) a description of the sample received; (g) references to the specifications and a description of test method; (h) the identification of the test equipment used;

(i) the identification number of any reference substance and the lot No's of the reagents used;

(j) if applicable, the results of the system suitability test;

(k) the identification of reagents and solvents used;

(l) the results obtained;

(m) the interpretation of the results and the final conclusions;

15.6 The record should be completed contemporaneously.

15.7 All the results obtained should be appropriately checked by a second analyst and signed and appropriately signed, approved and authorized.

15.8 Errors should be appropriately corrected.

15.10 Current versions of the relevant pharmacopeias and European Standards Publications of Cosmetics should be used in the laboratory.

15.11 Analytical records should be appropriately archived.

16. Validation of analytical procedures

Clause	Requirement
16.1	The laboratory should perform appropriate validation or verification procedures for the analytical methods employed for testing.
16.2	The laboratory should have a written process describing all elements of method validation.
16.3	The SOP should describe which analytical performance characteristics need to be verified for the various types of analytical procedures.
16.4	The laboratory should perform system suitability testing, where appropriate.

16.5 A major change to the analytical procedure or composition of the product requires revalidation of the method.

17. Testing and Reporting	
Clause	**Requirement**
17.1	Samples should be tested according to an approved or authorized plan where any deviations should be adequately recorded. During analysis samples should be stored securely.
17.2	All deviations from the provided method should be adequately documented and explained.

18. Evaluation of test results Reports and Certificates of Analysis	
Clause	**Requirement**
18.1	An SOP is required to describe the review and evaluation of test results and describe: (a) Where statistics should be employed; (b) The confirmation of compliance with the specification; (c) How doubtful or atypical results are investigated, and definition of decision rules; (d) The investigation of OOS; (e) Trend analysis.
18.2	An SOP is required for describing the investigation when a doubtful result (suspected OOS result) has been identified.

18.3 The final analytical test report should compile the results and provide a conclusion of the examination of a sample and based on the analytical worksheet.

18.4 If a report requires any amendments a new corrected document should be issued.

18.5 The analytical report should provide the following content:

(a) The laboratory registration number of the sample.
(b) The laboratory test report number;
(c) The laboratory testing the sample;
(d) The originator of the request for analysis;
(e) Full details of the sample;
(f) The purpose of the investigation;
(g) A reference to the specifications employed or the test methods used;
(h) The results of all the tests obtained;
(i) A discussion of the results obtained;
(j) A conclusion as to whether or not the sample complied with the specification;
(k) The date on which the test(s) was (were) completed;
(l) The signature of the head of the laboratory or authorized person;
(m) The name and address of the original manufacturer and, if applicable, those of the re-packer and/or trader;
(n) The date on which the sample was received;
(o) The expiry date or retest date;
(p) A statement indicating that the analytical test report, or any portion thereof, cannot be reproduced without the authorization of the laboratory.

19. Certificates of analysis	
Clause	**Requirement**
19.1	The COA should contain the following information: (a) The registration number of the sample. (b) Date of receipt; (c) The name and address of the laboratory testing the sample; (d) The name and address of the originator of the request for analysis; (e) The name, description and batch number of the sample; (f) The name and address of the original manufacturer; (g) The reference to the specification used for testing the sample; (h) The results of all tests performed; (i) a conclusion as to whether or not the sample was found to be within the limits of the specification; (j) Expiry date or retest date if applicable; (k) Date on which the tests were completed; (l) The signature of the head of laboratory or another authorized person.

20. General Safety Rules	
Clause	**Requirement**
20.1	ALL staff members should be provided with appropriate, documented safety training.
20.2	The laboratory should have procedures and enforce “Good Practice” regarding the following: (a) Use of safety data sheets (MSDS);

(b) Smoking, eating and drinking in the laboratory;

(c) Use of fire-fighting equipment;

(d) Wearing protective clothing and eye protection;

(e) Use and handling highly potent, infectious or volatile substances;

(f) Use and handling of highly toxic substances;

(g) Use of warning labels on all containers of chemicals;

(h) Spark proofing of solvent stores;

(i) Rules on safe handling of cylinders of compressed;

(j) Rules regarding working alone;

Instructing staff in first-aid techniques and emergency care and availability of first-aid materials, including safety showers and eye wash stations.

20.3 The laboratory should have rules regarding:

(a) Mouth pipetting;

(b) Safe handling of glassware, corrosive reagents and solvents;

(c) Warnings provided regarding exothermic reactions;

(d) Use of oxidizing agents;

(e) Disposal of chemicals;

(f) Use of known carcinogens and mutagens as reagents.

Microbiology GLP Check-List of Cosmetic	
Clause	**Requirements**
	1- Principles
1.1	The laboratory should be a legal entity licensed from EDA, or a defined part of a legal entity licensed from EDA, that is legally responsible for its laboratory activities.
1.2	Principles described for personnel, premises, equipment and documentation should apply to the quality control laboratory.
	2-Personnel
2.1	Current job descriptions for all personnel involved in any activity in the laboratory including tests and/ or calibrations,
2.2	Microbiological testing should be either performed or supervised by an experienced person, qualified to degree level in microbiology or equivalent.
2.3	Staff should have basic training in microbiology and relevant practical experience before being allowed to perform work covered by the scope of testing (Training evidence or records should be documented).
2.4	If the laboratory includes opinions and interpretations of test results in reports, this shall be done by authorized personnel with suitable experience

3–Premises

3.1 The microbiology laboratory should be separated from production area and restricted to authorized personnel only.

3.2 Microbiology laboratories should be designed to suit the operations to be carried out in them. There should be sufficient space for all activities to avoid mix ups, contamination and cross-contamination (dedicated area for each activity)

3.3 Laboratories should be appropriately designed (smooth surfaces) to enable appropriate cleaning, disinfection and minimize the risks of contamination.

3.4 Temperature and humidity controls and records should be in place for microbiological laboratories.

3.5 In general, laboratory equipment should not be routinely moved between areas of different cleanliness class or used outside the microbiology area, unless there are specific precautions in place to prevent cross-contamination.

4- Cleaning, disinfection and hygiene

4.1 There should be a documented cleaning and disinfection program**.**

4.2 Adequate hand-washing and hand-disinfection facilities should be available**.**

4.3 Swing doors should open to the high-pressure side and be provided with self-closers.

4.4 False ceilings should be sealed to prevent contamination from the void space above them.

4.5 Airlock doors should not be opened simultaneously. An interlocking system and a visual and/or audible warning system should be operated to prevent the opening of more than one door at a time.

4.6 Adjacent rooms of different grades, if present, should have a pressure differential of approximately10-15 Pascal (guidance value). Particular attention should be paid to the protection of the zone of greatest risk, i.e. the immediate environment to which the product and the cleaned components in contact with it are exposed.

4.7 If the lab contains classified areas; indicators of pressure differentials should be fitted between areas where this difference is important, and the pressure differentials should be regularly recorded and failure alarmed.

5-Test methods

5.1 The laboratory should use all test methods necessary to confirm that the product complies with acceptance criteria.

5.2 Standard (European Standards Publications of Cosmetics) test methods are considered to be validated.

5.3 Test methods not based on compendial or other recognized references should be validated before use.

6-Equipement

6.1 Each item of equipment, instrument or other device used for testing, verification and calibration should be uniquely identified.

6.2 The microbiological lab. Should be of the following qualified minimum instrument requirements:

- One Autoclave (SOP of 2 activities time separation is required)

- Two Laminar air flow units in controlled room (with air locked duple doors)

-Fridge

- three incubators

-Microscope

- Balance

6.3 **Qualification**

Equipment, instruments and other devices should be designed, constructed, adapted, located, calibrated, qualified, verified and maintained as required by the operations to be carried out in the local environment.

6.4 **Incubators, water-baths and ovens**

The operating temperature of this type of equipment should be monitored and records retained.

6.5 **Autoclaves**

Autoclaves should be capable of meeting specified time and temperature tolerances; monitoring pressure alone is not acceptable.

The effectiveness of autoclave operation may be checked by the use of chemical or biological indicators for sterilization or decontamination purposes.

- Clear operating instructions should be provided based on the heating profiles determined for typical uses during validation/revalidation.
- Records of autoclave operations, including temperature and time, maintained for every cycle.
- Monitoring of autoclave may be achieved by one of the following:
- using a thermocouple and recorder to produce a chart or printout.
- direct observation and recording of maximum temperature achieved and time at that temperature.

6.6 **Weights and balances**

Weights and balances shall be calibrated traceably at regular intervals (according to their intended use) using appropriate standard weights **traceable** to certified standard weights.

6.7 **Volumetric equipment**

- For "single-use" disposable volumetric equipment, laboratories should obtain supplies from companies with a recognized and relevant quality system.
- If the supplier does not have a recognized quality system, laboratories should check each batch of equipment for suitability.

7- Reagents, solutions, reference standards, culture media

7.1 Reagents, solutions, reference standards, culture media, etc. should be identified by the following information: a) the name; b) its strength or concentration, when appropriate; c) expiration date, when appropriate; d) the name and/or signature of the person who prepared it, when appropriate; e) opening date; f) storage conditions, when appropriate.

7.2.1 **Media**

- Media should be prepared in accordance with any manufacturer's instructions, taking into careful account specifications such as time and temperature for sterilization.
- Growth promotion and, if appropriate, other suitable performance tests should be done on all media on every batch and on every shipment.

7.2.2 Microwave devices should not be used for the melting of media due to the inconsistent distribution of the heating process.

7.2.3 Batches of media should be identifiable and listed, their conformance with quality specifications documented (e.g. growth promotion and inhibitory properties.

The suitable performance of culture media, diluents and other suspension fluids should be checked, with regard to:

—Recovery of 50–200% (after inoculation of not more than 100 colony-forming units (CFU) should be demonstrated;

— inhibition or suppression of non-target organisms;

— Other appropriate properties (e.g. pH, volume and sterility).).

7.2.4 Media should be stored under appropriate conditions recommended by the manufacturer, e.g. cool, dry and dark.

7.2.5 Water of a suitable microbiological quality and which is free from bactericidal, inhibitory or interfering substances, should be used for preparation unless the test method specifies otherwise**.**

8 -Reference cultures

8.1 Reference cultures are required for establishing acceptable performance of media (including test kits), for validating methods and for assessing/evaluating ongoing performance.

To demonstrate traceability, laboratories must use reference strains of microorganisms obtained **directly** from recognized national or international collections

8.2 Reference strains may be sub-cultured once to provide reference stocks.

It is recommended to store reference stocks in aliquots either deep-frozen or lyophilized. If reference stocks have been thawed, they must not be refrozen and reused.

8.3 Working stocks should not normally be sub-cultured, usually not more than **five passages** from the original reference strain.

9-Sampling and sample handling

9.1
- Sampling should only be performed by trained personnel (documented training).
- It should be carried out aseptically using sterile equipment, appropriate precautions should be taken to ensure that sample integrity is maintained through the use of sterile sealed containers for the collection of samples where appropriate.

9.2
- The laboratory should have procedures that cover the delivery of samples and sample identification.

9.3
- Samples should be identified by: a) the name or identifying code; b) the batch number; c) the date of sampling; d) the container from which the sample was taken; e) the sampling point, if applicable.

9.4 Samples should be stored (retained) until the test results are obtained, or longer if required

10-Disposal of contaminated waste material

10.1
- The procedures for the disposal of contaminated materials should be designed to minimize the possibility of contaminating the test environment or materials.
- It is a matter of good laboratory management and should conform to national/international environmental or health and safety regulations.

11-Testing procedures

11.1 Testing should normally be performed according to procedures described in the national, regional and international standard methods and reported in SOPs for documentation.

11.2 Alternative testing procedures may be used if they are appropriately validated and equivalence to official methods has been demonstrated.

12-Test reports

12.1 If the result of the enumeration is negative, it should be reported as “not detected for a defined unit” or “less than the detection limit for a defined unit”. The result should not be given as “zero for a defined unit” unless it is a regulatory requirement.

12.2 Qualitative test results should be reported as “detected/not detected in a defined quantity or volume”.

References

1. EU Cosmetic Regulation (EC) No1223/2009
2. SCCS – Cosmetic 2018-10th REVISION
3. WHO good practices for pharmaceutical quality control laboratories, Annex 1, WHO TRS 957, 2010
4. WHO good practices for pharmaceutical microbiology laboratories, Annex 2, WHO TRS 961, 2011
5. WHO guidelines on quality risk management Annex 2, WHO TRS 981, 2013
6. Guidance on good data and record management practices, Annex 5, WHO TRS 996, 2016.
7. WHO guidelines for preparing laboratory information file, Annex 13, WHO Technical Report Series 961, 2011.
8. EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex 19 Reference and Retention Samples
9. General European OMCL Network (GEON) Quality Management system documents.
10. ICH quality guidelines.
11. Latest editions of pharmacopeias USP and BP, FDA guidance.
12. ISO/IEC 17025 (2017) General requirements for the competence of testing and calibration laboratories
13. ISO 22716 (2007) Cosmetics — Good Manufacturing Practices (GMP)
14. ISO 21149 Cosmetics – Microbiology – Enumeration and detection of aerobic mesophilic bacteria
15. ISO 18415 Cosmetics – Microbiology – Detection of specified and non-specified micro-organisms.
16. ISO- methods for the detection of specific microorganisms: E. coli (ISO 21150), Pseudomonas aeruginosa (ISO 22717), Staphylococcus aureus (ISO22718) and Candida albicans (ISO 18416).
17. ISO/FDIS 16212 Cosmetics – Microbiology – Enumeration of yeast and mould.
18. ISO 17516:2014

ملحق 3

المستندات المطلوب تسليمها ورقيا

- أصل إيصال سداد مقابل الخدمة لكلا من(طلب الحصول على شهادة الإعتماد، طلب الإعتماد للإختبارات الخاصة بالمجموعات الرئيسية من مستحضرات التجميل المقدمة)
- أصل خطاب التفويض المذكورة بنموذج التقديم.
- أصل نموذج التقديم موقع من الشخص المفوض.
- تعهد من المعمل بتوافر كافة الأجهزة والمواد القياسية والكيماويات اللازمة لإجراء كافة الإختبارات المطلوب إعتمادها
- في حال القيام بتحليل بعض الإختبارات في معمل بجهة حكومية يتم تقديم تعهد مختوم وموقع من المعمل المقدم الطلب.

المرفقات

مرفق 1

Microbiological analysis results data requirement

Microbial count test

1- The sample size, sampling date, and the sampler name.

2- All equipment used in the test procedure i.e. incubators, autoclave, pH meter, balance, LAF and any other equipment used with their code numbers.

3- The batch numbers of media and any diluent or neutralizer used in the test, their preparation date, and sterilization cycle number.

4- The number of the SOP used to carry out the test.

5- The analyst and supervisor signature.

المرفقات

مرفق 2

Categories to be accredited

No	Category	Required tests
1-	Skin Care products (hand, face, body)	• Heavy metals by AAS/ICP • Physical tests • Microbiological tests
Additional tests for sub-categories		
a-	Sunbathing products	SPF
2-	Hair care products	• Heavy Metals by AAS/ICP • Physical tests • Microbiological tests
Additional tests for sub-categories		
a-	Products for waving, straightening and fixing	Limit for formaldehyde by GC/UV
b-	Cleansing products (lotions, powders, shampoos)	1,4 Dioxane by GC
c-	Anti-dandruff shampoos	1,4 Dioxane by GC
3	Shaving products (creams, foams, lotions, etc.)	• Heavy Metals by AAS/ICP • Physical tests • Microbiological tests
4	Products for making up and removing makeup from the face and the eyes	• Heavy Metals by AAS/ICP • Physical tests • Microbiological tests
5	Products intended for application to the lips	• Heavy Metals by AAS/ICP • Physical tests • Microbiological tests

6	**Products for care of the teeth and the mouth**	• **Heavy Metals by AAS/ICP** • **Hydrogen peroxide by titration** • **Physical tests** • **Microbiological tests**
7	**Products for nail care and nail lacquer**	• **Heavy Metals by AAS/ICP** • **Hydrogen peroxide by titration** • **Physical tests** • **Microbiological tests**
8	**Products for external intimate hygiene**	• **Heavy Metal by AAS/ICP** • **1,4 Dioxane by GC** • **Physical tests** • **Microbiological tests**
9	**Kids fingers paints, and kids face painting**	• **Heavy metals by AAS/ICP** • **Limit for formaldehyde by GC/UV** • **Physical tests** • **Microbiological tests**
10	**Any cosmetic products containing high percent of ethanol or isopropanol**	• **Methanol by GC**

المرفقات

مرفق 3

List of Physical, Chemical & Microbial tests and their limits for quality control of cosmetic products:

A- Physical test; the pH range:

the pH of cosmetic product should be in the range (4-8) excluding hair colorant and excluding the product with PH mentioned in Annex 3 according to their composition ingredients as shown in the table*. Certain product which formulated with PH value outside this range are acceptable if they had evidence to demonstrate that the PH is necessary to achieve the required cosmetic effect and have a demonstrable safety report.

A	**Category**	**pH range**
1	**Skin care products** (a) Cleanser (b) Toner (c) Sunscreen (d) Moisturizers (e) Serum (f) AHA and BHA exfoliators. (g) Vitamin C products (h) Retinol products	(a) 4.5-7 (b) 5-7 (c) 5-7.5 (d) 5-7 (e) 4-6 (f) 3.7-5 (g) 3-4 (h) 3.7-5
2	**Hair care products** (a) Shampoos for adults (b) Shampoo for babies (c) Hair dyes: i. Black & brown shades ii. Other shades	(a) 5-8 (b) 5-7 (c)i. 9-11 ii.6-11

	(d) Developer (e) *straightening products containing metal hydroxides (f) Some hair treatments products containing keratin & protein	(d) 1.8-4 (e) up to 12.7 (f) <4
3	**For products contain Thioglycolic acid and its salts as** (a) *Hair products: for general or professional use (b) *Depilatories (c) Hair rinse-off products For products contain Thioglycolic acid esters (d) Hair waving or straightening products	 (a) 7- 9.5 (b) 7 - 12.7 (c) up o 9.5 (d) 6 - 9.5
4	**Soap (1% aqueous solution)**	8-11

B	Chemical tests	Limit of Safety
1	**Determination of 1,4 Dioxane** (a) Shampoo, shower gel, cleansing product (b) Any products contain SLS, SLES, PEG	(a), (b) NMT 10 ppm
3	**Determination of Methanol** Products contain ethanol or isopropanol (e.g., body mist)	-NMT 5% as % of Ethanol or Isopropanol
5	**Determination of Formaldehyde** (a) Nail hardener (b) Oral product (toothpaste, mouth wash) (c) other products	(a) NMT 5% (b) NMT 0.1% (c) NMT 0.2%
10	**Determination of Hydrogen peroxide** (a) Hair products (b) Skin products	(a) NMT 12 % (b) NMT 4 %

	(c) Nail hardening products (d) Oral products, including mouth rinse, tooth paste and tooth whitening or bleaching products (e) Tooth whitening or bleaching products (professional use) (f) Products intended for eyelashes	(c) NMT 2 % (d) ≤ 0.1 (e) > 0.1 % ≤ 6 % (f) NMT 2 % All % calculated as H_2O_2 present or released
17	**Determination of heavy metals** (a) pb (b) As (c) Cd (d) Hg	(a) NMT 10 ppm (10 µg/g) (b) NMT 3 ppm (c) NMT 3 ppm (d) NMT 3 ppm

C	**Microbiological tests for cosmetic products**		
	Category of products	**Type of test**	**Specification**
1	**All cosmetic products except the products used around the eyes, products used for infants under three years, and products used on mucous membranes**	Total microbial count (T.M.C.)	N.M.T 10^3 CFU/ml or gm
		Specified micro-organisms: a) Staphylococcus aureus b) Pseudomonas aeruginosa c) Candida albicans d) Escherichia coli	Absent in 1ml or 1gm
2	**Products used around the eyes, products for infants under three years, and products used on mucous membra**nes	Total microbial count (T.M.C.)	N.M.T 10^2 CFU/ml or gm
		Specified micro-organisms: a) Staphylococcus aureus	

		b) Pseudomonas aeruginosa c) Candida albicans d) Escherichia coli	Absent in 1ml or 1gm

الإيميل الرسمي لبرنامج إعتماد معامل مراقبة جودة مستحضرات التجميل

dc.cosmolabaccredit@edaegypt.gov.eg

الروابط الإلكترونية لبرنامج الإعتماد

نموذج خاص بحجز مواعيد دفع رسوم خدمة:Link of Appointment Form

https://form.jotform.com/212603597453054

نموذج خاص بملحق:EDA Accreditation, Annex 1

https://forms.office.com/r/ehiNFCWqR2

نموذج خاص باستكمال ملحق:EDA Accreditation, Resubmission of Annex 1

https://forms.office.com/r/Gp1MuwbNeF

نموذج خاص بتأكيد ميعاد الزيارة:EDA Accreditation, Visit Confirmation Letter

https://forms.office.com/r/vHBs4sW1n8

نموذج خاص بالخطة التصحيحية:EDA Accreditation, CAPA Plan

https://forms.office.com/r/xU4gduBqKn

نموذج خاص بالتطبيق الأول للخطة EDA Accreditation, CAPA Plan Implementation 1 التصحيحية:

https://forms.office.com/r/6L67hz3RgN

نموذج خاص بالتطبيق الثاني للخطة EDA Accreditation, CAPA Plan Implementation 2 التصحيحية:

https://forms.office.com/r/Xa1A5kwR6B

نموذج EDA Accreditation, Attachments of Accredited Product - Results of Analysis خاص بمرفقات مستحضر معتمد و نتائج التحليل:

https://forms.office.com/r/vyaN4AQdGu

نموذج خاص بالتحديثات: EDA Accreditation, Annex of Updates

https://forms.office.com/r/41L4AViWSM