

## **Regulatory and Guidance Guideline and Business Rules for Antiseptics/Disinfectants Registration**

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**The contents address several topics, including:**

## **1 - Introduction**

This regulatory guideline is concerned with clarifying rules and procedures of Antiseptics/Disinfectants registration and how to submit registration and re-registration files of Antiseptics/Disinfectants, starting from method of submission and the required documents for registration (including all registration or re-registration procedures) until final registration license issuance.

## **2 – Scope of implementation**

This regulatory guideline shall be applied to Antiseptics/Disinfectants products submitted for registration or re-registration whether they were locally manufactured products, locally manufactured products by third party (toll manufacturing), locally manufactured products under license from abroad or imported products.

## **3- Abbreviations**

## **4 – Definitions**

**Antiseptic/Disinfectant products:** They are those products that kill or stop the growth of pathogenic microorganisms, whether they are bacteria, viruses, fungi or yeasts for the purpose of reducing or preventing the appearance of a disease without having any other therapeutic purpose and do not have a medicinal effect. They are divided into:

**Antiseptics:** They are products that have a topical antiseptic effect on the skin or mucous membranes. They are divided into the following:

- **Personal domestic use Antiseptics:**

Antiseptic products that are used by the individuals at home, such as those antiseptics that are used in first aid for minor wounds or when an individual take an injection by himself.

- **Personal commercial use Antiseptics:**

Antiseptic products that are available to the public which used to reduce the number of microorganisms temporarily found on the skin in the commercial institutions or at work.

- **Professional Healthcare use Antiseptics:**

Antiseptic products which are used by healthcare professionals to reduce the number of microorganisms that temporarily found on or reside in the skin in health institutions such as hospitals and clinics. They are divided into:

Antiseptics used by medical staff, and Antiseptics used to prepare the patient's skin before the surgical operations.

**Disinfectants:** They are products applied on hard surfaces, such as medical devices or applied to disinfect medical places such as hospitals, clinics or places where animals are handled. These products are registered as disinfectants in accordance with the decision of the Scientific Committee for Evaluating Disinfectants which was approved by the Technical Committee for Registration of Medical devices, Disinfectants and Insecticides on 10/10/2017 to determine the borderline products in cooperation with the Medical devices Unit, provided that the initial use of the products shall be Disinfection and not sterilization. They are divided into:

- **High Level Disinfectants:**

They are disinfectants having the ability to get rid of all disease-causing microbes and also to kill some bacterial spores. They reach to the point of sterilization in case of using them for a long period on the surface to be disinfected. They are used to disinfect devices that penetrate the skin or mucous membranes down to sterile areas of the body, such as surgical instruments and surgical endoscopes, and also to disinfect devices that have direct contact with body fluids (such as blood or spinal fluid), such as dialysis devices. This type of device is called critical devices, so that the risk of infection transmission is very high in case that these devices are not sterilized.

- **Intermediate Level Disinfectants:**

They are Disinfectants having the ability to get rid of all disease-causing microbes, but they have no effect on bacterial spores. They are used to disinfect medical instruments that have contact with intact skin (non-critical devices). They may also be used to disinfect some instruments that have contact with non-intact skin and they also may be used to disinfect medical instruments that have contact with mucous membranes inside the body or have contact with non-intact skin, but they

do not penetrate sterile areas in the body. They are called (semi-critical devices) such as thermometers or endoscopes inserted through the mouth or anus.

- **Low Level Disinfectants:**

They are disinfectants having the ability to eliminate disease-causing microorganisms on hard, non-porous surfaces, but they have no effect on tuberculosis (TB) bacteria and bacterial spores. They are used to disinfect instruments and devices that have contact with intact skin (non-critical devices) such as stethoscopes.

- **Vet. use disinfectants:**

Disinfectants that are used in areas where animals are housed or kept. They include disinfection of drinking water, water delivery systems, air disinfection, animal and poultry farms and the equipment used in them, egg-laying areas, animal production areas, hatcheries, chicken processing places, slaughterhouses, trucks and other vehicles, hatching rooms, incubators, and livestock buildings, and disinfecting the teat before and after milking or on the skin of animals for hygiene purposes.

## **5 - The main topic**

The requirements, conditions and procedures of registration in the General Administration of Biocides Registration are subjected to the specialized committee for registration of household, public health pesticides and antiseptics formed by the Ministerial Resolution No. (479) of 2016, which stipulates merging of both the Scientific Committee for the Evaluation of Disinfectants and Sterilizers and the Scientific Committee for the Registration of Household and public health Insecticides which were formed by Promulgated by the Ministerial Resolution No. (377) 2015 to become a single committee under the name (the specialized committee for registration of household, public health pesticides and antiseptics).

### **General rules for registration of antiseptics/disinfectants:**

- To register a product as an antiseptic/disinfectant, it is required that its active ingredients shall have antiseptic/disinfectant properties only without having any other therapeutic effects, it should be used topically on the skin, mucous membranes, or hard surfaces in accordance with the decision of the committee concerned with the disinfectants and insecticides registration dated on April 13<sup>th</sup>, 2016.

- It is required to be one of the following pharmaceutical forms approved by the committee responsible for registering antiseptics and pesticides: (antiseptic solution, surgical antiseptic, antiseptic spray, antiseptic mouthwash, antiseptic gargle, antiseptic vaginal douche, antiseptic shampoo, ointment, cream, gel, lotion, antiseptic liquid soap, antiseptic medical swabs, antiseptic wet wipes, antiseptic gauze, antiseptic eye drops, antiseptic lozenges, antiseptic dry powder for spraying, disinfectant surface powder, disinfectant tablets for surfaces and disinfectant fumigation trays).

In case of new pharmaceutical forms emerging, they shall be presented to the specialized committee for registration of household, public health pesticides and antiseptics.

- The production line on which the production shall take place shall be available in order to register the antiseptic/disinfectant products in accordance with the technical requirements of the factories and production lines of antiseptics/disinfectants.

In case of manufacturing a product whose active ingredient is "Povidone Iodine" it is required to have a separate production line.

- Each company shall be committed to use one trade name for each active ingredient. In case that the company wishes to have multiple trade names for the same active substance, it shall submit its justifications before proceeding with the registration procedures to be presented to the specialized committee for registration of household, public health pesticides and antiseptics in accordance with its decision promulgated on September 18<sup>th</sup>, 2018.
- In case of antiseptic/disinfectant products imported from a reference country, the product should be registered and marketed in the country of origin or in one of the approved reference countries or be approved by the World Health Organization, the Food and Drug Administration or the US Environmental Protection Agency.
- In case of antiseptic/disinfectant products imported from a non-reference country and marketed in one of the reference countries, the certificate of free sale of the product in an approved reference country should be presented.
- In case of antiseptic/disinfectant products imported from a non-reference country and not marketed in one of the reference countries, it requires the presence of a similar reference product with the same pharmaceutical form

and active ingredient concentration. That product shall be evaluated by the specialized committee for registration of household, public health pesticides and antiseptics in order to take a decision to accept or reject.

- Antiseptic/Disinfectant products shall be re-registered every 10 years based on an application submitted by the product owner to the general administration of biocides registration in the last year of the validity of the registration license (the validity of the registration license is 10 years), provided that the company shall fulfill the requirements of re-registration. The product shall be allowed to be marketed during the period of re-registration and during of the approval validity to proceed with the re-registration procedures.
- In case that the preliminary approval of re-registration procedures expired before completing the required studies, it is permitted to extend the validity of preliminary approval provided that the financial consideration shall be paid.

**Procedures of submitting the registration file:**

- The fulfilled registration file shall be uploaded to the electronic platform according to the form prepared for reviewing the reception file (checklist) (attached) in accordance with the references FDA, WHO, EPA, ECHA, USP, BP, BNF, Martindale or any new approved references.
- The registration file shall be accompanied with a scanned copy of the payment receipt. The file shall be revised within 14 working days and the applicant shall be informed by any required documents via the e-mail. In case of the required documents are essential (major), the file shall be rejected and the company shall be informed then the file shall be re-uploaded again after fulfilling the required documents. If the required documents are unessential (minor), the file shall be received and the company shall be informed of the required documents.

Essential requirements (major)	Unessential requirements (minor)
1. Absence of a document from the checklist or the expiration of a document.	1. Correction or fulfilling data contained in the submitted application.
2. Submitting an incompatible reference with the product or from a non-competent authority or whose data is incomplete.	2. Correcting or clarifying the functions and concentrations of the inactive ingredients in the composition form.
3. The business activity of the company mentioned in the commercial register approval is not suitable for registering antiseptic/disinfectants products.	3. Correction and completing the information required on the label and packaging of the product according to the provided reference.
4. Absence of a production line in the factory license.	4. Amending data or results in the certificate of analysis.
5. The factory license is not suitable for registering of antiseptic/disinfectant products.	
6. Not authenticating contracts in the Legal Affairs Department or not authenticating the documents of the imported products by the Chamber of Commerce and the Egyptian Embassy in the country of origin.	
7. Absence of the raw material supplier ISO 9001 certificate or Good Manufacturing Practice GMP of quality manufacturing.	
8. Absence of CADC analysis approval or Stability administration approval (in the case of final files).	
9. the company submitting the registration application is not registered in the electronic company's registration. (company profile)	



- The file shall be revised initially and technically then the company shall be informed by the requirements, if any, via the e-mail. In case that registration file is not fulfilled for a period exceeding one year from the date of the last follow-up, the registration application is considered invalid according to the decision of the specialized committee for registration of household, public health pesticides and antiseptics on Jan. 14<sup>th</sup>, 2020.
- The file shall be presented to the specialized committee for registration of household, public health pesticides and antiseptics within 14 working days from the date of file fulfillment. In case that the committee asked to amend some data of the product, the Applicant shall be informed by the decisions of the specialized committee for registration of household, public health pesticides and antiseptics within 7 working days from the date of committee's decision in order to fulfill the file.
- In case of rejection by the specialized committee for registration of household, public health pesticides and antiseptics, the applicant may submit an appeal within 3 months from the issuance date of the committee's decision of rejection.
- In case of approval by the specialized committee for registration of household, public health pesticides and antiseptics, the Administration of biocides Registration shall issue a preliminary approval to proceed with the registration procedures. The validity period of the preliminary approval shall be two years (renewable for another year at most in case of the company failure to complete the essential requirements in accordance with the decisions of the committee concerned with registering medical devices, disinfectants and insecticides on March 17<sup>th</sup>, 2016 and the specialized committee for registration of household, public health pesticides and antiseptics on December 26<sup>th</sup>, 2017 provided that the company shall be committed to do the following:

A- In the case of local antiseptic/disinfectant products or those manufactured by third part (toll manufacturing) or manufactured under license from abroad (new registration), the Applicant shall be obligated to carry out the following:

- Analyzing of an R&D batch in Egyptian Drug Authority laboratories (Registration Division)

- Submitting an accelerated stability study in accordance with the applied rules by the Stability administration

**B- In the case of antiseptic/disinfectant products imported from abroad, the applicant shall be obligated to carry out the following:**

- Analyzing samples in Egyptian Drug Authority laboratories (Registration Division)
- Providing a long-term stability study in accordance with the applied rules by the Stability administration.

**C - In the case of antiseptic/ disinfectant products (re-registration), the applicant shall be obligated to carry out the following:**

- Analyzing a production batch in Egyptian Drug Authority laboratories (Registration Division) (required only in case that a variation occurred from the previously registered one).
- Submitting a long-term stability study in accordance with the rules applied by the Stability administration.
- In case of expiry of the validity period of the preliminary approval to proceed with the registration procedures (two years) before fulfilling the required requirements, a request to extend the validity period of the approval to proceed with the registration procedures shall be submitted, provided that the prescribed service fee shall be paid and that request shall include the product status in term of fulfilling the requirements in order to be revised and to issue the approval of extending the preliminary approval period for another year.
- In case that the deadline for submitting the final file is exceeded by a maximum of one year from the date of expiry of the deadline for submitting the file, the file is allowed to be accepted (fulfilling the studies), provided that the prescribed service fee shall be paid.
- After fulfilling the requirements required in the preliminary approval of proceeding with the registration/re-registration procedures, the applicant shall upload the final registration file entirely on the electronic platform. The file shall be revised within 15 working days and the applicant shall be informed by any required documents. In case of the requirements are essential, the file shall be rejected, the company shall be informed and the

file shall be re-uploaded after fulfilling the required documents. In case of the requirements are unessential, the file shall be received and the company shall be informed by the requirements via the e-mail.

- In case of fulfilling it, it shall be presented to the specialized committee for registration of household, public health pesticides and antiseptics then the product is given a registration number and a final registration license shall be issued which is valid for 10 years
- Antiseptic/Disinfectant products shall be re-registered every ten years based on a request submitted by the product owner to the administration of biocides registration during the last year of the registration license validity, provided that the company shall fulfill the requirements of re-registration. The product is permitted to be marketed during the validity of the preliminary approval to proceed with the procedures of re-registration.

#### **Work rules developed during the Corona crisis:**

- It is permitted to issue an exceptional preliminary approval to proceed with the registration procedures that allows the manufacturing of a production batch which shall be analyzed in the laboratories of the Central Administration of Drug Control, provided that it shall remained sealed. After issuance of the conformity analysis result, a final registration license shall be issued immediately conditioned by conducting an accelerated stability study.
- An exceptional temporary license (valid for 6 months) shall be issued for the liquid products referenced by the FDA in accordance with the temporary policy for preparation of certain alcohol-based hand sanitizer products during the public health emergency, provided that the first three production batches shall be analyzed in the laboratories of the Central Administration of Drug Control as a condition for releasing of the batches. An accelerated stability study shall be conducted in accordance with the applied rules by the Stability Administration.
- The temporary license can be extended 3 consecutive times for a period of 6 months each time, provided that the prescribed service fee shall be paid for each extension. The temporary license is converted into a final license (valid for a period of 10 years) after fulfilling all registration requirements.

**References:**

- Decisions of the specialized committee for registration of household, public health pesticides and antiseptics.
- Decisions of the president of Egyptian Drug Authority.

## Appendixes

### Checklist for Application OF ANTISEPTICS & DISINFECTANTS REGISTRATION

#### Requirements for Soft and Hard File Submission

1-Application form with detailed Information. (Signed from Chairman and sealed)	نموذج أبليكيشن كامل البيانات بختم الشركة وإمضاء مدير الشركة
2-Submission fees. 3000 L.E for local products New reg. 4000 L.E for New imported 4000 L.E for Re-reg File. (local and imported) + 1000 LE for labeling + 1000 LE for naming (in case of new reg. only)	إيصال الدفع: في حالة المستحضرات المحلية تسجيل جديد 3000 جنيه في حالة المستحضرات المستوردة 4000 جنيه في حالة إعادة التسجيل للمحلي والمستورد 4000 جنيه + 1000 مراجعة ماكت ونشرة + 1000 مراجعة الاسم التجاري (في حالة التسجيل الجديد فقط)
3-Syndicate Fees (For hard file Submission File) 100 LE +7 LE Stamps	إيصال دمغة طبية بقيمة 100 جنيه وطوابع بقيمة 7 جنيهات
4-Letter of Attorney of authorized person -Bank signature Approval	خطاب تفويض من الشركة للشخص المسئول عن المتابعة عليه صحة توقيع بنكي لإمضاء مدير الشركة
5-Composition sheet (authenticated in case of imported) On Manufacturer Paper	بيان التركيب على ورق المصنع بإمضاء مدير الأبحاث والتطوير أو مدير الإنتاج (موثق من الغرفة التجارية والسفارة المصرية ببلد المنشأ في حالة المستورد)
6-Layout Comply with the refrence	- بطاقة المستحضر متوافقة مع المرجع المقدم مع المستحضر
7-Leaflet (If only it will be inserted in commercial packs)	نشرة (فقط في حالة وجودها بالعبوة التجارية)
8-Reference copy.	مرجع معتمد بنفس المواد الفعالة والشكل الصيدلي
9-Certificate of Analysis of finished products. (signed with QC manager and With Manufacturer specifications)	شهادة تحليل للمستحضر على ورق المصنع بإمضاء مدير الرقابة على الجودة موضح بها مواصفات المصنع

10-Commercial Register Approval	سجل تجارى للشركة مقدمة طلب التسجيل ساري
11-Tax Card	بطاقة ضريبية للشركة مقدمة طلب التسجيل
12- Copy of last Updated product registration license (in case of Re-reg)	نسخة من آخر إخطار تسجيل للمستحضر (في حالة إعادة التسجيل فقط)
13-product composition Approved from EDA labs (For Re-Reg)	بيان التركيب المعتمد من معامل هيئة الدواء (في حالة إعادة التسجيل فقط)
<b>Certificates in case of local &amp; toll:</b>	
1-Declaration of source of active raw materials.	خطاب توضيح مصدر المادة الخام الفعالة.
2-Certificate of Analysis of active raw material from Manufacturers.	شهادة تحليل للمادة الفعالة من المورد (مصنع المادة الفعالة)
3-GMP or ISO certificate for Manufacturer of active ingredient	شهادة أيزو 19001 أو شهادة GMP لمصنع المادة الفعالة
5-Naming List arranged with Applicant Priority.	قائمة أسماء للمستحضر
6-Pharmaceutical Plant License.	رخصة المصنع المحلي موضح بها خط الإنتاج الذي سيتم التصنيع عليه
7-Manufacturing Agreement between Applicant and Manufacturer (Toll &F- Toll only) including attachments	عقد تصنيع بين المصنع ومالك المستحضر (في حالة ال toll & F toll) ساري عليه صحة توقيع بنكي وموثق من الشئون القانونية بهيئة الدواء المصرية مع ملحق عقد التصنيع به اسم المستحضر
9-Storage Agreement (Toll &F-Toll only)/If not stated in Man. agreement	عقد تخزين (في حالة ال toll & F toll) ساري و عليه صحة توقيع بنكي وموثق من الشئون القانونية بهيئة الدواء المصرية
<b>Certificated in case of imported &amp; under license products:</b>	
1-Copy of CPP or Free sale certificate of final Product in Exporting Country (Imported, Bulk, Under License)/(In case of Non Reference Exporting Company, submit a document proves Marketing in a Reference country"	نسخة من شهادة تسجيل المستحضر أو شهادة التداول للمستحضر من بلد المنشأ موضح بها مالك المستحضر والمصنع وموثقة من الغرفة التجارية والسفارة المصرية ببلد المنشأ.
2-Agency Agreement (Sole Agency or Product Agency)	عقد وكالة (عقد حصري أو عقد وكالة للمستحضر) موثق من الغرفة التجارية والسفارة المصرية ببلد المنشأ.

3-GMP or ISO certificate for Manufacturer of finished product	شهادة GMP أو ايزو للمصنع
4-Copy of EDA Record Importing Register (If it is not the first product)	شهادة قيد سجل مستوردين بهيئة الدواء المصرية موضح بها اسم الشركة المصدرة (يرفق تعهد بإصدارها في حالة التسجيل لأول مرة)
5-Packing Letter from Exporting Country with full pack details (Only if not present in CPP) Local company registration card submitted. Application for registration in the Agents Register "S14" from the General Authority for Export and Import Control. The local company's registration card in the importers' register "S4" from the General Authority for Export and Import Control	خطاب تعبئة المستحضر من الشركة المصدرة موضح بها نوع العبوات وأحجامها تفصيليا موثقة من الغرفة التجارية والسفارة المصرية ببلد المنشأ.
Local company registration card submitting the registration request in the Agents Register "Register 14" from the General Authority for Export and Import Control.	بطاقة قيد الشركة المحلية مقدمة طلب التسجيل بسجل الوكلاء "س14" من الهيئة العامة للرقابة على الصادرات والواردات.
Local company registration card in the importers' register "Register 14" from the General Authority for Export and Import Control	بطاقة قيد الشركة المحلية بسجل المستوردين "س4" من الهيئة العامة للرقابة على الصادرات والواردات
<b>In case of hard file:</b>	
1- Preliminary Approval (for Hard File Submission only)	موافقة السير في إجراءات التسجيل
2- Stability Approval (for Hard File Submission only)	موافقة إدارة الثبات
3- EDA labs Analysis Approval attached to the approved composition with EDA stamp (For Hard File Submission only)	مطابقة معامل هيئة الدواء مرفق معها بيان التركيب المعتمد من المعامل

Kindly submit your file arranged according to Check list requirements with separators.

Mail for Appointments: [Biocides@edaegypt.gov.eg](mailto:Biocides@edaegypt.gov.eg)