Central Administration of Pharmaceutical Products
General Administration of Biocides Registration

Guideline

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

Year 2025

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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

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

GA-Biocide-R: General Administration of Biocides Registration

CAPP: Central Administration of Pharmaceutical Products

CADC: Central Administration of Drug Control

EDA: Egyptian Drug Authority

GMP: Good Manufacturing Practice

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. 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 according to 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 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 13th, 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 18th, 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 link of antiseptics/disinfectants registration 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 15 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 submitting the file on the electronic link of antiseptics/disinfectants registration, the registration application is considered invalid according to the decision of the specialized committee for registration of household,

public health pesticides and antiseptics on Feb. 11th, 2025.

- The file shall be presented to the specialized committee for registration of household, public health pesticides and antiseptics within 15 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 General 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 17th, 2016 and the specialized committee for registration of household, public health pesticides and antiseptics on December 26th, 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 Central Administration of Drug Control (Administration of Evaluation and Approval)
- 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 Central Administration of Drug Control (Administration of Evaluation and Approval)
  N.B. Considering the imported products from reference countries, the applicant company has the option to follow either the normal pathway or the following mentioned pathway which is the possibility to postpone the analysis step until after the issuance of the final registration license, which is conditional on the analysis of the first incoming consignment by the Administration of Evaluation and Approval

- Providing a long-term stability study in accordance with the applied rules by the Stability administration.

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

- Analyzing a production batch in Central Administration of Drug Control (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 addition to accelerated stability study only in case that a variation occurred from the previously registered one).

- 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 link of antiseptics/disinfectants registration, 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.

6-References:

- Decisions of the specialized committee for registration of household, public health pesticides and antiseptics in its session on:

18/2/2020, 21/5/2024 & 11/2/2025

- Accreditations of the president of Egyptian Drug Authority on:

20/9/2021

7-Appendixes

CHECKLIST FOR APPLICATION OF ANTISEPTICS &DISINFECTANTS REGISTRATION

Documents required for all Registration types.

1-Application form with detailed Information with the mail of the company owner. (Signed from Chairman and sealed)	نموذج ابليكشن كامل البيانات بختم الشركة و امضاء مدير الشركة موضحا البريد الالكتروني لصاحب 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)	ايصال الدفع : فى حالة المستحضرات المحلية تسجيل جديد3000 جنيه فى حالة المستحضرات المستوردة 4000 جنيه فى حالة اعادة التسجيل للمحلى و المستورد 4000 جنيه + 1000 مراجعة ماكت و نشرة + 1000 مراجعة الاسم التجارى (فى حالة التسجيل الجديد فقط)
3- Syndicate fees 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 بنكى لامضاء مدير الشركة
5-Composition certificate on Manufacturer Paper (authenticated in case of imported) Note: In case of soft file submitted for new product, the Composition certificate can be submitted on company's paper signed by the company's owner and stamped by the company's stamp	بيان التركيب على ورق المصنع بامضاء مديرالابحاث والتطوير او مدير الانتاج (موثق من الغرفة التجارية و السفارة المصرية ببلد المنشأ فى حالة المستورد) ملحوظة: فى حالة الملف المبدئي لمستحضر جديد يمكن تقديم بيان تركيب على ورق الشركة بإمضاء صاحب الشركة و مختوم بختم الشركة
6-Layout Comply with the reference	بطاقة المستحضر متوافقة مع المرجع المقدم مع المستحضر
7-Leaflet (If only it will be inserted in commercial packs)	نشرة (فقط فى حالة وجودها بالعبوة التجارية)
8-Copy of approved Reference for the same active ingredients with the same concentration and dosage form	مرجع معتمد بنفس المواد الفعالة وتركيزها و الشكل الصيدلى

9-Certificate of Analysis of finished products. (signed with QC manager and with Manufacturer specifications) Note: In case of soft file submitted for new product, the COA can be submitted on company's paper signed by the company's owner and stamped by the company's stamp	شهادة تحليل للمستحضر على ورق المصنع بامضاء مدير الرقابة على الجودة موضح بها مواصفات المصنع ملحوظة: فى حالة الملف المبدئي لمستحضر جديد يمكن تقديم شهادة تحليل للمستحضرعلى ورق الشركة بإمضاء صاحب الشركة و مختوم بختم الشركة
10- Valid Commercial Register Approval	سجل تجارى للشركة مقدمة طلب التسجيل سارى (موضح به نشاط تصنيع لدى الغير فى حالة ال toll)
11-Valid Tax Card	بطاقة ضريبية للشركة مقدمة طلب التسجيل سارية
12- Copy of all papers of last Updated product registration license (in case of Re-reg)	نسخة من جميع أوراق اخر اخطار تسجيل للمستحضر (فى حالة اعادة التسجيل فقط)
13-CADC Analysis Approval with the product composition Approved from CADC (For Re-Reg) attached to it.	مطابقة المعامل مرفق بها بيان التركيب المعتمد من معامل الادارة المركزية للرقابة الدوائية (فى حالة اعادة التسجيل فقط)
IN CASE OF Local, Toll & F-Toll Products	
1-Declaration of source of active raw material(s).	خطاب توضيح مصدر المادة الخام الفعالة -
2-Certificate of Analysis of active raw material from Manufacturer.	شهادة تحليل للمادة الفعالة من المورد (مصنع المادة الفعالة)
3-GMP or ISO 9001 certificate for Manufacturer of active ingredient	شهادة أيزو 9001 او شهادة GMP لمصنع المادة الفعالة
4-Naming List arranged with Applicant Priority.	قائمة اسماء للمستحضر
5-Pharmaceutical Plant License with antiseptics manufacturing line (separate line for manufacturing of povidone iodine is a must in case the active ingredient of the product is povidone iodine)	رخصة المصنع المحلى موضح بها خط الانتاج المطهرات (مع ضرورة وجود خط منفصل لانتاج البوفيدون ايودين فى حالة إذا كانت المادة الفعالة للمستحضر بوفيدون ايودين)
6-Manufacturing Agreement between Applicant and Manufacturer (Toll &F-Toll only) including attachments Trade name of Product, Valid □ Bank Signature Approval, Authenticated from EDA legal Affairs	عقد تصنيع بين المصنع و مالك المستحضر(فى حالة ال Toll & F toll) سارى و عليه صحة توقيع بنكى وموثق من الشئون القانونية بالادارة المركزية للصيدلة مع ملحق عقد التصنيع به اسم المستحضر
7-Storage Agreement (Toll &F-Toll only)/ If not stated in Man. agreement OR Warehouse license if the company has its own warehouse	عقد تخزين (فى حالة Toll & F toll)سارى وعليه صحة توقيع بنكى وموثق من الشئون القانونية بهيئة الدواء المصرية أو رخصة مخزن اذا كانت الشركة لديها مخزن وسيتم التخزين في مخازنها

IN CASE OF Imported & Under license Products	
1-Copy of CPP or Free sale certificate of final Product in Exporting Country (Imported, Bulk, Under License) Legalized and authenticated from competent authority (In case of Non-Reference Exporting country, submit a document proves Marketing in a Reference country)	نسخة من شهادة تسجيل المستحضر او شهادة التداول للمستحضر من بلد المنشأ موضح بها مالك المستحضر والمصنع وموثقة من الغرفة التجارية و السفارة المصرية ببلد المنشأ (في حالة ان الدولة المصدرة غير مرجعية، يجب تقديم ما يثبت التداول في دولة مرجعية)
2-Agency Agreement (Sole Agency or Product Agency)	عقد وكالة (عقد حصرى اوعقد وكالة للمستحضر) موثق من الغرفة التجارية و السفارة المصرية ببلد المنشأ
3-Valid GMP or ISO certificate for Manufacturer of finished product □Scope including Active Ingredient	شهادة GMP او ايزو للمصنع سارية و لابد أن يغطى نطاق الشهادة المادة الفعالة
4-Copy of EDA Record Importing Register (If it is not the first product)	شهادة ترخيص قيد سجل مستوردين بهيئة الدواء المصرية موضح بها اسم الشركة المصدرة (يرفق تعهد باصدارها فى حالة التسجيل لاول مرة)
5-Packing Letter from Exporting Country with full pack details (Only if not present in CPP)	خطاب تعبئة المستحضر من الشركة المصدرة موضح بها نوع العبوات و احجامها تفصيليا موثقة من الغرفة التجارية والسفارة المصرية ببلد المنشأ
6- Local company registration card in the Agent Register (Register 14) from the General Organization for Export & Import Control	بطاقة قيد الشركة المحلية مقدمة طلب التسجيل بسجل الوكلاء " س14 " من الهيئة العامة للرقابة على الصادرات والواردات
7– Local company registration card in the Importers Register (Register 4) from the General Organization for Export & Import Control	بطاقة قيد الشركة المحلية مقدمة طلب التسجيل بسجل المستوردين "س4" من الهيئة العامة للرقابة على الصادرات والواردات
IN CASE OF HARD FILE	
1-Preliminary Approval	موافقة السير فى اجراءات التسجيل
2- Stability Approval with finished product specification & Composition certificates attached	موافقة ادارة الثبات مرفق بها شهادة مواصفات المستحضر وبيان التركيب
3-CADC Analysis Approval attached to the approved composition with EDA stamp	مطابقة معامل الادارة المركزية للرقابة الدوائية مرفق معها بيان التركيب المعتمد من المعامل

Kindly submit your file arranged according to Check list requirements

E-mail : Biocides@edaegypt.gov.eg

7- Document History

Version number	Release Date	Summary of Change
1	02/2020	----------
2	11/2023	- Accepting the final file after exceeding a maximum of one year from the date of expiry of the deadline for its submission (fulfilling the studies), provided that the prescribed service fee shall be paid - Addition of work rules developed during the Corona crisis
3	02/2025	- Modifying the time frame for preliminary file revision and its presentation to the committee from its fulfillment from 14 to 15 working days - Modifying the decision to invalidate registration application if the file isn't fulfilled within one year from the date of the last follow-up into: within one year from the date of file submission on the electronic link of antiseptics/disinfectants registration - Another pathway approval considering the imported products from reference countries, the applicant company has the option to follow either the normal pathway or the following mentioned pathway which is the possibility to postpone the analysis step until after the issuance of the final registration license, which is conditional on the analysis of the first incoming consignment by the Administration of Evaluation and Approval - Checklist update