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TANZANIA FOOD AND DRUGS AUTHORITY

GUIDELINES FOR SUBMISSION OF DOCUMENTATION FOR MARKETING AUTHORIZATION OF BIOCIDAL (ANTISEPTIC AND DISINFECTANT) PRODUCTS

First Edition

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Abbreviations

ASTM	American Society for Testing and Materials
BP	British Pharmacopoeia
CAS number	Chemical Abstracts Service Registry Number
CEN	European Committee of Standardization
ISO	International Organisation for Standardisation
JP	Japanese Pharmacopoeia
OECD	Organisation for Economic Corporation Development
Ph. Eur	European Pharmacopoeia
RH	Relative Humidity
TFDA	Tanzania Food and Drugs Authority
USP	United States Pharmacopoeia

Foreword

This is the first edition of the Guidelines for Registration of Antiseptics and Disinfectants in Tanzania which has been drafted by the Tanzania Food and Drugs Authority (TFDA). The guidelines have been made under Section 5(1)(a) of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 which empowers TFDA to regulate all matters relating to quality, safety and effectiveness of food, drugs, cosmetics and medical devices.

The Authority has a legal responsibility of ensuring that all medicinal products including antiseptics or disinfectants obtain a written authorization from the TFDA prior to marketing of the products. It is therefore anticipated that all those who will be intending to market antiseptics and disinfectants in Tanzania will oblige with the aforementioned legal provisions and follow the procedures and requirements as set out in these guidelines.

The guidelines provide guidance to applicants to make sure that the products they manufacture or procure and apply for registration meet Tanzanian registration requirements. Applicants are encouraged to familiarize with the guidelines and follow them when preparing and submitting applications for registration of antiseptics and disinfectants. However, the requirements highlighted are minimal and whenever there will be additional information, these may be submitted to TFDA.

Adherence to these guidelines will ensure that all relevant information is provided for registration of the products and therefore will facilitate efficient and effective evaluation as well as approval process. It will also help to avoid queries which results in unnecessary delays in obtaining approvals.

It is anticipated that the guidelines will be revised regularly in response to the experiences gathered from its utilization. We therefore welcome comments and inputs that will help in improving the guidelines.

As a corollary to the above, it is equally important to note that TFDA reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Authority to adequately assess the safety, efficacy or quality of a product. TFDA is committed to ensure that such requests are justifiable and that decisions are clearly documented.

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Introduction

The Tanzania Food, Drugs and Cosmetics Act, Cap 219 defines “drug'' or ''medicine'' or ''pharmaceutical product'' as any substance or mixture of substances manufactured, sold or presented for use in:

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or the symptoms thereof, in man or animal;
(b) restoring, correcting or beneficial modification of organic or mental functions in man or animal; or
(c) disinfection in premises in which food and drugs are manufactured, prepared or kept, hospitals, equipment and farm houses;

Section 22 (1) of the Act prohibits manufacture for sale, sell, offer, supply or import any product regulated under this Act unless it is registered in accordance with the provisions of the Act and the person holds the appropriate license or permit required and issued by the Authority.

Furthermore, Section 51 (1) of the Act provides conditions for registration of medicinal products in Tanzania if availability of the medicine including antiseptics and disinfectants is of the public interest; it is safe, efficacious and of acceptable quality and that the product complies with any other requirements as may be prescribed by the Authority.

These guidelines prescribe information to be submitted by applicants who intends to register antiseptics and disinfectants in Tanzania. The information will be subject to assessment by TFDA. The guidelines provide guidance regarding the preparation and submission of information necessary for the pre-marketing assessment and approval of antiseptic and disinfectant products in Tanzania. It will assist applicants to prepare documentation to support quality, safety and efficacy claims for antiseptic and disinfectant products.

The guidance document is thus divided into the following parts:

Section 1: General requirements
Section 2: Antiseptic products
Section 3: Disinfectant products
Section 4: Annexes

The guidelines should be read in conjunction with the relevant sections of other applicable guidelines as indicated in these guidelines.

Glossary of Terms

The terms listed below are defined specifically for the purpose of these guidelines:

"Act" means the Tanzania Food, Drugs and Cosmetics Act, Cap 219.

"Active substance" means a biologically or chemically active substance or compound that is intended to be used in the manufacture of a product as an active compound (ingredient).

"Antiseptic" means a product that inactivates, reduces, prevents or arrests growth of microorganisms with the inherent intent to mitigate or prevent disease on the skin or mucous membrane (mouth washes only).

"Applicant" means a person who owns a formula or trademark of a product, who may be a manufacturer or a person to whose order and specifications the product is manufactured, and who shall be the registration holder and have the primary responsibility of the product on the Tanzanian market.

"Authority" means the Tanzania Food and Drugs Authority, or the acronym 'TFDA' established by Section 4 of the Act.

"Bactericide" means an antimicrobial agent capable of destroying bacteria, but not necessarily bacterial spores or mycobacteria.

"Biocidal product" means an active substance and preparation containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

"Disinfectant" means an antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on environmental surfaces and inanimate objects.

"Fungicide" means an antimicrobial agent capable of destroying fungi, including their spores.

"Hard surface disinfectant" means a disinfectant that kills potentially pathogenic microorganisms on hard non-porous inanimate surfaces or inanimate objects.

"Manufacturer" means a person or firm that is engaged in the manufacture of antiseptic or disinfectant product(s).

"Mycobactericide" means an antimicrobial agent capable of destroying mycobacteria.

“Persistence’ means a claim that the product will deliver a longer action than only the immediate reduction of microorganisms.

“Pharmacopoeia” means current edition of United States Pharmacopoeia (USP), British Pharmacopoeia (B.P.), European Pharmacopoeia (Ph. Eur), The International Pharmacopoeia (Int. Ph) and Japanese Pharmacopoeia.

“Product variants” means a range of products produced by the same manufacturer in the same site, similar in composition and intended for the same use but available in different colours, fragrances and flavours.

“Product” means antiseptic or disinfectant.

“**Registration holder**” means the holder of the marketing authorization for the biocidal products.

“**Registrant (Market Authorization Holder)**” means any person who may either be the trademark owner or person authorized by him, who has rights to sale the product and is responsible for placing the product on the Tanzanian market.

“Resident organisms” means those organisms normally permanently reside on the skin.

“Rubs” means antiseptic products to be used without water.

“Sanitizer” means a product that reduces the level of microorganisms present by significant numbers, e.g. 99.9% or more, or to acceptable levels.

“Specifications” means the combination of physical, chemical, biological and microbiological test requirements that determine whether antiseptic or disinfectant product is suitable for the intended use.

“Sporicide” means an antimicrobial agent capable of destroying bacterial spores.

“Sterilant” means a chemical agent which is used to sterilize medical devices.

“Transient organisms” means organisms picked up by contact with the environment but may remain in situ long enough to be transferred (e.g. from patient to patient, from surgeon to patient or animal, etc).

“Virucide” means an antimicrobial agent capable of destroying viruses.

“Washes” means antiseptic products to be used with water.

SECTION 1: GENERAL REQUIREMENTS

1.1 An application for registration of a disinfectant or antiseptic shall be made by an applicant who intends to sell any disinfectant or antiseptic in Tanzania. Such applicant shall be a person who is a resident of Tanzania or a company incorporated in Tanzania.

1.2 An applicant shall:-

(a) Apply for registration of the product to the Authority by submitting a duly filled in application form as provided in **Annex I** of these guidelines accompanied with three (3) samples of smallest commercial packs of the product. The submission shall be both in hard copy and an electronic PDF format in a CD-Rom, with exception of application form which shall be presented in word document.

(b) Submit separate application for each product or product variant. Hard copies of the application should be filed in a spring A4 size file with collapsible edge made of biodegradable material. Data shall be presented on A4 and 80g/m paper with readily readable letters of at least 12 font sizes. Every page shall be numbered sequentially. Extension sheets, tables, diagrams and other supporting documents shall as far as possible be of the same size, well annotated, numbered and appropriately cross-referenced.

(c) Every application shall be accompanied by appropriate fees as specified in the Fees and Charges Regulations in force at the time of application. Any application that will not be accompanied by appropriate fees will not be accepted. Applications for registration of product variant shall be charged half of the prescribed fees. The fees may be paid to following account:-

(i) For foreign currency; Tanzania Food and Drugs Authority, Account No. 100380013 USD, Citibank, Tanzania Ltd. Dar es Salaam – Head office Peugeot House, 36 Upanga Road, P. O. Box 71625, Dar es Salaam Tanzania Swift Code: CITITZTZ.

(ii) For local currency; Tanzania Food and Drugs Authority, Account No. 6503900110 National Microfinance Bank, Kariakoo Branch or by banker's draft.

When payment is made by bank transfer all bank charges shall be borne by the applicant who shall also make sure he sends an advice note giving details of the payment in particular the name of the applicant, the product or products paid for and amount of fees paid.

1.3 The authority shall grant registration of a disinfectant or antiseptic if it is satisfied that:-

(a) The disinfectant or antiseptic intended to be registered is of acceptable quality, safety and efficacy.

(b) The disinfectant or antiseptic complies with requirements prescribed in these guidelines.

1.4 The Authority may during assessment of application require the applicant to submit additional samples, documents, and information and give clarification as the case may be. The processing of an application shall be kept on hold until such samples, documents, information or clarification is provided.

1.5 If the applicant fails to respond to the issues in sub section 1.4 above within 90 days from the date of request the application shall be closed and the registration of the product may only be considered upon submission of a new application. The Authority after being satisfied that the product complies with requirements prescribed in these guidelines it will inform the applicant in writing that the product has been granted market authorization.

1.6 Where the Authority refuses to approve the registration of a product; it shall notify the applicant in writing of such decision and the reason(s) thereof.

1.7 If the applicant is not satisfied with the decision of the Authority he may, within 60 days from the date of notification furnish the Director General with representations to review its decision. The Authority after considering the submitted representations may grant registration to the product or if not satisfied it will not grant registration.

1.8 The registration of a product shall be valid for five (5) years unless suspended, cancelled or revoked by the Authority or withdrawn by a registrant.

1.9 For each registered product an annual retention fees as prescribed in the Fees and Charges Regulations shall be paid on or before the end of January of each year for which the fees are due.

1.10 If for any reason the registrant changes any matter related to a registered product including but not limited to change of composition, packaging, labelling or any other change, shall before marketing the changed product, notify and obtain approval of the Authority of the change. The notice to the Authority shall be submitted in a filled application form provided as **Annex II** citing the reason(s) for such change and accompanied by an amount of 10 USD to be paid for each variation.

1.11 The Authority will evaluate reasons provided in the notice referred to under sub section 1.10 and if satisfied with such reasons it will approve the

changes by issuing approval notice. If not satisfied the Authority will not approve the changes and it will notify the registrant the reasons thereof.

1.12 The registrant may at any time by giving notice in writing to the Authority withdraw the registration of the registered product.

1.13 Applications for renewal of registration shall be made at least 30 days before the expiry of existing registration by submitting the following:-

(a) Dully filled in application form for renewal of registration as outlined in **Annex III** of these guidelines.

(b) Three (3) samples of the smallest commercial packs from the same batch along with batch certificates of analysis.

(c) Non refundable application fees as specified in the Fees and Charges Regulations.

1.14 Every registrant shall be responsible for:-

(a) All information supplied in support of the application for registration and variation thereof.

(b) Ensuring safety, quality and efficacy of the registered product and that the product at all times complies with all requirements as provided in these guidelines.

(c) Effect voluntary and compulsory product recall whenever necessary.

(d) Observation of sanitation and hygiene in manufacturing premises and equipments.

SECTION 2: ANTISEPTIC PRODUCTS

2.1 Introduction

An antiseptic product is considered to be one that inactivates, reduces, prevents or arrests growth of microorganisms with the inherent intent to mitigate or prevent diseases. For the purpose of these guidelines, microorganisms are defined as bacteria, yeast, fungi, and viruses.

2.2 Scope

These guidelines apply to antiseptic skin products for human and veterinary use that are intended for use in professional and personal settings. Antiseptic products can include both those to be used with water (referred to as washes) or without water (referred to as rubs) and may be presented in different dosage forms. Antiseptic skin products also include preoperative skin preparations.

The guidelines do not apply to human-use antiseptic products for burn victims or application to sites other than the skin (only antiseptic mouthwashes without any medicinal claim are included in this guideline).

2.3 Classification of Antiseptics

2.3.1 Personal use antiseptics

2.3.1.1 Personal domestic use antiseptics

Personal domestic (or household) use antiseptic products are those used by an individual in a domestic setting to reduce transient organisms on the skin. This includes, but may not be limited to, consumer-use first aid antiseptics for application in cleansing minor wounds, self-administered pre-injection or ear piercing.

2.3.1.2 Personal commercial use antiseptics

Personal commercial use antiseptics are those made available to the general public for occasional use and are intended to reduce transient organisms on the skin in a commercial or institutional setting.

2.3.2 Professional use antiseptics

2.3.2.1 Food premises use antiseptics

Products for professional food premises are those which are indicated for use by food handlers to reduce transient organisms on the skin in a commercial or institutional setting including food processing plants, restaurants, supermarkets, and fast food outlets.

2.3.2.2 Professional healthcare use antiseptics

Products for professional healthcare use are those which are indicated for use by individuals to reduce transient and/or resident organisms on the skin in a healthcare setting (such as hospitals, nursing homes, human and veterinary clinics and dental offices).

Professional healthcare use antiseptics can be broken down as follows:-

(a) Professional hygienic hand rub: product used for post-contamination treatment of lightly-soiled hands that involves rubbing hands without addition of water, and which is designed for frequent use.
(b) Professional hygienic hand wash: product used for post contamination treatment that involves washing hands, and which is designed for frequent use.
(c) Surgical hand rub: product used for preoperative treatment, which involves rubbing hands without addition of water.
(d) Surgical hand wash: product used for preoperative treatment that involves washing hands, either with or without the use of a scrub brush.
(e) Patient preoperative skin preparations: product used to prepare patient skin prior to surgical procedures.

2.4 Documentation requirements for registration

Documents to be included under this section should include information to demonstrate quality, efficacy and safety of the product.

2.4.1 Manufacturing and marketing authorization

Submit a valid Manufacturing license of manufacturing site of the product. Submit a Marketing Authorization to demonstrate that the product is registered or licensed in the country of origin.

2.4.2 Chemistry, Manufacturing and Controls

2.4.2.1 Chemistry

(a) Active substance should be identified by its non-proprietary name, chemical name and CAS number (if available).

(b) Provide copy of certificate of analysis of active substance from supplier or manufacturer of the substance.

(c) The formulation of a commercial pack and production scale batch should be provided in tabular form as indicated in the application form. This information should be in the form of a quantitative listing of all ingredients used in its manufacture and in the final product formulation, taking into

account that the percentage of the chemical formulation components should add up to 100%.

2.4.2.2 Manufacturing process

(a) Describe all stages involved in the manufacture of the finished product. This shall be in the form of a detailed narrative and a simplified flow diagram accompanied by a list of equipment used at each stage. Basic principles involved should be clearly set out from dispensing to packaging. All stages should be illustrated i.e. filling, weight checking, labelling, packing in hardboard and sealing. All steps involved and their operations should be carefully described including the conditions subjected to each operation i.e. temperature, PH adjustments, processing time etc.

(b) Provide the actual batch manufacturing and packaging records for one production scale batch.

2.4.2.3 Quality control

2.4.2.3.1 Specifications and analytical methods

Summarized specifications of the final product should be provided, i.e. the acceptable limits of the entire physical, chemical, biological and (where applicable) microbiological parameters.

Specification should include but not limited to:-

(a) Description
(b) Identity - test method should be specific for active substance(s)
(c) Assay - test method should be specific and stability indicating for active substance(s)
(d) Additional specifications and test methods for liquid preparation includes; pH, Microbial limits, Specific gravity.

A full description of analytical and other control procedures carried out to ascertain the final product specifications stated above should be given.

Provide a copy of certificate of analysis of at least one batch of finished product.

2.4.2.3.2 Stability studies

Submit data on accelerated stability testing at conditions (40±2°C/75±5 % RH) and long term study at conditions (30±2°C/75±5 %RH) for three batches of finished product. For more details please refer to Guidelines on Submission of Documentation for Registration of Human Medicinal Products, available at *http://www.tfda.or.tz/index.php?option=com_phocadownload&view=category&id=22&Itemid=300*.

2.4.3 Efficacy and Safety

Submission of efficacy and safety data may be exempted from application of registration provided the product meets the following criteria:-

(a) Contain either of the following active substances in these concentrations:

Table No.: 1: List of products exempted from efficacy and safety data

S/N	Name of active substance	Concentration
1	Ethanol Ethyl alcohol Anhydrous alcohol	60-80%
2	Isopropanol Isopropyl alcohol 2-propanol	60-70%
3	Povidone-iodine	0.5–10.0%
4	Benzalkonium chloride	0.1 - 0.15%
5	Chlorhexidine gluconate	0.05 - 0.5%
6	Chloroxylenol	2.0 - 4.0%
7	Methylbenzethonium chloride	0.5 - 3.0%
8	Triclocarban	0.05 - 0.5%
9	Triclosan	1.5% only

(b) Route of administration: Topical
(c) Dosage form(s): Established scientifically recognized dosage forms.

Note:

- The product should also meet the general labelling requirements.
- Combinations of ingredients in the above table may result in the product being classified as a new antiseptic product in which case the requirements of sections 3.4.3.1 and 3.4.3.2 will be applicable.
- This list is not exhaustive. Any ingredient not listed in the table above but has a monograph in the pharmacopeia will be exempted from efficacy and safety data requirements, provided a copy of the referenced monograph is attached.

2.4.3.1 Efficacy

For antiseptic products not meeting the above criteria both *in vitro* and *in vivo* tests are required in order to demonstrate efficacy against a broader range of organisms.

The choice of the test method and microorganism (including strain) should be in line with international standards (CEN and ASTM International).

The demonstration of efficacy, both *in vitro* and *in vivo* study reports should be submitted taking into consideration of the requirements stipulated in the table below:

Table No. 2: Study reports required to support efficacy of the product

	1-In vitro test	**2 - In vivo test**
Test report which proves the antiseptic activity of the product	For surrogate and non-surrogate test organisms: one independent report.	For non-surrogate test organisms: one independent report.
		For surrogate test organisms: two independent reports.

Test reports should include at a minimum:-

(a) Identification of the standard method used to verify the product efficacy.
(b) Proof of the effectiveness of the neutralizer utilized in the tests for both the reference standard and the test product.
(c) The relationship of each test to specific area of application.
(d) The type and level of soil load included in the test.
(e) The time differential (between application of the test product and the collection of organisms) used in the test and whether the time stated is sufficient to meet the required criteria of specific activity.
(f) Initial number of the test organisms.
(g) Information on the batch number, expiry date, and date of manufacture for the batch tested.
(h) Proof of a washout period if a cross-over study is employed or if a subject is reused.
(i) Proof of glove compatibility for surgical scrub products.
(j) The minimum inhibitory concentration (MIC) for the product, when available.
(k) Conclusion, describing whether the product meets the specific criteria relative to the reference method(s) employed.

Note:
Based on practicality, no product will be accepted if it's *in vivo* time-to-effect upon completion of application is greater than 30 seconds (for a leave on product) or 1 minute (for a wash off product).

2.4.3.2 Safety

Data to demonstrate safety of antiseptic product should include the following:-

(a) Published and/or unpublished safety data testing local tolerance, such as: Irritation and sensitization (in the presence and absence of UV exposure when this is likely to be a risk factor) and preferably conducted in human species; photo-allergenicity; photo-carcinogenicity, etc.

(b) When evidence is not available to show that topically-applied medicinal ingredients are not absorbed systemically to a significant degree, toxicity data should be submitted.

(c) Safety tests for (a) and (b) should be performed in accordance with relevant internationally-accepted test methods (e.g. OECD, ICH).

2.4.4 Data to support specific claims

2.4.4.1 Products used in professional food premises

(a) For products that are intended to be used in professional food premises, data to demonstrate the residual amount of the product that will be found on hands of employees after application of the product and the level that may be expected to be transferred to food products should be provided (after precautionary safety approaches were undertaken such as potable water rinse or drainage of excess of product). This information should be in the form of actual analytical data or theoretical estimates based on the proposed use level of the product.

(b) The Estimated Dietary Intake (EDI) resulting from the use of the product. This should include any information that is used to estimate the dietary exposure such as type of foods, residual levels, etc.

(c) Any available data (full reports) on the mammalian oral toxicity of the product.

(d) Data recommendations should be made available for supporting an application for personal commercial use wherein claims are made against a specific organism, antiviral claims, or those relating to persistence, sterility, time kill, % reduction and/or log-reduction.

2.4.4.2 Log reduction claims

(a) Products claiming log reduction values (e.g. kills 99.9% of bacteria) data should be submitted to support the claim for the specific formulation and using the recommended test methods.

    (i) For personal and commercial use products only efficacy against bacteria and fungi should be demonstrated unless claims are also made against mycobacterium and/or viruses.

(ii) For products intended for use in professional food premises and professional health care setting, a minimum log reduction in vivo should be demonstrated.

2.4.4.3 Persistence claims

Persistence is defined as a claim that the product will deliver a longer action than only the immediate reduction of microorganisms on hands. Persistence claims for personal use products can only be made relative to bacteria. Should an applicant wish to make persistence claims against other organisms, a strong supporting scientific rationale outlining an appropriate test method should be provided (e.g. technology used or special formulation).

Professional-use surgical scrubs and preoperative patient skin preparations must demonstrate a minimum persistence of at least six (6) hours.

2.4.4.4 Time kill claims

Antiseptic products are expected to have a minimum time-to-effect of 30 seconds (for waterless hand rubs) to 1 minute (for washes or scrubs using water) upon completion of application according to the proposed directions for use. As this is considered the norm for antiseptics, a claim that a product is fast-acting would have to demonstrate both a significantly shorter time-to-effect and still maintain clinical relevance, and should use the test methods outlined for log reduction testing (organisms dependent on indications, with bacteria/fungi as a minimum).

2.4.4.5 Sterility

Any product claiming to have a sterilizing effect must provide strong supporting data for such claim.

2.4.5 Container/closure system(s) and other packaging

The suitability of the container closure system(s) used for the storage, transportation (shipping) and use of the final product should be discussed. Discussion should consider e.g., choice of materials, protection from moisture and light, compatibility of the materials of construction with the dosage form (including sorption to container and leaching) and performance. Give a detailed description of the container/closure system(s), including any liner or wadding, and provide details of the composition of each component. Provide the specifications for any part of the container/closure system(s), which comes into contact with the product or is protective. The specifications should include description and identification (and critical dimensions, with drawings where appropriate). Describe other (e.g. outer) packaging, and state what materials they are made from.

2.4.6 Labelling

All antiseptic products intended to be sold in Tanzania must be labelled in English and/or Kiswahili. The applicant should provide art-work of the proposed label of the antiseptic product.

A label should contain a minimum of the following information:-

(a) Name of the product
(b) Active substance: the identity and concentration of each active substances
(c) Declaration of the net content
(d) Declaration of the batch number.
(e) Name and address of the manufacturer
(f) Inclusion of appropriate symbols and cautionary statements.
(g) Expiry date
(h) Storage conditions
(i) Precautions and warnings
    - For external use only. Do not ingest.
    - Avoid contact with the eyes.
    - Discontinue use and consult a health care practitioner if irritation and redness develops.
    - Keep out of reach of children.

(j) Other labelling information:
    - Labels which include the authorized claims should also describe the intended area of application and specific attributes of the product, such as: bactericidal, fungicidal, mycobactericidal or virucidal.
    - The label should clearly reflect the same conditions of use as employed in the tests used to demonstrate efficacy (e.g. directions for use, warnings, etc).
    - Products with more than one indication or claim, label must include the full warnings and adequate directions for use for each indication.
    - If surrogates were used in testing this should be stated on the labels.
    - Dispensing units when they contain an antiseptic product, they should be labelled in accordance to the requirements of these guidelines.
    - For antiseptic products intended for commercial use, the following statements should be included on the label:-
        - For commercial use
        - For hand wash: “Use ….mL and lather in hands with water for at least 30 seconds. Rinse well”.
        - For hand rub: “Use …mL and rub thoroughly into hands for at least 30 seconds. Allow to dry”.
    - For antiseptic products intended for professional food premises, the following statements should be included on the label:-
        - For use in food premises
        - To reduce bacteria, mycobacteria, fungi, and viruses on skin;
        - Avoid food contamination during use and storage.

- Do not refill container.
- This product may not be effective against parasites.
- For hand wash: “Use …mL and lather in hands with water for at least 30 seconds. Rinse well”.
- For hand rub: “Use …mL and rub thoroughly into hands for at least 30 seconds. Allow to dry”.
- For volatile products: “after use of this product, food handlers’ hands are to be dry and free of product residue prior to handling food products”
- For non-volatile products: “after use of this product food handlers are to rinse their hands with potable water prior to handling food products”

- For antiseptic products intended for professional health use, the following statements should be included on the label:-
  - Allow product to evaporate completely prior to use in electro cautery procedures [Note: only for alcohol-based products].
  - For healthcare hand wash only: Use … mL and lather in hands with water for at least 30 seconds. Rinse well.
  - For healthcare hand rub only: Use … mL and rub thoroughly into hands for at least 30 seconds. Allow to dry.
  - Do not refill container
  - For professional hand wash or hand rub: “For Hospital and Healthcare Professional Use. To reduce bacteria, mycobacteria, fungi, and viruses on skin.”
  - Surgical hand rub and hand wash: “For Hospital and Healthcare Professional Use. Preoperative antiseptic hand rub or surgical hand rub. To reduce bacteria and fungi on skin to diminish the risk of surgical site infection. Reapply every 6 hours or if hands are re-contaminated.”
  - Patient preoperative skin preparation: “For Hospital and Healthcare Professional Use. Preoperative antiseptic skin preparation. To reduce bacteria and fungi on skin to diminish the risk of surgical site infection. Reapply every 6 hours or if skin is re-contaminated”.
- For antiseptic products containing ethanol or isopropanol only:-
  - Flammable.
  - Keep away from open flame and sources of heat.
- For all types of antiseptic products the following statements are allowed to be used on the labels:-
  - Antiseptic cleanser.
  - Medicated cleanser.
  - Kills harmful bacteria or germs
- For products containing povidone-iodine the following statement may be made for wound cleansing: Apply to wound once or twice daily.
- For products intended as hand sanitizers the following statement may be made: Rub product onto hands and allow drying.

SECTION 3: DISINFECTANTS

3.1 Introduction

The term "disinfectant" as defined and interpreted in these guidelines is considered to include bactericides, fungicides, virucides, mycobactericides, tuberculocides, sporicides, sterilants, or combinations of these. A disinfectant without specific target organisms indicated on the product label is regarded only as a bactericide.

3.2 Scope

These guidelines apply to substances or mixture of substances manufactured, sold or presented for use in disinfection in premises in which food and drugs are manufactured, prepared or kept, hospitals, veterinary clinics, equipments and farm houses.

3.3 Classification of Disinfectants

For the purpose of these guidelines disinfectants are classified based on the risk level of the device on which the product is intended to be used on as shown in the table below:

Table No. 3: Classifications of disinfectants

Disinfectant class	**Risk level of device**	**Device definition**	**Definition of disinfectant class**
Gaseous sterilant and critical device sporicide, also referred to as critical sporicide	Critical	Present a high risk of infection if they are not sterile, i.e. contaminated with any organism, including spores. Routinely penetrate the skin or mucus membranes into normally sterile areas of the body (e.g., implants, scalpels, needles, surgical instruments, laparoscopes), or come into direct contact with recalculating body fluids, (e.g., kidney dialysis tubing and dialyzers, or blood oxygenators).	A disinfectant which helps achieves sterilization.
High-level Disinfectant.	Semi critical	Contact with mucous membranes during use but do not usually penetrate	A disinfectant that kills all microbial pathogens,

Disinfectant class	Risk level of device	Device definition	Definition of disinfectant class
		normally sterile areas of the body, e.g. endoscopes, anesthesia breathing circuits, respiratory therapy equipment, dental mirrors, etc…	except Large numbers of bacterial endospores according to labeling.
Intermediate level.	Non critical	Contact only intact skin during routine Use, e.g. stethoscopes, bedpans, etc…	A disinfectant that kills all microbial pathogens, except bacterial endospores, when used according to labelling.
Low-level Disinfectant.			A disinfectant that kills pathogenic and potentially pathogenic microorganisms on hard non-porous inanimate surfaces or inanimate objects, when used according to labelling. Veterinary hygiene biocide products are used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.

3.4 Documentation requirements for registration

Documents to be included under this section should include information to demonstrate quality, efficacy and safety of the product.

3.4.1 Manufacturing and marketing authorization

Submit a valid Manufacturing license of manufacturing site of the product. Submit a Marketing Authorization to demonstrate that the product is registered or licensed in the country of origin.

3.4.2 Chemistry, Manufacturing and Controls

3.4.2.1 Chemistry

(a) Active substance should be identified by its non-proprietary name, chemical name and CAS number (if available).

(b) Provide copy of certificate of analysis of active substance from supplier or manufacturer of the substance.

(c) The formulation of a commercial pack and production scale batch should be provided in tabular form. This information should be in the form of a qualitative and quantitative listing of all ingredients used in its manufacture and in the final product formulation, taking into account that the percentage of the chemical formulation components should add up to 100%.

3.4.2.2 Manufacturing process

(a) Describe all stages involved in the manufacture of the finished product. This shall be in the form of a detailed narrative and a simplified flow diagram accompanied by a list of equipment used at each stage. Basic principles involved should be clearly set out from dispensing to packaging. All stages should be illustrated i.e. filling, weight checking, labelling, packing in hardboard and sealing. All steps involved and their operations should be carefully described including the conditions subjected to each operation i.e. temperature, PH adjustments, processing time etc.

(b) Provide the actual batch manufacturing and packaging records for one production scale batch.

3.4.2.3 Quality control

3.4.2.3.1 Specifications and analytical methods

Summarized specifications of the final product shall be provided, i.e. the acceptable limits of the entire physical, chemical, biological and (where applicable) microbiological parameters.

Specification should include but not limited to:-

(a) Description
(b) Identity - test method should be specific for active substance(s)
(c) Assay - test method should be specific and stability indicating for active substance(s)
(d) Additional specifications and test methods for liquid preparation includes; pH, Microbial limits, Specific gravity etc.

A full description of analytical and other control procedures carried out to ascertain the final product specifications stated above should be given.

Provide a copy of certificate of analysis of at least one batch of finished product.

3.4.2.3.2 Stability studies

Submit data on accelerated stability testing at conditions (40±2°C/75±5 % RH) and long term study at conditions (30±2°C/75±5 %RH) for three batches of finished product. For more details please refer to Guidelines on Submission of Documentation for Registration of Human Medicinal Products, available at *http://www.tfda.or.tz/index.php?option=com_phocadownload&view=category&id=22&Itemid=300*

3.4.3 Efficacy and Safety

Submission of efficacy and safety data may be exempted from application for registration of a product provided that the active substance or product has a monograph in the pharmacopoeia.

For non-pharmacopoeia active substance or product, data to demonstrate the efficacy claim and safety of the product should be submitted. Data must be able to demonstrate the efficacy of the product against the target organism when used normally under the claimed conditions of use.

The efficacy and safety studies should be carried out according to national guidelines or standards (if these are available and applicable) or internationally recognized guidelines or standards such as:-

(a) Individual manufacturer standard method approved by the Authority
(b) Data from the actual development of the product approved by the Authority
(c) ISO, CEN, OECD, ASTM International

3.4.4 Container/closure system(s) and other packaging

The suitability of the container closure system(s) used for the storage, transportation (shipping) and use of the final product should be discussed. Discussion should consider e.g., choice of materials, protection from moisture and light, compatibility of the materials of construction with the dosage form (including sorption to container and leaching) and performance. Give a detailed description of the container/closure system(s), including any liner or wadding, and provide details of the composition of each component. Provide the specifications for any part of the container/closure system(s), which comes into contact with the product or is protective. The specifications should include description and identification (and critical dimensions, with drawings where appropriate). Describe other (e.g. outer) packaging, and state what materials they are made from.

3.4.5 Labelling

All disinfectant product intended to be sold in Tanzania must be labelled in English and/or Kiswahili. The applicant should provide art-work of the proposed label of the disinfectant product.

A label should contain a minimum of the following information:-

(a) Name of the product
(b) Active substances: the identity and concentration of each active substance
(c) Net contents.
(d) Batch number
(e) Name and address of the manufacturer
(f) Inclusion of appropriate symbols and cautionary statements such as for pressurized metal cans
(g) Expiry date
(h) Storage conditions
(i) Intended use:
    - Claims (e.g. as a disinfectant, sterilant, sporicide etc)
    - Site of use (premises where food is manufactured, processed or kept, health care facilities, etc.) and the types of inanimate objects (e.g., work surfaces, floors, walls in patient care areas, etc.) or medical devices (e.g., bronchoscopes, bedpans, contact lenses, etc.) to be disinfected. In addition, for contact lenses, the type of lens (e.g., soft, hard, gas permeable, etc.) should be specified.
(j) Directions for use:
    - The label should provide specific instructions to the user for preparing the in-use dilution of the product in order to achieve the intended antimicrobial effect. More than one dilution may be specified if several different applications are intended. In use period should also be stated.

    - Contact time. More than one contact time may be specified if several different applications are intended.

    - If the product is to be used at a temperature other than 30°C, this temperature should be specified and the label should indicate that heating or cooling to the specific temperature is required for efficacy.

    - If applicable, the volume and directions for the use of an activator should be included.

    - The labelling for products not labelled for single use should clearly indicate their expiry dating after activation and/or dilution and under reuse conditions as appropriate.

    - Disinfectants for use on medical devices: “Thoroughly clean the device prior to its disinfection”.

- Appropriate rinse procedures to ensure the absence of unacceptable residues on the surface of device after disinfection or sterilization are required.

- For products labelled with efficacy claims against blood borne viral pathogens such as HIV, HBV and HCV, the following additional labelling criteria should be included:-
  - A term like "HIV" is acceptable, but should also be identified as "human immunodeficiency virus". Similarly, the terms HBV and HCV are acceptable, but should also be respectively identified as “hepatitis B virus” and “hepatitis C virus”.
  - Direction for use should indicate that the product is intended for use against the blood borne pathogens listed on the labelling, e.g., HIV, HBV, HCV, in settings where these microorganisms would be expected to be encountered, such as settings where contamination by blood or body fluids is likely.
  - Directions for use should also provide specific decontamination procedures, including:-
    a. The need for surfaces to be cleaned prior to disinfection.
    b. Personnel that clean items soiled with blood or body fluids: “wear appropriate barrier protection, such as disposable gloves, gowns, and masks”.
    c. Directions for the disposal of cleaning materials and waste.

(k) Directions for use:
- Precautions and warnings
- Keep out of reach of children,
- Not for internal use,
- Use in ventilated area,
- Avoid contact with eyes,
- Use safety glasses,
- In case of contact, flush with water immediately and contact a doctor.

SECTION 4: ANNEXES

Annex I

TANZANIA FOOD AND DRUGS AUTHORITY

APPLICATION FORM FOR REGISTRATION OF ANTISEPTICS/ DISINFECTANTS

General Instructions:

Please read all the instructions carefully prior to completing this Application form.

Provide as much detailed, accurate and final information as possible. Note that all areas are to be filled out by the applicant EXCEPT where indicated by grey areas which are for TFDA Official Use Only!

Please state the exact location (Annex number) of any appended documents in the relevant sections of the form.

A properly filled out and signed original copy of the form with all its annexes (including a copy in MS Word and PDF on a CD-ROM) must be submitted together with the product dossier. The entire dossier should be submitted both as hard-copy and on CD-ROM. The application should be sent to the following address:

Director General
Tanzania Food and Drugs Authority
P.O. Box 77150
EPI Mabibo
Off Mandela Road
Dar-es-Salaam
Tanzania.

(This document should be submitted in word format)

Application Number	
Date of submission of the dossier	
Number of files	
Name of First Assessor	
Name of Second Assessor	
Date of first Assessment	
Date of second Assessment	
Outcome of the assessment	

1.0 ADMINISTRATIVE INFORMATION	
1.1	Type of the product application (tick as appropriate) Antiseptic ☐ Disinfectant ☐
1.2	Proprietary Name of the product
1.3	Generic name of the product
1.4	Name and strength of active substance(s)
1.5	Name and address (physical and postal) of Applicant
(Company) Name: Address: Country: Telephone: Telefax: E-Mail:	
1.5.1	Form of the product: ☐Solution ☐Suspension ☐Gel ☐Aerosol ☐Emulsion ☐Gaseous ☐Powder ☐Bar ☐Tablet ☐ Cream ☐Others – specify....
1.5.2	Intended use:
1.6	Packing/pack size:
1.7	Visual description
1.8	Proposed shelf life (in months):
1.8.1	Proposed shelf life (after reconstitution or dilution):
1.8.2	Proposed shelf life (after first opening container):
1.8.3	Proposed storage conditions:
1.8.4	Proposed storage conditions after first opening:
1.9	Other sister products registered or applied for registration
1.9.1	Do you hold Marketing Authorization (s) of other product (s) containing the same active substance (s) in the TFDA? Yes/No If yes state; Product name (s), strength (s), pharmaceutical form (s): Indication(s):
1.9.2	Have you applied for Marketing Authorization medicinal product (s) containing the same active substance (s) in the TFDA? Yes/No If yes state; Product name (s), strength (s), pharmaceutical form (s): Indication(s):
1.10	Distribution category: Pharmacy Only ☐ General sale ☐ Others☐
1.11	Country of manufacture:

1.12	Product Marketing Authorisation in the country of manufacture. If not registered/licensed state reasons

☐Authorised Country: Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:

1.13	Name(s) and complete physical address(es) of the manufacturer(s)
1.13.1	Name(s) and physical address (es) of the manufacturing site of the finished product.

Company name:
Physical address:
Postal address:
Country:
Telephone:
Telefax:
E-Mail:

1.13.2	Name(s) and physical address(es) of the manufacturer(s) of the active substance(s)

Company name:
Physical address:
Postal address:
Country:
Telephone:
Telefax:
E-Mail:

1.14	Qualitative and Quantitative composition (active substance (s) and excipient(s) A note should be given as to which quantity the composition refers (e.g. ml or g).

Name of active substance(s)*	Reference/monograph standard	Quantity /unit (ml, g)	Quantity per batch	Reasons of inclusion
1.				
2.				
3.				
e.t.c				
Name Excipient(s)				
1.				
2.				
3				
e.t.c				

2.0 LABELLING

3.0 SUMMARIES Provide condensed summaries of the key quality, efficacy and safety information from the product dossier. The summaries should include sufficient information from each section of the product dossier to provide an overview of the information submitted in the product dossier. The summaries should also emphasize critical key parameters of the product and provide discussion of key issues that integrates information from sections in the product dossier.	
Chemistry, Manufacturing and Controls	
	Chemistry
	Manufacturing process
	Quality control
	Specifications and analytical methods
	Stability studies
Efficacy and Safety	
	Efficacy
	Safety
Data to support specific claims (for antiseptics)	
	Products used in professional food premises
	Log reduction claims
	Persistence claims
	Time kill claims
	Sterility
4.0 DECLARATION BY AN APPLICANT	
	I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge. I also agree that I shall carry out vigilance to monitor the safety of the product in the market and provide safety update reports to TFDA. It is hereby confirmed that fees will be paid/have been paid according to the TFDA fees and regulation Name: …… Position in the company:…… Signature: …… Date:…… Official stamp:…….

	* Note: If fees have been paid, attach proof of payment
Issues to be communicated to the applicant	

Annex II

TANZANIA FOOD AND DRUGS AUTHORITY

APPLICATION FORM FOR VARIATION OF A REGISTERED ANTISEPTIC OR DISINFECTANT PRODUCT

General Instructions:

Please read all the instructions carefully prior to completing this Application form.

Provide as much detailed and accurate information as possible. Note that all areas are to be filled out by the applicant EXCEPT where indicated by grey calour which are for TFDA Official Use Only!

All parts of the dossier that are affected by a variation shall be resubmitted according to the structure of the Guidelines on Application for Registration of Biocidal (Antiseptics and Disinfectants) products. Moreover, any further documentation required along with the change should be appended.

Summary(ies) of the intended change(s) in should be presented in tabulated format in which the current state/situation and the situation after the intended change are compared in order to outline the scope of the change in a transparent manner. A justification should always follow why the change needs to be introduced.
A properly filled out and signed original copy of the form with all its annexes (including a hard copy and an electronic copy in MS Word on a CD-ROM and PDF) must be submitted.

A complete application should be sent to the following address:

Director General
Tanzania Food and Drugs Authority
P.O. Box 77150
EPI Mabibo
Off Mandela Road
Dar-es-Salaam
Tanzania

(This document should be submitted in word format)

Registration Number	
Date of submission of the dossier	
Number of files	
Name of Assessor	
Date of Assessment	
Outcome of the assessment	

1.0 ADMINISTRATIVE INFORMATION	
1.1	Type of the product application (tick as appropriate) Antiseptic ☐ Disinfectant ☐
1.2	Proprietary Name of the product
1.3	Generic name of the product
1.4	Name and strength of active substance(s)
1.5	Name and address (physical and postal) of Applicant
(Company) Name: Address: Country: Telephone: Telefax: E-Mail:	
1.5.1	Form of the product: ☐Solution ☐Suspension ☐Gel ☐Aerosol ☐Emulsion ☐Gaseous ☐Powder ☐Bar ☐Tablet ☐ Cream ☐Others – specify….
1.5.2	Intended use:
1.6	Packing/pack size:
1.7	Visual description
1.8	Proposed shelf life (in months):
1.8.1	Proposed shelf life (after reconstitution or dilution):
1.8.2	Proposed shelf life (after first opening container):
1.8.3	Proposed storage conditions:
1.8.4	Proposed storage conditions after first opening:
1. 9	Country of manufacture:
1.10	Name(s) and physical address (es) of the manufacturing site of the finished product.
Company name: Physical address: Postal address: Country: Telephone: Telefax: E-Mail:	
2.0 VARIATIONS	
2.1	Changes made to the product

2.2	Description of the changes
2.3	Justification for changes
3.0 DECLARATION BY AN APPLICANT	
	I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge. It is hereby confirmed that fees will be paid/have been paid according to the TFDA fees and regulation Name: …… Position in the company:…… Signature: …… Date:…… Official stamp:…… * Note: If fees have been paid, attach proof of payment

Annex III

TANZANIA FOOD AND DRUGS AUTHORITY

APPLICATION FORM FOR RENEWAL OF REGISTRATION OF ANTISEPTICS/ DISINFECTANTS

General Instructions:

Please read all the instructions carefully prior to completing this Application form.

Provide as much detailed, accurate and final information as possible. Note that all areas are to be filled out by the applicant EXCEPT where indicated by grey areas which are for TFDA Official Use Only!

This application form should be accompanied by a Batch Manufacturing Record (BMR) & Batch Packaging Record of one recently manufactured production scale batch.
Please attach as an annex for any other document if applicable.

A properly filled out and signed original copy of the form with all its annexes (including a copy in MS Word and PDF on a CD-ROM) must be submitted together with the product dossier. The entire dossier should be submitted both as hard-copy and on CD-ROM. The application should be sent to the following address:

Director General
Tanzania Food and Drugs Authority
P.O. Box 77150
EPI Mabibo
Off Mandela Road
Dar-es-Salaam
Tanzania.

(This document should be submitted in word format)

Registration Number	
Date of submission of the dossier	
Number of files	
Name of Assessor	
Date of Assessment	
Outcome of the assessment	

1.0 ADMINISTRATIVE INFORMATION

1.1	Type of the product application (tick as appropriate) Antiseptic ☐ Disinfectant ☐
1.2	Proprietary Name of the product
1.3	Generic name of the product
1.4	Name and strength of active substance(s)
1.5	Name and address (physical and postal) of Applicant
(Company) Name: Address: Country: Telephone: Telefax: E-Mail:	
1.5.1	Form of the product: ☐Solution ☐Suspension ☐Gel ☐Aerosol ☐Emulsion ☐Gaseous ☐Powder ☐Bar ☐Tablet ☐ Cream ☐Others – specify....
1.5.2	Intended use:
1.6	Packing/pack size:
1.7	Visual description
1.9	Proposed shelf life (in months):
1.9.1	Proposed shelf life (after reconstitution or dilution):
1.9.2	Proposed shelf life (after first opening container):
1.9.3	Proposed storage conditions:
1.9.4	Proposed storage conditions after first opening:
1.10	Distribution category: Pharmacy Only ☐ General sale ☐ Others☐
1.11	Country of manufacture:
1.12	Product Marketing Authorisation in the country of manufacture. If not registered/licensed state reasons

☐Authorised Country: Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:

1.13	Name(s) and complete physical address(es) of the manufacturer(s)
1.13.1	Name(s) and physical address (es) of the manufacturing site of the finished product.
Company name: Physical address: Postal address:	

Country: Telephone: Telefax: E-Mail:	
1.13.2	Name(s) and physical address(es) of the manufacturer(s) of the active substance(s)
Company name: Physical address: Postal address: Country: Telephone: Telefax: E-Mail:	
1.14	Qualitative and Quantitative composition (active substance (s) and excipient(s) A note should be given as to which quantity the composition refers (e.g. ml or g).

Name of active substance(s)*	Reference/monograph standard	Quantity /unit (ml, g)	Quantity per batch	Reasons of inclusion	
1.					
2.					
3.					
e.t.c					
Name Excipient(s)					
1.					
2.					
3					
e.t.c					
2.0 LABELLING					

3.0 VARIATION

Submit summaries of all variations made to the product from last date of registration.

4.0 DECLARATION BY AN APPLICANT

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.
I also agree that I shall carry out vigilance to monitor the safety of the product in the market and provide safety update reports to TFDA.
It is hereby confirmed that fees will be paid/have been paid according to the TFDA fees and regulation
Name: ……
Position in the company:……
Signature: ……
Date:……
Official stamp:……..

* Note: If fees have been paid, attach proof of payment

Issues to be communicated to the applicant