G U I D E L I N E S

ON THE REQUIREMENTS

FOR THE REGISTRATION OF

MEDICAL SUPPLIES

P A R T II

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INTRODUCTION

Medical supplies such as surgical dressings, surgical ligatures and sutures are standardized in many pharmacopeias and other monographs. The provisions of the medical supplies acts of many countries stipulate that this category of products comply with the quality specifications set for them.

In view of this international trend, the Drug Administration and Control Authority of Ethiopia has prepared this guideline. The purpose of the guideline is to provide manufacturers with information concerning documentation to be submitted for approval and registration of the categories of products covered by this guideline.

The guideline consists of two sections, each section covering different class of products. Section I outlines sets of data which should be submitted along with an application for the first registration of surgical dressings, whereas section II enumerates requirements for the registration of surgical ligatures and sutures. Some sub-sections of this guideline are cross referenced with the ''Guideline on the Requirements for the registration of drugs for human use, July, 1996 edition. Consequently, the later guideline is to be considered as complementary to the former and users of this guideline are advised to use it in conjunction with the above guideline for the registration of human drugs.

It is also to be understood that all applications submitted to the Drug Control and Administration Authority should be original and in the English language. When any part of the document, except the package labeling, is originally written in another language, a legalized translation into the English language must be submitted along with the original version.

DEFINITION

For the purpose of this guideline, the following have the meanings hereby assigned to them:

1. "Absorbable surgical ligatures and sutures"- Threads or strand of materials which are digested by body enzymes or hydrolyzed by tissue fluids. They include the following:

   - cat gut (boilable, non-boilable)
   - reconstituted collagen
   - synthetic absorbable polymers
   - kangaroo tendon
   - ribbon gut and fascia lata

2. "Ligature" - A thread or a strand of material used to constrict and seal off a blood vessel.

3. "Medical supplies" - refer to surgical dressings; surgical Ligatures and sutures.

4. "New medical supply" is one which has not been previously marketed in Ethiopia through the regular and legal supply system before the issuance of this guideline.

5. "Non absorbable sutures and ligature"- strand of materials that are suitably resistant to the action of living mammalian tissue. They include the following:
   - Silk
   - Linen
   - Polyamides (Nylon)
   - Polyester
   - Polyolefins
   - stainless steel wire

6. "Surgical dressings" refer to a wide range of materials used for dressing of wounds. They are employed as coverings, adsorbents, protective or supports for injured or diseased parts and they include:
   - Bandages (of all kinds)
   - Cotton wools (" " ")
   - Gauzes (" " ")
   - Plasters (" " ")
   - Lints (" " ")
   - Other wound dressing materials.

7. " Suture" - A thread or a strand of material used to approximate, sew or stitch together the edges of various tissues and hold them in a position until healing has taken place.

REQUIREMENTS FOR THE REGISTRATION OF SURGICAL DRESSINGS

SECTION I:

1. **Aplication form**

1.1. The application form for surgical dressings registration (Form SD 01) consists of 2 pages with 14 numbered items to be filled out completely by the applicant (manufacturer or agent) (Please see Annex I, on page__)

1.2. The date of application should correspond to the date of submission of the application to the office of the Drug Administration and Control Authority.

2. **Agency Agreement**

2.1. An agency agreement should be made between the manufacturer of the product in question and the agent responsible for the sale of the product in Ethiopia

2.2. The agreement should be signed by both parties and the seal/stamp of both parties should also be affixed to the documents.

2.3. The agreement should specify that the representative chosen is the sole agent in Ethiopia..

2.4. The agent representing the manufacturer should hold a license issued by the Ministry of Trade.

3. Certificate of Good Manufacturing Practice (GMP)

3.1. The certificate of GMP should be that issued by the National competent authority.

3.2. The certificate should indicate

3.2.1. that the manufacturer has been approved and registered by the National competent authority as a manufacturer of surgical dressings;

3.2.2. the type(s) of surgical dressing(s) approved for manufacture;

3.2.3. that the manufacturing plant in which the product is produced is subject to inspection at suitable intervals;

3.2.4. that the manufacturer complies with the requirements of a guide to Good manufacturing practice for surgical dressings;

3.2.5. the date of the certificate is issued and the period of its validity.

3.3. The certificate should be original and current

3.4 The certificate should be authenticated by the Ethiopian Embassy in the country of origin. Were this prove to be difficult, consultation with the Drug Administration and Control Authority is necessary.

4. **Product Certificate**

4.1. as 3.1 above
4.2. The certificate should indicate:
4.2.1. the name of the product
(i.e official and brand names including synonyms);
4.2.2. the content of medicament/antiseptic, dye and other impregnating materials (if there are any);
4.2.3. the number and date of registration of approval for marketing.
4.2.4. that the product is freely sold in the country of origin; if not, the reasons, therefore should be clearly stated.

4.3. The certificate should be original and current.

NOTE: The certificate of GMP and product certificate may be included in one certificate or presented individually.

5. Technical documentation

5.1. Manufacturing and Packaging procedure

5.1.1. a concise description of the chemical treatment, processing and other methods of preparation mentioning the source and nature of the fabrics or fibers of the textile; including the final packaging and labelling procedures;

5.1.2. description on the precautions and In-process controls that are made in connection with different stages of the manufacturing process, that are of importance in ensuring the quality of the finished product;

5.2. **Specifications**

The applicant must submit a set of specifications for the examination of the final product and define the limits for each parameter to be tested.

However, specifications used by a manufacturer should at least include the specifications given in the monographs of USP and/or BPC and/or European pharmacopeia and/or Ethiopian standards as the case may be;

5.3. **Methods of Examination**

5.3.1. The manufacturer should submit appropriate method of examination of the surgical dressings with full details of the procedures to be followed and descriptions of the required apparatus and specific testing conditions such as atmospheric conditions. Should the manufacturer use the methods of examination and specifications contained in well known pharmacopeias or compendiums, reference can be made to these.

5.4. Stability study report (where applicable)

5.4.1. the manufacturer should determine the shelf life of his products that bear expiration date on the basis of a stability study and submit the data thus generated.

5.4.2. the stability data must show:

5.4.2.1. the type of surgical dressing
5.4.2.2. the batch number and size (minimum two)
5.4.2.3. date of manufacture
5.4.2.4. type and chemical nature of the packaging materials (test should be performed in the proposed market container-closure systems)
5.4.2.5. methods of examination
5.4.2.6 initial and all subsequent results of testing. The data must include the result of studies at suitable test intervals and must cover the whole shelf life of the product.
5.4.2.7 a summary consisting of proposed shelf-life and storage recommendations based on the data generated.

5.5. Sample of package labeling

5.5.1. package labeling includes package leaflet, label on the immediate container, and outer wrapper or carton.
5.5.2. four samples of one or more of the above package labeling materials or a catalogue which illustrates them and display the required information conspicuously should be submitted.
5.5.3. the label on the package or the package leaflet must:
(a) show the name of the product;
(b) state the length, width, type and other identification of the surgical dressing;

(c) show the name and proportion of any added medicament and impregnating materials
(d) give instructions for storage and handling
(e) indicate that the product is sterile (for sterile products)
(f) show the expiration dates, where it is relevant, and the batch number.
(g) Name and address of the manufacturer.

5.6. Nature/type of the immediate container/packaging material.

SECTION II:

REQUIREMENTS FOR THE REGISTRATION OF SURGICAL LIGATURES AND SUTURES

1. **Application Form**

1.1. As indicated in section I, No. 1.1.(Please see form SLS 01, Annex II)
1.2. As indicated in section I, No.1,2

2. **Agency Agreement**

2.1 As indicated in section I, No.2.1
2.2 As indicated in section I, No. 2.2
2.3 As indicated in section I, No. 2.3
2.4 As indicated in section I, No.2.4.

3. Certificate of Good Manufacturing Practice (GMP)

3.1. As indicated in section I, No.3.1.
3.2. The certificate should indicate

3.2.1. that the manufacturer has been approved and registered by the National competent authority as a manufacturer of surgical ligations and sutures;
3.2.2. the type (s) of surgical ligature (s) and suture(s) approved for manufacture;
3.2.3. As indicated in section I, No. 3.2.3.
3.2.4. that the manufacturer complies with the requirements of a guide to Good manufacturing practice for surgical ligatures and sutures;
3.2.5. as indicated in section I, No. 3.2.5.

3.3. As indicated in section I, No.3.3.

3.4. As indicated in section I, No.3.4.

4. Product Certificat

4.1. As indicated in section I, No.3.1.
4.2. The certificate should indicate;
4.2.1. the name(s) of basic raw material (s) from which the ligature/suture is manufactured;
4.2.2. the name(s) of color additive(s), preservative(s) and coating or impregnating materials(s) used;
4.2.3. As indicated in section I, No. 4.2.3.
4.2.4. As indicated in section I, No. 4.2.4.
4.3. As indicated in section I, No.4.3.

5. **Technical Documentation**

5.1. Manufacturing and Packaging Procedures

5.1.1. list of the basic raw materials from which the ligature/suture is manufactured..

5.1.2. the name(s) of color additive(s), preservative(s), and coating or impregnating materials used.

5.1.3. a brief and general description of the manufacturing methods and packaging procedure.

5.1.4. description on the precautions and in process controls that are made in connection with different stages of the manufacturing process, that are of importance in ensuring the quality of the finished product;

5.2. Specifications

As indicated in section I, No.5.2.

5.3. Method of examination

As indicated in section I, No. 5.3.1.

5.4. Stability study/report

As indicated in section I, No. 5.4.1- 5.4.2. inclusive, substituting "surgical dressings" by "surgical ligatures/sutures"

5.5. Sample of package labeling

5.5.1. as indicated in section I, No. 5.5.1.

5.5.2. as indicated in section I, No. 5.5.2.

5.5.3. the label on the package or the package insert must state:

a) the name and type of the suture/ligature
b) the size number;
c) the length of the strand (s) in cm or m,
d) whether the strand(s) are "plain", "hardened" or "chromicised";
e) the name(s) and percentage of any bactericide in the fluid;
f) that the product is sterile, if the product is sterile;
g) storage and handling conditions;
h) the expiration date, where it is relevant; and the batch number;
i) that the container should not be subjected to heat treatment;
j) that, for treated sutures, the suture is non capillary; and
k) other indications by which the history of the suture may be traced.

6. **Report on pre-clinical studies for new surgical ligatures and suture**

6.1. Safety study

All new ligatures and sutures that are to be implanted in the body must be intensively and extensively evaluated for safety and the following data must be submitted..

6.1.1. Toxicological Data (for absorbable sutures only)

6.1.1.1. Essentials of the Report

A report on a toxicology should consist of:

a) a summary
b) a description of the experiment system used;
c) a description of the species and strains of animals used;
d) the dose and site of implantation;
e) the critical parameters observed or measured before and after the commencement of the study
f) the results of the study with an appropriate statistical analysis and conclusion.

6.1.1.2. Types of toxicological studies to be performed

a) acute toxicity
b) chronic toxicity
c) teratology (for absorbable sutures and ligatures)
d) tumorigenicity
e) allergenicity and immunogenicity.

6.2. Surgical efficacy study

6.2.1. Essentials of the report

A report on the study of the efficacy of new surgical ligatures and sutures must include:

a) a summary
b) a description of the experiment system used
c) a description of the species and strains of animals used
d) the dosage level and site of implantation
e) a description of the critical clinical parameters or characteristics studied;
f) results of the study with an appropriate statistical analysis and conclusion: The results should be presented in tabular as well as graphical form.

NOTE: A study of the in vivo performance of absorbable ligatures/sutures should at least include:

- examination of the tensile strength retention (expressed in percentage of the original mass); and
- other characteristics such as non-capillarity, brittleness and other behaviors related to knot security and knot tying.

6.3. Pharmacokinetics study (for absorbable sutures/ligatures only)

A pharmacokinetics study must show:

- the rate and extent of absorption of the ligature/suture;
- the rate and extent of elimination of the metabolic products of the degradation of the suture/ligature;

7. **Report on clinical studies for new surgical ligatures and sutures**

The proof of safety and efficacy obtained using animals must be reproduced and demonstrated in clinical studies using human subject.

The report on such clinical trial should be compiled and presented according to the format outlined in section II, No. 6.2, of the "Guideline on the requirements for the registration of drugs for human use, which is part I of the consolidated guidelines.

ANNEX I

APPLICATION FORM FOR THE REGISTRATION OF SURGICAL DRESSINGS (FORM SD01)

Drug Administration and Control Authority
Drug Evaluation and Registration Department
P.O.Box 5681
Addis Ababa, Ethiopia

1. Date of application: _____
2. Official name of the product: _____
   Synonymes _____
   Brand name _____
3. Presentation _____
4. Packages:
   Chemical nature _____
   Pack size _____
5. Shelf life _____
6. Registration number of the product in the country of origin
   _____
7. Name and address of the manufacturer _____
   _____
8. License number of the manufacturer _____
9. Name and address of the agent representing the manufacturer

_____
_____
_____

10. Nature and source of the material used for manufacturing the textile

_____
_____
_____

11. Content of medicament/antiseptic and other impregnating materials.

Chemical constituent	Strength
_____	_____
_____	_____
_____	_____
_____	_____

12. Use of the product:

_____
_____
_____

13. Regulatory status in other countries (indicate also the date)

a) Marketed with out approval ☐

b) Approved and marketed ☐

c) Under Trial ☐

d) Withdrawn, if any with reasons _____

14. Supporting Documents or Documents attached _____

_____

_____

Name, official Designation and Professional status of the Applicant _____

_____

_____

_____

Signature _____

TO BE FILLED IN BY AUTHORITY

Application No _____

Date of Receipt _____

Approved subject to conditions (date) _____

Finally approved _____

Registration Date _____

Registration No._____

Name and signature of authority

_____

ANNEX 2

APPLICATION FORM FOR THE REGISTRATION OF SURGICAL LIGATURES AND SUTURES (form SLS 01)

Drug Administration and Control Authority
Drug Evaluation and Registration Department
P.O.Box 5681
Addis Ababa, Ethiopia

TO BE FILLED IN BY APPLICANT

1. Date of Application _____
2. Official name of the product _____
   Synonym _____
   Brand name _____
3. Gauge number _____
4. Presentation _____
5. Packages:
   Chemical nature _____
   Pack size _____
6. Shelf life _____
7. Registration number of the product in the country of origin
   _____
8. Name and address of the manufacturer _____
   _____
   _____
9. License number of the manufacturer _____
10. Name and address of the agent representing the manufacturer
    _____
    _____
    _____
    _____
11. Nature and source of the basic material used for manufacturing the ligature/suture
    _____
    _____
    _____
12. List of color additive(s), preservative(s), and coating or impregnating material(s):

Chemical constituent	Strength
_____	_____
_____	_____
_____	_____
_____	_____

13. Category of the product:

Absorbable ☐
Non-Absorbable ☐

14. Sterility:
Sterile ☐
Non-Sterile ☐

15. Use of the product: _____
_____
_____

16. Regulatory status in other countries (indicate also the date):

a) Marketed without approval ☐
b) Approved and marketed ☐
c) Under Trial ☐
d) Withdrawn, if any, with reasons _____
_____

17. Supporting Documents attached. _____
_____
_____

Name, official designation and professional status of the applicant _____
_____
_____
_____

Signature
_____

TO BE FILLED IN BY

AUTHORITY

Application number _____
Date of Receipt _____
Approved subject to conditions (date)_____
Finally approved _____
Registration date _____
Registration number _____

Name and signature of authority

_____

GUIDELINES

ON THE REQUIREMENTS

FOR THE REGISTRATION OF MANUFACTUERERS OF

MEDICAL DEVICES

Part IV

Content

Page

INTRODUCTION

The objective of this guideline is to provide manufacturers of medical devices with information concerning documentation to be submitted by them in order to be registered with the Drug Administration and Control Authority.

The guideline consists of two sections: section I dealing with official documents and section II dealing with information associated with the profile of the applying company.

All manufacturers intending to import their medical devices into Ethiopia are required to apply to Drug Administration and Control Authority for prior registration and product listing. Application forms are obtainable from the Authority.

Definitions

1."Diagnostics" are biochemicals which are used to test organ function, determine blood volume, and hemopoietic function or reveal anatomic evidence of disease or other conditions by outlining various body structures and cavities. It includes all biochemicals, such as reagents, antibiotic sensitivity discs and test kits for diagnosis of disease and other conditions (e.g. pregnancy)

2. " Invitro diagnostics" refer to diagnostics which are used outside the body or which do not achieve any of their principal intended purposes by chemical action in or on the body or by being memtabolize.

3." Invivo diagnostics" refer to diagnostics which are administered or appleid to human beings and achieve their principal intended purposes by chemical action in or on the body or by being metabolized. Diagnostics which work by such chemical or metabolic action are regulated as "drugs".

4. " Medical device" includes medical equipment and invitro diagnostics.

5. " Medical Equipment" are health care instruments which do not achieve any of their principal intended purposes by chemical action in or on the body or by being metabolized. Instruments or articles which work by such chemcial or metabolic action are regulated ad drugs.

The term " Medical equipment" includes a great number of instruments and appliances such as thermometers, B.P apparatuses, syringes and needles, catheters, gloves, tubes of all kinds, cardiac devices, kidney dialysis machines, microscopes, x-ray machine and electronic devices to name a few.

6. " New diagnostic" is one which has not been previously marketed in Ethiopia through the regular and regal supply system before the issuance of this guideline.

SECTION I LEGALIZED DOCUMENTS

This section deals with certificates and legalized documents) to be submitted for registration.

1. **Certificate of compliance with manufacturing standards**

1.1. The applicant should submit:

1.1.1. A photocopy of valid manufacturing License issued by the National competent authority;

1.1.2. A valid quality system certificate issued by a recognized certifying authority (e.g. ISO, DIN, TUV, BSI, etc.) , if available.

1.1.3. A confirmatory letter issued by the National competent Authority which indicates the names of the products and explains whether the products are freely sold in country of origin; If not, the reasons, therefore should be clearly stated.

1.2. The documents indicated in 1.1.1. to 1.1.3 above should be authenticated by the Ethiopian Embassy in the country of origin.

2. Agency agreement

2.1. An agency agreement should be made between the manufacturer and the agent responsible to act on behalf of the manufacturer.

2.2. The agreement should specify that the representative is the sole agent in Ethiopia.

2.3. The agreement should be signed by both parties.

2.4. The agent representing the manufacturer should hold a license issued by the Ministry of Trade.

SECTION II COMPANY PROFILE

This section deals with documents to be supplies by the manufacturer.

1. **Back ground information**

The manufacturer should submit background information about the company indicating the following major points.

1.1. year of establishment,
1.2. Development since establishment,
1.3. Capital,
1.4. Organogram (organizational chart of the company)
1.5. Total working force,
1.6. Ownership,
1.7. Subsidiaries if any)

2. **Production Unit**

The manufacturer should describe, in words or in schematic presentation, the production system and in process standard control mechanism.

3. **Quality Control Units**

The manufacturer should describe the quality control procedure on raw materials, and finished products

4. **Research and Development Unit (R and D), if there is any**

The manufacturer should give detailed information on at least the following major points.

4.1. The year R and D was initiated
4.2. Qualification of the personnel engaged in R and D
4.3. Major research areas and achievements attained.,
4.4. Affiliation with other institutions (if there is any)

5. Product Registration and Marketing Experience of the Industry (Manufacturer)

The manufacturer should submit full information on its marketing experience and registration status of its products indicating:

5.1. List of countries to which it exports most of its products.
5.2. List of countries in which its products or the company itself is registered
5.3. List of countries where its product(s) has/have been withdrawn from the market. (if so, give reasons for withdrawal).

6. **Samples of package labelling (for manufactuerers of diagnostics only)**

6.1. Package labeling includes package leaflet, label on the immediate container, and outer wrapper or carton. All of the labelling information required must be in English.

6.2. Four samples of one or more of the above package labelling materials or a catalogue which illustrates them and display the required information conspicuously should be submitted.

6.3. The label on the container must:

a) state the name and chemical formula,
b) show hazard symbols and safety recommendations
c) percentage content of the main substance 9s)
d) expiry date (where it is applicable) and batch number.

6.4. The accompanying package insert or catalogue or manual for test kits must, in addition to the information indicated in (1) (c) above, state:

a) use or application
b) test principle
c) testing procedure
d) reagents/test kit
e) specimen
f) calculations
g) interpretation of results
h) reference values (normal values or negative and positive reactions)
i) interference
j) specificity
k) accuracy, reliability and reproducibility of the test
l) storage instructions
m) instruction for the disposal of the diagnostic (i.e how to convert the diagnostic to ecologically acceptable or harmless compound)
n) presentation (how supplied); and
o) other precautions or inforamtion.

ANNEX I

APPLICATION FORM FOR THE REGISTRATION OF MANUFACTURERS OF MEDICAL DEVICES

FORM MMD/R

TO:
_____
_____

1. Date of application: _____
2. Name and address of the Manufacturer:

_____
_____

3. License number of the manufacturer in the country of origin

_____

4. Documents attached:
   Certificate of compliance with manufacturing standards.
   Agency agreement ☐
   Company profile ☐
   Consent form ☐

Other (please specify below)

_____
_____
_____

Name and official/designation of the applicant (person(s) representing the manufacturer).
_____
_____

Signature _____
Date _____

ANNEX 11

CONSENT FORM

We, ……assure you that the legalized documents, the company profile, and other documents that we have submitted are true and correct.

We agree to inform the Drug Administration and Control Authority, of Ethiopia, about any change or modification made on the information given in the documents submitted.

We also agree to allow officials from the Drug Administration and Control Authority ,of Ethiopia, to visit and have first-hand information about the industry at any time

We recognize and accept the right of the Drug Administration and Control Authority of Ethiopia, to suspend or to revoke the registration certificate that is already issued to us if any fraud or anything contradictory to our registration documents is discovered.

Signed by:

Person authorized to
Sign on behalf of the manufacturer

Date:

(Manufacturer's full name and address)