STANDARDS FOR THE ESTABLISHEMENT AND PRACTICE OF PHARMACEUTICAL COMPOUNDING LABORATORY

Drug Administration and Control Authority (DACA) of Ethiopia

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I. INTRODUCTION

The drug products available in the market are mostly ready-made finished drug products. These are manufactured in industries using the standard on Good Manufacturing practice. This is done to produce effective, safe, and quality drug products.

But it is a common practice to prepare topical preparations in compounding laboratories in premises like Hospital Pharmacies and retail pharmacies. These are prepared extemporaneously for individual patients, or in bulk. And these preparations, like other finished drug products, should fulfill efficacy, safety, and quality parameters. These are achieved through established standards that Guides the preparation of compounded pharmaceutical products.

However, in the Ethiopian situation in premises where it is applicable, the compounded pharmaceutical products are prepared without the set requirements and procedures; where basic equipments are not available and in the absence of qualified personnel. In most of the hospital pharmacies, retail pharmacies, and Regional health bureaux the compounding laboratory practice is not well exercised and full attention is not given.

And the preparation of compounded pharmaceutical products are carried out traditionally without uniformity and continuity. This is attributed to the absence of standard that guides the preparation of compounded Pharmaceutical Products. In order to systematize and enable Pharmacy Professionals prepare quality pharmaceutical products, it is a timely need to standardize pharmaceutical compounding laboratories. It is on the above backgrounds that the development of this standard becomes the necessity.

1.1. OBJECTIVES OF THE STANDARD

Objectives of the standard is:-

- To give guidance to Regional Health Bureaux, Hospitals, and Pharmacies that intend to establish and run a pharmaceutical compounding Laboratory.
- To adhere the set-up and the practice of Good Pharmaceutical Compounding Laboratories.
- To enable institutions in the preparation of quality pharmaceutical preparations intended for use.

1.2 SCOPE OF THE STANDARD

This standard applies to Regional Health Bureaux, (RHB) Hospitals and community pharmacies

1.3 DEFINTION

The definition and interpretation contained in section of this standard shall be applicable to such terms when used in this part and throughout this document.

1. ***A Pharmaceutical compounding***, in this standard, means the preparation of bulk topical pharmaceutical products, reagents for diagnostic laboratory in bulk and extemporaneous medical drugs to fill a prescription written for a patient by licensed physician.

2. ***Active ingredient –*** means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease

3. ***Batch number or control number*** – means any distinctive combination of letters, numbers, or symbols, or any combination of them from which the complete history of the preparation, processing, packing, holding and distribution of a batch or lot of drug product or other material can be determined.

4. ***Batch*** – means a specific quantity of a drug or other material that is intended to have a uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

5. ***Label*** – means a display of written, printed, or graphic matter upon the immediate container of any drug product or material.
6. ***Package*** – means the immediate container or wrapping in which any preparation is contained for use or storage.

7. ***Reagents*** – are substances used either as such or a constitutes of solutions.

8. ***Strength*** – means the concentration of the drug substance for example weight/ weight, weight/volume, or unit dose/volume basis.

9. ***Bulk preparations*** – are preparations prepared in large volumes or in masses, intended to be used for a short period of time. Not to be stocked for long period.

II. REQUIREMENTS FOR ESTABLISHING PHARMACEUTICAL COMPOUNDING LABORATORY

1. SITE

1.1 The site for a compounding laboratory should be appropriate for the purpose of preparing good quality product and protected from contamination of any type.

1.2 The pharmaceutical compounding laboratory should be within the compound of the premises.

1.3 The laboratory should be far from areas or premises, that can cause contamination to the Raw materials or finished products, and equipment, such as bacteriological laboratory, kitchen, waste disposal site and other similar areas.

1.4 The laboratory should not allow access to personnel other than those authorized to undertake or assist in compounding activities.

2. INFRASTRUCTURE

2.1 The Pharmaceutical Compounding Laboratory shall have adequate supply of water of acceptable quality for cleaning, preparation, dilution, etc. purposes.

2.2 The compounding Laboratory shall have electricity for the purpose of lighting, distillation, heating, melting and other related activities.

2.3 The laboratory shall have a drainage system that allows the clearance of dirty water after cleaning.

2.4 The compounding laboratory shall have enough benches on which preparation takes place and should be made from materials easy for cleaning.

2.5 There shall also he adequate laboratory chairs, shelves.

2.6 The compounding laboratory shall be equipped with fire extinguisher.

3. PERSONNEL

3.1 A pharmaceutical compounding laboratory should be headed by a registered pharmacist who will be in charge /control/ of the overall compounding process.

3.2 A pharmaceutical compounding laboratory shall also have supporting staffs such as senior or junior pharmacy technicians if necessary.

3.3 Other supporting staff for cleaning, other manual work shall be deployed whenever possible.

4. PREMISES

4.1 A pharmaceutical compounding laboratory shall have adequate number of rooms suitable for the purpose of pharmaceutical compounding.

4.2 A pharmaceutical compounding laboratory shall have rooms of minimum sizes as indicated blow:

S/N	Room	No	Size	Height	Site
1	Staff Room	1	3×2 sq.m	As required	All sites except community pharmacies
2	Compounding Room	1	4×4 sq.m	2.7 m	RHB
3	Compounding Room	1	3×3 sq.m	2.7 m	Hospital and community pharmacy
4	Toilet	1	As required	As required	All

4.3 The walls, floor ceilings, and floor of a compounding laboratory shall be smooth, have no cracks or holes.

4.4 The walls, floor and ceilings shall be painted and/or made of washable material.

4.5 The compounding room shall have adequate light and ventilation (ventilator, etc.)

4.6 The compounding room should be protected from direct sunlight.

4.7 The window(s) of the compounding room shall be high enough and sealed.

5. EQUIPMENT

Equipments should be spaced out in order to avoid congestion, and to minimize the risks of confusion and contamination.

A pharmaceutical compounding laboratory should have the following minimum types of equipment, utensils and working materials.

A. Equipment and materials for compounding Labs. In Regional Health Buraux, and Hospitals.

Ser. No.	Description
1.	Working bench
2.	Mortar and Pestle of 250 ml.
3.	Water Distillator, Stainless Steel of 20 liter/HR Capacity, 220 V
4.	Electrical Water Bath, Stainless Steel of four openings, 220 V
5.	Electrical Hor-Plate, 121x24"W stainless steel, 220 V
6.	Spatula Stainless Steel, Blade Length 10"
7.	Evaporating dish glazed inside, 250 ml capacity
8.	Even-Arm Balance of 1 kg capacity
9.	Asbestos Gloves 11" long
10.	Solid Glass Spherical Beads 6mm Diameter
11.	Wash Bottle 250 ml capacity, Polyethylene
12.	Funnel Lab. Ribbed 160mm Dam Polyethylene or glass
13.	Funnel Lab. Pouring, 220 mm Dam. Polyethylene or glass
14.	Glass Rod 5, 6, and 7 mm of 1 lb.
15.	Beaker Lab. Low-Rim with Spouts and Rolled Rims (Glass) 250 ml.
16.	Beaker lab. Law-Rim with Spouts and Rollde Rims (Glass) 400 ml.
17.	Beaker lab. Low-Rim with Spouts and Rolled Rims (Glass) 1000 ml.
18.	Flask Volumetric Lab. 250 ml. HRG
19.	Flask Volumetric Lab. 500 ml. HRG
20.	Flask Volumetric Lab. 1000 ml HRG
21.	Aspirator Rigid of 25 Liters Capacity Polyethylene
22.	Stainless Steel Bucket, 20 – 30 liters capacity 2 with handle and cover
23.	Heavy Duty Stirrer, 220v, 18" Impeller
24.	Analytical Balance
25.	Container Stainless steel 50 liter capacity
26.	Capping machine (e.g. Corking machine)

B. Equipments and Materials for Compounding Laboratory in Community Pharmacy

Ser. No.	Description
1.	Analyticl Balance
2.	Mortar & Pestle 250 ml
3.	Hot water bath, electrical
4.	Hot plate, electrical
5.	Spatula, stainless steel
6.	Ointment tile
7.	Wash bottle
8.	Funnel (glass or poly ethelene)
9.	Beaker (different sizes)
10.	Graduated cylinders (different volumes)
11.	Glass rod

III. WORKING PROCEDURES

6. SANITATION

6.1 All mixing and packing containers and other utensils used in the compounding process shall be cleaned before and after each preparation.

6.2 All equipment on the compounding laboratory shall be protected from dust and other adverse factors that may alter their proper functioning.

6.3 The compounding laboratory rooms shall be clean and free from accumulate waste and vermin.

6.4 The compounding laboratory shall have a written sanitation programme indicating:

- Areas to be cleaned and cleaning intervals;
- Cleaning procedures to be followed and whenever necessary, equipment and materials to be used for cleaning, and
- Personnel assigned to and responsible for cleaning operations.

6.5 Eating, smoking and other unrelated activities shall not be permitted in compounding room.

6.6 All personnel involved in the compounding laboratory should wear appropriate working clothes (e.g. Gown and ahead covering)

7. DOCUMENTATION

7.1 All documents of the raw materials, and compounded products shall be kept properly.

7.2 Record books for writing working formula and other relevant information shall be neatly kept.

7.3 Other records related to stock and distribution shall be maintained to control the movement of compounded products.

7.4 Original prescription or a copy of the prescription shall be retained when compounding for individual patient. Each prescriptions shall bear an appropriate control number.

8. STARTING MATERIALS

8.1 All starting materials shall be handled, i.e. received and quarantined, identified, stored, labeled (if originally not labeled) and issued in accordance with written instructions.

8.2 Documents and relevant records pertaining to sub-Article 9.1 shall be kept as per the procedures stipulated under Article 8.

9. BULK AND EXTEMPORANEOUS PREPARATIONS

a) Bulk Preparations

Products intended to be produced in bulk shall be prepared according to the following procedures (Regional Health Bureau and Hospitals)

9.1 A Master Formula for each type of pharmaceutical product should be available and be used during all preparation activities.

9.2 A working Formula should be worked out depending on the quantity /volume/ of the product under preparation and displayed during each compounding process.

9.3 The Working Formula shall bear the signature of the technician who has done the weighing process and shall be counter-checked and signed by the Professional in charge of the compounding laboratory.

9.4 The Working Formula shall be copied along with the directives on the working formula sheet.

9.5 The Working Formula Sheet shall indicate: Name of the RHB or Hospital Type (Name) of the preparation and amount to be prepared name and weight of ingredients used, control number (batch number), date of preparation, name of the person on preparation, and time taken to complete the preparation.

b) Extemporaneous preparation

A compounded product intended for individual patient shall be prepared in accordance with a written prescription. (Hospital and Community Pharmacy)

9.6 The prescription shall be copied to the working sheet indicating: Patient name, age, sex and address, type and quantity of each active ingredient used, time the preparation started and completed, name of the person on compounding, signature of the professional in-charge of the lab.; name and qualification of the prescriber, date of the prescription and compounding and control number, according to the working procedure.

9.7 Each preparation shall be given a control number that enables follow-up and control activities. The control number shall be recorded on the original or copy of the prescription retained in the compounding laboratory.

9.8 The control number on the working sheet and finished preparation shall be identical and should be checked before dispensing the product.

10. PACKAGING AND LABELING

10.1 Suitable and standard type of packaging material should be used for all finished compounded products.

10.2 Bottles or containers that show visible sign of dirt, or crack or dust shall not be used as packaging material.

10.3 All bulk preparations shall bear an appropriate label written in an indelible ink.

10.4 The label on bulk preparations shall bear the following:

- Name of the product
- Date of preparation
- Batch number
- Volume /weight/ of the preparation
- Name and address of the compounding institution
- Storage condition

10.5 Labels on compounded products for individual patient shall have the following information:

- Name of Patient and Address
- Quantity of each ingredient used
- Dose and administration
- Storage condition
- Name and Address of the compounding institution
- Volume or total weight
- Date of preparation
- Control number

10.6 Packaging and Labeling material shall be stored, handled and stocked in a way that enables control and avoid intermixing.

11. FINISHED PREPARATIONS /PRODUCTS/

Finished bulk preparations shall be stored in accordance with the standard pharmaceutical storage procedure and desegregated by batch and date of preparation.

12. WASTE DISPOSAL PROCEDURE

12.1 The materials unfit for distribution whether starting material, packaging and/or finished products shall be disposed as per the disposal guideline

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12.2 All rejected materials shall be clearly identified, recorded and stored separately before disposal or return to the supplier in the case of starting materials.