	Title: GUIDELINES FOR SMALL SCALE MANUFACTURING OF PHARMACEUTICALS, COSMETICS, NUTRITIONAL AND CHEMICAL AGENTS IN SIERRA LEONE	
Rev No: 02	**Doc No: PBSL/GL/015**	Version no. 03
Issue date: 15 May 2024	**Effective date: 17 May 2024**	Approved by: Registrar

Adopted By PBSL	
Start of public Consultation	
End of public Consultation	
Agreed by QMS committee	
Approved by Board	

Pharmacy Board of Sierra Leone

PMB 322

Central Medical Stores Compound

New England Ville

Freetown

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1.0 INTRODUCTION

Small Scale pharmaceuticals, cosmetics, chemical industries are industries that are extremely small in scale or scope or capability. Having two (2) or three (3) staff members and a share capital business of not more than fifty million Leones.

A small industry of pharmaceuticals, chemical, nutritional and cosmetics product operation still has to comply with the labeling, adulteration and other provisions found in the Pharmacy and Drug Act and regulation of the Board. It is necessary to emphasize that no pharmaceuticals, cosmetics, chemical agents and the nutritional products should be manufactured, imported, exported, advertised, sold or distributed in Sierra Leone unless it has been registered in accordance with the provisions of the Pharmacy and Drug Act 2001, Part V and VI. Consequently, the products shall not be

manufactured in Sierra Leone unless the factory is inspected and certificate of recognition is issued by PBSL.

2.0 OBJECTIVES

These guidelines aims to prescribe the minimum Good Hygiene Practice (GHP) requirements for the facilities, controls to be used in the manufacture, processing, and packaging of small scale products to ensure that they meet good manufacturing practice.

3.0 SCOPE

These guidelines are for the general public and in particular individual that wants to engage in manufacturing of pharmaceutical, cosmetics, chemicals and nutritional agents on a small-scale.

4.0 SPECIFIC REQUIREMENTS

4.1 GENERAL

4.1.1 Small Scale pharmaceuticals, cosmetics, chemical industries are industries that are extremely small in scale or scope or capability. Having two (2) or three (3) staff members and a share capital business of not more than fifty million Leones.

4.1.2 These guidelines are for the general public and in particular individual that wants to engage in manufacturing of pharmaceutical, cosmetics, chemicals and nutritional agents on a small-scale.

4.1.3 Special PBSL numbers will be granted to companies in this category.

4.1.4 These guidelines prescribe the minimum Good Hygiene Practice (GHP) requirements for the facilities, controls to be used in the manufacture, processing, and packaging of small scale products to ensure that they meet good manufacturing practice.

4.1.5 A small industry of pharmaceuticals, chemical, nutritional and cosmetics product operation still has to comply with the labeling, adulteration and other provisions found in the Pharmacy and Drug Act and regulation of the Board.

4.1.6 It is necessary to emphasize that no pharmaceuticals, cosmetics, chemical agents and the nutritional products should be manufactured, imported, exported, advertised, sold or distributed in Sierra Leone unless it has been registered in accordance with the provisions of the Pharmacy and Drug Act 2001, Part V and VI. Consequently, the products shall not be manufactured in Sierra Leone unless the factory is inspected and certificate of recognition is issued by PBSL.

4.2 PERSONNEL

4.2.1 There should be at least 2 or 3 qualified personnel to perform assigned duties.

4.2.2 Personnel should practice good sanitation and hygienic habits

4.2.3 Each personnel engaged in the manufacturing process should have

a) Basic education /Adequate Training and relevant experience in the manufacturing process

4.2.4 Personnel should wear protective gears, such as head, face, hand, and arm coverings to protect products from contamination.

4.3 BUILDING/FACILITIES

4.3.1 PRODUCTION AREA.

i. The apartment provided for production can either be a purpose-built structure or an existing standard room, with a separate entrance and exit.

ii. Must be adequate for the orderly placement of equipment and materials to prevent mixups between different materials.

iii. Windows and entrance doors should be screened with insect-proof netting and the doors should be self-closing to prevent contamination.

iv. Adequate ventilation, cooling, lighting should be provided in all areas in order to facilitate easy identification of materials, cleaning, maintenance and proper operations.

4.3.2 FINISHED PRODUCT STORE

All finished products must be stored on pallets in a cool dry place to prevent contamination and adulteration caused by an insect, household chemicals, water damage and unsanitary condition.

4.4 EQUIPMENT

4.4.1 The design of equipment should be such as to make it adequate and suitable for its intended use.

4.4.2 Its layout and design must aim to minimize the risk of mix-ups and permit effective cleaning and maintenance in order to avoid cross-contamination, the build-up of dust, dirt or any other contaminant that can affect the quality of the product.

4.4.3 The parts of the equipment that makes contact with products should be made of non-toxic/non-reactive materials.

4.5 RAW/PACKAGING MATERIALS AND SOURCE

4.5.1 Raw and packaging materials should be purchased from traceable sources.

4.5.2 They should be of good quality and standards.

4.5.3 All incoming materials should be stored under appropriate storage conditions.

4.6 QUALITY ASSURANCE/QUALITY CONTROL

Small Scale Producing industry are required to send samples of their finished products to a public analyst for comprehensive analysis and document same in a file while rectifying any anomaly in the parameter reading by carrying out the needed process change(s) for the overall product quality conformity.

4.7 ENVIRONMENTAL SANITATION AND PERSONNEL HYGIENE

4.7.1 Appropriate sanitation measures should be taken to avoid contamination risks of all kinds.

4.7.2 The entire production area(s) should be cleaned frequently and thoroughly in accordance with the standard operational procedure (SOP) for cleaning.

4.7.3 Equipment should be thoroughly cleaned in strict compliance to the SOP.

4.7.4 Water system toilets and washing facilities should be appropriately located, designed, equipped and the sanitation shall be maintained satisfactorily in strict compliance to the SOP.

4.7.5 Eating, Drinking and Smoking should not be permitted when production is ongoing in the production area.

4.7.6 Production staff should undergo a medical examination at least once a year.

4.7.7 Persons known to be suffering from communicable diseases or with wounds should be excluded from duty until they are certified medically fit.

4.7.8 Wastes should be adequately disposed of in strict compliance to the SOP.

4.8 DOCUMENTATION

The aim of documentation is to define the specification for all materials and methods of manufacture and control, to ensure that all personnel concerned with manufacturing process know what to do and when to do it. The required documentation includes the following:

4.8.1 Standard Operating Procedure (SOP's) for Production.

4.8.2 Standard Operating Procedure for cleaning of equipment and production area(s).

4.8.3 Standard Operating Procedures for Waste Disposal.

4.8.4 Standard Operating Procedures for pest control/Fumigation certificates

4.8.5 Standard Operating Procedures for fire prevention

4.8.6 Personnel File (Education Certificates and Training or experience records)

4.9 CONSUMER COMPLAINT AND RECALL

All consumer complaints must be thoroughly investigated and documented and steps must be taken to prevent future occurrence. If a recall is decided upon, it should be done quickly using the production batch history through the product distribution records. All records of recalled products must be kept. In event of recall, PBSL must be fully notified of all actions at the receipt of a customer(s) complaint, during the investigation and actual recall activity.

4.10 DISTRIBUTION SYSTEM

Record of product distribution network must be properly kept for easy recall of defective products. Distributors' names, addresses, phone, email etc. should be obtained.

4.11 TRANSPORTATION AND HANDLING:

Products should be handled and transported under conditions which prevent deterioration, contamination, spoilage, and breakage to ensure that the product quality is maintained up to the time of delivery to the consumer.

4.12. LABEL

The product should be labeled adequately in the English language. The label should also contain composition/ingredient(s) list, and within the label should be stated the net weight/volume of content, address, lot/batch number, production date, expiry date, direction for use (see guidelines for registration of medicinal products)

4.13. PRODUCT REGISTRATION

The products manufactured should be registered with PBSL upon industry registration (See guidelines for registration of medicinal products) following documents will be submitted for the processing of the product

(a) A letter requesting for production inspection addressed to the Registrar, Pharmacy Board of Sierra Leone.

(b) The letter should be accompanied by the following:

- Standard Operating Procedures (SOP) for Cleaning equipment,
- SOP for Sanitation of environment,
- SOP for Hygiene of personnel.
- List of equipment,
- Certificate of Fumigation,
- Certified copy of Company registration,
- Business registration documents,
- Vetted label/primary packaging material and
- Registration of Product Brand

(c) Letter of request should be submitted to the PBSL accompanied with all the above-listed documents and be submitted to the Pharmacy Board of Sierra Leone.

5.0 GLOSSORY

NONE

6.0 REFERENCES

NONE

7.0 ANNEXES

NONE

Prepared by	***Reviewed by***	***Approved by***
Head of FIIC	Head, Quality Assurance	Registrar
Dr Abdulai Kanu	Dr Michael Lahai	Dr James P. Komeh