



**APPLICATION FORM FOR THE  
REGISTRATION OF MEDICINAL  
PRODUCTS**

PBSL-F-73/01



**Applicant's  
Check list**

**PBSL  
Double Check**

- Covering Letter
- Signed Declaration
- Fully Completed Application (Appendix I-V)
- Drug Master File
- Complete filled Batch Manufacturing Records (BMR)
- Certificate(s) of Analysis (Raw Materials)
- Certificate of Analysis (Finished Product)
- Certificate of Pharmaceutical Product (CPP)
- Certificate of registration from country of origin
- Stability Studies Protocol/Report for three batches
- Name and Address of Qualified Persons
- Samples of the Product
- Primary Standards
- Four (4) Copies of Label and Packaging Material
- Four (4) Copies of Package Insert

**Applicant**

**PBSL Staff**

Name:\_\_\_\_\_



Name:\_\_\_\_\_

Signature:\_\_\_\_\_

Signature:\_\_\_\_\_

Date:\_\_\_\_\_

Date:\_\_\_\_\_

	<b>APPLICATION FORM FOR THE REGISTRATION OF MEDICINAL PRODUCTS</b>	
	<b>PBSL-F-73/01</b>	

(To be submitted in duplicate)

Cover letter addressed to:

**THE PHARMACY BOARD OF SIERRA LEONE  
CENTRAL MEDICAL STORES COMPOUND  
NEW ENGLANDVILLE  
JOMO KENYATTA ROAD  
FREETOWN  
SIERRA LEONE  
P. M. B. 322  
E-mail: [pharmbdsl@hotmail.com](mailto:pharmbdsl@hotmail.com)**

Samples and printed matter should be forwarded to the Board through the local agent; customs duty and clearance to be effected by the applicant in all instances.

<b>A. PARTICULARS OF PRODUCT</b>
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Proprietary name.....

Approved name (INN).....

Dosage form:.....Strength:..... Colour:.....

Commercial presentation(s):.....

Country of Origin.....

Category of distribution:

*Restricted prescription-only distribution  
(Specify, e.g., hospitals only)*

*Scheduled narcotic*



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*POM (Prescription only medicines)*

*P (Pharmacy medicine)*

*OTC (Over-the-counter medicine)*

Pharmacological classification:.....

**B. PARTICULARS OF APPLICANT**

Name of Applicant:.....

Business Address:.....

.....

.....

.....



Phone:..... Fax:.....

E-mail:.....

N.B Post office Box or Private mail Bag unacceptable.

**C. PARTICULARS OF MANUFACTURER**

Name of manufacturer:.....

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Premises address:.....  
.....  
.....

Postal address:.....

Phone:..... Fax:.....

E-mail .....

N.B Post office Box or Private mail Bag unacceptable.

**D. PARTICULARS OF LOCAL AGENT**

Name of local agent:.....

Business address:.....



Phone:..... Fax:.....

E-mail:.....

**E. CERTIFICATION BY A RESPONSIBLE PERSON IN THE APPLICANT COMPANY**

***Certification***

I/We the undersigned certify that all the information in the accompanying documentation concerning this application for registration for:

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Proprietary name:.....

Approved generic name(s)[INN]:.....

Strength(s) per dosage unit:.....

Dosage form.....

Applicant company:.....

.....

is correct and true, and reflects the total information available.



Name:.....

Position in company:.....

Signature:.....

Date:..... Official Stamp:.....

**APPENDIX I  
GENERAL PRODUCT SPECIFICATIONS**

	<b>APPLICATION FORM FOR THE REGISTRATION OF MEDICINAL PRODUCTS</b>	
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Name of drug.....

Name of applicant.....

Dosage form..... Strength..... Colour.....

(a) Attach list of all active ingredients in the format illustrated in the example below:

Approved chemical name	Quantity per dosage unit	Reason for inclusion of ingredient	Specification
Paracetamol	325 mg	Analgesic/Antipyretic	BP
Diclofenac sodium	50 mg	Analgesic/antiinflammatory	BP

(b) Attach list of all non active ingredients in the format illustrated in example below:

Approved name of Ingredient	Quantity per dosage unit	Specification	Reason for inclusion of ingredient
Starch	112.6 mg	BP	Binder
Magnesium stearate	2.0 mg	BP	Lubricant

(c) Additional raw materials (if any) used in the manufacturing process but not present in the final product.

(d) Give specifications of packaging materials (where no specifications for packaging materials exist, this must be mentioned)



.....  
 .....

(e) List any ingredient liable to cause dependence and /or listed in the United Nations lists of psychotropic and narcotic drugs?

.....

Reference to the following publications will, where applicable be accepted:

- I. British Pharmacopoeia
- II. European Pharmacopoeia

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- III. United States Pharmacopoeia
- IV. International Pharmacopoeia
- V. British Pharmaceutical Codex
- VI. Extra Pharmacopoeia
- VII. Such other works of reference as may be approved by the Board from time to time

**APPENDIX II**

**PARTICULARS OF MANUFACTURING PROCEDURE, RELATED CONTROLS AND DOCUMENTATION**

Name of Drug.....

Name of Applicant .....

Dosage Form.....Strength ..... Colour .....

(a) Give a brief summary of the manufacturing procedure

.....

.....



.....

(b) Indicate the particulars of manufacturer(s) of each raw material used in the table below:

Name of raw material	Name of manufacturer	Address

Attach the following:



- (i) Original copies of certificate(s) of analysis of raw material
- (ii) Certificate(s) of in-house quality control tests performed on raw materials

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- (c) Attach a copy of a complete Drug Master File and process validation protocols for the manufacture of this product.
- (d) Attach the complete filled batch records including the final analytical report and authorization for release.
- (e) Attach names, addresses and qualifications of Authorized Person(s) in charge of production, quality control, packaging and release of product
- (f) State estimated shelf-life of drug .....
- (g) Provide stability data and justification on which shelf life has been predicted\*

.....



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**\*Refer to PBSL Guidelines for Registration of Medicinal Products**

**APPENDIX III  
ADMINISTRATIVE STATUS OF THE PRODUCT**

Name of Drug: .....

Name of Applicant: .....

Dosage Form: .....Strength: ..... Colour:.....

(a) Attach a copy of Certificate of Pharmaceutical Product issued by the competent authority in accordance with the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

(b) Has an application for the registration of the drug been made in any other country?

YES NO

(i) If YES, list countries

.....  
.....

(c) Has the drug been registered in any other country?

YES NO



(i) If YES attach copies of certificates of registration in respect of such drug issued by the appropriate authority established for the registration of drugs in the country.

.....

(d) Has the registration of the drug been rejected, refused, deferred or cancelled in any country?

YES NO

(i) If YES, state details

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.....

(e) Is the drug manufactured in other countries?

YES

NO

(i) If YES, state details and list manufacturing plants from which imports can be made to Sierra Leone.

.....

**APPENDIX IV  
TOXICOLOGICAL, PHARMACOLOGICAL AND CLINICAL INFORMATION**

Name of Drug: .....

Name of Applicant: .....

Dosage Form: ..... Strength: ..... Colour: .....



**GENERICIS**

(a) Bioequivalence data shall be required for **all** oral solid dosage forms. This shall be a comparative study with the innovator product or a verifiable Lead Market Brand acceptable to the Board.

**NEW CHEMICAL ENTITIES AND INNOVATOR PRODUCTS**

(b) Particulars referring to the pharmacological, toxicological and efficacy data obtained from preclinical studies undertaken on the drug



(c) All documentation referring to the tests which have been performed on **humans** regarding the efficacy of the drug (Phases I, II and III)

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- (d) Primary standards for the active ingredient, related substances, and identifiable impurities should be submitted.

### **SOLID ORAL DOSAGE FORMS**

- (e) Dissolution test reports shall be submitted

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**APPENDIX V**

**LIST OF ATTACHED DOCUMENTS AND MATERIAL**

Name of Drug: .....

Name of Applicant: .....

Dosage Form: ..... Strength: ..... Colour:.....

Attach **4 (four)** copies of labels, package inserts and packaging materials proposed for marketing in this country.

The text of labels and written material should conform to labelling regulations in force in Sierra Leone (Refer to *the Pharmacy Board of Sierra Leone guidelines on packaging and Labeling*)