

Confidential



FORM 8A

PHARMACY, MEDICINES & POISONS BOARD

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

APPLICATION FOR A PRODUCT LICENCE (SUMMARY SHEET)

Sections 35(1) and 37(1)

(Please read section M on page 7 before completing form)

A. Product Identification

1. PMPB Ref No. <i>(for office use only)</i>	2. Proprietary (Trade) Name	3. Non-proprietary name (INN)
4. Dosage form and colour	5. Strength	6. Route of administration
7. Suggested Price (Optional)		

B. Applicant details

1. Name of applicant			
2. Address of Applicant (including contact person)		3. City/town	4. County
5. Telephone No.	6. Fax No.	7. Telex	8. E-mail

C. Manufacturer details

1. Name of Manufacturer		2. Address	
3. City/town	4. Country	9. Manufacturing Licence No. attach copies of certificates	10. Licence date
5. Tel No.	6. Fax No.	11. Name and address of licensing authority	

7. Telex No.	8. E-mail address	12. Date of Last GMP inspection. Attach copies of certificates issued by both local NRA and PMPB
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D. Product details

1. Therapeutic category	2. Main indication(s)		
3. Dosage details and method of use	4. Stability data (on three (3) consecutive production batches): Provide detailed studies and results (attach validation reports for analytical tests methods used). The stability studies should be conducted in line with Zone IV A for products meant for storage under prevailing environmental conditions.		
5. Shelf life (see 4)	6. Storage conditions. Supported by the stability data.		
7. Complete quantitative formula (per dose form)			
a) Substance	b) Function	c) Amount	d) QC specifications
i)			
ii)			
iii)			
iv)			
v)			
vi)			

vii)			
viii)			
		8. Total weight or volume of dose form	

E. Active ingredient details

1. Active ingredient name	2. Source of active ingredient (attach copies of cGMP certificates of API manufacturer, COA, API Stability Study Summary and indicate retest periods).	3. Standard USP, BP, etc	4. Demonstrate equivalence of In House (IH) standard to pharmacopoeia where applicable. Attach manufacturing, analytical test validation reports for IH API and Standards.
i)			
ii)			
iii)			

Chemistry, Manufacturing and Control of API

API	Detailed validated method of synthesis of API (flow diagrams), including process validation reports.	In process controls for critical quality attributes including particle size distribution: (d10, d50, d90), polymorphism and isomerism	Solubility at pH 1.2, 4.5 or 6.8

F. Manufacturing and Quality Control information

1. Method of manufacture of dosage form (attach flow diagrams and validation reports for manufacturing processes)
2. In process control details (sampling stages and validated test methods used, attach validation reports for analytical tests used)
3. QC specifications of the final product (attach as annex)

4. Details of the validated method of analysis for the final product (attach analytical validation reports)		
5. Batch No.	6. Date of Manufacture	7. Expiry date
8. Executed and Blank Batch Manufacturing Records. Results of batch testing (<i>Certificate of Analysis including that for Biobatch or batch used for dissolution profile</i>). Validation reports for analytical tests should be provided as an annex.		
9. Certificate of Pharmaceutical Product in line with WHO format		
10. Free Sale Certificate		

G. Bio-equivalence Data

<p>Detailed study of comparative bioavailability, with pharmacokinetics data; include study protocols, results and conclusions of study demonstrating bio-equivalence for BCS class II and IV APIs. Attach copies of ethical approval, CV of PI, certificate of accreditation of Contract Clinical Research Organization, reports of validated analytical test methods used for QC analysis of pharmacokinetic data etc etc. Submit comparative dissolution data for BSC class I and III APIs. Refer PMPB Biowaiver Guidelines</p>
<p>Attach as annex</p>

H. Container information

1. Size of container (No. of unit doses)	2. Description of container closure system including nature of materials and art work.
i)	
ii)	

iii)	

I. Distribution and Promotional information

1. What is the intended scheduling status of the product? (Tick appropriate box)

a) CD Controlled drug	b) POM Prescription only medicine	c) PIM Pharmacist initiated medicine	d) P Pharmacy only medicine	e) GSL General Sales List medicine	F) VET Veterinary use only medicine

2. How is it proposed to promote the medicinal product? (tick appropriate box)

- a) To the medical and pharmacy professions only
- b) To the general public by point of sale displays in pharmacies
- c) To the general public
- d) Other (please specify)

J. Current Regulatory status of product in other countries (attach relevant supporting documents)

1. Country	2. Product Licence No.	3. Date of first Registration
i)		
ii)		
iii)		
iv)		
v)		

K. Date and Signature of Authorised person (s)

1. Date of application <hr/>	2. Signature of Authorized person e.g. Pharmacist
3. Official Company seal/stamp	

L. Registration Information (for office use only)

1. Application fee	2. Application fee Receipt No.	3. Registration Fee	4. Reg. Fee Receipt No.
5. Registration date	6. Registration expiry date	7. Registration Number	
8. Full Name and signature <p style="text-align: center;">REGISTRAR, <i>Pharmacy, Medicines and Poisons Board</i></p>			

M. Notes (to be read before completing form)

Special Note

Applicants should note that the spaces provided in the application form are not large enough to accommodate all the requested information. Additional information should be attached as annexes where necessary.

1. How to complete the Application Form

- a) Applicants should complete all sections of the form. A table of contents should always be provided for ease of reference to the various sections especially those provided as annexure.
- b) Box A3 (non-proprietary name INN or Generic name): for combination products each component must be stated here.
- c) Box D6 (storage conditions); if a specific storage temperature or temperature range is applicable to the product, this should be stated in full (e.g. "below 15 degrees C"). Any additional storage requirements should also be stated here.
- d) Box D7 (b) (Function): state the function of each of the ingredient of the product (e.g. active ingredient, colouring agent, preservative, etc)
- e) Box D8 (Total weight/volume): state total weight of the solid dosage form (e.g. tablet) or volume of liquid dosage form (e.g. liquid, suspension) in which the composition is being expressed.
- f) Box K: signature of Authorized person usually a Pharmacist employed by the company/applicant to legally certify that all information submitted is authentic and correct.

2. Separate applications should be made for each dosage form of the same product (e.g. tablet, syrup injection)

3. Separate applications should be made for each strength of the same product (e.g. Aspirin 300mg and Aspirin 500mg)

4. A single application is required for the same product packed in different sizes (e.g. Aspirin 300mg 1000's 100's and 20's)

5. Applicants should send five (5) copies of the proposed package insert product label, outer package label and other proposed promotional materials together with the application dossier.

6. Applicants should enclose (4) sealed samples of each commercial pack size in the format that will eventually be on the market after registration and a minimum of 5g of the corresponding API. The total quantity of sample should exceed the quantity required for both qualitative and quantitative laboratory analysis. Samples may be sent by post or other means but carriage and other clearance charges should be paid directly by the applicant or his/her appointed agent.

7. Applicants should send reference standards together with samples

8. Application and Registration fees are due at the time of submission of the dossier and are payable to the *Pharmacy, Medicines and Poisons Board* by cheque, bank draft, telegraphic transfer or money order.

9. Application fees are not refundable where a product has been rejected. Funds may however be transferred, on request, to other products applied for or for renewal of licence of previously registered products. The current fee structure is available on request.

10. All applications should be sent in duplicate (an electronic copy and a hard copy) to the Registrar, Pharmacy, Medicines and Poisons Board, PO Box 30241, Capital City, Lilongwe 3, Malawi.

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Email: info@pmpb.mw

