



ZAMBIA MEDICINES REGULATORY AUTHORITY

**The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)**

**The Medicines and Allied Substances (Pharmaceutical Licence)
Regulations, 2018**

APPLICATION FOR A PHARMACEUTICAL LICENCE							
Please write in BLOCK LETTERS			Shaded fields for official use only		Application No.		
					Date/Time		
<i>Information Required</i>			<i>Information Provided</i>				√
APPLICATION DETAILS							
1.	Name(s) of business						
2.	Physical Address:						
3.	Postal Address:						
4.	Business premises						
	(a) Tel. No.:						
	(b) Fax:						
	(c) Mobile Phone No.:						
	(d) E-mail address:						
PARTICULARS OF PROPRIETOR(S)/DIRECTORS(S)							
5.	Full Names	Sex	Nationality	Residential Address	Occupation	Date of Birth	NRC/ Passport No.
6.	(a)	Has any of the Proprietors or Directors been convicted of an offence in the past five (5) years?					
		YES <input type="checkbox"/>		NO <input type="checkbox"/>			
		If Yes, please give details					

				
	(b) Have the proprietors or Directors ever been denied issuance of a pharmaceutical licence or had it revoked? If Yes, please give details				
	(c) Please tick (✓) activity (ies) as applicable Manufacture <input type="checkbox"/> Wholesale <input type="checkbox"/>				
7.	Please complete as applicable				
	Particulars	Responsible Person	Suitably Qualified Person	Head of Production	Head of Quality Control
	Full names				
	Qualifications				
	Registration Certificate No.				
	Address				
	Experience (state period)				
	Signature				
8.	Products to be manufactured, sold or dealt in				
	Please indicate the proposed dosage form of medicine to be manufactured below:				
	1.				
	2.				
	3.				
	4.				
	5.				
	6.				
	7.				
	8.				
	9.				
	10.				
9.	Type of manufacture (Please tick (✓) what is applicable below)				
	<input type="checkbox"/> Complete manufacture				
	<input type="checkbox"/> Contract manufacture				
	<input type="checkbox"/> Partial manufacture				
	<input type="checkbox"/> Primary repackaging and labelling				
	<input type="checkbox"/> Secondary repacking and labelling				
	<input type="checkbox"/> Local manufacture of natural remedies				
10.	Attachments				
	(a) Practicing certificate for the responsible person				
	(b) Contract of employment of the responsible with applicant				
	(c) Site Master File				
	(d) Certificate of Registration/Incorporation of applicant				
	DECLARATION				
	I declare that the information I have stated is correct and truthful to the best of my knowledge and belief.				

 Name Designation
 Signature Date

FOR OFFICIAL USE ONLY

Date of submission:

Application Number:

Application in order (proceed for inspection):

Application deficient (notify applicant on deficiencies):

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 Director-General

