

GENERAL INFORMATION	
Name of formality	Good Manufacturing Practices Certificate for Traditional Medicine
Type of formality	Certificate
Date of last modification	09.12.2020
Responsible Authority	Food and Drugs Department
Who should apply for this formality?	To introduce the implementation of businesses in accordance with the Good Manufacturing Practices of traditional medicine and health supplement products such as production, processing, storage, distribution, import of raw materials, export by various processes to meet the GMP standards.
Qualifications needed by the business to get the formality	Must be a factory engaged in the business of manufacturing traditional medicine

LEGAL FRAMEWORK			
Name	Number	Date	Comment
Law on Drugs and Medical Products (Amended)	07/NA	21.12.2011	
Provision on the Manufacture of Medicine and Medical Products	937/MOH	12.05.2004	
Provision on Good Manufacturing Practice and Drug Quality Control	1021/MOH	11.08.1999	

REQUIRED DOCUMENTS FORMALITIES		
Name	Type	Comment
\$_{SUPPORT_NAME}\$	\$_{SUPPORT_TYPE}\$	\$_{SUPPORT_COMMENT}\$

LIST OF ATTACHED DOCUMENTS FOR FIRST TIME APPLICATION

Name of document	Type of document	File of document
\${ATTACHMENT_NAME}	\${ATTACHMENT_TYPE}	\${ATTACHMENT_FILE}

LIST OF ATTACHED DOCUMENTS FOR RENEW APPLICATION		
Name of document	Type of document	File of document
\${ATTACHMENT_NAME_RENEW}	\${ATTACHMENT_TYPE_RENEW}	\${ATTACHMENT_FILE_RENEW}

MEAN OF PRESENTATION		
Means of presentation	At the Authority Offices	
Address of authority	Food and Drugs Department, Ministry of Public Health	
Time it takes to the authorities to process the formality	15	15 official days

RENEWAL INFORMATION		
Does the formality have a validity or an expiration date?		How long will the formality be valid for? (in months)
YES		24
What is the process and conditions to get the formality?		
What is the process and conditions to renew the formality?	Renewal conditions are the same as the initial application process	

ISSUING FEES				
Has application fees?	Service fees businesses need to disburse	Certificate fees businesses need to disburse	Application fees businesses need to disburse	Total fees businesses need to disburse
YES	0.00	2000000.00	0.00	2000000.00
Comments	Pay the fee for the GMP certificate after obtained the approval			

ADDITIONAL ISSUING FEES				
Additional fee names				
NO	0.00	0.00	0.00	0.00
Additional fee comments				

RENEWAL FEES				
Has renewal fees?	Service fees businesses need to disburse	Certificate fees businesses need to disburse	Renewal fees businesses need to disburse	Total renewal fees businesses need to disburse
YES	0.00	2000000.00	0.00	2000000.00
Comments	Pay the fee for the GMP certificate after obtained the approval			
ADDITIONAL RENEWAL FEES				
Additional renewal fees names				
NO	0.00	0.00	0.00	0.00
Additional renewal fees comments				