

GENERAL INFORMATION	
Name of formality	Permit to Produce Sample Drug for Domestic Drug Formula Registration
Type of formality	Other
Date of last modification	19.11.2020
Responsible Authority	Food and Drugs Department
Who should apply for this formality?	Domestic drugs manufacturer.
Qualifications needed by the business to get the formality	1. For locally manufactured drugs, those who intend to produce drugs must submit an application for the production of a sample drug according to the Application Form 1. Once a permit for producing sample drug is granted, the manufacturer shall submit the application for registration Form 2 within 3 to 6 months2. For imported drugs, those who intend to import drugs from abroad must apply for a permit to import a sample drug according to the Application Form 1. Once a permit for importing a sample drug is granted, the manufacturer shall submit the application for registration Form 2 within 3 to 6 months.

LEGAL FRAMEWORK			
Name	Number	Date	Comment
Law on Drugs and Medical Products (Amended)	07/NA	21.12.2011	
Provision on Medicine Registration	1441/MOPH	13.08.2003	

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		
Address of authority	Food and Drugs Department, Ministry of Public Health	
Time it takes to the authorities to process the formality	0	Pursuant to the Regulation on Drug Registration 1441/MOH, the application period is 3 months.

RENEWAL INFORMATION	
Does the formality have a validity or an expiration date?	How long will the formality be valid for? (in months)
YES	6
What is the process and conditions to get the formality?	
What is the process and conditions to renew the formality?	Pursuant to the Regulation on Drug Registration 1441/MOH

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	100000.00	0.00	0.00	100000.00
Comments				

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	100000.00	0.00	0.00	100000.00
Comments				
ADDITIONAL RENEWAL FEES				
Additional renewal fees names				
NO	0.00	0.00	0.00	0.00
Additional renewal fees comments				