

GENERAL INFORMATION	
Name of formality	Certificate of Analysis
Type of formality	Certificate
Date of last modification	23.11.2020
Responsible Authority	Food and Drugs Department
Who should apply for this formality?	Any individual, legal entity, or organization intending to conduct a business related to food and drugs must first obtain a research sample certified by the Food and Drugs Department (as defined in the law).
Qualifications needed by the business to get the formality	Have a delivery note from the Food and Drugs Department/Business Unit

LEGAL FRAMEWORK			
Name	Number	Date	Comment
Law on Drugs and Medical Products (Amended)	07/NA	21.12.2011	
Law on Food (Revised)	33/NA	24.07.2013	
Order on the Management of Safe Food Production, Exportation and Importation	856/MOPH	12.05.2006	
Decision on Drinking Water in the Closed Containers	585/MOH	12.05.2006	
Presidential Ordinance on Fees and Service Fees	003/PO	26.12.2012	

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	0	The period of the analysis depends on the items needed to be analyzed (for example, the analysis of drinking water for registration or the extension of 14 items under the Decision on Drinking Water in a Closed Container will take about 1 month)

RENEWAL INFORMATION	
Does the formality have a validity or an expiration date?	How long will the formality be valid for? (in months)
NO	0
What is the process and conditions to get the formality?	
What is the process and conditions to renew the formality?	- According to the Decision on Drinking Water in Closed Containers- If it is a pharmaceutical product, a health-related analysis will be issued for each production lot (Lot No.)- Certificate of analysis for the product registration (Regulation on Registration)

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	0.00	0.00	0.00
Comments	The fee for analyzing each item is based on the Ordinance on Fees and Service Charges No. 003/PO, dated 26 December 2012 (Article 47, III, pp. 93-95).- Agreement between the user and the provider of the research service			
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
NO	0.00	0.00	0.00	0.00
Comments				
ADDITIONAL RENEWAL FEES				
Additional renewal fees names				
NO	0.00	0.00	0.00	0.00
Additional renewal fees comments				