Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Self-Assessment Tool Kit for Lot Release Certification

General instructions during submission of applications:

Submissions shall be suitably bound (not stapled nor clipped) and placed in a plastic envelope.
The second page shall contain the table of contents of the application.
An authorized English translation shall accompany any material not issued in English.
Each document submitted should have an accompanying tab or mark for easy identification and location.
All documents should be arranged logically according to this tool-kit.

FDA Registered Product Name : _____
Dosage Strength/ Form : _____
Brand Name : _____
Lot/Batch No. : _____

DOCUMENTS	NO. OF UNITS/ SETS/COPIES TO BE SUBMITTED	REQUIREMENTS (Pls. check)	Y	N	NA	REMARKS/ FINDINGS
A. GENERAL REQUIREMENTS						
1. Lot Release Application Form	**2**	Original	☐	☐	☐	
		Signatory is an authorized representative	☐	☐	☐	
		Duly accomplished, accurate and signed	☐	☐	☐	
		Duly accomplished, accurate and signed	☐	☐	☐	
2. Certificate of Product Registration (CPR)	**2**	Valid at the time of application	☐	☐	☐	
		Name of manufacturer, trader, importer, distributor same as reflected in LTO, if not, must have amendment	☐	☐	☐	
3. License to Operate (LTO)	**1**	Validity at the time of application				
		Manufacturer	☐	☐	☐	
		Trader	☐	☐	☐	
		Importer	☐	☐	☐	
		Distributor	☐	☐	☐	
4. Summary Lot Protocol/ In- process control and testing results (in the absence of summary lot protocol)	**1**	SLP Template (Hard and soft copy) *One-time submission only	☐	☐	☐	
		Original/ Certified True Copy Flow diagram	☐	☐	☐	
		Batch Numbering System	☐	☐	☐	
5. Certificate of Analysis (CA) of Finished Product and Diluent (if applicable)	**1**	Original/ Certified True Copy	☐	☐	☐	
		Duly signed and dated bearing the same lot/ batch number as the sample submitted	☐	☐	☐	
		With complete test results	☐	☐	☐	
		No evidence of tampering / alteration of	☐	☐	☐	

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		information(erasures countersigned by an authorized signatory)	
6. NRA/NCL Batch Release Certificate (In case of batch release exemption, letter of exemption from the NRA/ NCL or state article indicating the product is batch release exempted)	**1**	Original/ Certified True Copy ☐ ☐ ☐ Lot/batch no. and expiration date indicated same as on the representative sample ☐ ☐ ☐	
7. Representative Sample	**3**	In commercial presentation with batch/lot number the same as that of the submitted CA of the finished product ☐ ☐ ☐ Lot/batch no. and expiry date indicated on the representative sample same as on the application form ☐ ☐ ☐ Submitted in appropriate storage condition ☐ ☐ ☐	
	1	SOP for Sampling Method (SOP from license holder that will provide evidence that random sampling was conducted for samples that will be submitted for visual inspection) ☐ ☐ ☐	
8. Detached labeling materials and product insert	**3**	Primary label ☐ ☐ ☐ Secondary label ☐ ☐ ☐ Diluent ☐ ☐ ☐ Product Insert ☐ ☐ ☐	
	1	Compliant to Generic Labeling Requirement AO 55s ☐ ☐ ☐ Generic Labeling Exemption (if applicable) ☐ ☐ ☐	
9. Packing List / Invoice/ Airway bill	**1**	Consistent with the number of units indicated on the application form ☐ ☐ ☐	

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B. ADDITIONAL REQUIREMENTS				
For Donated Vaccines/ Biological Products 1. Identification of Medical Officer who will be responsible for prompt reporting of any ADR/AEFI , among others, to FDA 2. Report / Recommendation of the RFOO on the inspection of the actual shipment For Governement procured products (EPI and non-EPI's) 1. Purchase Order and or Notice of Award from the Dept. of Health	**1**	Resume of Medical Officer	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	

Assessed by: _____ ☐ **Accepted** ☐ **Denied**

Date: _____