



National Quality Control Laboratory

Hospital Road , KNH Complex, P.O. Box 29726, 00202 Nairobi, Kenya
Telephone: 2726963, +254 - 020 - 3544525/30 • Fax: 2718073
Email: info@nqcl.go.ke Website: www.nqcl.go.ke



SAMPLE INFORMATION FORM

Date Sample Submitted: 29-Aug-2018 Laboratory Reference No: NDQB201808060

Product Generic/Brand Name: POLIOMYELITIS VACCINE (ORAL)

Product Chemical Name: Polimyelitis Vaccine (oral) Trivalent type 1,2 & 3

Product Description: _____

Product Presentation: Clear colourless solution for oral administration packed in a clear glass vial fitted with a green plastic flip-off cap.

Label claim: Each dose of 2 drops (0.1 ml) contains Polio Virus (Sabin)

Batch/Lot No: 1808P0240Z Product License No: _____

Date of manufacture: Not indicated Date of Expiry: Jan 2020

Name of Client and Disease Surveillance & Response Unit

Address: P.O.Box 20781 - 00202, KNH, Nairobi, KENYA.

Client Reference No: _____

Manufacturer: Serum Institute of India Ltd.

Country of Origin: INDIA Samples Issued: 5 Vials Samples Returned: _____

Test(s) requested:	Limits:	Monograph (specify year and exact page):
a) <u>Identification</u>	_____	U.S.P. _____
b) _____	_____	B.P. _____
c) _____	_____	Ph. Eur. _____
d) _____	_____	Ph. Intl. _____
e) _____	_____	Other's _____
f) _____	_____	_____

Analyst: Kennedy Rutto Signature: _____ Date: _____

Checked by: _____ Signature: _____ Date: _____

Approved by: _____ Signature: _____ Date: _____

ASSAY DATA FORM

ASSAY

Standard Preparation for Assay:

Sample Preparation for Assay:

CHROMATOGRAPHIC CONDITIONS:**ASSAY**

Column No: _____ Type of Column: _____
Column Temp (°C): _____
Detection λ (nm): _____ Injection Vol (μ L): _____

Mobile Phase: Composition (% v/v) & Ratios

_____ Flow Rate (mL/min): _____
Pump Pressure (bars): _____

DISSOLUTION

Column No: _____ Type of Column: _____
Column Temp (°C): _____
Detection λ (nm): _____ Injection Vol (μ L): _____

Mobile Phase: Composition (% v/v) & Ratios

_____ Flow Rate (mL/min): _____
Pump Pressure (bars): _____

REFERENCE SUBSTANCES:

NO	Reference Substances/Related Substances	NQCL Code/Batch	Purity (%)
1.			
2.			
3.			
4.			
5.			

REAGENTS USED						
	Reagent Name	Manufacturer	Lot/Batch No.	Date Opened	Expiry Date	Remarks
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						

EQUIPMENT USED					
	Equipment Name	NQCL No./Code	Date of Last Calibration	Date of Next Calibration	Remarks
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					

APPENDIX

Describe in Summary the reagent preparation procedures including mobile phase and buffers.

Report any other tests carried out on the sample.

WORKSHEET TRACKING						
No.	ACTIVITY	FROM: OFFICER/ ANALYST	SIGNATURE	TO: OFFICER/ ANALYST	SIGNATURE	DATE
1						
2						
3						
4						
5						
6						
7						