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SAMPLE INFORMATION FORM

Date Sample Submitted: _____ Laboratory Reference No: _____

Product Generic/Brand Name: _____

Product Chemical Name: _____

_____

Product Description: _____

_____

_____

Product Presentation: _____

_____

Label claim: _____

_____

Batch/Lot No: _____ Product License No: _____

Date of manufacture: _____ Date of Expiry: _____

Name of Client and Address: _____

_____

Client Reference No: _____

Manufacturer: _____

Country of Origin: _____ Samples Issued: _____ Samples Returned _____

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

Analyst: _____ 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: 180 Type of Column: 150*4.6 mm, C18

Column Temp (°C): 45

Detection λ (nm): 260 Injection Vol (µL): 10

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

GRADIENT

Flow Rate (mL/min): 1.0

Pump Pressure (bars): 92-99

DISSOLUTION

Column No: 122 Type of Column: 150*4.6, C18

Column Temp (°C): 30

Detection λ (nm): 254 Injection Vol (µL): 5

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

GRADIENT

Flow Rate (mL/min): 1.2

Pump Pressure (bars): 87-96

REFERENCE SUBSTANCES:

NO	Reference Substances/Related Substances	NQCL Code/Batch	Purity (%)
1.	Dolutegravir Sodium	07WS18000031	99.2
2.	Lamivudine	07WS18000074	98.9
3.	Tenofovir Disoproxil Fumarate	07WS170000103	98.58
4.			
5.			

DISSOLUTION

Standard Preparation for Dissolution:

Dissolution Conditions

	1st Run	2nd Run	3rd Run
Dissolution Medium:	0.01M pH 6.8 PHOSPHATE BUFFER	0.01M pH 6.8 PHOSPHATE BUFFER	
Volume used:	900	900	
Apparatus:	2	2	
Rotations per minute:	75	75	
Time (min)	45, 0, 0, 0, 0	45, 0, 0, 0, 0	

Describe below any subsequent dilutions after the dissolution:

REAGENTS USED						
	Reagent Name	Manufacturer	Lot/Batch No.	Date Opened	Expiry Date	Remarks
1.	NaOH PELLETS	RANKEM	P14D101230	24TH OCT 2017	MARCH 2019	OK
2.	SODIUM DIHYDROGEN PHOSPHATE MONOHYDRATE	SIGMA ALDRICH	BCBR9968V	25TH SEP 2017	25TH SEP 2022	OK
3.	DI-AMMONIUM HYDROGEN PHOSPHATE	RIGK	02940	21ST MARCH 2018	MARCH 2019	OK
4.	SODIUM LAURYL SULPHATE	FINAR	75781011FO	18TH JUNE 2017	MAY 2020	OK
5.	POTASSIUM DIHYDROGEN PHOSPHATE	SIGMA ALDRICH	MKCD6422	29TH MARCH 2018	29TH MARCH 2023	OK
6.	PHOSPHORIC ACID	MACRON	1509801821	12TH JULY 2018	08TH APRIL 2019	OK
7.	METHANOL HPLC	RANKEM	R166G14	22ND AUG 2018	JUNE 2019	OK
8.	ACETONITRILE HPLC	RANKEM	R099H14	22ND AUG 2018	JULY 2019	OK

EQUIPMENT USED					
	Equipment Name	NQCL No./Code	Date of Last Calibration	Date of Next Calibration	Remarks
1.	HPLC P	NQCL/2012/387	12/09/2017	12/09/2018	OK
2.	HPLC R	NQCL/2012/393	12/09/2017	12/09/2018	OK
3.	HPLC N	NQC/2012/381	12/09/2017	12/09/2018	OK
4.	DISSOLUTION TESTER L	NQCL/2012/398	JULY 2018	JULY 2019	OK
5.	WEIGHING BALANCE	NQCL/2007/258	20TH FEB 2018	19TH FEB 2019	OK
6.	pH METER	NQCL/2015/466	OCT 2017	OCT 2018	OK
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	**Issuing**	**Mr. Peter Omwancha**		**Peter Ngumo**		
2						
3						
4						
5						
6						
7						