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: _____ 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)	Identification		U.S.P	
b)	Dissolution		B.P.	
c)	Assay		Ph. Eur.	
d)	Uniformity of Weight		Ph. Intl.	
e)			Other's	
f)				

Analyst: Mary Magda Signature: _____ Date: 19-02-2015

Checked by: _____ Signature: _____ Date: _____

Approved by: _____ Signature: _____ Date: _____

UNIFORMITY OF WEIGHT: TABLETS/CAPSULES/SACHETS/VIALS

No.	Tablets/Capsules/ Sachets/Vials (mg)	Empty Capsule/ Sachet/Vial (mg)	Capsule/Sachet/Vial Content (mg)	% Deviation From mean (for deviating tabs/caps)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
Total:	_____		_____	
Avg:	_____		_____	
Calculation of Deviation Limits:				

Comments: _____

ASSAY DATA FORM

ASSAY

Standard Preparation for Assay:

Sample Preparation for Assay:

DISSOLUTION

Standard Preparation for Dissolution:

Dissolution Conditions

	1st Run	2nd Run	3rd Run
Dissolution Medium:			
Volume used:			
Apparatus:			
Rotations per minute:			
Time (min)			

Describe below any subsequent dilutions after the dissolution:

CHROMATOGRAPHIC CONDITIONS:

ASSAY

Column No: _____ Type of Column: _____

Column Temp (°C): _____ _____

Detection λ (nm): _____ Injection Vol (µL): _____

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 (µL): _____

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.			

pH MEASUREMENTS

Outline the Sample Preparation Procedure

Determination of pH :

No.	Sample pH Readings
1.	
2.	
3.	
4.	
	Mean:

pH of the Sample : _____

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						