



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

	1 st Run	2 nd Run	3 rd 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 (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						