Republic of Kenya

Ministry of Health

National Quality Control Laboratory

A WHO Prequalified and an ISO/IEC 17025:2017 Accredited Testing Facility
Hospital Road, KNH Complex, P.O. Box 29726 – 00202, Nairobi, Kenya
Telephone: +254 – 020 – 3544525/30, +254 703 311563
Email: info@nqcl.go.ke Website: www.nqcl.go.ke

NQCL/F 01 – 07

ANALYSIS REQUEST FORM

1. **Name and Address of Applicant (Company):** _____
2. **Company Tel. No. & Email Address:** _____
3. **Name and Presentation of Product:** _____
4. **Name and Address of Manufacturer:** _____
5. **Reason for Test (Pre-registration/ Post Marketing Surveillance/ Pre-distribution/ Investigative/ Research/ Other - specify)** _____
6. **Sample Information:**
   a) **Date of manufacture:** _____ **Date of Expiry:** _____
   b) **Batch/Lot Number:** _____
   c) **Name and Amount of Active Ingredients on label:** _____
   d) **Quantity Submitted:** _____
7. **Applicant's Reference Number:** _____
8. **Test required by applicant. Mark (✓) against each test required on the table below:**

	Test	(✓)	*Method		Test		*Method
1	Uniformity of Weight/ Volume			11	Water Content (Karl Fischer)		
2	Content Uniformity			12	Loss on Drying		
3	Identification			13	Optical Rotation		
4	Assay			14	Relative Density		
5	Dissolution			15	Melting Point		
6	Disintegration			16	Microbial Contamination Test		
7	Friability			17	Sterility		
8	Uniformity of Volume			18	Bacterial Endotoxin Test		
9	pH (Acidity/Alkalinity)			19	Microbial Identification		
10	Related Substances/Impurities						

If other is selected as a method please elaborate: _____

*The client must specify method of analysis to be used; U.S.P., B.P., Ph. Eur., Ph. Int., Manufacturer's Method (Please abbreviate as MoA) or Other.

Note: In all cases, preference is given to use of monographs from officially recognized current versions of pharmacopoeias (United States Pharmacopoeia (USP), British Pharmacopoeia (BP), European Pharmacopoeia (Ph. Eur.) and International Pharmacopoeia (Ph. Int.).
Clients have three days to contact NQCL if they desire to change or use a method that was not identified at the time of sample receipt.

9. Other items submitted: Mark (✓) appropriately

CRS		MOA & Validation Data		Related Substances		Others (specify)	

10. Name, Designation and Signature of Person Authorizing Request for Analysis:

Name: _____ **Designation:** _____ **Signature:** _____ **Date:** _____

Contact details (Phone Number): _____

FOR LABORATORY USE ONLY: Payment Details

Receipt No.:		Amount Paid:		Accountant:		Signature:		Date:	

Date Received: _____

Received by: _____ **Authorized by:** _____

Laboratory Reference No. NDQ _____

SAMPLE RECEIVING CHECKLIST

(For Laboratory Use Only)

		✓ Appropriate box
ANALYSIS REQUEST FORM		
1.	Duly filled and signed in duplicate.	Yes: ☐ No: ☐ N/A: ☐
2.	Appropriate tests selected as per quotation	Yes: ☐ No: ☐ N/A: ☐
3.	Right Method Indicated against each test	Yes: ☐ No: ☐ N/A: ☐
SAMPLE INSPECTION		
1.	Quantity as per sample submission guidelines	Yes: ☐ No: ☐ N/A: ☐
2.	Sampling labelling requirements met (*Name, Expiry date, Batch number, label claim, Manufacturer, Manufacturer's address, Country of origin*)	Yes: ☐ No: ☐ N/A: ☐
3.	Sample packaged in a commercial pack in good condition	Yes: ☐ No: ☐ N/A: ☐
4.	Storage conditions maintained as per the manufacturer's instructions	Yes: ☐ No: ☐ N/A: ☐
5.	More than 1 year remaining on shelf life.	Yes: ☐ No: ☐ N/A: ☐
6.	Sample details match details filled on the analysis request form.	Yes: ☐ No: ☐ N/A: ☐
7.	Co-packed with diluent(s)/device	Yes: ☐ No: ☐ N/A: ☐
8.	Diluent(s)/device captured in quotation/revised quotation.	Yes: ☐ No: ☐ N/A: ☐
ACCOMPANYING DOCUMENTS		
1.	Manufacturer's Method of Analysis provided	Yes: ☐ No: ☐ N/A: ☐
2.	Specifications included with the method of analysis	Yes: ☐ No: ☐ N/A: ☐
3.	Validation data on CD	Yes: ☐ No: ☐ N/A: ☐
4.	Amount paid corresponds to the Quotation provided	Yes: ☐ No: ☐ N/A: ☐
5.	Cold Chain Tracking Document (For Cold Chain drugs)	Yes: ☐ No: ☐ N/A: ☐
CHEMICAL REFERENCE STANDARD DETAILS		
1.	Packaged in an airtight amber colored glass bottle;	Yes: ☐ No: ☐ N/A: ☐
2.	At least 6 months to expiry;	Yes: ☐ No: ☐ N/A: ☐
3.	Certificate of Analysis with full details on potency, batch number, traceable to a primary (pharmacopeial) or certified standard and storage conditions;	Yes: ☐ No: ☐ N/A: ☐
4.	Minimum amount 200 mg;	Yes: ☐ No: ☐ N/A: ☐
5.	Met the ambient shipment requirements;	Yes: ☐ No: ☐ N/A: ☐
6.	Met the requirements for cold chain shipment (2°C to 8°C);	Yes: ☐ No: ☐ N/A: ☐
7.	Met the requirements for frozen shipment (-10°C to -25°C).	Yes: ☐ No: ☐ N/A: ☐
DEVIATIONS		
1.	Any deviations from the sample submission guidelines	Yes: ☐ No: ☐ N/A: ☐
If yes, please give detailed reasons;		

	Deviation Initiated by:	Quality Assurance Approval:
Name:		
Signature:		
Date:		