

Terms of Reference for QC testing of Finished Pharmaceutical Products (Antimalarial) imported into Nigeria.

1.0 Rationale for the Assignment

Pharmaceutical Finished Product (FPP) quality has been a concern of the World Health Organization (WHO) from its inception. As requested in Article 2 of the WHO Constitution, developing, establishing and promoting international standards with respect to food, biological, pharmaceutical and similar products is one of the functions of the organisation (WHO). Every Pharmaceutical product has established identity, strength, purity and other quality characteristics designed to ensure the required levels of safety and effectiveness are met. It is therefore important that in line with International best practices and UNOPS Quality Assurance Policy on procurement of Medicines, Medical Devices and other Health Products, that all health products procured under the project be quality assured and monitored throughout the production, and distribution process.

2.0 Objectives of the assignment

The objective of this ToR is to procure a Quality Control and Laboratory Testing Service for Finished Pharmaceutical Products (Antimalarial) imported into Nigeria.

3.0 Scope of work

To achieve the above-mentioned objective, the contractor is required to perform the following tasks:

- Quality Control Testing
- Quality Control Reporting
- Provide certified professional/ technical advice on any other matters regarding the QC testing observations

4.0 Sample Size and Sampling

Contractor is required to provide the sample size required for testing each batch of sample. Batches of FPPs for quality control testing will be sampled in accordance with the laboratory standard procedure/process for sample withdrawal/collection.

4.1 Customs Clearance and Sample Reception

Samples for quality control testing will be collected in-country immediately after customs clearance; collected samples will be dispatched to the laboratory for QC through courier and following standard sample movement procedures/practice; **therefore customs clearance and sample transportation cost should not be included into the financial/price offer made.**

Upon receipt of sample(s), the contracted Laboratory shall share a confirmation of receipt of the sample by email with UNOPS, including sample photos with clear documentation of the batch number of all samples.

5.0 Products for Testing, Materials, Testing methods and Parameters for QC testing

5.1 Products for QC Testing

The products that will be tested are Finished Pharmaceutical products indicated for the treatment of Malaria as described below;

Lot No.	Product/Specification	Formulation	Pack Size	Reference Pharmacopoeia/ Monograph
1	1.1 Artesunate/Amodiaquine, 25/67.5mg	Non-Dispersible Tablet	Blister of 3Tabs (1X3)	Ph. Int. /Manufacturer's Reference
	1.2 Artesunate/Amodiaquine, 50/135mg	Non-Dispersible Tablet	Blister of 3Tabs (1X3)	Ph. Int. /Manufacturer's Reference
2	2.1 Dihydroartemisinin (DHA)/Piperaquine Phosphate (PPQ) 20mg/160mg	Dispersible Tablet	Blister of 3Tabs (1X3)	Manufacturer's Reference
	2.2 Dihydroartemisinin (DHA)/Piperaquine Phosphate (PPQ) 40mg/320mg	Dispersible Tablet	Blister of 3Tabs (1X3)	Manufacturer's Reference
	2.3 Dihydroartemisinin (DHA)/Piperaquine Phosphate (PPQ) 40mg/320mg	Non-Dispersible Tablet	Blister of 6Tabs (1X6)	Manufacturer's Reference

	2.4 Dihydroartemisinin (DHA)/Piperazine Phosphate (PPQ) 40mg/320mg	Non-Dispersible Tablet	Blister of 9Tabs (1X9)	Manufacturer's Reference
	2.4 Dihydroartemisinin (DHA)/Piperazine Phosphate (PPQ) 40mg/320mg	Non-Dispersible Tablet	Blister of 12Tabs (2X6)	Manufacturer's Reference
3	3.1 Artesunate/Pyronaridine phosphate 20mg/60mg	Dispersible Granule	Sachets	Ph. Eur.
	3.2 Artesunate/Pyronaridine phosphate 60mg/180mg	Non-Dispersible Tablet	Blister of 9Tabs (1X9)	Ph. Eur.
4	4.1 Artesunate 60mg powder for solution for injection - 1 vial, comprises 1 vial (glass) of artesunate powder co-packed with 1 ampoule of sodium bicarbonate injection (1ml:50mg) and 1 ampoule of sodium chloride injection (5ml:45mg) Packed (1x6)	Co-Packed Powder for Injection	Co-Packed Vial	Ph. Int. /Manufacturer's Reference
5	5.1 Rectal Artesunate Suppositories 100mg	Soft Gel Rectal Capsule	Blister of 2Caps (1x2)	USP/BP/Ph. Eur./ Manufacturer's Reference

5.2 Materials Required

Contracted QC Laboratory is responsible for providing all materials (except Samples), standards, reference, and equipment to be used for performance of the service required and meeting other expenditure necessary to perform this service, including courier fee for sending reports.

5.3 Methods for QC testing

The specifications/methods for analysis shall be in accordance with the referenced Pharmacopoeia/monogram (International Pharmacopoeia - IP, British Pharmacopoeia - BP, and United State Pharmacopoeia - USP, otherwise, the manufacturer's specifications and validated methods shall be used after obtaining UNOPS email approval.

5.4 Parameters for QC testing

In general, the following tests/parameters should be performed and reported.

1. Appearance
2. Identification
3. Related Substances
4. Water Content
5. Active Pharmaceutical Ingredient (API) Assay
6. Dissolution tests
7. Microbial limit test
8. Uniformity of weight /Uniformity of Dosage Unit

6.0 Analysis Report

Reports shall be in a format acceptable to UNOPS and shall be sent in electronic version to only UNOPS Nigeria Office.

Reports to be provided to UNOPS are as follows:

- a. Individual Report
- b. Consolidated report

When the tested products are found acceptable (compliant with the Specifications), the analysis reports shall be sent to UNOPS Nigeria and must include a standardized management summary including:

1. Name of Product analysed
2. Manufacturers Name
3. Sample quantity Analysed
4. Type of Packaging (if any)
5. Manufacturing and Expiry Date
6. Start / End Date of Analysis
7. Date of the Analysis Result
8. Batch &/or Lot Number of the Product
9. Date of Delivery of Sample to Laboratory
10. Temperature of Sample (if applicable)
11. Name of the Laboratory (if the service is outsourced)
12. Key findings of the analytical test
13. A Remarks section includes comments about the analysis conducted by Laboratory
14. Approval and Signatures by Laboratory Authority

15. For some cases, UNOPS requires technical advice from the contracted laboratory about the non-comply analyses result

When the tested products are found not acceptable or Out Of Specifications (OoS), the QC laboratory shall investigate the OoS following its internal procedures, and where required/permitted by the UNOPS - communicate with the manufacturer/supplier of the drugs in order to clarify/verify the severity of the issue. A specific alert has to be sent immediately to UNOPS. The alert shall include the following:

1. Manufacturing and batch data: Product, manufacturing and packing site and batch number
2. A description of the extent of the issue (area and severity of the diversion from accepted standards)
3. A brief description of the possible implications for the patient with regards to safety and efficacy
4. Description of actions already taken
5. A set of recommended actions and corrective measures
6. The ordinary reporting has to follow the alert.
7. Prior to any further action, the QC laboratory has to obtain a clearance from UNOPS.

7.0 Required Accreditation and Certification for QC/Testing Laboratory

The Contracted QC laboratory must meet the following criteria in full:

1. Must be an **ISO17025:2017** Certified for the required QC testing scope
2. Have the technical capability to adopt the in-house specifications for testing as provided by the manufacturer for non-compensia products.
3. Should be in a position to perform the method transfer process to validate the in-house method provided by the manufacturer.
4. Should be adequately equipped with appropriate equipment and should have the technical capabilities including well-qualified and trained staff to undertake the quality control on products required for testing.
5. Should be capable of communicating with the manufacturer (where required/permitted by UNOPS) in case samples are found to be out-of-specifications, to take decision to declare the products as non-compliant and advice on actions to be taken.

7.1 Required Document

Contracted QC Laboratory is required to provide the following documents with the quotation submitted.

- Valid **ISO17025:2017** certificate with Testing/analysis scope
- Latest laboratory quality management audit report.

8.0 Records Management

The contracted Laboratory is responsible to provide any reports when required by UNOPS and shall be responsible to keep analysed samples for a minimum 1-month.

9.0 Deliverables and timeframe

Please note that UNOPS desires this service to be done urgently and expeditiously in order to inform decision making.

The contracted QC Laboratory is required to advise on the turn-around time at which testing results and reports will be issued to UNOPS relative to the workflow and deliverables in table 2 below.

S/N	Deliverables	Responsible Party	# of Days
1	Sample collection/Sampling	UNOPS (QC Laboratory to advise sample collection method)	1
2	Sample Dispatch/Transportation to QC Testing laboratory	UNOPS	3
3	Sample Receipt, Documentation and feedback	QC Laboratory	1
4	Quality Control Testing and Analysis	QC Laboratory	10
5	Reporting, Report Approval and submission	QC Laboratory	3
6	Review / Feedback on submitted report	UNOPS	2
Total Number of Days/Turnaround Time			20

Note: The bidder must provide a proposed/offered timeline for the entire services however kindly note that laboratories with a faster turnaround time will be given higher priority during evaluation.