

**USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM**  
PROCUREMENT AND SUPPLY MANAGEMENT

**REPORT OF QUALITY CONTROL OF  
ACTS AND ARTESUNATE**

**March 2021**

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## ACRONYMS

CHWs:	Community Health Workers
FDA:	Food and Drug Authority
GHSC-PSM:	Global Health Supply Chain-Procurement Supply Management
HPLC:	High Performance Liquid Chromatography
MOPDD:	Malaria and Other Parasitic Disease Division
PMI:	U.S President'S Malaria Initiative
Q.C:	Quality control
RBC:	Rwanda Biomedical Center
RMS:	Rwanda Medical Supply
TLC:	Thin Layer Chromatography
USAID:	US Agency for International Development

# EXECUTIVE SUMMARY

To achieve the Rwanda's Extended Malaria Strategic Plan 2013–2020 in its strategy 3 “Strengthen quality assurance and control of all malaria consumables and commodities”, the President's Malaria Initiative (PMI) is supporting the National Malaria control program and Rwanda Food Drug Authority (Rwanda FDA) to conduct the quality control of antimalarial medicines sampled across the different supply chain levels. The aim of the activity is to assess whether antimalarial medicines keep or not the quality after being stored and distributed throughout supply chain levels.

The sample collection was conducted in November 2020 in 8 districts selected to represent all five Rwanda provinces. The sampling criteria followed geographical and endemic zones representation, Samples were collected at the central medical store, district stores, health facilities and CHWs levels. The selection of health facilities included both high and low malaria cases and one CHW in each of the five districts was also selected.

Nyagatare and Kirehe from Eastern Province, Burera from Northern Province, Ruhango and Gisagara from Southern Province, Rubavu and Rusizi from Western Province, and Gasabo from Kigali City are the 8 districts where samples were collected from.

The samples size was 100 tablets for each type of ACTs and 110 vials for Artesunate injectable. In total 84 and 9 samples were collected for ACTs and Artesunate injectable, respectively.

The samples were collected by a team composed of staff from GHSC-PSM, Rwanda Biomedical Center/ Malaria and Other Parasitic Disease Division (RBC/Mal&OPDD), Rwanda Medical Supply (RMS) Ltd and Rwanda FDA. Samples were sent to the selected testing laboratory named InphA GmbH Medicine Control Laboratory through DHL, and the testing took place between January and February 2021. Tests performed for ACTs are uniformity of mass, disintegration / dissolution), identity test and related substances (impurities Assay while Compliance with the monograph for parenteral preparations (Clarity and color of solution, Particulate matter, pH, Water content, Sterility, Filling quantity variation), Identity tests, Bacterial endotoxins, Related substances Assay and sterility are the tests performed for Artesunate.

The results from different tests performed showed that all samples tested fell within the acceptable range, which means that samples tested are of good quality and are summarized below:

*Table 1 Number of samples per product item*

Descriptions	Quantity of samples	Q.C results
Artemether Lumefantrine 6x1	21	Complied
Artemether Lumefantrine 6x2	21	Complied
Artemether Lumefantrine 6x3	21	Complied
Artemether Lumefantrine 6x4	21	Complied
Artesunate injection	9	Complied
<b>Total samples</b>	<b>93</b>	

# BACKGROUND

To achieve the Rwanda's Extended Malaria Strategic Plan 2013–2020 in its strategy 3 “Strengthen quality assurance and control of all malaria consumables and commodities”, the President's Malaria Initiative (PMI) is supporting the National Malaria control program and Rwanda Food Drug Authority (Rwanda FDA) to conduct the quality control of antimalarial medicines sampled across the different supply chain levels. The aim of the activity is to assess whether antimalarial medicines keep or not the quality after being stored and distributed throughout supply chain levels.

The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) Project has supported the quality control of in country stock of ACTs and Artesunate injectable through the US President's Malaria Initiative funding. The activity used funding allocated to malaria product quality control in FY 17, FY18, FY19 and FY 20 Rwanda Malaria Operation Plans (MOPs). Funding from the four previous MOPs were combined to be able to meet the activity cost with the minimum samples that were deemed necessary to have a comprehensive representation of the in-country stock from all levels. This report describes how the activity was conducted from the samples collection to the quality control of the samples.

Before starting the activity, a concept note describing the technical, logistic and financial organization of the activity was developed and discussed with the technical team from Mal&OPDD, GHSC-PSM, RMS and Rwanda FDA, finally approved by Mal&OPDD leadership. Prior to data collection, a qualified testing laboratory was selected by GHSC-PSM.

## SAMPLE COLLECTION OF ACTS AND ARTESUNATE

### Sampling methodology

The project organized a collection of samples in 8 RMS branches , 8 health centers and 4 community in each of 5 provinces. The sample collection was conducted in collaboration with RBC/Mal&OPDD, RMS and Rwanda FDA who provided 4 staff for the sample collection: two from Rwanda FDA, one from RMS, and one from RBC/MOPDD. Sites were selected in each province following the malaria situation.

The methodology was developed in close collaboration with the Director of Quality Assurance/Quality Control Department from RMS and the Division Manager for Pharmacovigilance and safety Monitoring from Rwanda FDA to ensure we follow international and country standards for the quality control of antimalarial medicines.



Photo 1 picture taken during sample collection at RMS Gasabo Branch

The selection criteria were based on low and high malaria cases. Samples were collected in the following sites of 4 supply chain levels: central level, district, health center and community.

Sample collection in the community was performed in one community per province with exception for west where we collected in 2 community and none in North because in the North the community case management is very rare due to their very low malaria endemicity.

*Table 2 Sample collection sites in 5 provinces*

Province	District	Health Center	Community
East	Nyagatare RMS branch	Nyagatare HC	Kinihira cell, Kinihira village
	Kirehe RMS branch	Kirehe HC	-
South	Ruhango RMS branch	Kigoma HC	Bihoma cell, Rwoga village
	Gisagara RMS branch	Gisagara HC	-
West	Rusizi RMS branch	Nkanka HC	Rugabano cell, Karambo village
	Rubavu RMS branch	Byahi HC	Byahi cell, Buhuru village
North	Burera RMS branch	Kirambo HC	-
Kigali City	Gasabo RMS branch	Kagugu HC	-
	RMS H.Q	-	-

The samples collected had at least passed minimum period of 1 month at selected sites to assess if the storage conditions of drugs have not affected the quality of antimalarial products.

The quantity of samples was also determined with the support of quality control experts from RMS and Rwanda FDA; the minimum quantity for ACTs per sample was 100 tablets per each ACT age group category while being 110 vials for Artesunate.

During sampling collection, a sample collection form which include preliminary information of the sample, storage conditions at the site and visual description. (See in annex....) was filled.

Table 3 Quantities of samples per product category

Product	# of tablets per sample/site	# of tablets per blister	# of blisters per ACTs age group/site	Unit of measure	#of blisters for 2 sites: DP and HC	# of samples
AL 6x1	100 tablets	6	17	Blisters	34	2
AL 6x2	100 tablets	12	9	Blisters	18	2
AL 6x3	100 tablets	18	6	Blisters	12	2
AL 6x4	100 tables	24	5	Blisters	10	2
Total ACTs samples per district						8
Total ACTs in 8 districts						64
ACTs from MPPD						4
AL (4 age groups) from the community in 4 endemic districts						16
<b>Artesunate injection</b>						<b>9</b>
<b>Total samples</b>						<b>93</b>

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### Sample codification

The sample codification is necessary in order to keep the confidentiality of samples collected for quality control. This was agreed with RMS and Rwanda FDA partners as follow:

- First character: represents the province
  - Second and third characters: represent RMS branch
  - Fourth and fifth characters represent the site
- Last 5 characters represent product name and dosage for ACTs

### Sample transportation

The laboratory which was selected to perform quality control test shared with the Project the requirements to meet the safety of the samples during transport.

The requirements were as the follow:

1. Sample size for each container
2. Information to be provided for each container for custom services
3. Notice information transportation company that samples are for laboratory testing purposes only

Samples were packed in specialized packaging to keep them safe throughout transportation and avoid breakage of vials. The collected samples were sent to an International transportation company DHL working in Rwanda early December 2020, which dispatched the samples to the selected laboratory in Germany named InphA GmbH Medicine Control Laboratory with respect of the storage conditions (room temperature) as specified by the manufacturer.



# QUALITY CONTROL OF ACTS AND ARTESUNATE

## Laboratory analysis performed

The samples were received by the selected laboratory InphA GmbH Medicine Control Laboratory. All samples were checked and different tests were performed in January 2021 and February 2021. The following are the tests performed:



Photo 2 Artemether Lumefantrine gringing, in preparation of the dissolution test for ACTs

### ACTs tablets

- Compliance with the monograph for tablets (Uniformity of mass, disintegration / dissolution)
- Identity test
- Related substances (impurities)
- Assay.



Photo 3 Artesunate particles test

### Artesunate injection:

- Compliance with the monograph for parenteral preparations (Clarity and color of solution, Particulate matter, pH, Water content, Sterility, Filling quantity variation)
- Identity tests
- Bacterial endotoxins
- Related substances
- Assay



# RESULTS OF THE QUALITY TESTING PER SAMPLE

The InphA GmbH Medecin Control Laboratory performed the quality testing and submitted to the Project individual certificates of samples tested. Each of the certificates showed the results per chemical or physical analysis performed per sample. 100% of all the samples of ACTs and Artesunate injectable met the quality standards. The table below shows the details findings for each sample tested:

Table 4 Results of the Q.C performed per sample

District	Product name	Manufacturer	Batch number	Expiry date	Product country code	Quantity of blister/vial per sample	Q.C results	Product laboratory code	# of samples per site sent for Q.C	# of samples that complied QC
	RUBAVU RMS branch									
RUBAVU	Artemether Lumefantrine 20mg/120mg 6X1	Novartis Saglik	KU235	Jan-22	WRUDPAL6X1	17	Complied	M-210018		
	Artemether Lumefantrine 20mg/120mg 6X2	ajanta pharma limited	PA0649G	Jun-21	WRUDPAL6X2	9	complied	M-210028		
	Artemether Lumefantrine 20mg/120mg 6X3	CiplaQCIL	QK91328	Jul-22	WRUDPAL6X3	6	complied	M-210051		
	Artemether Lumefantrine 20mg/120mg 6X4	Strides shasun limited	7239274	Aug-21	WRUDPAL6X4	5	complied	M-210067		
	Artesunate injection 60mg	Guilin pharmaceutical co., Ltd	LA190650	Apr-22	WRUDPARTES	110	complied	M-210090	5	5
	BYAHI HC									
	Artemether Lumefantrine 20mg/120mg 6X1	Ajanta pharma limited	PA1789G	21-Jun	WRUHCAL6X1	17	complied	M-210030		
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA1809G	21-Jun	WRUHCAL6X2	9	complied	M-210031		
	Artemether Lumefantrine 20mg/120mg 6X3	Strides shasun limited	7236363	21-Jan	WRUHCAL6X3	6	complied	M-210063		
	Artemether Lumefantrine 20mg/120mg 6X4	Strides shasun limited	7238532	21-Jul	WRUHCAL6X4	5	complied	M-210065		
	COMMUNITY :BYAHI cell; village									
	Artemether Lumefantrine 20mg/120mg 6X1	Ajanta pharma limited	PA1789G	21-Jun	WRUCOAL6X1	17	complied	M-210029	4	4
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA1809G	21-Jun	WRUCOAL6X2	9	Complied	M-210032		

District	Product name	Manufacturer	Batch number	Expiry date	Product country code	Quantity of blister/vial per sample	Q.C results	Product laboratory code	# of samples per site sent for Q.C	# of samples that complied QC	
	Artemether Lumefantrine 20mg/120mg 6X3	Strides shasun limited	7236363	21-Jan	WRUCOAL6X3	6	complied	M-210064			
	Artemether Lumefantrine 20mg/120mg 6X4	Strides shasun limited	7238532	21-Jul	WRUCOAL6X4	5	complied	M-210066			
RUSIZI	RUSIZI RMS branch										
	Artemether Lumefantrine 20mg/120mg 6X1	CIPLA LTD,PLOT 9&10,INDIA	ID00253	Oct-22	WRSDPAL6X1	17	Complied	M-210010			
	Artemether Lumefantrine 20mg/120mg 6X2	AJANTA PHARMA LIMITED,INDIA	PA1809G	Jun-21	WRSDPAL6X2	9	Complied	M-210040			
	Artemether Lumefantrine 20mg/120mg 6X3	CIPLA QCIL,Kampala,Uganda	QK91330	Jul-22	WRSDPAL6X3	6	Complied	M-210052			
	Artemether Lumefantrine 20mg/120mg 6X4	STRIDES SHASUN LIMITED,INDIA	7239412	Sep-21	WRSDPAL6X4	5	Complied	M-210068			
	Artesunate injection 60mg	GUILIN PHARMACEUTICAL CO LTD	LA190808	Apr-21	WRSDPARTES	110	Complied	M-210094			5
	NKANKA HC										
	Artemether Lumefantrine 20mg/120mg 6X1	CIPLA LTD,PLOT 9&10,INDIA	ID00254	Nov-22	WRSHCAL6X1	17	Complied	M-210012	4	4	
	Artemether Lumefantrine 20mg/120mg 6X2	AJANTA PHARMA LIMITED,INDIA	PA0609G	Jun-21	WRSHCAL6X2	9	Complied	M-210042			
	Artemether Lumefantrine 20mg/120mg 6X3	CIPLA QCIL,Kampala,Uganda	QK91330	Jul-22	WRSHCAL6X3	6	Complied	M-210053			
	Artemether Lumefantrine 20mg/120mg 6X4	STRIDES SHASUN LIMITED,INDIA	7239412	Sep-21	WRSHCAL6X4	5	Complied	M-210069			
	COMMUNITY :RUGABANO cell; KARAMBO village										
	Artemether Lumefantrine 20mg/120mg 6X1	CIPLA LTD,PLOT 9&10,INDIA	ID00253	Oct-22	WRSCOAL6X1	17	Complied	M-210011	4	4	
	Artemether Lumefantrine 20mg/120mg 6X2	AJANTA PHARMA LIMITED,INDIA	PA1809G	Jun-21	WRSCOAL6X2	9	Complied	M-210041			
	Artemether Lumefantrine 20mg/120mg 6X3	CIPLA QCIL,Kampala,Uganda	QK91330	Jul-22	WRSCOAL6X3	6	Complied	M-210054			
	Artemether Lumefantrine 20mg/120mg 6X4	STRIDES SHASUN LIMITED,INDIA	7239412	Sep-21	WRSCOAL6X4	5	Complied	M-210070			
	GASABO	GASABO RMS branch									
		Artemether Lumefantrine 20mg/120mg 6X1	CIPLA LTD,PLOT9&10,INDIA	ID00253	Oct-22	KGADPAL6X1	17	Complied	M-210013	5	5

District	Product name	Manufacturer	Batch number	Expiry date	Product country code	Quantity of blister/vial per sample	Q.C results	Product laboratory code	# of samples per site sent for Q.C	# of samples that complied QC
	Artemether Lumefantrine 20mg/120mg 6X2	AJANTA PHARMA LIMITED,INDIA	PA1809G	Jun-21	KGADPAL6X2	9	Complied	M-210045		
	Artemether Lumefantrine 20mg/120mg 6X3	STRIDES SHASUN LIMITED,INDIA	7236363	Jan-21	KGADPAL6X3	6	Complied	M-210071		
	Artemether Lumefantrine 20mg/120mg 6X4	STRIDES SHASUN LIMITED,INDIA	7239274	Aug-21	KGADPAL6X4	5	Complied	M-210073		
	Artesunate injection 60mg	GUILIN PHARMACEUTICAL CO LTD,CHINE	ZA1190612	Apr-21	KGADPARTES	110	Complied	M-210095		
	KAGUGU HC									
	Artemether Lumefantrine 20mg/120mg 6X1	AJANTA PHARMA LIMITED,INDIA	PA1789G	Jun-21	KGAHCAL6X1	17	Complied	M-210044	4	4
	Artemether Lumefantrine 20mg/120mg 6X2	AJANTA PHARMA LIMITED,INDIA	PA0609G	Jun-21	KGAHCAL6X2	9	Complied	M-210043		
	Artemether Lumefantrine 20mg/120mg 6X3	STRIDES SHASUN LIMITED,INDIA	7236363	Jan-21	KGAHCAL6X3	6	Complied	M-210072		
	Artemether Lumefantrine 20mg/120mg 6X4	STRIDES SHASUN LIMITED,INDIA	7239274	Aug-21	KGAHCAL6X4	5	Complied	M-210074		
KIREHE	KIREHE RMS branch									
	Artemether Lumefantrine 20mg/120mg 6X1	CIPLA LTD	ID00254	Nov-22	EKIDPAL6X1	17	complied	M-210003	5	5
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA0609G	Jun-21	EKIDPAL6X2	9	complied	M-210021		
	Artemether Lumefantrine 20mg/120mg 6X3	CIPLA QCIL	BQK9132B	Jul-22	EKIDPAL6X3	6	complied	M-210048		
	Artemether Lumefantrine 20mg/120mg 6X4	strides shasunlimited	7239411	Sep-21	EKIDPAL6X4	5	complied	M-210062		
	Artesunate injection 60mg	Guillin Pharmaceutical co.ltd	LA190650	Apr-22	EKIDPARTES	110	complied	M-210091		
	NARUBUYE HC									
	Artemether Lumefantrine 20mg/120mg 6X1	Ajanta pharma limited	KU235	Jan-22	EKIHCAL6X1	17	complied	M-210020	4	4
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA1809G	Jun-21	EKIHCAL6X2	9	complied	M-210022		
	Artemether Lumefantrine 20mg/120mg 6X3	strides shasunlimited	7236364	Jan-21	EKIHCAL6X3	6	complied	M-210060		
Artemether Lumefantrine 20mg/120mg 6X4	strides shasunlimited	7239274	Aug-21	EKIHCAL6X4	5	complied	M-210061			
NYAGATA RE	NYAGATARE RMS branch									
	Artemether Lumefantrine 20mg/120mg 6X1	CIPLA LTD	ID00253	Oct-22	ENYDPAL6X1	17	complied	M-210009	5	5
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA18096	Jun-21	ENYDPAL6X2	9	complied	M-210037		
	Artemether Lumefantrine 20mg/120mg 6X3	Strides shasun limited	7236363	Jan-21	ENYDPAL6X3	6	complied	M-210081		

District	Product name	Manufacturer	Batch number	Expiry date	Product country code	Quantity of blister/vial per sample	Q.C results	Product laboratory code	# of samples per site sent for Q.C	# of samples that complied QC	
	Artemether Lumefantrine 20mg/120mg 6X4	Strides shasun limited	7239412	Sep-21	ENYDPAL6X4	5	complied	M-210086			
	Artesunate injection 60mg	Guillin pharmaceutical co.ltd	LA190650	Apr-22	ENYDPARTES	4	complied	M-210089			
	NYAGATARE HC										
	Artemether Lumefantrine 20mg/120mg 6X1	Ajanta pharma limited	PA17896	Jun-21	ENYHCAL6X1	17	complied	M-210035	4	4	
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA18096	Jun-21	ENYHCAL6X2	9	complied	M-210038			
	Artemether Lumefantrine 20mg/120mg 6X3	Strides shasun limited	7238532	Jul-21	ENYHCAL6X3	6	complied	M-210083			
	Artemether Lumefantrine 20mg/120mg 6X4	Strides shasun limited	7238532	Jul-21	ENYHCAL6X4	5	complied	M-210084			
	COMMUNITY :KINIHIRA cell; KINIHIRA village										
	Artemether Lumefantrine 20mg/120mg 6X1	Ajanta pharma limited	PA17896	Jun-21	ENYCOAL6X1	17	complied	M-210036	4	4	
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PAO649G	Jun-21	ENYCOAL6X2	9	complied	M-210039			
	Artemether Lumefantrine 20mg/120mg 6X3	Strides shasun limited	7236363	Jan-21	ENYCOAL6X3	6	complied	M-210082			
	Artemether Lumefantrine 20mg/120mg 6X4	Strides shasun limited	7238532	Jul-21	ENYCOAL6X4	5	complied	M-210085			
	RUHANGO RMS branch										
	Artemether Lumefantrine 20mg/120mg 6X1	Cipla	ID 00254	Nov-22	SRUDPAL6X1	17	Complied	M-210004	5	5	
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA 1809 G	Jun-21	SRUDPAL6X2	9	Complied	M-210025			
Artemether Lumefantrine 20mg/120mg 6X3	CiplaQCIL	BOK 91329	Jun-22	SRUDPAL6X3	6	Complied	M-210049				
Artemether Lumefantrine 20mg/120mg 6X4	Strides shasun limited	7239274	Aug-21	SRUDPAL6X4	5	Complied	M-210078				
Artesunate injection 60mg	Guillin Pharmaceutical co.ltd	LA 180616	May-21	SRUDPARTES	110	Complied	M-210088				
KIGOMA HF											
Artemether Lumefantrine 20mg/120mg 6X1	Novartis Saglik	KM 850	Mar-21	SRUHCAL6X1	17	Complied	M-210016	4	4		
Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA 0649 G	Jun-21	SRUHCAL6X2	9	Complied	M-210024				
Artemether Lumefantrine 20mg/120mg 6X3	Strides shasun limited	7236364	Mar-21	SRUHCAL6X3	6	Complied	M-210077				
Artemether Lumefantrine 20mg/120mg 6X4	Strides shasun limited	7239274	Aug-21	SRUHCAL6X4	5	Complied	M-210079				
COMMUNITY :Bihoma cell; Rwoga village											

District	Product name	Manufacturer	Batch number	Expiry date	Product country code	Quantity of blister/vial per sample	Q.C results	Product laboratory code	# of samples per site sent for Q.C	# of samples that complied QC	
	Artemether Lumefantrine 20mg/120mg 6X1	Novartis Saglik	KM 850	Mar-21	SRUCOAL6X1	17	Complied	M-210017	4	4	
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA 0649 G	Jun-21	SRUCOAL6X2	9	Complied	M-210023			
	Artemether Lumefantrine 20mg/120mg 6X3	Cipla QCIL	BOK 91330	Jul-21	SRUCOAL6X3	6	Complied	M-210050			
	Artemether Lumefantrine 20mg/120mg 6X4	Strides shasun limited	7239274	Aug-21	SRUCOAL6X4	5	Complied	M-210080			
GISAGARA	GISAGARA RMS branch										
	Artemether Lumefantrine 20mg/120mg 6X1	Cipla	ID 00254	Nov-22	SGIDPAL6X1	17	complied	M-210006	5	5	
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA 0760 B	Jan-23	SGIDPAL6X2	9	complied	M-210026			
	Artemether Lumefantrine 20mg/120mg 6X3	Cipla	BQK 91328	Jul-22	SGIDPAL6X3	6	complied	M-210005			
	Artemether Lumefantrine 20mg/120mg 6X4	Strided shasun limited	7239412	Sep-21	SGIDPAL6X4	5	complied	M-210058			
	Artesunate injection 60mg	Guillin Pharmaceutical co.ltd	LA 190808	Apr-22	SGIDPARTES	110	complied	M-210093			
	GISAGARA HF										
	Artemether Lumefantrine 20mg/120mg 6X1	Cipla	ID 00254	Nov-22	SGIHCAL6X1	17	complied	M-210007	4	4	
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA 18096	June-21	SGIHCAL6X2	9	complied	M-210027			
	Artemether Lumefantrine 20mg/120mg 6X3	Strided shasun limited	7236364	January-21	SGIHCAL6X3	6	complied	M-210057			
	Artemether Lumefantrine 20mg/120mg 6X4	Strided shasun limited	7239412	Sep-21	SGIHCAL6X4	5	complied	M-210059			
	BURERA	BURERA RMS branch									
		Artemether Lumefantrine 20mg/120mg 6X1	CIPLALTD	ID00254	Nov-22	NBUDPAL6X1	17	complied	M-210014	5	5
		Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA 1809G	Jun-21	NBUDPAL6X2	9	complied	M-210046		
Artemether Lumefantrine 20mg/120mg 6X3		CiplaQCIL	QK91330	Jul-22	NBUDPAL6X3	6	complied	M-210055			
Artemether Lumefantrine 20mg/120mg 6X4		Strides shasun limited	7239411	Sep-21	NBUDPAL6X4	5	complied	M-210075			
Artesunate injection 60mg		Guilin pharmaceutical CO., Ltd	LA190650	Apr-22	NBUDPARTES	110	complied	M-210087			
KIRAMBO HF											
Artemether Lumefantrine 20mg/120mg 6X1		CIPLALTD	ID00254	Nov-22	NBUHCAL6X1	17	complied	M-210015	4	4	
Artemether Lumefantrine 20mg/120mg 6X2		Ajanta pharma limited	PA 1809G	Jun-21	NBUHCAL6X2	9	complied	M-210047			
Artemether Lumefantrine 20mg/120mg 6X3		CiplaQCIL	QK91330	Jul-22	NBUHCAL6X3	6	complied	M-210056			

District	Product name	Manufacturer	Batch number	Expiry date	Product country code	Quantity of blister/vial per sample	Q.C results	Product laboratory code	# of samples per site sent for Q.C	# of samples that complied QC
	Artemether Lumefantrine 20mg/120mg 6X4	Strides shasun limited	7239411	Sep-21	NBUHCAL6X4	5	complied	M-210076		
RMS Central level	RMS Central level									
	Artemether Lumefantrine 20mg/120mg 6X1	Cipla ltd	ID00254	Nov-22	KGLRMSAL6X1	17	complied	M-210008		
	Artemether Lumefantrine 20mg/120mg 6X2	Ajanta pharma limited	PA0690B	Jan-23	KGLRMSAL6X2	9	complied	M-210034		
	Artemether Lumefantrine 20mg/120mg 6X3	Ajanta pharma limited	PA0560A	Dec-22	KGLRMSAL6X3	6	complied	M-210033		
	Artemether Lumefantrine 20mg/120mg 6X4	Ipca laboratories ltd	HWE1020152	Feb-22	KGLRMSAL6X4	5	complied	M-210019		
	Artesunate injection 60mg	Guillin pharmaceutical co.ltd	LAI90650	Apr-22	KGLRMSARTES	110	complied	M-210092	5	5
Total samples									93	93

## CHALLENGES AND RECOMMENDATION

The main challenge faced for the implementation of the Quality control of antimalaria medicines was the delay of its implementation because funding planned in individual MOP could not cover the quality control activity cost to meet the minimum samples that were deemed necessary to have a comprehensive representation of the in country stock from all levels. It is recommended to increase funding allocated for this support in future MOPs if the activity have to be conducted every year.

## CONCLUSION

The samples collection and transportation as well as the quality control testing of ACTs and Artesunate vials were successfully conducted and brought to an end. 100% of all the samples of ACTs and Artesunate injectable met the quality standards, This gives confidence that not only quality ACTs and Artesunate are being procured for Rwanda but also that, the same quality is maintained during storage and distribution across different supply chain levels including the community.



## ANNEX

- Annex 1: Sample collection form
- Annex 2: Results certificate for Artemether Lumefrantrine
- Annex 3: Result certificate for Artesunate injection.

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## SAMPLE COLLECTION FORM

1. Sample code: ..... (Region/product/sequence number/sampling date...../...../.....)
2. Name & Address of Premises where sample was taken:
  - a. Physical Address.....
  - b. Postal address.....
  - c. Telephone No.....
  - d. Email address..... (if applicable)
3. Product name of the sample: .....
  - a. Description/identification (colour).....
  - b. Name of active pharmaceutical ingredient(s) (INN)
  - c. Strength .....
  - d. Dosage form (tablet, oral powder, etc): ..... ..
  - e. Package size & type: ..... ..
  - f. Batch/lot number: .....
  - g. Date of manufacture: .....Expiry date.....
  - h. Remaining shelf life ..... %
4. Name and physical address of the manufacturer: ..... ..
5. Number of units collected (tins, packet).....
6. Is the product registered in the country? Yes/ No.

a. If Yes, indicate the registration number: ..... ..

7. Storage condition of product at the premises:.....

8. Details of representative of the premises and Drug Inspector (s)/Sampling officer(s)

S.No	Name	Organization	Signature	Date

**Note: Sample must remain in their original containers.**