



Republic of Kenya
Ministry of Health
National Quality Control Laboratory

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CERTIFICATE OF ANALYSIS

CERTIFICATE No.: CAN/2017-18/338

REF. No: NDQF201801313

PRODUCT: LUMEFANTRINE SECONDARY REFERENCE STANDARD

DATE RECEIVED: 29 Jan. 2018
LABEL CLAIM: Lumefantrine 500 mg.

BATCH No.: A101002IP
PRESENTATION: Yellow coloured, free flowing powder packed in an amber coloured glass vial with a rubber closure and an aluminium band.

MFG. DATE: -
MANUFACTURER: Technology Solutions For Global Health

EXP. DATE: -
ADDRESS: P. O. Box AF 3228,
Adenta, Accra,
GHANA.

CLIENT REF No: -
CLIENT: Technology Solutions for Global Health

TEST(S) REQUESTED: Identification & Assay.

RESULTS

TEST	METHOD	COMPENDIA	SPECIFICATION	DETERMINED	REMARKS
Identification	HPLC	Client protocol No.: PRO-T4H02-00	RT of the component peak in the test preparation corresponds to that in the standard preparation	Super-imposable component peak at RT $33.3 \pm 10\%$ min. present in both the test and standard preparations	COMPLIES
Assay	HPLC	Client protocol No.: PRO-T4H02-00	-	98.839%	

CONCLUSION: The reference standard has a purity factor of 98.839%

ANALYST: DR. N. MWAURA

DATE: 26. Feb. 18

ANALYST: DR. E. MBAE

DATE: 26. Feb. 18

DIRECTOR: DR. H. K. CHEPKWONY

DATE: 26. Feb. 18

