



Republic of Kenya
Ministry of Health
National Quality Control Laboratory

Hospital Road, KNH Complex, P.O. Box 29726, 00202 Nairobi, Kenya
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CERTIFICATE OF ANALYSIS

CERTIFICATE No: CAN/2016-17/690

PRODUCT:

MENINGOCOCCAL A CONJUGATE LYOPHILIZED
VACCINE MENAFRIVAC 5 Micrograms

REF. NO: NDQD201611238

LABEL CLAIM:

Each dose of 0.5 mL contains: Meningoccal A polysaccharide 5 mcg, Tetanus Toxoid (carrier protein) 5 to 16.5 mcg.

DATE RECEIVED:

Powder: 24.11.2016
Diluent: 24.11.2016

Diluent: Each mL contains: Al+++ content as Aluminium phosphate 0.6 mg, Sodium Chloride 0.9% w/v, Thiomersal 0.01%, Sterile Water for Injections q.s.

PRESENTATION:

Off white lyophilized powder for reconstitution into a solution for intramuscular administration, contained in a clear colourless glass vial with a white coloured flip-off cap and 50 such vials packed in a unit box.

BATCH NO:

Powder: 178T6004
Diluent: 108I6003BZ

Diluent: Cloudy suspension contained in a clear colourless 5 mL glass ampoule on a plastic rack of 10 ampoules, packed in a transparent ziplock paper bag.

MFG. DATE:

Powder: Not Indicated
Diluent: Not Indicated

MANUFACTURER:

SERUM Institute of India Ltd.

ADDRESS:

212/2, Hadapsar, Pune - 411 028,
INDIA.

EXP. DATE:

Powder: May. 2019
Diluent: Oct. 2020

CLIENT:

Serum Institute of India Pvt Ltd.,
% Sai Pharmaceuticals Ltd,
P. O. Box 66551 - 00800, Nairobi,
KENYA.

CLIENT REF NO.

TEST(S) REQUESTED:

Sterility and Acidity/Alkalinity.

RESULTS

TEST	METHOD	COMPENDIA	SPECIFICATION	DETERMINED	REMARKS
Sterility	Membrane Filtration	BP2016 Vol. V App. XVI A.	No Microbial Growth	Powder and Diluent No Microbial Growth	COMPLIES
Acidity/Alkalinity	pH	Manufacturer's In-House Method	5.0 - 7.0	6.8	COMPLIES

CONCLUSION:

The sample complies with the specifications for the tests performed.

ANALYST:

MR. D. OLUOCH

DATE: 18-05-2017

ANALYST:

DR. G. WANG'ANG'A

DATE: 18-05-2017

DIRECTOR:

DR. H. K. CHEPKWONY

DATE: 18-05-2017



National Quality Control Laboratory

ISO/IEC 17025:2005 Accredited Testing Facility

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INVOICE

INVOICE No: 690/16-17

Date: 18th May 2017

Serum Institute of India Ltd,

% Sai Pharmaceuticals Ltd,

P. O. Box 66551 - 00800, Nairobi,

KENYA.

Re: ANALYSIS OF LISTED PRODUCT.

PRODUCT:	MENINGOCOCCAL A CONJUGATE LYOPHILIZED VACCINE MENAFRIVAC 5 Micrograms
BATCH NO:	Powder: 178T6004 Diluent: 108I6003BZ
CERTIFICATE NO:	CAN/2016-17/690
LABORATORY REF NO:	NDQD201611238
CLIENT REF NO:	-
TEST(S) REQUESTED:	Sterility and Acidity/Alkalinity.

COST OF ANALYSIS:

TEST	METHOD	COMPENDIA	COST (Kshs)
Sterility	Membrane Filtration	BP 2016 Vol. V	135,360.00
Acidity/ Alkalinity	pH	Manufacturer's In-House Method	2,160.00
TOTAL COST			137,520.00
AMOUNT PAYABLE			<u>137,520.00</u>

DIRECTOR: DR. H. K. CHEPKWONY

DATE: 18/05/2017

All cheques should be made payable to: NATIONAL QUALITY CONTROL LABORATORY