

Country :Moldavia
Customer :101536, UNICEF
Order :7100022870/000020

CERTIFICATE OF RELEASE

Manufacturer GlaxoSmithKline Biologicals Rixensart - Belgium
Product Polio Sabin (OPV)
Product description Oral Polio Vaccine (live)
Batch number AOP4A623AA
Quantity 10.000 VIA X 10 dose(s)
100 PCK X 100 VIA X 10 dose(s)
Expiry September/2020
Date of manufacture October/2018

I hereby confirm that this batch has been manufactured and controlled in compliance with the cGMP regulations and in accordance with the local regulatory requirements of the receiving market . This includes that, for any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/or formulation of the batch of product specified above, all measures have been taken to demonstrate compliance with Directive 2001/83/EC and amending Directives 2003/63/EC and 2004/27/EC

Charlotte POISSEROUX
Industrial Pharmacist

08 AVR. 2019

QA Release

Eric Sarlet
Qualified Person
QA Director
GSK Biologicals
Rue de l'Institut 89
1330 Rixensart
Belgium



GlaxoSmithKline Biologicals SA
Rue de l'Institut, 89
B-1330 Rixensart
Belgique

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www.gsk.com

CERTIFICATE

Certification by qualified person taking overall responsibility for production and control of the product :

I herewith certify that **POLIO SABIN (OPV) vaccine**

BIVALENT ORAL POLIOMYELITIS VACCINE TYPE 1-3 (Sabin strain)

Batch nr. : **AOP4A623AA**
Manufacture date : **October 2018**
Expiry date : **September 2020**

was manufactured by GlaxoSmithKline, Belgium, and tested according to the procedures approved by the competent authorities and complies with the quality requirements.

This includes that, for any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/or formulation of the batch of product specified above, all measures have been taken to demonstrate compliance with directive 2001/83/EEC, amendments 2003/63/EC and 2004/27/EC.

Charlotte POISSEROUX
Industrial Pharmacist

08 AVR. 2019

QA Release

PO Eric Sarlet
QA Director
Qualified Person
GSK Biologicals
rue de l'Institut, 89
1330 Rixensart
Belgium

Registered as
GlaxoSmithKline Biologicals SA
Rue de l'Institut, 89 BE-1330 Rixensart

TVA BE 0440.872.918 RPM Nivelles
Deutsche Bank AG 826-0006444-59



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STATEMENT

Oral Polio vaccine (live) batch nr.

AOP4A623A (Filling lot)

was used to manufacture the Oral Polio vaccine (live) batch nr.

AOP4A623AA (Packaging lot).

The attached release certificate is applicable for the shipped goods.

Laurane BOURGUEGON
QA Release

08 AVR. 2019

For QA Release Department
GSK Biologicals Belgium

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22 NOV. 2018

BE/18/2554

TO WHOM IT MAY CONCERN

CERTIFICATE FOR THE RELEASE OF POLIO VACCINE

The following lot **AOP4A623AA** of **BIVALENT ORAL POLIOMYELITISVACCINE TYPE 1-3 (Sabin strain)**, produced by *GlaxoSmithKline Biologicals* (Rixensart – Belgium), whose number appears on the labels of the final containers, complies with the relevant specifications in the Belgian registration file and *Part A of the WHO Recommendations to assure the quality, safety and efficacy of live attenuated poliomyelitis vaccine (oral)*¹.

This product is manufactured and controlled in accordance with the requirements for *Good Manufacturing Practices for Pharmaceutical Products: Main Principles*², *Good Manufacturing Practices for Biological Products*³ and *Guidelines for Independent Lot Release of Vaccines by Regulatory Authorities*⁴.

As a minimum, this certificate is based on examination of the summary protocol of manufacturing and control.

Final Lot Nr	Nr of released containers in this final lot	Expiry date
AOP4A623AA	402.800	September 2020

Components:
Vaccine (filling lot Nr.): AOP4A623A

Type of packaging: Vial
Number of doses per unit pack: 10 doses

The Chief of the National Control Laboratory

Geneviève Waeterloos, M. Sc., Head,
Quality of Vaccines and Blood Products Service

¹WHO Technical Report Series, Nr. 980, 2014, Annex 2
²WHO Technical Report Series, Nr. 986, 2014, Annex 2
³WHO Technical Report Series, Nr. 999, 2016, Annex 2
⁴WHO Technical Report Series, Nr. 978, 2013, Annex 2



GENEALOGICAL TREE

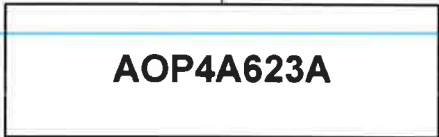
GlaxoSmithKline Biologicals SA
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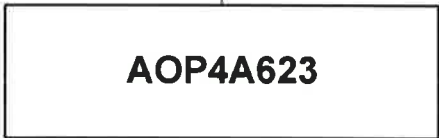
FINAL PACKAGING LOT



FINAL CONTAINER



FINAL BULK



Registered as
GlaxoSmithKline Biologicals SA
Rue de l'Institut, 89 BE-1330 Rixensart

TVA BE 0440.872.918 RPM Nivelles
Deutsche Bank AG 826-0006444-59

CERTIFICATE OF ANALYSIS
COVER PAGE



PAGE 01 FROM 01

PRODUCT:

**POLIOVIRUS SABIN TYPE (1,3) LIVE ATTENUATED ORAL VACCINE - (10-0-6) -
FINAL CONTAINER**

BATCH NUMBER:

AOP4A623A

CERTIFICATE OF ANALYSIS

SUMMARY PAGE

Batch number : AOP4A623



PAGE 01 FROM 01

PRODUCT :

POLIOVIRUS SABIN TYPES (1,3) LIVE ATTENUATED ORAL VACCINE - (10-0-6) - FINAL BULK

BATCH STATUS :

PASS: Inspection Lot Conform

Made by Caroline Geenens on 28.04.2017 at 10:44

TEST	SPECIFICATION	RESULT
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FINAL BULK

STERILITY TEST FTM BY MEMBRANE FILTRATION (AT 30-35°C)	Absence of growth.	PASS
STERILITY TEST TSB BY MEMBRANE FILTRATION (AT 20-25°C)	Absence of growth.	PASS

CERTIFICATE OF ANALYSIS

SUMMARY PAGE

Batch number : AOP4A623A



PAGE 01 FROM 01

PRODUCT :

POLIOVIRUS SABIN TYPE (1,3) LIVE ATTENUATED ORAL VACCINE - (10-0-6) - FINAL CONTAINER

BATCH STATUS :

PASS: Inspection Lot Conform

Made by Marie-Françoise RADELET on 17.05.2017 at 10:16

TEST	SPECIFICATION	RESULT
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FINAL CONTAINER

DESCRIPTION	SPECIFICATION	RESULT
IDENTITY MONOVALENT POLIO VIRUS TYPE 1 BY SERONEUTRALISATION	Clear liquid, yellowish pink, free of foreign particles.	PASS
IDENTITY MONOVALENT POLIO VIRUS TYPE 3 BY SERONEUTRALISATION	Positive.	POSITIVE
IDENTITY POLYSORBATE 80 BY COLORIMETRY	Positive.	POSITIVE
STERILITY TEST FTM BY MEMBRANE FILTRATION (AT 30-35°C)	Absence of growth.	PASS
STERILITY TEST TSB BY MEMBRANE FILTRATION (AT 20-25°C)	Absence of growth.	PASS
pH	Between 6.0 and 7.0.	6.6
MAGNESIUM CHLORIDES CONTENT BY TITRIMETRY	Between 193.1 and 213.5 mg MgCl ₂ .6H ₂ O per ml.	201.2 mg MgCl ₂ .6H ₂ O/ml
VOLUME	Not less than 1.00 ml for 10 doses.	PASS
POTENCY POLIO VIRUS TYPE 1 BY CELL CULTURE TITRATION	Not less than 6.0 Log CCID ₅₀ per dose.	6.2 Log CCID ₅₀ /d
POTENCY POLIO VIRUS TYPE 3 BY CELL CULTURE TITRATION	Not less than 5.8 LogCCID ₅₀ per dose.	6.0 Log CCID ₅₀ /d
POTENCY POLIO VIRUS BY CELL CULTURE TITRATION (AGED 2 DAYS AT 37°C)	Not more than 0.5 Log CCID ₅₀ per dose.	0.4 Log CCID ₅₀ /d