GlaxoSmithKline

Country :Moldavia

Customer :100426, UNICEF

Order :7100023160/000050

CERTIFICATE OF RELEASE

Manufacturer	GlaxoSmithKline Biologicals Rixensart - Belgium
Product	Rotarix Liquid
Product description	HUMAN ROTAVIRUS LIVE ATTENUATED RIX 4414 VACCINE STRAIN
Batch number	AROLC581AA
Quantity	63.000 TUB X 1 dose(s) 1.260 PCK X 50 TUB X 1 dose(s)
Expiry	April/2021
Date of manufacture	May/2019

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

16 OCT. 2019

QA Release

p

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

T +32 (0) 2 656 81 11
F +32 (0) 2 656 80 00
www.gsk.com

STATEMENT

Rotarix (Human rotavirus live attenuated rix 4414 vaccine strain) batch nr.
AROLC581A (filling lot)
was used to manufacture the Rotarix (Human rotavirus live attenuated rix 4414 vaccine strain) batch nr.
AROLC581AA (packaging lot).

The attached release certificate is applicable for the shipped goods.

Giuseppina SICILIANO
16 OCT. 2019
QA Release

For QA Release Department,
GSK Biologicals Belgium

sciensano

Quality of Vaccines and Blood Products

NATIONAL CONTROL LABORATORY BELGIUM

Contact: Geneviève Waeterloos
Tél: +32-2-642.52.39
Fax: +32-2-642.52.10
Secretariat: Pascale Prévédello
E-mail: genevieve.waeterloos@sciensano.be

19 JUIL. 2019

BE/19/1643

TO WHOM IT MAY CONCERN

CERTIFICATE FOR THE RELEASE OF ROTARIX VACCINE

The following lot **AROLC581A** of **ROTARIX** vaccine (**RIX4414 strain**), live attenuated **Rotavirus** vaccine (oral), produced by *GlaxoSmithKline Biologicals* (Rixensart – Belgium), whose number appears on the labels of the final containers, complies with the relevant specifications in the European registration file and *Part A of the **WHO Guidelines** to assure the quality, safety and efficacy of **live attenuated Rotavirus** vaccines (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
AROLC581A	275.443	April 2021

Type of packaging: tube
Number of doses per unit pack: 1 dose

Van der AA Lieke
Vaccine responsible
National Control Laboratory

The Chief of the National Control Laboratory

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

[1]WHO Technical Report Series, Nr. 941, 2007, Annex 3
[2]WHO Technical Report Series, Nr. 986, 2014, Annex 2
[3]WHO Technical Report Series, Nr. 999, 2016, Annex 2
[4]WHO Technical Report Series, Nr. 978, 2013, Annex 2

Sciensano Rue Juliette Wytsmanstraat 14 1050 Brussels Belgium
T + 32 2 642 51 11 F + 32 2 642 50 01 info@sciensano.be www.sciensano.be

Batch Final Packaging	Incoming Batch	Labelled Lot	Batch Diluent	Batch Final Container	Incoming Batch	Batch Final Bulk
AROLC581AA	AROLC581A	N/A	N/A	**AROLC581A**	AROLC581	**AROLC581**

CERTIFICATE OF ANALYSIS

COVER PAGE

GlaxoSmithKline

PRODUCT :

ROTAVIRUS (89-12) LIVE ATTENUATED ORAL VACCINE (FULL LIQUID) - FINAL CONTAINER

BATCH NUMBER :

AROLC581A

CERTIFICATE OF ANALYSIS

SUMMARY PAGE

Batch number : AROLC581

GlaxoSmithKline

PRODUCT : ROTAVIRUS (89-12) LIVE ATTENUATED ORAL VACCINE (FULL LIQUID) - FINAL BULK

BATCH STATUS : PASS: Inspection Lot Conform
Made by Caroline Geenens on 05.06.2019 at 12:33

TEST	SPECIFICATION	RESULT
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 : AROLC581A

GlaxoSmithKline

PRODUCT : ROTAVIRUS (89-12) LIVE ATTENUATED ORAL VACCINE (FULL LIQUID) - FINAL CONTAINER

BATCH STATUS : PASS: Inspection Lot Conform
Made by Florence Vantieghem on 05.07.2019 at 09:13

TEST	SPECIFICATION	RESULT
FINAL CONTAINER		
DESCRIPTION	Clear, colourless, liquid, free from visible particles.	PASS
IDENTITY ROTAVIRUS BY CELL CULTURE TITRATION	Positive.	POSITIVE
IDENTITY SUCROSE BY HPLC	Positive.	POSITIVE
IDENTITY DISODIUM ADIPATE BY HPLC	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
VOLUME	Not less than 1.5 ml.	PASS
pH	Between 6.3 and 7.3.	7.0
SUCROSE CONTENT BY HPLC	Between 912 and 1286 mg per dose.	1,074 mg/d
DISODIUM ADIPATE CONTENT BY HPLC	Between 112.8 and 152.7 mg per dose.	131.7 mg/d
POTENCY ROTAVIRUS BY CELL CULTURE TITRATION	Not less than 6.3 log CCID50 per dose.	6.7 Log CCID50/d
POTENCY ROTAVIRUS BY CELL CULTURE TITRATION (LOSS AFTER 7 DAYS AT 37°C)	Not more than 0.5 log from the release titre.	0.3 Log CCID50/d