Bilthoven Biologicals
Cyrus Poonawalla Group

Certificate of Conformity / release notification

Certification by qualified person of Bilthoven Biologicals B.V. taking the overall responsibility for production and control of the medicinal product.

Name	**Poliomyelitisvaccin**
Marketing authorization no.	RVG 17642
Batch no.	1846001A
Manufacturing date	24-Oct-2018
Expiry date	24-Oct-2021

I herewith certify that the above indicated batch of medicinal product has been manufactured 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 2001/83EC and amending Directives 2003/63/EC and 2004/27/EC.

☒ The batch has been released for distribution on the Unicef market

☐ The batch has been released for distribution to a third party manufacturer in

Name	drs. M.A. van Peyma - Hoekzema
Function	Qualified Person
Date	28-Jan-2019
Signature	

Visiting Address:
Bilthoven Biologicals B.V.
Antonie van Leeuwenhoeklaan 9- 13
3721 MA BILTHOVEN, THE NETHERLANDS

Postal address:
P.O.-Box 457
3720 AL BILTHOVEN
KvK 53751221

T +31 (0)30 800 4800
F +31 (0)30 800 4848
E info@bbio.nl
I www.bbio.nl

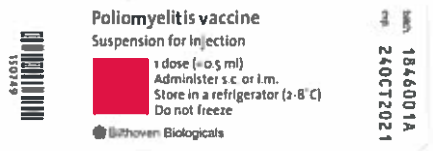
Summary protocol / Certificate of Analysis

Manufacturer	
Name manufacturer	**Bilthoven Biologicals B.V.**
Address	**P.O. Box 457** **3720 AL Bilthoven** **The Netherlands**
Proprietary name	**Inactivated poliomyelitis vaccine (IPV)**
Trade name	**Poliomyelitis vaccin**
Marketing authorization no°	**RVG-17642**

Note: all dates are represented as dd-mm-yyyy

Final lot(s)					
Volume of 1 human dose			**0.5 ml**		
Batch number of final bulk			**1841000285**		
Date of manufacture of final bulk			**18-10-2018**		
Lot no.	**No. of vials filled**	**No. of vials packed**	**Volume filled (ml)**	**Date of manufacture**	**Expiry date** *storage at 5±3 °C*
1846001	**60465**	**n.a.**	**0.6**	**24-10-2018**	**24-10-2021**
1846001A		**25277**	**0.6**	**24-10-2018**	**24-10-2021**

Labels appearing on the vials:



Summary protocol IPV vaccine 1846001

TSE compliance

Materials derived from ruminants used in the manufacture of this batch:

	n° certificate	date of submission dossier to competent authority
Donor bovine serum	CEP 2000-171 and/or CEP 2000-341 and/or CEP 2001-452	-
Trypsine	Not applicable (contains only lactose)	-

Certification

Certification by qualified person taking the overall responsibility for production and control of the inactivated poliomyelitis vaccine.

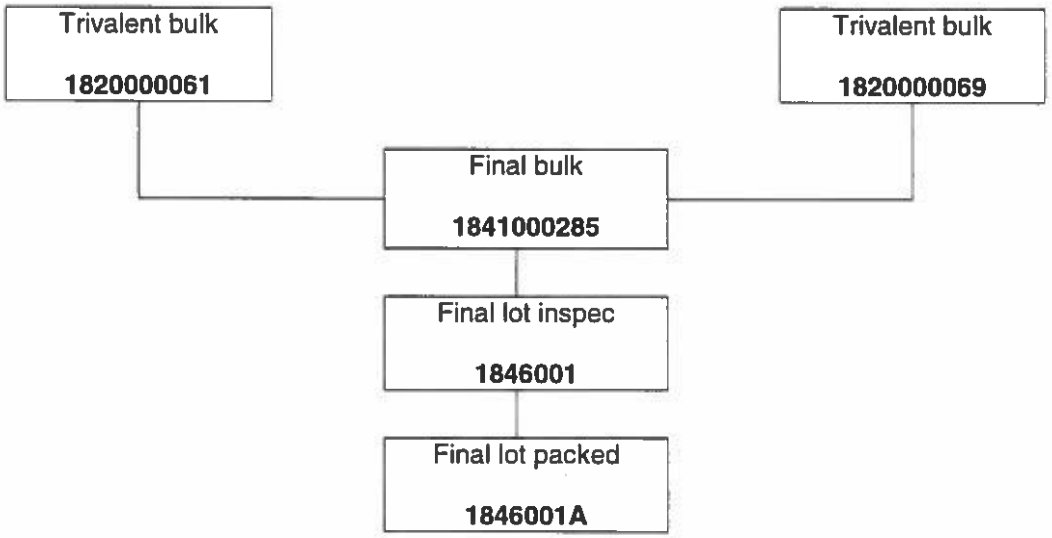
I herewith certify that IPV batch N° **1846001A** was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirements. This includes that, for any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/or formulation of the batch of product specified above, all measures have been taken to demonstrate compliance with Commission Directive 2001/83/EC and amending Directives 2003/63/EC and 2004/27/EC.

Qualified Person: Drs. L.C. Sundermann / Drs. M.A. van Peyma / Drs. T. Lammerink

Signature: _____

Date of issue: 23-Jan-19

Production Flow Sheet 1846001



IPV vaccine, final lot.....1846001

Final lot		**Result or data**	***Specification***
Corresponding final bulk		**1841000285**	
Filling-site		**Bilthoven**	
Date of filling (=manufacturing date)		**24-10-2018**	
Batch number of final lot		**1846001**	
Volume filled		**0.5 ml**	
Expiry date, storage at 5 ± 3°C		**24-10-2021**	*max. 36 months after date of potency test*
		Result or data	***Specification***
D-antigen content, confirmation of identity			
method		**Ph. Eur. 2.7.1**	
date		**03-12-2018**	
result	type 1	**46 DU/hd**	*≥ 30 DU/hd*
	type 2	**8 DU/hd**	*≥ 6 DU/hd*
	type 3	**36 DU/hd**	*≥ 24 DU/hd*
Appearance		**Clear orange-red liquid**	*clear orange-red liquid*
Test for sterility			
method		**Ph. Eur. 2.6.1**	
media		**thioglycollate / TSB**	
number of vials tested		**40**	
date test on		**30-10-2018**	
date test off		**13-11-2018**	
result		**no growth observed**	*no growth of bacteria or funghi*
Test for protein content			
method		**Calculated from trivalent bulk value**	
result		**2.9 µg/ml**	*≤ 20 µg/ml*
Test for endotoxins			
method		**Ph. Eur. 2.6.14**	
date of test		**28-11-2018**	
result		**<1 IU/hd**	*≤ 5 IU/hd*
Test for pH			
method		**electrometric with glass electrode**	
date		**27-11-2018**	
result		**7.0**	*6.8 – 7.4*
Test for extractable volume			
method		**ANA-20073**	
number of vials tested		**5**	
date test on		**03-12-2018**	
Result, mean of 5 vials		**0.5 ml**	*≥ 0.5 ml*

* hd = human dose

Remarks:

IPV vaccine, final bulk.....1841000285

Final bulk		**Result or data**	*Specification*
Nominal composition			
poliomyelitis	type 1	**80 DU/ml**	
	type 2	**16 DU/ml**	
	type 3	**64 DU/ml**	
Nature and concentration of preservatives			
formaldehyde		**0.83 mmol/l**	
2-phenoxyethanol		**36.2 mmol/l**	
Volume of human dose		**0.5 ml**	
Date of manufacture		**18-10-2018**	
Batch number of final bulk		**1841000285**	
Volume of final bulk		**400 l**	
Expiry date for final lot processing		**18-10-2019**	*12 months after manufacturing date final bulk*
Expiry date of corresponding final lot, storage at 5 ± 3°C		**24-10-2021**	*max. 36 months after date of potency test*
Storage in type 1 glass container or stainless steel container at 2-8°C			

Composition	**Batch no.**	**Volume (l)**	**Concentration**	**Exp. date**
IPV, trivalent bulk	**1820000061**	**40**	**400 – 80 - 320**	**06-09-2020**
IPV, trivalent bulk	**1820000069**	**40**	**400 – 80 – 320**	**06-09-2020**

		Result or data	*Specification*
Test for sterility			
method		**Ph. Eur. 2.6.1**	
media		**thioglycollate / TSB**	
volume inoculated		**10 ml / 10 ml**	
date test on		**23-10-2018**	
date test off		**06-11-2018**	
result		**no growth observed**	*no growth of bacteria or funghi*
Test for pH			
method		**electrometric with glass electrode**	
date		**19-10-2018**	
result		**7.0**	*6.8 – 7.4*
Test for formaldehyde			
method		**HPLC**	
date		**22-10-2018**	
result		**0.9 mmol/l**	*0.7 – 1.0*
Test for 2-phenoxyethanol			
method		**HPLC**	
date		**22-10-2018**	
result		**35 mmol/l**	*31 – 42*
Potency test poliomyelitis			
D-antigen content			
method		**Ph. Eur. 2.7.1**	
date		**24-10-2018**	
result	type 1	**92 DU/ml**	*≥ 60*
	type 2	**17 DU/ml**	*≥ 12*
	type 3	**67 DU/ml**	*≥ 48*

Remarks:

National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

EU Official Control Authority
BATCH RELEASE CERTIFICATE

Finished Product

Examined under Article 114 of Directive 2001/83/EC as amended by Directive 2004/27/EC (Immunological Medical Products) and in accordance with the Administrative Procedure for Official Control Authority Batch Release within the EU.

Trade name	**Poliomyelitisvaccin**
Non–proprietary name	**Poliomyelitis Vaccine (Inactivated)**
Batch number appearing on package and other identification numbers associated with this batch	**1846001**
Type of container	**vial**
Total number of containers in this batch	**60465**
Number of doses per container	**1**
Date of start of period of validity	**24–10–2018**
Date of expiry	**24–10–2021**
Marketing authorisation number	**RVG 17642**
Name and address of manufacturer	**Bilthoven Biologicals B.V.** **A. van Leeuwenhoeklaan 9–13** **3721 MA Bilthoven The Netherlands**
Name and address of market authorisation holder	**Bilthoven Biologicals B.V.** **A.van Leeuwenhoeklaan 11** **3721 MA Bilthoven The Netherlands**

This batch has been examined using documented procedures which form part of a quality system accredited to the ISO/IEC 17025 standard.
The examination has been based on the review of the manufacturer's protocol and the appropriate control laboratory tests as indicated in the marketing authorization application.

This batch is in compliance with the specifications laid down in the relevant Ph. Eur. monographs and the above Marketing Authorisation and is released.

Certificate Number : **181596**

Date of issue : 18–12–2018

Dr. B. de Vries
Centre for Health Protection, RIVM, Bilthoven

NATIONAL CONTROL LABORATORY
THE NETHERLANDS

TESTING
RvA L 098

Bilthoven Biologicals
Cyrus Poonawalla Group

Certificate of Conformity / release notification

Certification by qualified person of Bilthoven Biologicals B.V. taking the overall responsibility for production and control of the medicinal product.

Name	**Poliomyelitisvaccin**
Marketing authorization no.	RVG 17642
Batch no.	1846002A
Manufacturing date	29-Oct-2018
Expiry date	24-Oct-2021

I herewith certify that the above indicated batch of medicinal product has been manufactured 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 2001/83EC and amending Directives 2003/63/EC and 2004/27/EC.

☒ The batch has been released for distribution on the Unicef market

☐ The batch has been released for distribution to a third party manufacturer in

Name	drs. M.A. van Peyma - Hoekzema
Function	Qualified Person
Date	11-Jan-2019
Signature	

Visiting Address:
Bilthoven Biologicals B.V.
Antonie van Leeuwenhoeklaan 9- 13
3721 MA BILTHOVEN, THE NETHERLANDS

Postal address:
P.O.-Box 457
3720 AL BILTHOVEN
KvK 53751221

T +31 (0)30 800 4800
F +31 (0)30 800 4848
E info@bbio.nl
I www.bbio.nl

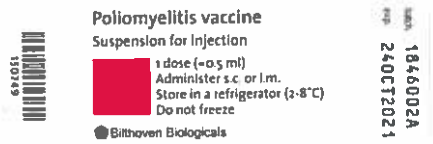
Summary protocol / Certificate of Analysis

Manufacturer	
Name manufacturer	**Bilthoven Biologicals B.V.**
Address	**P.O. Box 457** **3720 AL Bilthoven** **The Netherlands**
Proprietary name	**Inactivated poliomyelitis vaccine (IPV)**
Trade name	**Poliomyelitis vaccin**
Marketing authorization no°	**RVG-17642**

Note: all dates are represented as dd-mm-yyyy

Final lot(s)					
Volume of 1 human dose				**0.5 ml**	
Batch number of final bulk				**1841000285**	
Date of manufacture of final bulk				**18-10-2018**	
Lot no.	**No. of vials filled**	**No. of vials packed**	**Volume filled (ml)**	**Date of manufacture**	**Expiry date** *storage at 5±3 °C*
1846002	**60017**	**n.a.**	**0.6**	**29-10-2018**	**24-10-2021**
1846002A		**59805**	**0.6**	**29-10-2018**	**24-10-2021**

Labels appearing on the vials:



Summary protocol IPV vaccine 1846002

TSE compliance

Materials derived from ruminants used in the manufacture of this batch:

	n° certificate	date of submission dossier to competent authority
Donor bovine serum	CEP 2000-171 and/or CEP 2000-341 and/or CEP 2001-452	-
Trypsine	Not applicable (contains only lactose)	-

Certification

Certification by qualified person taking the overall responsibility for production and control of the inactivated poliomyelitis vaccine.

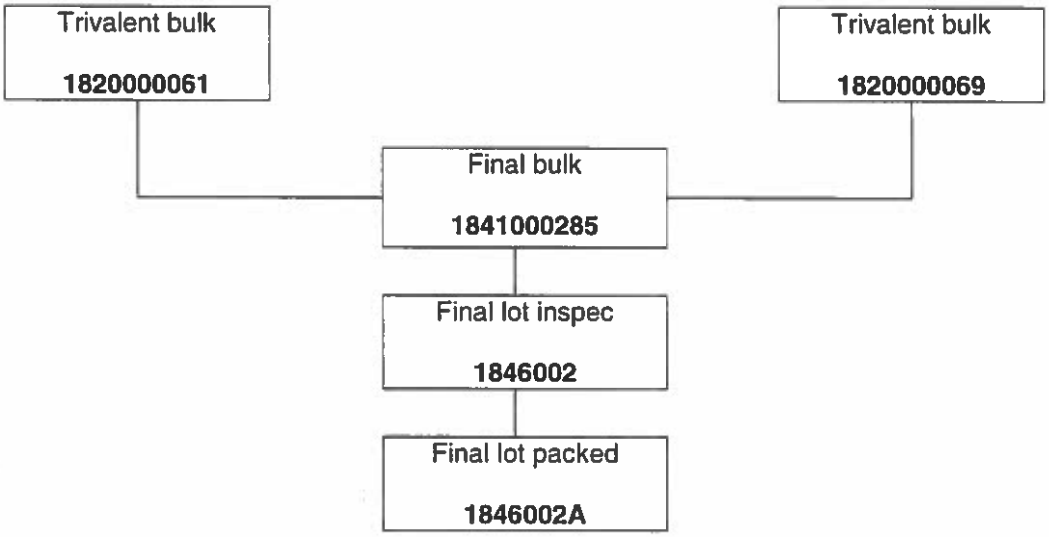
I herewith certify that IPV batch N° **1846002A** was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirements. This includes that, for any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/or formulation of the batch of product specified above, all measures have been taken to demonstrate compliance with Commission Directive 2001/83/EC and amending Directives 2003/63/EC and 2004/27/EC.

Qualified Person: Drs. L.C. Sundermann / Drs. M.A. van Peyma / Drs. T. Lammerink

Signature: _____

Date of issue: 11-Jan-2019

Production Flow Sheet 1846002



IPV vaccine, final lot.....1846002

Final lot		**Result or data**	***Specification***
Corresponding final bulk		**1841000285**	
Filling-site		**Bilthoven**	
Date of filling (=manufacturing date)		**29-10-2018**	
Batch number of final lot		**1846002**	
Volume filled		**0.5 ml**	
Expiry date, storage at 5 ± 3°C		**24-10-2021**	*max. 36 months after date of potency test*
		Result or data	***Specification***
D-antigen content, confirmation of identity			
method		**Ph. Eur. 2.7.1**	
date		**03-12-2018**	
result	type 1	**45 DU/hd**	*≥ 30 DU/hd*
	type 2	**8 DU/hd**	*≥ 6 DU/hd*
	type 3	**36 DU/hd**	*≥ 24 DU/hd*
Appearance		**Clear orange-red liquid**	*clear orange-red liquid*
Test for sterility			
method		**Ph. Eur. 2.6.1**	
media		**thioglycollate / TSB**	
number of vials tested		**40**	
date test on		**02-11-2018**	
date test off		**16-11-2018**	
result		**no growth observed**	*no growth of bacteria or funghi*
Test for protein content			
method		**Calculated from trivalent bulk value**	
result		**2.9 µg/ml**	*≤ 20 µg/ml*
Test for endotoxins			
method		**Ph. Eur. 2.6.14**	
date of test		**29-11-2018**	
result		**<1 IU/hd**	*≤ 5 IU/hd*
Test for pH			
method		**electrometric with glass electrode**	
date		**06-12-2018**	
result		**7.0**	*6.8 – 7.4*
Test for extractable volume			
method		**ANA-20073**	
number of vials tested		**5**	
date test on		**03-12-2018**	
Result, mean of 5 vials		**0.5 ml**	*≥ 0.5 ml*

* hd = human dose

Remarks:

Bilthoven Biologicals
Cyrus Poonawalla Group

IPV vaccine, final bulk.....1841000285

Final bulk		Result or data	*Specification*
Nominal composition			
poliomyelitis	type 1	**80 DU/ml**	
	type 2	**16 DU/ml**	
	type 3	**64 DU/ml**	
Nature and concentration of preservatives			
formaldehyde		**0.83 mmol/l**	
2-phenoxyethanol		**36.2 mmol/l**	
Volume of human dose		**0.5 ml**	
Date of manufacture		**18-10-2018**	
Batch number of final bulk		**1841000285**	
Volume of final bulk		**400 l**	
Expiry date for final lot processing		**18-10-2019**	*12 months after manufacturing date final bulk*
Expiry date of corresponding final lot, storage at 5 ± 3°C		**24-10-2021**	*max. 36 months after date of potency test*
Storage in type 1 glass container or stainless steel container at 2-8°C			

Composition	Batch no.	Volume (l)	Concentration	Exp. date
IPV, trivalent bulk	**1820000061**	**40**	**400 – 80 - 320**	**06-09-2020**
IPV, trivalent bulk	**1820000069**	**40**	**400 – 80 – 320**	**06-09-2020**

		Result or data	*Specification*
Test for sterility			
method		**Ph. Eur. 2.6.1**	
media		**thioglycollate / TSB**	
volume inoculated		**10 ml / 10 ml**	
date test on		**23-10-2018**	
date test off		**06-11-2018**	
result		**no growth observed**	*no growth of bacteria or funghi*
Test for pH			
method		**electrometric with glass electrode**	
date		**19-10-2018**	
result		**7.0**	*6.8 – 7.4*
Test for formaldehyde			
method		**HPLC**	
date		**22-10-2018**	
result		**0.9 mmol/l**	*0.7 – 1.0*
Test for 2-phenoxyethanol			
method		**HPLC**	
date		**22-10-2018**	
result		**35 mmol/l**	*31 – 42*
Potency test poliomyelitis			
D-antigen content			
method		**Ph. Eur. 2.7.1**	
date		**24-10-2018**	
result	type 1	**92 DU/ml**	*≥ 60*
	type 2	**17 DU/ml**	*≥ 12*
	type 3	**67 DU/ml**	*≥ 48*

Remarks:

National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

EU Official Control Authority
BATCH RELEASE CERTIFICATE

Finished Product

Examined under Article 114 of Directive 2001/83/EC as amended by Directive 2004/27/EC (Immunological Medical Products) and in accordance with the Administrative Procedure for Official Control Authority Batch Release within the EU.

Trade name	**Poliomyelitisvaccin**
Non–proprietary name	**Poliomyelitis Vaccine (Inactivated)**
Batch number appearing on package and other identification numbers associated with this batch	**1846002**
Type of container	**vial**
Total number of containers in this batch	**60017**
Number of doses per container	**1**
Date of start of period of validity	**24–10–2018**
Date of expiry	**24–10–2021**
Marketing authorisation number	**RVG 17642**
Name and address of manufacturer	**Bilthoven Biologicals B.V.** **A. van Leeuwenhoeklaan 9–13** **3721 MA Bilthoven The Netherlands**
Name and address of market authorisation holder	**Bilthoven Biologicals B.V.** **A.van Leeuwenhoeklaan 11** **3721 MA Bilthoven The Netherlands**

This batch has been examined using documented procedures which form part of a quality system accredited to the ISO/IEC 17025 standard.
The examination has been based on the review of the manufacturer's protocol and the appropriate control laboratory tests as indicated in the marketing authorization application.

This batch is in compliance with the specifications laid down in the relevant Ph. Eur. monographs and the above Marketing Authorisation and is released.

Certificate Number : **181602**

Date of issue : 18–12–2018

NATIONAL CONTROL LABORATORY * THE NETHERLANDS *

Dr. B. de Vries
Centre for Health Protection, RIVM, Bilthoven

TESTING
RvA L 098

Health Care Inspectorate - Pharmaceutical Affairs and Medical Technology

CERTIFICATE NUMBER: *NL/H 17/1013375*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Netherlands confirms the following:
The manufacturer: ***Bilthoven Biologicals B.V.***
Site address: ***Antonie v Leeuwenhoekln 9 - 13, BILTHOVEN, 3721MA, Netherlands***

Has been inspected under the national inspection programme in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Art. 100 of the Medicines Act

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:
Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-03-14*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]
- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC .

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

---

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products

2017-04-24

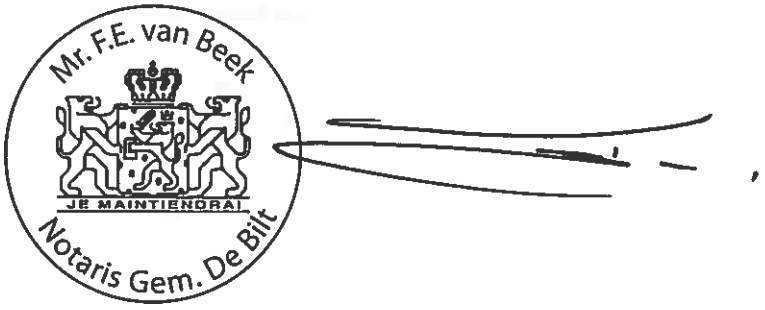
Inspectie voor de Gezondheidszorg
Ministerie van Volksgezondheid, Welzijn en Sport
Rijksoverheid Rijksoverheid Rijksoverheid

Name and signature of the authorised person of the Competent Authority of Netherlands

Dr. Annigje Rietveld
Health Care Inspectorate - Pharmaceutical Affairs and Medical Technology
Tel: *+31 88 1205000*
Fax: *+31 88 1205001*

Issued as a true copy as specified in Section 49, subsection 3 of the Dutch Notaries Act by me, Mr. Frans Eduard van Beek LL.M., civil-law notary practising in the Municipality of De Bilt, the Netherlands.

Signed in Bilthoven, the Netherlands, on the eighteenth of May two thousand seventeen



Health Care Inspectorate - Pharmaceutical Affairs and Medical Technology

CERTIFICATE NUMBER: *NL/H /17/1013375B*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Netherlands confirms the following:
The manufacturer: ***Bilthoven Biologicals B.V.***
Site address: ***Antonie van Leeuwenhoeklaan 9-13, BILTHOVEN, 3721MA, Netherlands***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:
Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-03-14*** , it is considered that it complies with :

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC .

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

---

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Manufacture of active substance. Names of substances subject to inspection :
TETANUS TOXOID(en) / ANATOXINE TÉTANIQUE(fr) / TOKSOID TĘŻCOWY(pl)
DIPHTHERIA TOXOID(en) / TOKSOID BŁONICZY(pl)
BACILLUS CALMETTE-GUERIN VACCINE(en)
POLIOMYELITIS VIRUS (INACTIVATED) TYPE 1 PRODUCED IN VERO CELLS(en)
POLIOMYELITIS VIRUS (INACTIVATED) TYPE 2 PRODUCED IN VERO CELLS(en)
POLIOMYELITIS VIRUS (INACTIVATED) TYPE 3 PRODUCED IN VERO CELLS(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : TETANUS TOXOID	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification 3.3.4 Modification 3.3.5 Other : inactivation by tooidation
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.3 Microbiological testing including sterility testing 3.6.4 Biological Testing
Active Substance : DIPHTHERIA TOXOID	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification 3.3.4 Modification 3.3.5 Other : inactivation by toxoidation
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.3 Microbiological testing including sterility testing 3.6.4 Biological Testing
Active Substance : BACILLUS CALMETTE-GUERIN VACCINE	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.2 Cell Culture : live cells 3.3.3 Isolation / Purification 3.3.4 Modification
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.3 Microbiological testing including sterility testing 3.6.4 Biological Testing
Active Substance : POLIOMYELITIS VIRUS (INACTIVATED) TYPE 1 PRODUCED IN VERO CELLS	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.2 Cell Culture : vero cells 3.3.3 Isolation / Purification 3.3.4 Modification 3.3.5 Other : inactivation
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.3 Microbiological testing including sterility testing 3.6.4 Biological Testing
Active Substance : POLIOMYELITIS VIRUS (INACTIVATED) TYPE 2 PRODUCED IN VERO CELLS	
3.3	**Manufacturing of Active Substance using Biological Processes**

	3.3.1 Fermentation 3.3.2 Cell Culture : vero cells 3.3.3 Isolation / Purification 3.3.4 Modification 3.3.5 Other : inactivation
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.3 Microbiological testing including sterility testing 3.6.4 Biological Testing
Active Substance : POLIOMYELITIS VIRUS (INACTIVATED) TYPE 3 PRODUCED IN VERO CELLS	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.2 Cell Culture : vero cells 3.3.3 Isolation / Purification 3.3.4 Modification 3.3.5 Other : inactivation
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.3 Microbiological testing including sterility testing 3.6.4 Biological Testing

4. Other Activities - Active Substances :
API reg # 6018

2017-05-08

Name and signature of the authorised person of the Competent Authority of Netherlands

Inspectie voor de Gezondheidszorg
Rijksoverheid
Ministerie van Volksgezondheid, Welzijn en Sport

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Issued as a true copy as specified in Section 49, subsection 3 of the Dutch Notaries Act by me, Mr. Frans Eduard van Beek LL.M., civil-law notary practising in the Municipality of De Bilt, the Netherlands.

Signed in Bilthoven, the Netherlands, on the eighteenth of May two thousand seventeen