antígeno de la cepa B. Por lo tanto, el método de SRID bivalente es el método de elección para la determinación del antígeno HA de las cepas B en las formulaciones tetravalentes.

En el futuro, para asegurar que el método bivalente es capaz de detectar la posible disminución del antígeno B, se realizarán estudios forzados de degradación para el método clásico y el bivalente con las 3 nuevas combinaciones de cepas B provenientes de lotes comerciales, según el protocolo que se presenta a continuación.

Protocolo de degradación:

El protocolo es similar al protocolo anterior, que se describe en la sección 3.2.3, la única diferencia es el número de niveles de degradación y el número de determinaciones (no se realizan pruebas de 75 % de degradación y se realiza solo una determinación para el 100 % de degradación).

Las muestras de la formulación tetravalente se prepararán mezclando los monovalentes correspondientes a la formulación trivalente habitual. La cepa B agregada se estudiará en 4 niveles (mientras que la otra cepa B se mantiene intacta):

- Tres niveles de degradación mediante tratamiento térmico para reducir el contenido de antígeno HA: 25 %, 50 % y 100 % (es decir, totalmente degradado);
- Un nivel sin degradación: 0 %.

Cabe destacar que, en el futuro, el contenido de antígeno HA en cada muestra del estudio de degradación para las cepas B se determinará mediante los métodos clásico y bivalente de SRID, con dos pruebas independientes para cada resultado, excepto para la cepa B totalmente degradada, para la cual se realiza una sola medición.

En el futuro, se podrían realizar estudios de degradación adicionales, si una nueva combinación de cepas B presenta un mayor nivel de reactividad cruzada que el experimentado anteriormente.

Cabe destacar finalmente que, en el futuro, paralelamente al método de SRID bivalente realizado en el momento de la liberación, el método clásico todavía se realizará en los tres primeros lotes de PFAG de cada temporada, para mejorar el conocimiento sobre el fenómeno de reactividad cruzada y la especificidad de los reactivos disponibles. El método de SRID clásico se cualificará mediante la verificación de la linealidad y la exactitud para cada nueva cepa B o reactivos asociados.

A.N.M.A.T.
FOLIO
0956
MESA DE ENTRADAS

CERTIFICADOS ANALÍTICOS

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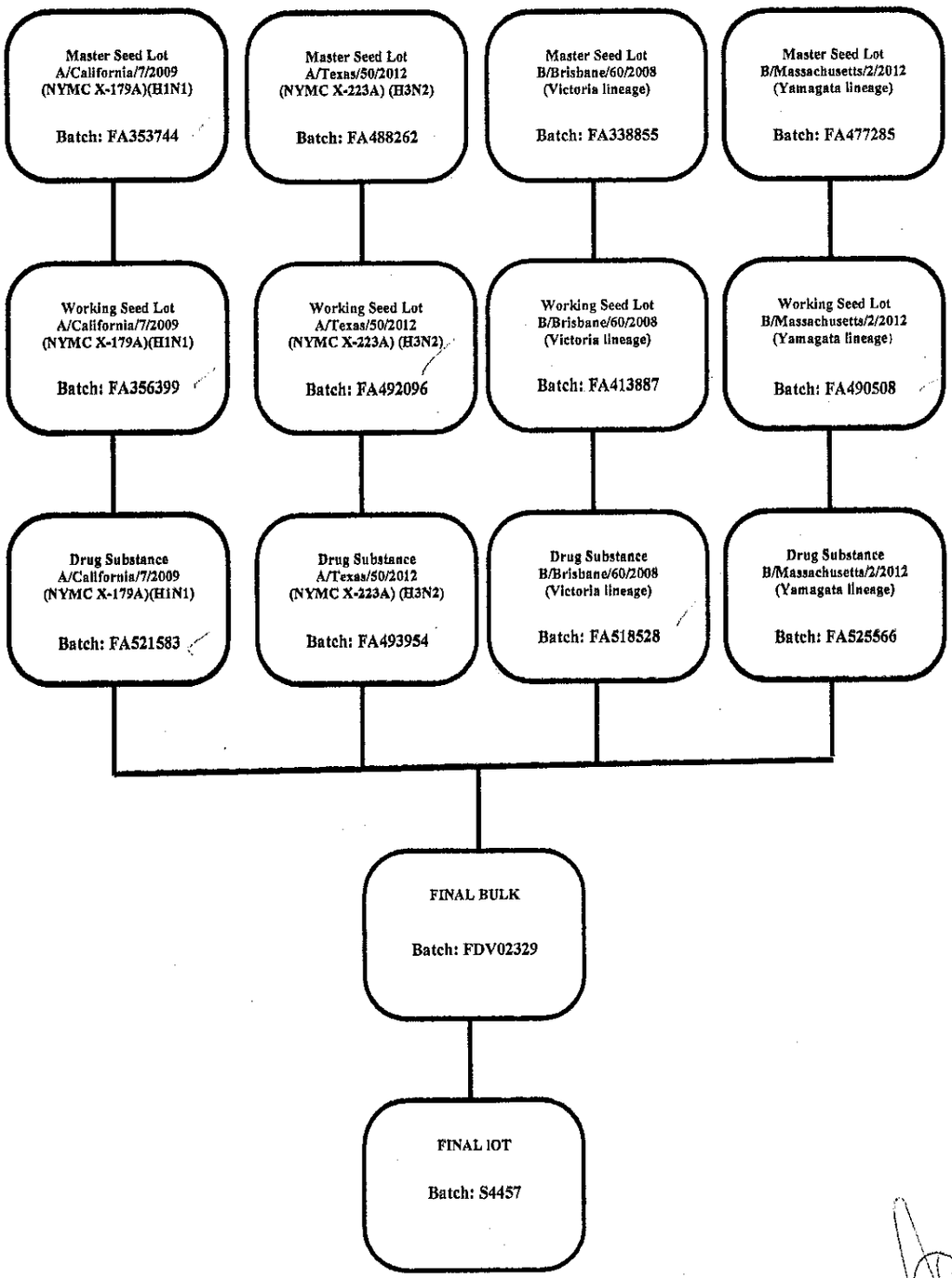
SANOFI PASTEUR

Production Flow Sheet – Batch S4457



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P.N.M.A.T. FOLIO 0158 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT
INFLUENZA VIRUS

Strain A/California/7/2009 (H1N1)pdm09 – like strain (A/California/7/2009, NYMC X-179A)

MASTER SEED LOT

Lot number : **FA353744**

Manufacturing date : **06.06.2009**

****

HAEMAGGLUTININ ANTIGEN IDENTIFICATION : **Positive**
By Haemagglutination Inhibition test

GENERAL CONCLUSION : **Conforms**

Release date : **07.08.2009**

Date : May 27th, 2016
Qualified Person :

H. Dumas

Product Quality and Disposition Department

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A.N.M.A.T. FOLIO 0959 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT
INFLUENZA VACCINE

Strain A/California/7/2009 (H1N1)pdm09 – like strain (A/California/7/2009, NYMC X-179A)

WORKING SEED LOT

Lot number : **FA356399**

Manufacturing date : **08.07.2009**

****

TEST FOR MYCOPLASMA BY MICROBIOLOGICAL CULTURE *By Culture method*	: **Conforms**
BACTERIAL AND FUNGAL STERILITY TEST *By membrane filtration*	: **No microbial growth**
TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE *By Inoculation to indicator cells and specific staining*	: **Conforms**
NEURAMINIDASE ANTIGEN IDENTIFICATION *By RT-PCR*	: **Positive**
HAEMAGGLUTININ ANTIGEN IDENTIFICATION *By Haemagglutination inhibition test*	: **Positive**
INFECTIOUS TITER *By EID50*	: **9 log10 EID50/ml**

GENERAL CONCLUSION : **Conforms**

Release date : **05.11.2011**

Date : May 30th, 2016
Qualified Person :

A. Dumas

Product Quality and Disposition Department

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A.N.M.A.T. FOLIO 0960 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT
INFLUENZA VACCINE
(SPLIT VIRION, INACTIVATED)

Strain A/California/7/2009 (H1N1)pdm09 – like strain (A/California/7/2009, NYMC X-179A)

BULK

Lot number : **FA521583**

Manufacturing date : **27.02.2014**

****

OCTOXYNOL -9 -CONTENT *By HPLC*	: **668 µg/ml**
HAEMAGGLUTININ ANTIGEN IDENTIFICATION *By Haemagglutinin inhibition test*	: **Positive**
HAEMAGGLUTININ ANTIGEN CONTENT *By SRID*	: **231 (218 - 246)** µg/ml
RESIDUAL INFECTIOUS VIRUS *By Inoculation of eggs*	: **No residual infectious virus**
BACTERIAL AND FUNGAL STERILITY *By Membrane filtration*	: **No microbial growth**
NEURAMINIDASE ANTIGEN IDENTIFICATION *By RT-PCR*	: **Not performed** (performed on the first three monovalent bulk batches manufactured from any new working seed lot)
NEURAMINIDASE ENZYMATIC ACTIVITY *By Enzymatic method*	: **Not performed** (performed on the first three monovalent bulk batches manufactured from any new working seed lot)

GENERAL CONCLUSION : **Conforms**

Release date : **24.07.2014**

Expiry date : **27.02.2016**

Date : 26 May 2016

Qualified Person :

Product Quality and Disposition Department

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SANOFI

A.N.M.A.T. FOLIO 0961 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT
INFLUENZA VIRUS

Strain A/Texas/50/2012 (H3N2) – derived strain used (NYMC X-223A)

MASTER SEED LOT

Lot number : **FA488262**

Manufacturing date : **28.02.2013**

****

HAEMAGGLUTININ ANTIGEN IDENTIFICATION : **Positive**
By Haemagglutination inhibition test

GENERAL CONCLUSION : Conforms

Release date : 04.06.2013

Date : May 21st, 2016
Qualified Person :

J. H. Dumas

Product Quality and Disposition Department

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A.N.M.A.T. FOLIO 0962 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT INFLUENZA VACCINE

Strain A/Texas/50/2012 (H3N2) – derived strain used (NYMC X-223A)

WORKING SEED LOT

Lot number : FA492096

Manufacturing date : 14.03.2013

****

TEST FOR MYCOPLASMA BY MICROBIOLOGICAL CULTURE *By Culture method*	: **Conforms**
BACTERIAL AND FUNGAL STERILITY TEST *By membrane filtration*	: **No microbial growth**
TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE *By Inoculation to Indicator cells and specific staining*	: **Conforms**
NEURAMINIDASE ANTIGEN IDENTIFICATION *By RT-PCR*	: **Positive**
HAEMAGGLUTININ ANTIGEN IDENTIFICATION *By Haemagglutination inhibition test*	: **Positive**
INFECTIOUS TITER *By EID50*	: **10 log10 EID50/ml**

GENERAL CONCLUSION : Conforms

Release date : **04.06.2013**

Date : May 30th, 2016
Qualified Person :

Product Quality and Disposition Department

ROXANA MONTEMILONE
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A.N.M.A.T. FOLIO 0963 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT
INFLUENZA VACCINE
(SPLIT VIRION, INACTIVATED)

Strain A/Texas/50/2012 (H3N2) – derived strain used (NYMC X-223A)

BULK

Lot number : **FA493954**

Manufacturing date : **19.04.2013**

****

OCTOXYNOL -9 -CONTENT *By HPLC*	: **624 µg/ml**
HAEMAGGLUTININ ANTIGEN IDENTIFICATION *By Haemagglutinin inhibition test*	: **Positive**
HAEMAGGLUTININ ANTIGEN CONTENT *By SRID*	: **209 (204 - 214)** µg/ml
RESIDUAL INFECTIOUS VIRUS *By Inoculation of eggs*	: **No residual infectious virus**
BACTERIAL AND FUNGAL STERILITY *By Membrane filtration*	: **No microbial growth**
NEURAMINIDASE ANTIGEN IDENTIFICATION *By RT-PCR*	: **Positive** (performed on the first three monovalent bulk batches manufactured from any new working seed lot)
NEURAMINIDASE ENZYMATIC ACTIVITY *By Enzymatic method*	: **Presence of neuraminidase activity** (performed on the first three monovalent bulk batches manufactured from any new working seed lot)

GENERAL CONCLUSION : **Conforms**

Release date : **01.09.2014**

Expiry date : **19.04.2015**

Date : May 26th, 2016
Qualified Person :

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A.N.M.A.T. FOLIO 0964 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT INFLUENZA VIRUS

Strain B/Brisbane/60-2008 – like strain (B/Brisbane/60/2008, wild type)

MASTER SEED LOT

Lot number : **FA338855**

Manufacturing date : **02.02.2009**

****

HAEMAGGLUTININ ANTIGEN IDENTIFICATION : **Positive**
By Haemagglutination inhibition test

GENERAL CONCLUSION : **Conforms**

Release date : **04.05.2009**

Date : May 27th, 2016
Qualified Person :

H Dumas

Product Quality and Disposition Department

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A.N.M.A.T. FOLIO 0965 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT
INFLUENZA VACCINE

Strain B/Brisbane/60-2008 – like strain (B/Brisbane/60/2008, wild type)

WORKING SEED LOT

Lot number : **FA413887**

Manufacturing date : **03.02.2011**

****

TEST FOR MYCOPLASMA BY MICROBIOLOGICAL CULTURE *By Culture method*	: **Conforms**
BACTERIAL AND FUNGAL STERILITY TEST *By membrane filtration*	: **No microbial growth**
TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE *By Inoculation to indicator cells and specific staining*	: **Conforms**
NEURAMINIDASE ANTIGEN IDENTIFICATION *By RT-PCR*	: **Positive**
HAEMAGGLUTININ ANTIGEN IDENTIFICATION *By Haemagglutination inhibition test*	: **Positive**
INFECTIOUS TITER *By EID50*	: **7 log10 EID50/ml**

GENERAL CONCLUSION : **Conforms**

Release date : **26.05.2011**

Date : May 30th, 2016
Qualified Person :

H. Dumais

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A.N.M.A.T. FOLIO 2966 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

Strain B/Brisbane/60-2008 – like strain (B/Brisbane/60/2008, wild type)

BULK

Lot number : **FA518528**

Manufacturing date : **27.01.2014**

****

OCTOXYNOL -9 -CONTENT *By HPLC*	: **638 µg/ml**
HAEMAGGLUTININ ANTIGEN IDENTIFICATION *By Haemagglutinin inhibition test*	: **Positive**
HAEMAGGLUTININ ANTIGEN CONTENT *By SRID*	: **188 (178 - 198)** µg/ml
RESIDUAL INFECTIOUS VIRUS *By Inoculation of eggs*	: **No residual infectious virus**
BACTERIAL AND FUNGAL STERILITY *By Membrane filtration*	: **No microbial growth**
NEURAMINIDASE ANTIGEN IDENTIFICATION *By RT-PCR*	: **Not performed** (performed on the first three monovalent bulk batches manufactured from any new working seed lot)
NEURAMINIDASE ENZYMATIC ACTIVITY *By Enzymatic method*	: **Not performed** (performed on the first three monovalent bulk batches manufactured from any new working seed lot)

GENERAL CONCLUSION : **Conforms**

Release date : **24.07.2014**

Expiry date : **27.01.2016**

Date : May 26th, 2016
Qualified Person :

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A.N.M.A.T. FOLIO 0967 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT
INFLUENZA VIRUS

Strain B/Massachusetts/2/2012

MASTER SEED LOT

Lot number : **FA477285**

Manufacturing date : **26.11.2012**

****

HAEMAGGLUTININ ANTIGEN IDENTIFICATION : **Positive**
By Haemagglutination inhibition test

GENERAL CONCLUSION : Conforms

Release date : 04.06.2013

Date : May 27th, 2016
Qualified Person :

Product Quality and Disposition Department

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A.N.M.A.T. FOLIO 0968 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT
INFLUENZA VACCINE

Strain B/Massachusetts/2/2012

WORKING SEED LOT

Lot number : **FA490508**

Manufacturing date : **28.02.2013**

****

TEST FOR MYCOPLASMA BY MICROBIOLOGICAL CULTURE *By Culture method*	: **Conforms**
BACTERIAL AND FUNGAL STERILITY TEST *By membrane filtration*	: **No microbial growth**
TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE *By Inoculation to indicator cells and specific staining*	: **Conforms**
NEURAMINIDASE ANTIGEN IDENTIFICATION *By RT-PCR*	: **Positive**
HAEMAGGLUTININ ANTIGEN IDENTIFICATION *By Haemagglutination inhibition test*	: **Positive**
INFECTIOUS TITER *By EID50*	: **10 log10 EID50/ml**

GENERAL CONCLUSION : **Conforms**

Release date : **04.06.2013**

Date : May 30th, 2016
Qualified Person :

H Dimais

Product Quality and Disposition Department

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A.N.M.A.T. FOLIO 0969 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICAT
INFLUENZA VACCINE
(SPLIT VIRION, INACTIVATED)

Strain B/Massachusetts/2/2012

BULK

Lot number : **FA525566**

Manufacturing date : **31.03.2014**

****

OCTOXYNOL -9 -CONTENT *By HPLC*	: **619 µg/ml**
HAEMAGGLUTININ ANTIGEN IDENTIFICATION *By Haemagglutinin inhibition test*	: **Positive**
HAEMAGGLUTININ ANTIGEN CONTENT *By SRID*	: **188 (175 - 202)** µg/ml
RESIDUAL INFECTIOUS VIRUS *By Inoculation of eggs*	: **No residual infectious virus**
BACTERIAL AND FUNGAL STERILITY *By Membrane filtration*	: **No microbial growth**
NEURAMINIDASE ANTIGEN IDENTIFICATION *By RT-PCR*	: **Positive** (performed on the first three monovalent bulk batches manufactured from any new working seed lot)
NEURAMINIDASE ENZYMATIC ACTIVITY *By Enzymatic method*	: **Presence of neuraminidase activity** (performed on the first three monovalent bulk batches manufactured from any new working seed lot)

GENERAL CONCLUSION : **Conforms**

Release date : **30.07.2014**

Expiry date : **31.03.2016**

Date : May 27th, 2016

Qualified Person :

H. Dumas

Product Quality and Disposition Department

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Do not Distribute

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A.N.M.A.T. FOLIO 0930 SALA DE ENTRADAS

Certificate of Analysis

Product name : 481 – QIV - Split Virion Inactivated - Unidose Presentation

Batch : FDV02329

Step : Final Bulk Product

Manufacturing Date : 05/JUN/2014

Prior batch : FA493954 : Conform on 30/AUG/2013
FA518528 : Conform on 27/MAY/2014
FA521583 : Conform on 08/APR/2014
FA525566 : Conform on 15/JUL/2014

FINAL BULK PRODUCT - FINAL BULK PRODUCT

QUALITY CONTROL TESTS	ACCEPTANCE CRITERIA	RESULTS
Bacterial and fungal sterility (by membrane filtration)	No microbial growth	Conforms
Formaldehyde content (by spectrophotometry)	≤ 60 µg/mL	37 µg/mL
Potein content (by Kjeldhal method)	≤ 600 µg/mL	319 µg/mL
Ovalbumin content (by ELISA)	≤ 100 ng/mL	10 ng/mL
[Total protein/hemagglutinin] ratio (By calculation)	≤ 6	2

- The batch FDV02329 was controlled according to the specifications described in the document #Q_0402362/3.0
- The results conform to the acceptance criteria above and approved in document #Q_0402362/3.0
- The results are as expected based on prior manufacturing stages and processes, when applicable

HEAD OF ARD EU	Dominique PETRE	This is an electronic signature	20/AUG/2014
	Name	**Signature**	**Date**

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A.N.M.A.T. FOLIO 0971 MESA DE ENTRADAS

QUALITY CONTROL CERTIFICATE

NAME OF THE PRODUCT	:	**QUADRIVALENT INFLUENZA VACCINE (Split Virion, Inactivated)**
LOT N°	:	**S4457**
PRESENTATION	:	Syringe 1 dose 0.5 mL
DATE OF MANUFACTURE	:	06 July 2014
FINAL BULK N°	:	FDV02329
BULKS N°	:	A/California/07/2009 – X-179A H1N1 FA521583, A/Texas/50/2012 – X223A H3N2 FA493954, B/Brisbane/60/2008 FA518528 B/Massachusetts/02/2012 FA525566
STORAGE CONDITIONS	:	+5°C +/- 3°C – Do not freeze

CONTROLS	SPECIFICATIONS	RESULTS
Bacterial and fungal sterility (by membrane filtration)	No microbial growth	**Conforms**
Appearance (by visual assessment)	Colorless opalescent liquid	**Conforms**
pH (by potentiometric determination)	6.8 – 7.6	**7.5**
Extractable volume (by weighing)	At least nominal volume	**0.52 mL – 0.52 mL – 0.52 mL – 0.52 mL – 0.51 mL**
Hemagglutinin identification/content (by SRD) :	Positive identification for the 4 strains Content :15 µg/dose (0.5 mL)	
A/California/07/2009 – X-179A (H1N1)	*confidence limit (P=0.95) ≥ 12 µg/dose (0.5 mL)*	**Positive** **20 (17 – 23) µg/dose**
A/Texas/50/2012 – X223A (H3N2)		**Positive** **19 (16 – 23) µg/dose**
B/Brisbane/60/2008		**Positive** **18 (17 – 19) µg/dose**
B/Massachusetts/02/2012		**Positive** **17 (16 – 18) µg/dose**
Endotoxins content (by LAL chromogenic kinetic method)	< 100 IU/dose	**< 0.25 IU/dose**
Abnormal toxicity (by injection into animals (Ph. Eur. Protocol))	No sign of death or illness within 7 days after inoculation	**Conforms**

Batch released on: 08 September 2014

Alice PADIEU-SEQUEIRA
R&D SQO – Clinical Batch Release

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