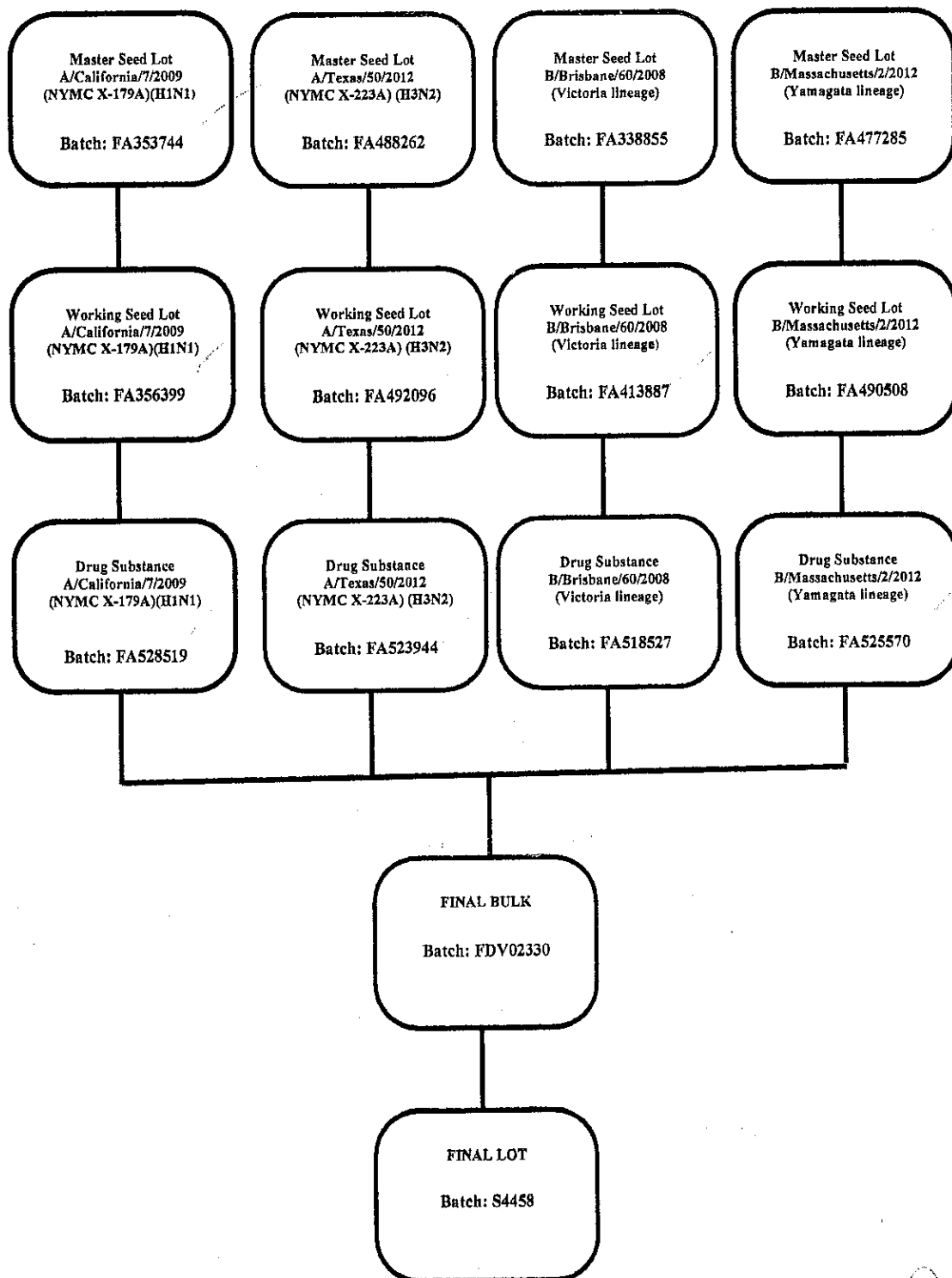





SANOPI PASTEUR 

Production Flow Sheet - Batch S4458




ROXANA MONTMILONE
DIRECTORA TÉCNICA
APODERADA
SANOFI PASTEUR S. A.



**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

Roxana Montemilone
ROXANA MONTEMILONE
DIRECTORA TÉCNICA
APODERADA
SANOPI PASTEUR S. A.

SANOPI



**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 : Conforms**
By Culture method

BACTERIAL AND FUNGAL STERILITY TEST : No microbial growth
By membrane filtration

**TEST FOR MYCOPLASMA BY EPIFLUORESCENCE
IN CELLULAR CULTURE : Conforms**
By Inoculation to indicator cells and specific staining

NEURAMINIDASE ANTIGEN IDENTIFICATION : Positive
By RT-PCR

HAEMAGGLUTININ ANTIGEN IDENTIFICATION : Positive
By Haemagglutination inhibition test

INFECTIOUS TITER : 9 log₁₀ EID₅₀/ml
By EID₅₀


GENERAL CONCLUSION : Conforms

Release date : 05.11.2011

Date : May 30th, 2016
Qualified Person :


Product Quality and Disposition Department

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**ROXANA MONTEMILIONE
DIRECTORA TÉCNICA
APODERADA
SANOPI PASTEUR S.A**



**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 : FA528519

Manufacturing date : 09.05.2014

- OCTOXYNOL -9 -CONTENT : 616 µg/ml
By HPLC
- HAEMAGGLUTININ ANTIGEN IDENTIFICATION : Positive
By Haemagglutinin inhibition test
- HAEMAGGLUTININ ANTIGEN CONTENT : 235 (213 - 269) µg/ml
By SRID
- RESIDUAL INFECTIOUS VIRUS : No residual infectious virus
By Inoculation of eggs
- BACTERIAL AND FUNGAL STERILITY : No microbial growth
By Membrane filtration
- NEURAMINIDASE ANTIGEN IDENTIFICATION : Not performed
By RT-PCR
(performed on the first three monovalent bulk batches manufactured from any new working seed lot)
- NEURAMINIDASE ENZYMATIC ACTIVITY : Not performed
By Enzymatic method
(performed on the first three monovalent bulk batches manufactured from any new working seed lot)

GENERAL CONCLUSION : Conforms

Release date : 25.07.2014

Expiry date : 09.05.2016

Date : *May 26, 2016*
Qualified Person :

Thomas
Product Quality and Disposition Department

SANOFI



**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 :

Product Quality and Disposition Department

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5
ROXANA MONTEMILONE
DIRECTORA TECNICA
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SANOFI PASTEUR S. A.



**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 : **Conforms**
By Culture method

BACTERIAL AND FUNGAL STERILITY TEST : **No microbial growth**
By membrane filtration

TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE : **Conforms**
By Inoculation to indicator cells and specific staining

NEURAMINIDASE ANTIGEN IDENTIFICATION : **Positive**
By RT-PCR

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

INFECTIOUS TITER : **10 log10 EID50/ml**
By EID50

GENERAL CONCLUSION : Conforms

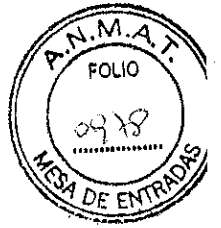
Release date : 04.06.2013

Date : *May 30th, 2016*
Qualified Person :

Product Quality and Disposition Department

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DIRECTORA TÉCNICA
APODERADA
SANOPI PASTEUR S A

SANOPI



**QUALITY CONTROL CERTIFICAT
INFLUENZA VACCINE
(SPLIT VIRION, INACTIVATED)**
Strain **A/Texas/50/2012 (H3N2) – derived
strain used (NYMC X-223A)**

BULK

Lot number : FA523944
Manufacturing date : 22.03.2014

OCTOXYNOL -9 -CONTENT : 625 µg/ml
By HPLC

HAEMAGGLUTININ ANTIGEN IDENTIFICATION : Positive
By Haemagglutinin inhibition test

HAEMAGGLUTININ ANTIGEN CONTENT : 206 (190 - 225) µg/ml
By SRID

RESIDUAL INFECTIOUS VIRUS : No residual infectious virus
By Inoculation of eggs

BACTERIAL AND FUNGAL STERILITY : No microbial growth
By Membrane filtration

NEURAMINIDASE ANTIGEN IDENTIFICATION : Not performed
By RT-PCR
(performed on the first three monovalent bulk batches manufactured from any new working seed lot)

NEURAMINIDASE ENZYMATIC ACTIVITY : Not performed
By Enzymatic method
(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 : 22.03.2016

Date : *May 26th, 2016*
Qualified Person :

Product Quality and Disposition Department

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ROXANA MONTEMILONE
DIRECTORA TÉCNICA
APODERADA
SANOFI PASTEUR S. A.

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**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. Demian

Product Quality and Disposition Department

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APODERADA
SANOPI PASTEUR S.A.

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**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 : **Conforms**
By Culture method

BACTERIAL AND FUNGAL STERILITY TEST : **No microbial growth**
By membrane filtration

TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE : **Conforms**
By Inoculation to indicator cells and specific staining

NEURAMINIDASE ANTIGEN IDENTIFICATION : **Positive**
By RT-PCR

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

INFECTIOUS TITER : **7 log₁₀ EID₅₀/ml**
By EID₅₀

GENERAL CONCLUSION : Conforms

Release date : 26.05.2011

Date : *May 30th, 2011*
 Qualified Person :

[Signature]
Product Quality and Disposition Department

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[Signature]
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 APODERADA
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**QUALITY CONTROL CERTIFICAT
INFLUENZA VACCINE
(SPLIT VIRION, INACTIVATED)**

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

BULK

Lot number : FA518527
Manufacturing date : 27.01.2014

OCTOXYNOL -9 -CONTENT : 619 µg/ml
By HPLC

HAEMAGGLUTININ ANTIGEN IDENTIFICATION : Positive
By Haemagglutinin inhibition test

HAEMAGGLUTININ ANTIGEN CONTENT : 221 (209 - 233) µg/ml
By SRID

RESIDUAL INFECTIOUS VIRUS : No residual infectious virus
By Inoculation of eggs

BACTERIAL AND FUNGAL STERILITY : No microbial growth
By Membrane filtration

NEURAMINIDASE ANTIGEN IDENTIFICATION : Not performed
By RT-PCR
(performed on the first three monovalent bulk batches manufactured from any new working seed lot)

NEURAMINIDASE ENZYMATIC ACTIVITY : Not performed
By Enzymatic method
(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

Product Quality and Disposition Department

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ROXANA MONTEMILONE
DIRECTORA TÉCNICA
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**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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ROXANA MONTEMILONE
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SANOFI PASTEUR S. A.

**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 : **Conforms**
By Culture method

BACTERIAL AND FUNGAL STERILITY TEST : **No microbial growth**
By membrane filtration

TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE : **Conforms**
By Inoculation to indicator cells and specific staining

NEURAMINIDASE ANTIGEN IDENTIFICATION : **Positive**
By RT-PCR

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

INFECTIOUS TITER
By EID50 : **10 log₁₀ EID50/ml**

GENERAL CONCLUSION : Conforms

Release date : 04.06.2013

Date : *May 30th, 2016*
Qualified Person :

H. Dimas
Product Quality and Disposition Department

SANOFI



**QUALITY CONTROL CERTIFICAT
INFLUENZA VACCINE
(SPLIT VIRION, INACTIVATED)**

Strain B/Massachusetts/2/2012

BULK

Lot number : FA525570

Manufacturing date : 01.04.2014

- OCTOXYNOL -9 -CONTENT : 608 µg/ml
By HPLC
- HAEMAGGLUTININ ANTIGEN IDENTIFICATION : Positive
By Haemagglutinin inhibition test
- HAEMAGGLUTININ ANTIGEN CONTENT : 186 (166 - 209) µg/ml
By SRID
- RESIDUAL INFECTIOUS VIRUS : No residual infectious virus
By Inoculation of eggs
- BACTERIAL AND FUNGAL STERILITY : No microbial growth
By Membrane filtration
- NEURAMINIDASE ANTIGEN IDENTIFICATION : Not performed
By RT-PCR
(performed on the first three monovalent bulk batches manufactured from any new working seed lot)
- NEURAMINIDASE ENZYMATIC ACTIVITY : Not performed
By Enzymatic method
(performed on the first three monovalent bulk batches manufactured from any new working seed lot)

GENERAL CONCLUSION : Conforms

Release date : 31.07.2016

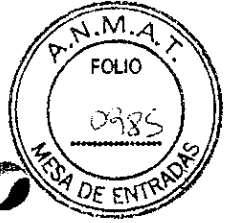
Expiry date : 01.04.2016

Date : May 26th, 2016
Qualified Person:

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Do not Distribute

Certificate of Analysis

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

Batch : FDV02330

Step : Final Bulk Product

Manufacturing Date : 19/JUN/2014

Prior batch : FA518527 : Conform on 20/MAY/2014

FA523944 : Conform on 24/APR/2014

FA525570 : Conform on 26/MAY/2014

FA528519 : Conform on 09/MAY/2014

FINAL BULK PRODUCT - FINAL BULK PRODUCT

Table with 3 columns: QUALITY CONTROL TESTS, ACCEPTANCE CRITERIA, RESULTS. Rows include Bacterial and fungal sterility, Formaldehyde content, Protein content, Ovalbumin content, and [Total protein/hemagglutinin] ratio.

- The batch FDV02330 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

Version number: 1

Page 1 of 1

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ROXANA MONTEMLONE
DIRECTORA TECNICA
APODERADA
SANOFI PASTEUR S A,

QUALITY CONTROL CERTIFICATE

NAME OF THE PRODUCT : **QUADRIVALENT INFLUENZA VACCINE (Split Virion, Inactivated)**

LOT N° : **S4458**

PRESENTATION : **Syringe 1 dose 0.5 mL**

DATE OF MANUFACTURE : **15 July 2014**

FINAL BULK N° : **FDV02330**

BULKS N° : **A/California/07/2009 – X-179A H1N1 FA528519
A/Texas/50/2012 – X223A H3N2 FA523944
B/Brisbane/60/2008 FA518527
B/Massachusetts/02/2012 FA525570**

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	7.3
Extractable volume (by weighing)	At least nominal volume	0.51 mL – 0.51 mL – 0.51 mL – 0.51 mL – 0.50 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)		Positive 16 (13 – 18) µg/dose
A/Texas/50/2012 – X223A (H3N2)	confidence limit (P=0.95) ≥ 12 µg/dose (0.5 mL)	Positive 18 (15 – 21) µg/dose
B/Brisbane/60/2008		Positive 17 (16 – 19) µg/dose
B/Massachusetts/02/2012		Positive 16 (15 – 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

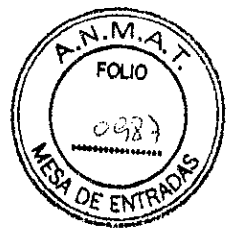
Alice PADIEU-SEQUEIRA
R&D SQO – Clinical Batch Release



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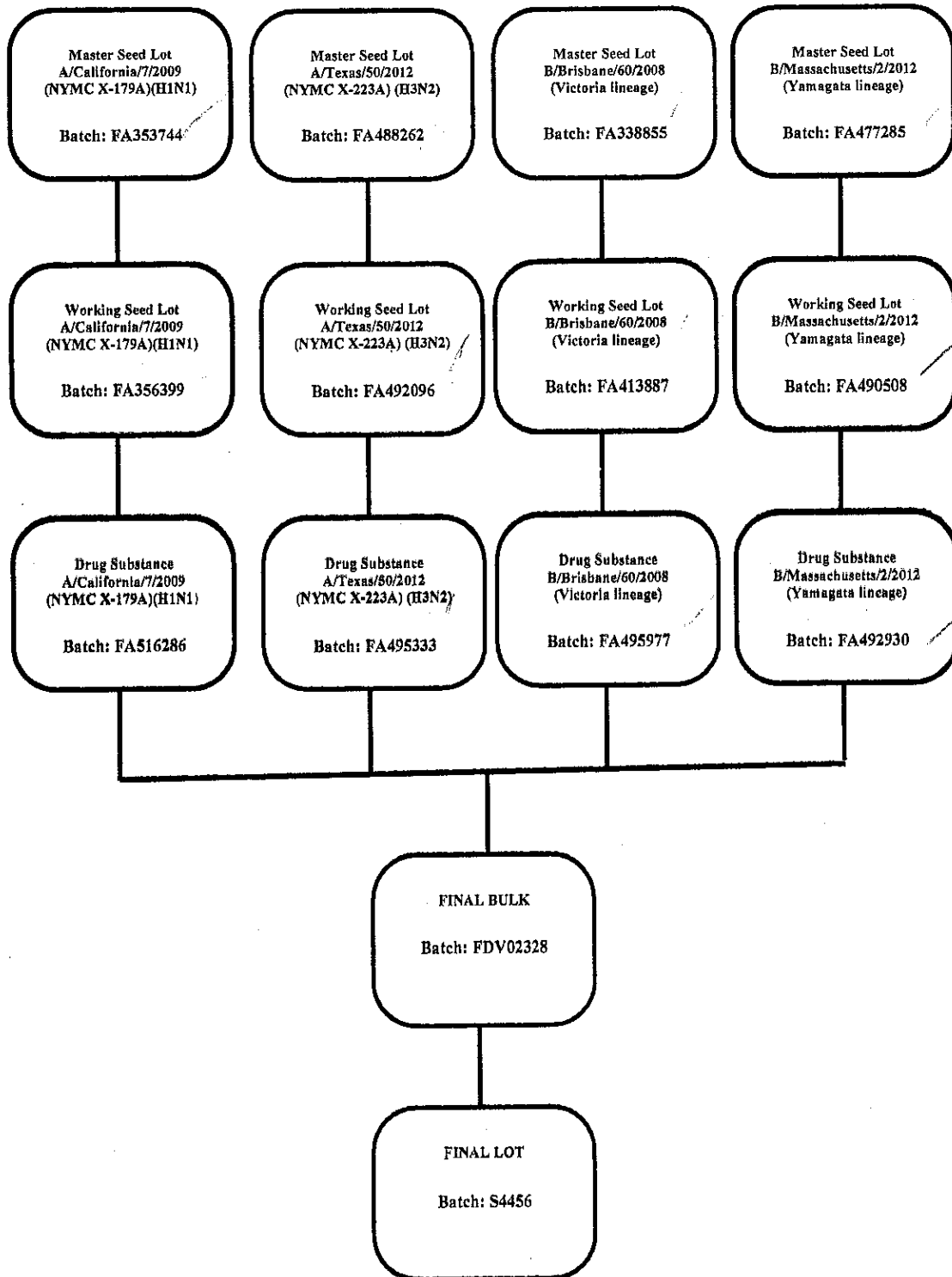


ROXANA MONTEMILONE
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APODERADA
SANOFI PASTEUR S. A.



SANOPI PASTEUR 

Production Flow Sheet - Batch S4456




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SANOPI PASTEUR S. A.



**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. Demas

Product Quality and Disposition Department

SANOFI



**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 : **Conforms**
By Culture method

BACTERIAL AND FUNGAL STERILITY TEST : **No microbial growth**
By membrane filtration

TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE : **Conforms**
By inoculation to indicator cells and specific staining

NEURAMINIDASE ANTIGEN IDENTIFICATION : **Positive**
By RT-PCR

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

INFECTIOUS TITER
By EID50 : **9 log10 EID50/ml**

GENERAL CONCLUSION : Conforms

Release date : 05.11.2011

Date : *May 30th, 2016*
Qualified Person :

Product Quality and Disposition Department

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APODERADA
SANOFI PASTEUR S.A.

Access date: 01 juil. 2016 13:20:12



**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 : FA516286

Manufacturing date : 22.12.2013

- OCTOXYNOL -9 -CONTENT : 566 µg/ml
By HPLC
- HAEMAGGLUTININ ANTIGEN IDENTIFICATION : Positive
By Haemagglutinin inhibition test
- HAEMAGGLUTININ ANTIGEN CONTENT : 232 (215 - 251) µg/ml
By SRID
- RESIDUAL INFECTIOUS VIRUS : No residual infectious virus
By Inoculation of eggs
- BACTERIAL AND FUNGAL STERILITY : No microbial growth
By Membrane filtration
- NEURAMINIDASE ANTIGEN IDENTIFICATION : Positive
By RT-PCR
(performed on the first three monovalent bulk batches manufactured from any new working seed lot)
- NEURAMINIDASE ENZYMATIC ACTIVITY : Presence of neuraminidase activity
By Enzymatic method
(performed on the first three monovalent bulk batches manufactured from any new working seed lot)

GENERAL CONCLUSION : Conforms

Release date : 04.09.2014

Expiry date : 22.12.2015

Date : May 26th, 2016.
Qualified Person :

Product Quality and Disposition Department

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
APODERADA
SANOFI PASTEUR S.A.

SANOFI



**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 :

Product Quality and Disposition Department

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[Signature]
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**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 : **Conforms**
By Culture method

BACTERIAL AND FUNGAL STERILITY TEST : **No microbial growth**
By membrane filtration

TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE : **Conforms**
By Inoculation to indicator cells and specific staining

NEURAMINIDASE ANTIGEN IDENTIFICATION : **Positive**
By RT-PCR

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

INFECTIOUS TITER : **10 log10 EID50/ml**
By EID50

GENERAL CONCLUSION : Conforms

Release date : 04.06.2013

Date : *May 30th, 2016*
Qualified Person :

[Signature]
Product Quality and Disposition Department

Parc Industriel d'Incarville, BP 101, 27101 Val De Reuil cedex, France

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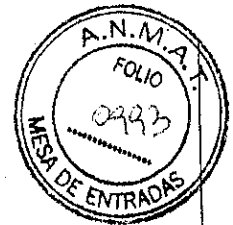
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**QUALITY CONTROL CERTIFICAT
INFLUENZA VACCINE
(SPLIT VIRION, INACTIVATED)**

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

BULK

Lot number : FA495333

Manufacturing date : 18.04.2013

OCTOXYNOL -9 -CONTENT <i>By HPLC</i>	: 633 µg/ml
HAEMAGGLUTININ ANTIGEN IDENTIFICATION <i>By Haemagglutinin inhibition test</i>	: Positive
HAEMAGGLUTININ ANTIGEN CONTENT <i>By SRID</i>	: 214 (210 - 218) µg/ml
RESIDUAL INFECTIOUS VIRUS <i>By Inoculation of eggs</i>	: No residual infectious virus
BACTERIAL AND FUNGAL STERILITY <i>By Membrane filtration</i>	: No microbial growth
NEURAMINIDASE ANTIGEN IDENTIFICATION <i>By RT-PCR</i>	: Positive (performed on the first three monovalent bulk batches manufactured from any new working seed lot)
NEURAMINIDASE ENZYMATIC ACTIVITY <i>By Enzymatic method</i>	: Presence of neuraminidase activity (performed on the first three monovalent bulk batches manufactured from any new working seed lot)

GENERAL CONCLUSION : Conforms

Release date : 23.08.2013

Expiry date : 18.04.2015

Date : *May 26th, 2016*

Qualified Person : *[Signature]*

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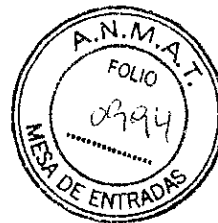
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**QUALITY CONTROL CERTIFICAT
INFLUENZA VIRUS**

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. Dumars

Product Quality and Disposition Department

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**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 : **Conforms**
By Culture method

BACTERIAL AND FUNGAL STERILITY TEST : **No microbial growth**
By membrane filtration

TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE : **Conforms**
By inoculation to indicator cells and specific staining

NEURAMINIDASE ANTIGEN IDENTIFICATION : **Positive**
By RT-PCR

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

INFECTIOUS TITER : **7 log10 EID50/ml**
By EID50

GENERAL CONCLUSION : Conforms

Release date : 26.05.2011

Date : *May 30th, 2016*
Qualified Person :

[Signature]
Product Quality and Disposition Department

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**QUALITY CONTROL CERTIFICATE
INFLUENZA VACCINE
(SPLIT VIRION, INACTIVATED)**

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

BULK

Lot number : FA495977

Manufacturing date : 25.04.2013

- OCTOXYNOL -9 -CONTENT : 536 µg/ml
By HPLC
- HAEMAGGLUTININ ANTIGEN IDENTIFICATION : Positive
By Haemagglutinin inhibition test
- HAEMAGGLUTININ ANTIGEN CONTENT : 216 (212 - 221) µg/ml
By SRID
- RESIDUAL INFECTIOUS VIRUS : No residual infectious virus
By Inoculation of eggs
- BACTERIAL AND FUNGAL STERILITY : No microbial growth
By Membrane filtration
- NEURAMINIDASE ANTIGEN IDENTIFICATION : Positive
By RT-PCR
(performed on the first three monovalent bulk batches manufactured from any new working seed lot)
- NEURAMINIDASE ENZYMATIC ACTIVITY : Presence of neuraminidase activity
By Enzymatic method
(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 : 25.04.2015

Date : *May 26th, 2016*
 Qualified Person : *[Signature]*
 Product Quality and Disposition Department

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**QUALITY CONTROL CERTIFICAT
INFLUENZA VIRUS**

Strain B/Massachusetts/2/2012

MASTER SEED LOT

Lot number : FA477285

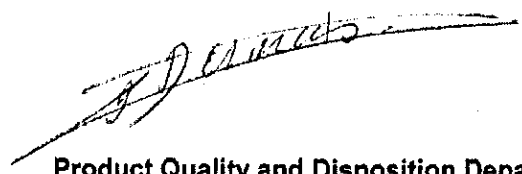
Manufacturing date : 26.11.2012

HAEMAGGLUTININ ANTIGEN IDENTIFICATION : Positive
By Haemagglutination inhibition test

GENERAL CONCLUSION : Conforms

Release date : 04.06.2013

Date : *July 27th, 2016*
Qualified Person :




Product Quality and Disposition Department

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**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 : **Conforms**
By Culture method

BACTERIAL AND FUNGAL STERILITY TEST : **No microbial growth**
By membrane filtration

TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE : **Conforms**
By Inoculation to indicator cells and specific staining

NEURAMINIDASE ANTIGEN IDENTIFICATION : **Positive**
By RT-PCR

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

INFECTIOUS TITER : **10 log10 EID50/ml**
By EID50

GENERAL CONCLUSION : Conforms

Release date : 04.06.2013

Date : *May 30th, 2016*
Qualified Person :

H. Demais
Product Quality and Disposition Department

Parc Industriel d'Incarville, BP 101, 27101 Val De Reuil cedex, France

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**QUALITY CONTROL CERTIFICAT
INFLUENZA VACCINE
(SPLIT VIRION, INACTIVATED)**

Strain B/Massachusetts/2/2012

BULK

Lot number : FA492930

Manufacturing date : 27.03.2013

OCTOXYNOL -9 -CONTENT : **564 µg/ml**
By HPLC

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

HAEMAGGLUTININ ANTIGEN CONTENT : **167 (163 - 171) µg/ml**
By SRID

RESIDUAL INFECTIOUS VIRUS : **No residual infectious virus**
By Inoculation of eggs

BACTERIAL AND FUNGAL STERILITY : **No microbial growth**
By Membrane filtration

NEURAMINIDASE ANTIGEN IDENTIFICATION : **Positive**
By RT-PCR
(performed on the first three monovalent bulk batches manufactured from any new working seed lot)

NEURAMINIDASE ENZYMATIC ACTIVITY : **Presence of neuraminidase activity**
By Enzymatic method
(performed on the first three monovalent bulk batches manufactured from any new working seed lot)

GENERAL CONCLUSION : Conforms

Release date : 04.09.2014

Expiry date : 27.03.2015

Date : *May 26th, 2016*
Qualified Person :

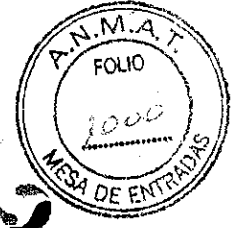
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Do not Distribute



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Certificate of Analysis

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

Batch : FDV02328

Step : Final Bulk Product

Manufacturing Date : 04/JUN/2014

Prior batch : FA492930 : Conform on 03/JUL/2013

FA495333 : Conform on 12/AUG/2013

FA495977 : Conform on 30/AUG/2013

FA516286 : Conform on 26/MAY/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
Protein content (by Kjeldhal method)	≤ 600 µg/mL	344 µg/mL
Ovalbumin content (by ELISA)	≤ 100 ng/mL	15 ng/mL
[Total protein/hemagglutinin] ratio (By calculation)	≤ 6	2

- The batch FDV02328 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

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20/AUG/2014

Name

Signature

Date

Version number: 1

Page 1 of 1

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