

**INFLUENZA VACCINE (SPLIT VIRION,
INACTIVATED) MONOVALENT POOLED
HARVEST**

ORIGINAL STRAIN A/ (H1N1)

Working virus seed lot used :

PRODUCTION

Dates of inoculation, harvest, disruption and inactivation

Inoculation	Harvest	Disruption	Inactivation

Disruption agent : Octoxynol 9
Treatment \geq 1 hour

Storage conditions before inactivation : + 5° + 3°C

Inactivation : By formaldehyde action

Concentration of inactivating agent : 0.2 %

Time of inactivation : 25-26 hours at +20°C +/- 5°C followed by a stage at +5°C +/- 3°C for 24-96 hours

Storage conditions after inactivation : + 5° + 3°C

Concentration and purification procedure : Isopycnic ultracentrifugation on a saccharose gradient

Antibiotics used during preparation : Neomycine sulfate in the inoculum

Filtration : On 0.22 μ m pore size membrane

Destinatario : A. Fattestion de l'ANSM
Export officiel non contrôlé
Modif : Batch Release protocol QIV

Information Confidentielle
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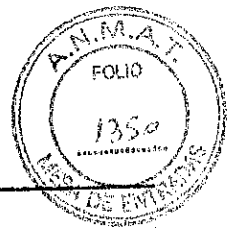
ROXANA MONTEMILONE
DIRECTORA TECNICA
APODERADA
SANOFI PASTEUR S. A.

Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable

Numéro : Q-0565202
Version : 2.0
Catégorie : 1





Certificate of Analysis

Product Name : INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

Process Stage : WORKING SEED LOT

Volume / Quantity :

Storage Condition : ≤ -60°C

Date of Manufacture :

Working Seed Lot

Test(s)	Acceptance Criteria	Result	Approval Date
TEST FOR MYCOPLASMA BY MICROBIOLOGICAL CULTURE <i>By Inoculation to suitable culture media</i>	Negative for the presence of mycoplasma when cultured on agar and broth		
BACTERIAL AND FUNGAL STERILITY <i>By Membrane filtration</i>	No microbial growth		
TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE <i>By Inoculation to indicator cells and specific staining</i>	Negative for the presence of mycoplasma when cultured in cells and treated with a fluorescent dye		
NEURAMINIDASE ANTIGEN IDENTIFICATION <i>By RT-PCR</i>	POSITIVE		
HAEMAGGLUTININ ANTIGEN IDENTIFICATION <i>By Haemagglutination inhibition</i>	POSITIVE		
INFECTIOUS TITER <i>By EID50</i>	≥ 6 log10 EID50/mL	log10 EID50/mL	

Export oficial non controlat
Modul: Batch Release production
Desubstantiat: A. Patentele de IANSM

Information Confidentielle
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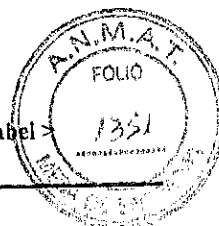
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Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable

Numéro : Q_0565202
Version : 2.0
Categorie : 1





INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)
WORKING VIRUS SEED
LOT WORKING VIRUS
SEED LOT A/H1N1 -

A/ PRODUCTION

Lot number :

Inoculation

Date of inoculation :
Inoculum : Primary seed lot
Passage number from primary seed lot :
Inoculated dilution (log10) :
Eggs used :
Inoculated volume per egg : mL
Number of eggs inoculated :
Temperature of incubation : **Optimal incubation conditions**
Added antibiotics : None

Harvest and purification

Date :
Storage conditions : $\leq - 60^{\circ}\text{C}$

Release date :

Destinataire : A l'attention de l'ANSM

Export officiel non contrôlé
Motif : Batch RESISE PROCESSION 1351

Information Confidentielle
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Numéro : Q_0565202
Version : 2.0
Catégorie : 1

Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable





B – CONTROLS

Test for mycoplasma

- by culture method

Method : Agar culture
Volume tested : ml
Media used : Hayflick – Frey
Temperature of incubation :
Positive controls :
Mycoplasma pneumoniae, Mycoplasma
orale, Mycoplasma gallisepticum,
Mycoplasma synoviae, Acholeplasma
laidlawii

. Test on :
. Test off :
Subculture at the 3rd day :
. Test on :
. Test off :
Subculture at the 7th day :
. Test on :
. Test off :
Subculture at the 14th day :
. Test on :
. Test off :
Subculture at the 21th day :
. Test on :
. Test off :

Result :

Positive control :
Mycoplasma pneumoniae :
Mycoplasma orale :
Mycoplasma gallisepticum :
Mycoplasma synoviae :
Acholeplasma laidlawii :

Result :

Destinataire : A l'attention de l'ANSM

Export officiel non contrôlé
Modif : Batch renvoie producteur

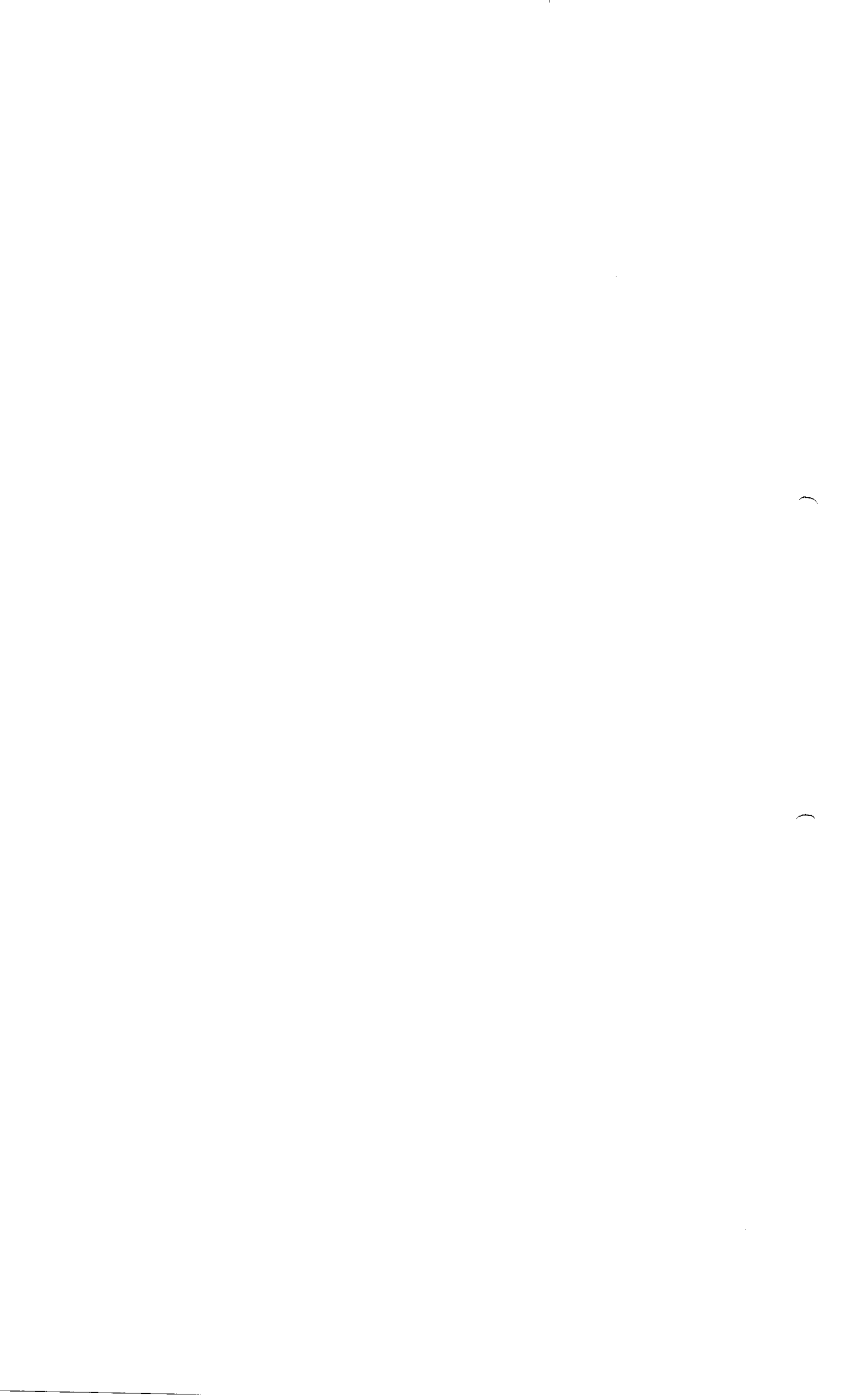
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Numéro : Q_0565202
Version : 2.0
Catégorie : 1

Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable





**Test for Mycoplasma
- by epifluorescence in cell culture**

Method : DNA fluorescence staining
 Cell used : ,th passage
 Volume tested : ml
 Temperature of incubation : °C
 Positive control : Mycoplasma hyorhinis and Mycoplasma orale
 Test on :
 Test off :
 Result :

Bacterial and fungal sterility

Method	: Membrane filtration	
Media	Thioglycollate medium	Soybean Casein Digest medium
Temperatures	30-35°C	20-25°C
Volume tested	ml	
Inoculum per Steritest	ml	ml
Volume of medium	100 ml	100 ml
Number of inoculated Steritest	1	1
Test on	:	
Test off	:	
Result	:	

Destinataire : A l'attention de l'ANSM

Export officiel non contrôlé
Mont : Batch release procedure

Information Confidentielle
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Statut : Applicable

Numéro : Q_0565202
Version : 2.0
Catégorie : I





Haemagglutinin Antigen Identification

Method Haemagglutination inhibition test
Date

Antisera used : = A/H1N1
= A/H3N2
= B/Victoria lineage
= B/Yamagata lineage

Antigens used : = A/H1N1
= A/H3N2
= B/Victoria lineage
= B/Yamagata lineage

Result:

ANTIGEN	ANTISERA			
	ANTI H1A/	ANTI H3 A/	ANTI B/Victoria	ANTI B/Yamagata
A/H1N1				
A/H3N2				
B/Victoria				
B/Yamagata				
WORKING VIRUS SEED LOT				

Conclusion

Destinataire : A Patenteur de LANSM

Export officiel non contrôlé
Motif : Base d'essai pour QV...

Information Confidentielle
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Numéro : Q_0565202
Version : 2.0
Catégorie : I





Infectious titer

Method : Haemagglutination (HA) System
used : Embryonated hen eggs Number
of tests :
Test on : Test
off :
Virus concentration per ml
expressed in log 10 : and Infectious Dose 50/ml
Mean of the titers : Infectious Dose 50/ml

Destinatario: A l'attention de l'ANSM

Export officiel non contrôlé
Matr: Baich renesse ipnauerqivv-1-212c

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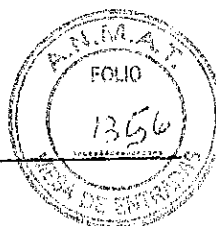
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Numéro : Q_0565202
Version : 2.0
Catégorie : 1





Certificate of Analysis

Product Name : INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

Process Stage : PRIMARY SEED LOT

Volume / Quantity :

Storage Condition : $\leq -60^{\circ}\text{C}$

Date of Manufacture :

Master Seed Lot

Test(s)	Acceptance Criteria	Result	Approval Date
HAEMAGGLUTININ ANTIGEN IDENTIFICATION <i>By Haemagglutination inhibition</i>	POSITIVE		

Destinatario : A Patenteon de l'ANSM

Export officiel non contrôlé
Motif : Batch Release protocol QIV

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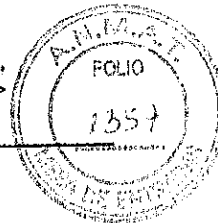
ROXANA MONTEMILONE
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Par : BOSSUT Isabelle
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Statut : Applicable

Numéro : Q_0565202
Version : 2.0
Catégorie : 1





**INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)
MASTER VIRUS SEED LOT

ORIGINAL STRAIN**

Name : A/H1N1
Origin :
Lot number :
Received :
Passage history on receipt :
MASTER VIRUS SEED LOT
A - PRODUCTION

Lot number :

Inoculation
Date of inoculation :
Passage number from reassortant received :
Dilutions of inoculum (log10) :
Eggs used :
Number of eggs per dilution :
Inoculated volume per egg . ml
Temperature of incubation : °C

Harvest of allantoic fluids
Date of harvest :
Pool of allantoic fluids at the dilution (log10) :
Filling and storage at ≤ - 60°C

Release date :

Desiminaire : A. Patenteur de VANSM
Export officiel non contrôlé
Matière : Batch Release protocol QIV

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Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable

Numéro : Q_0565202
Version : 2.0
Catégorie : I





B – CONTROLS

Haemagglutinin Antigen Identification

Method Haemagglutination inhibition test

Date

Antisera used : = A/H1N1
= A/H3N2
= B/Victoria lineage
= B/Yamagata lineage

Antigens used : = A/H1N1
= A/H3N2
= B/Victoria lineage
= B/Yamagata lineage

Result:

ANTIGEN	ANTISERA			
	ANTI H1A/	ANTI H3 A/	ANTI B/Victoria	ANTI B/Yamagata
A/H1N1				
A/H3N2				
B/Victoria				
B/Yamagata				
MASTER VIRUS SEED LOT				

Conclusion

Destinataire : A l'attention de FANSM

Export officiel non contrôlé
Motif : Batch Release protocol QIV

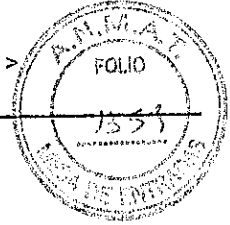
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Numero : Q_0565202
Version : 2.0
Categorie : 1

Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable



Certificate of Analysis

Product Name : INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

Process Stage : BULK

Volume / Quantity :

Storage Condition : +5°C+/-3°C

Date of Manufacture :

BULK

Expiry Date :

Test(s)	Acceptance Criteria	Result	Approval Date
OCTOXYNOL-9 CONTENT <i>By HPLC</i>	≤ 800 µg/mL	µg/mL	
HAEMAGGLUTININ ANTIGEN IDENTIFICATION <i>By Haemagglutination inhibition</i>	Positive		
HAEMAGGLUTININ ANTIGEN CONTENT <i>By SRID</i>	For formulation Mean : No specification		
	Lower confidence limit (P=0.95)		
	Higher confidence limit (P=0.95)		
BACTERIAL AND FUNGAL STERILITY <i>By Membrane filtration</i>	No microbial growth		
RESIDUAL INFECTIOUS VIRUS <i>By Inoculation of eggs</i>	No residual infectious virus		
NEURAMINIDASE ANTIGEN IDENTIFICATION <i>By RT-PCR</i>	Positive (RT-PCR method 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 (Enzymatic method performed on the three first batches manufactured from any new working seed lot)		

Expont officiel non contrôlé
 Désignation : A. Fabrication de FANSEN
 Modif : Batch Release protocol QIV

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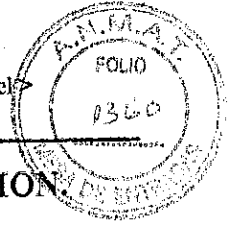
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Statut : Applicable

Numéro : Q_0565202
Version : 2.0
Catégorie : I





Additional information on lot - INFLUENZA VACCINE (SPLIT VIRION INACTIVATED)

Bacterial and Fungal Sterility

Method	Membrane filtration	
	Thioglycollate medium	Soybean Casein Digest medium
Media		
Temperatures	30-35°C	20-25°C
Volume tested	ml	
Inoculum per steritest	ml	ml
Volume of medium per steritest	100 ml	100 ml
Number of inoculated steritest	1	1
Test on		
Test off		
Result		

Residual Infectious Virus

Method Research for live virus into embryonated chicken eggs

First inoculation

Date
 Inoculated dilutions (log10) pure, -1, -2
 Volume inoculated by egg mL
 Number of inoculated eggs by dilution
 Incubation period and temperature hours at °C
 Date of egg cooling
 Date of harvest and mixture of allantoic fluids (AF) for each dilution

Harvest storage +5 +/-3°C

Second inoculation

Date
 Volume of AF inoculated by egg mL from each previous dilution

Destinataire : A l'attention de l'ANSM

Export officiel non contrôlé
Motif: Batch release process QIV

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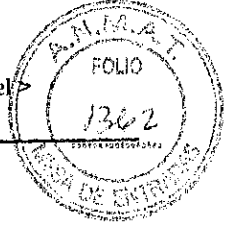
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Número : Q_0565202
Version : 2.0
Categoríe : 1

Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable







Haemagglutinin Antigen Identification

Method Haemagglutination inhibition test
Date

Antisera used : = A/H3N2
= A/H1N1
= B/Victoria lineage
= B/Yamagata lineage

Antigens used : = A/H3N2
= A/H1N1
= B/Victoria lineage
= B/Yamagata lineage

Result:

ANTIGEN	ANTISERA			
	ANTI H3A/	ANTI H1 A/	ANTI B/Victoria	ANTI B/Yamagata
A/H3N2				
A/H1N1				
B/Victoria				
B/Yamagata				
BULK				

Conclusion

Destinataire : A l'attention de l'ANSM

Export officiel non contrôlé
Motif : Batch/Process/Process/Process

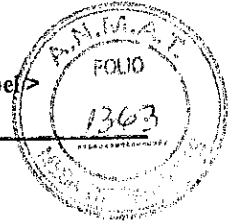
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Statut : Applicable





**INFLUENZA VACCINE (SPLIT VIRION,
INACTIVATED) MONOVALENT POOLED
HARVEST**

ORIGINAL STRAIN A/ (H3N2)

Working virus seed lot used :

PRODUCTION

Dates of inoculation, harvest, disruption and inactivation

Inoculation	Harvest	Disruption	Inactivation

Disruption agent : Octoxynol 9
Treatment > 1 hour

Storage conditions before inactivation : + 5° + 3°C

Inactivation : By formaldehyde action

Concentration of inactivating agent : 0.2 %

Time of inactivation : 25-26 hours at +20°C +/- 5°C followed by a stage at +5°C +/- 3°C for 24-96 hours

Storage conditions after inactivation : + 5° + 3°C

Concentration and purification procedure : Isopycnic ultracentrifugation on a saccharose gradient

Antibiotics used during preparation : Neomycine sulfate in the inoculum

Filtration : On 0.22 µm pore size membrane

Destruire : A l'attention de l'ANSM
Export officiel non contrôlé
Moir : Batch Release protocol OIV

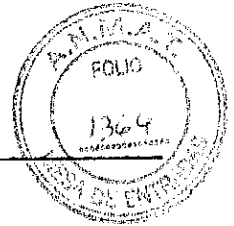
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ROXANA MONTEMILONE
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Número : Q_0565202
Version : 2.0
Categoría : I

Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable





Certificate of Analysis

Product Name : INFLUENZA VACCINE (SPLIT VIRION. INACTIVATED)

Process Stage : WORKING SEED LOT

Volume / Quantity :

Storage Condition : ≤ -60°C

Date of Manufacture :

Working Seed Lot

Test(s)	Acceptance Criteria	Result	Approval Date
TEST FOR MYCOPLASMA BY MICROBIOLOGICAL CULTURE <i>By Inoculation to suitable culture media</i>	Negative for the presence of mycoplasma when cultured on agar and broth		
BACTERIAL AND FUNGAL STERILITY <i>By Membrane filtration</i>	No microbial growth		
TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELLULAR CULTURE <i>By Inoculation to indicator cells and specific staining</i>	Negative for the presence of mycoplasma when cultured in cells and treated with a fluorescent dye		
NEURAMINIDASE ANTIGEN IDENTIFICATION <i>By RT-PCR</i>	POSITIVE		
HAEMAGGLUTININ ANTIGEN IDENTIFICATION <i>By Haemagglutination inhibition</i>	POSITIVE		
INFECTIOUS TITER <i>By EID50</i>	≥ 6 log ₁₀ EID50/mL	log ₁₀ EID50/mL	

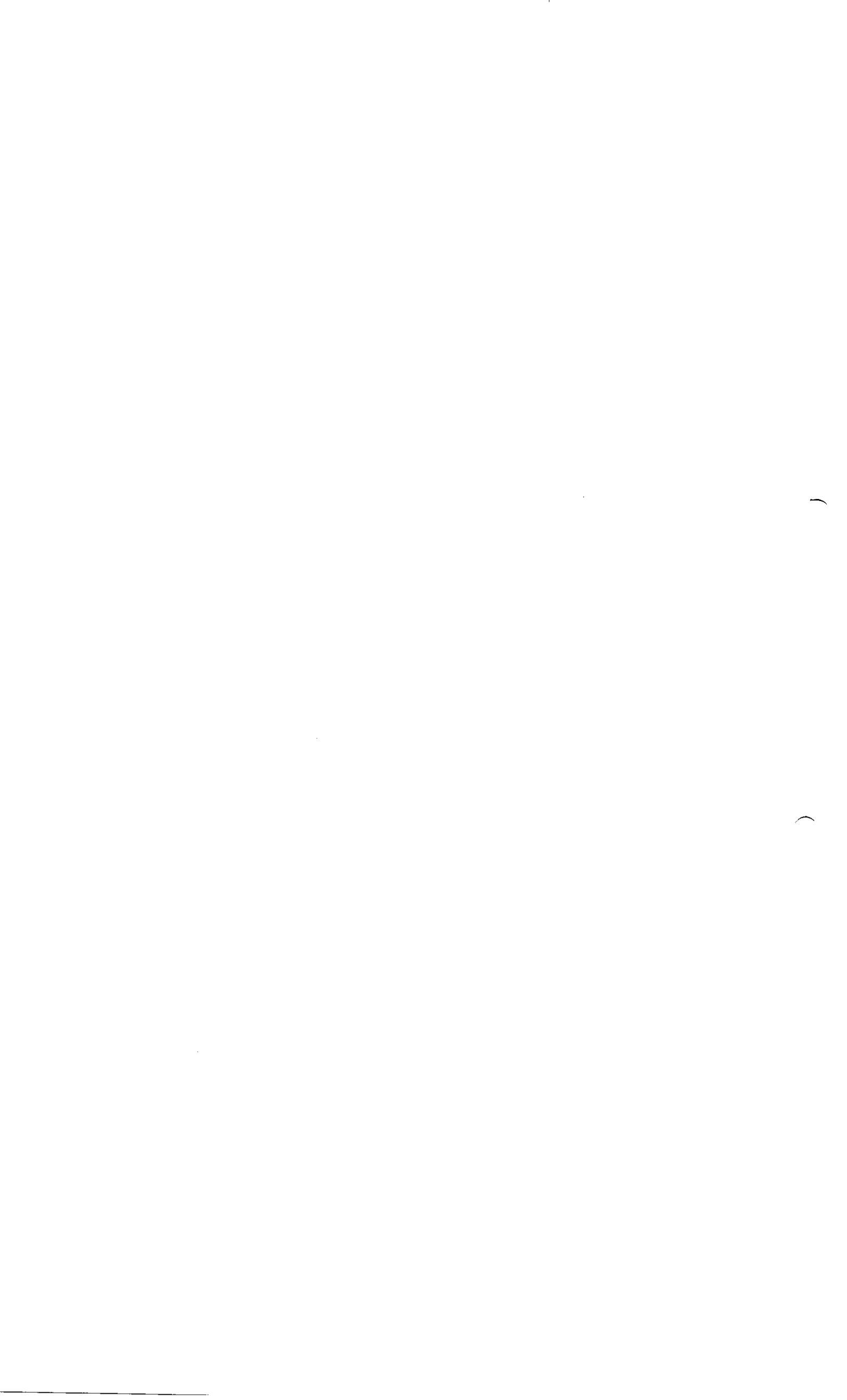
Export officiel non contrôlé
Motif : Batch/RTISS/PROD/01/01/13/13/13
Destinataire : A. Pasteur/Inoc.d.d. PANSM

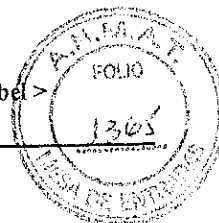
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Número : Q_0565202
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Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable





**INFLUENZA VACCINE
(SPLIT VIRION, INACTIVATED)

WORKING VIRUS SEED LOT

A/H3N2 -**

A/ PRODUCTION

Lot number :

Inoculation

Date of inoculation :

Inoculum : Primary seed lot

Passage number from primary seed lot :

Inoculated dilution (log10) :

Eggs used :

Inoculated volume per egg : mL

Number of eggs inoculated :

Temperature of incubation : **Optimal incubation conditions**

Added antibiotics : None

Harvest and purification

Date :

Storage conditions : $\leq - 60^{\circ}\text{C}$

Release date :

Destinataire : A l'attention de FANSM

Export officiel non contrôlé
Motif : Barch REEASC-1880601 QIV

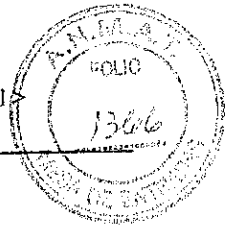
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Número : Q_0565202
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Categoría : 1

Par : BOSSUT Isabelle
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Statut : Applicable





B – CONTROLS

Test for mycoplasma

- by culture method

Method : Agar culture
 Volume tested : ml
 Media used : Hayflick – Frey
 Temperature of incubation :
 Positive controls :
 Mycoplasma pneumoniae, Mycoplasma
 orale, Mycoplasma gallisepticum,
 Mycoplasma synoviae, Acholeplasma
 laidlawii

. Test on :
 . Test off :
 Subculture at the 3rd day
 . Test on :
 . Test off :
 Subculture at the 7th day
 . Test on :
 . Test off :
 Subculture at the 14th day
 . Test on :
 . Test off :
 Subculture at the 21th day
 . Test on :
 . Test off :

Result :
 Positive control :
 Mycoplasma pneumoniae :
 Mycoplasma orale :
 Mycoplasma gallisepticum :
 Mycoplasma synoviae :
 Acholeplasma laidlawii :
 Result :

Destinataire : A l'attention de PANSUM

Export officiel non contrôlé
Motif : Batch release protocol QIV

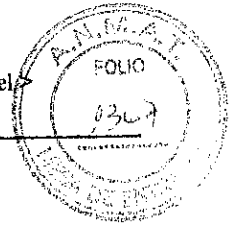
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Statut : Applicable





Test for Mycoplasma
- by epifluorescence in cell culture

Method : DNA fluorescence staining
 Cell used : ,th passage
 Volume tested : ml
 Temperature of incubation : °C
 Positive control : Mycoplasma hyorhinitis and Mycoplasma orale
 Test on :
 Test off :
 Result :

Bacterial and fungal sterility

Method : Membrane filtration

Media	Thioglycollate medium	Soybean Casein Digest medium
Temperatures	30-35°C	20-25°C
Volume tested	ml	
Inoculum per Steritest	ml	ml
Volume of medium	100 ml	100 ml
Number of inoculated Steritest	1	1
Test on	:	:
Test off	:	:
Result	:	:

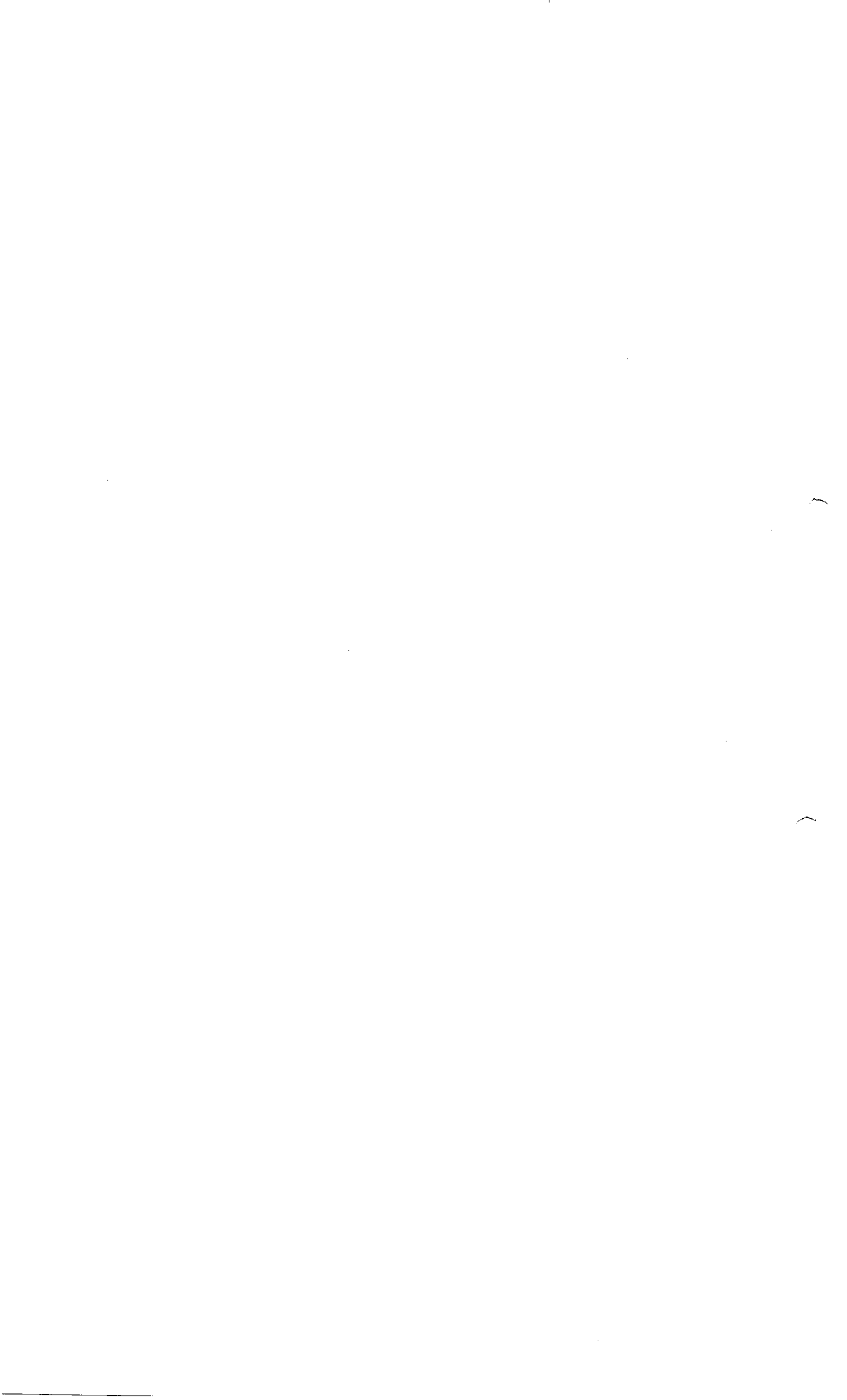
Destinatario : A l'attention de l'ANSM
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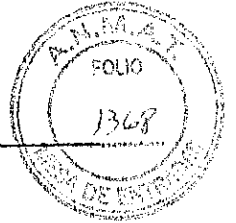
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Le : 24 oct. 2016 13:56:56

Statut : Applicable





Haemagglutinin Antigen Identification

Method Haemagglutination inhibition test

Date

Antisera used : = A/H3N2
 = A/H1N1
 = B/Victoria lineage
 = B/Yamagata lineage

Antigens used : = A/H3N2
 = A/H1N1
 = B/Victoria lineage
 = B/Yamagata lineage

Result:

ANTIGEN	ANTISERA			
	ANTI H3A/	ANTI H1 A/	ANTI B/Victoria	ANTI B/Yamagata
A/H3N2				
A/H1N1				
B/Victoria				
B/Yamagata				
WORKING VIRUS SEED LOT				

Conclusion

Destinataire : A l'attention de l'ANSM

Export officiel non contrôlé
Motif : Batch/Process/Version

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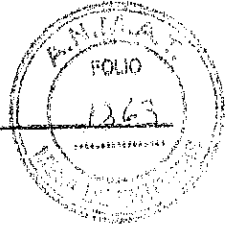
ROXANA MONTEMLONE
DIRECTORA TECNICA
APODERADA
SANOFI PASTEUR S.A.

Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable

Numéro: Q_0565202
Version : 2.0
Catégorie : I





Infectious titer

Method : Haemagglutination (HA) System
used : Embryonated hen eggs Number
of tests :
Test on : Test
off :

Virus concentration per ml
expressed in log 10 : and Infectious Dose 50/ml

Mean of the titers : Infectious Dose 50/ml

Destinataire : A. Pattention de FANSM

Export officiel non contrôlé
Motif : Batch release process QV1-212

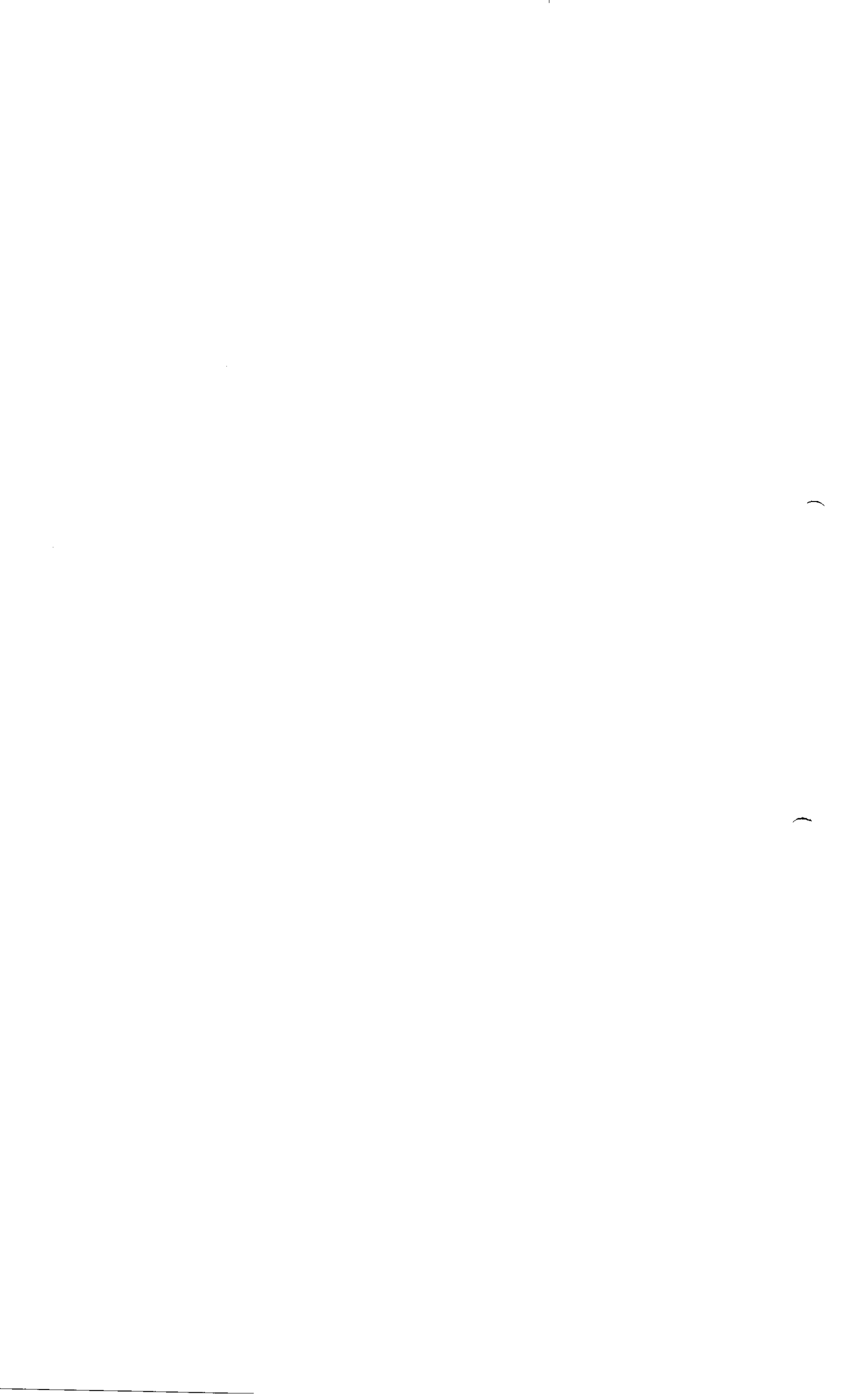
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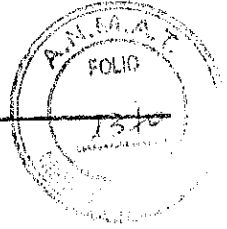
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Statut : Applicable

Numéro : Q_0565202
Version : 2.0
Catégorie : 1





Certificate of Analysis

Product Name : INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

Process Stage : PRIMARY SEED LOT

Volume / Quantity :

Storage Condition : ≤ -60°C

Date of Manufacture :

Master Seed Lot

Test(s)	Acceptance Criteria	Result	Approval Date
HAEMAGGLUTININ ANTIGEN IDENTIFICATION <i>By Haemagglutination inhibition</i>	POSITIVE		

Destinataire : A l'attention de l'ANSM

Export officiel non contrôlé
Motif : Batch Release protocol QIV

Information Confidentielle
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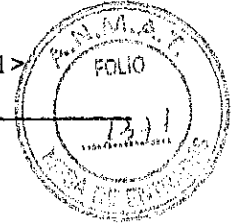
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Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable

Numéro : Q_0565202
Version : 2.0
Catégorie : 1





**INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)
MASTER VIRUS SEED LOT**

ORIGINAL STRAIN

Name : A/H3N2
Origin :
Lot number :
Received :
Passage history on receipt :

**MASTER VIRUS SEED LOT
A - PRODUCTION**

Lot number :

Inoculation

Date of inoculation :
Passage number from reassortant received :
Dilutions of inoculum (log10) :
Eggs used :
Number of eggs per dilution :
Inoculated volume per egg . ml
Temperature of incubation : °C

Harvest of allantoic fluids

Date of harvest :
Pool of allantoic fluids at the dilution (log10) :
Filling and storage at ≤ - 60°C

Release date :

Export officiel non contrôlé
Motif : Batch Release protocol QIV
Destinataire : A l'attention de FANSM

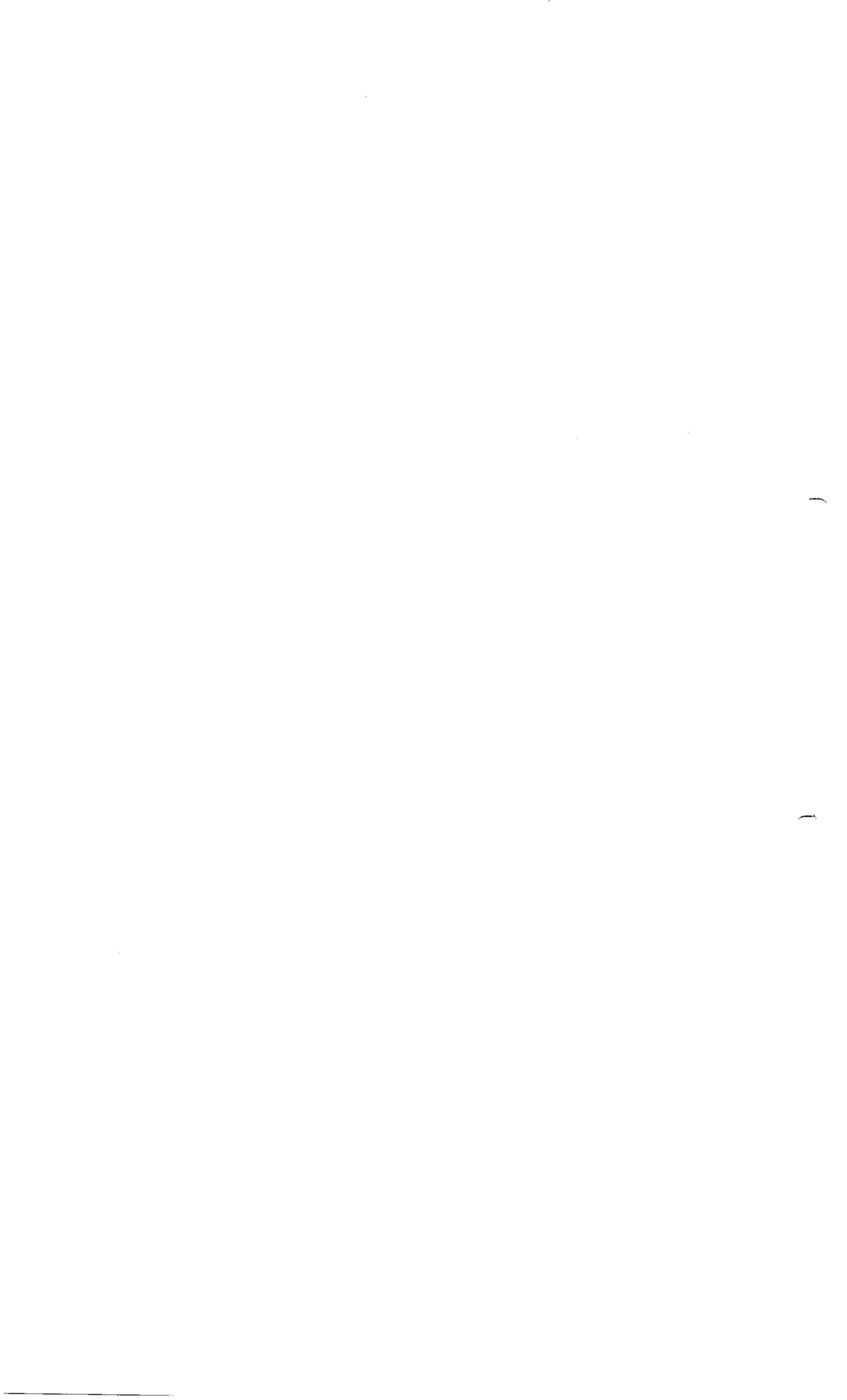
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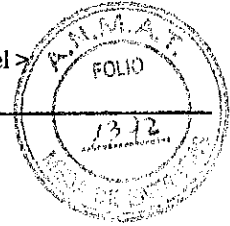
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Version : 2.0
Catégorie : I





B – CONTROLS

Haemagglutinin Antigen Identification

Method Haemagglutination inhibition test

Date

Antisera used : = A/H3N2
= A/H1N1
= B/Victoria lineage
= B/Yamagata lineage

Antigens used : = A/H3N2
= A/H1N1
= B/Victoria lineage
= B/Yamagata lineage

Result:

ANTIGEN	ANTISERA			
	ANTI H3A/	ANTI H1 A/	ANTI B/Victoria	ANTI B/Yamagata
A/H3N2				
A/H1N1				
B/Victoria				
B/Yamagata				
MASTER VIRUS SEED LOT				

Conclusion

Destinataire : A l'attention de l'ANSM

Export officiel non contrôlé
Motif : Batch Release protocol QIV

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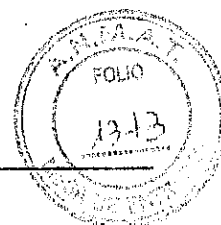
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Par : BOSSUT Isabelle
Le : 24 oct. 2016 13:56:56

Statut : Applicable

Numéro : Q_0565202
Version : 2.0
Catégorie : 1





Certificate of Analysis

Product Name : INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

Process Stage : BULK

Volume / Quantity :

Storage Condition : +5°C+/-3°C

Date of Manufacture :

BULK

Expiry Date :

Test(s)	Acceptance Criteria	Result	Approval Date
OCTOXYNOL-9 CONTENT <i>By HPLC</i>	≤ 800 µg/mL	µg/mL	
HAEMAGGLUTININ ANTIGEN IDENTIFICATION <i>By Haemagglutination inhibition</i>	Positive		
HAEMAGGLUTININ ANTIGEN CONTENT <i>By SRID</i>	For formulation Mean : No specification		
	Lower confidence limit (P=0.95)		
	Higher confidence limit (P=0.95)		
BACTERIAL AND FUNGAL STERILITY <i>By Membrane filtration</i>	No microbial growth		
RESIDUAL INFECTIOUS VIRUS <i>By Inoculation of eggs</i>	No residual infectious virus		
NEURAMINIDASE ANTIGEN IDENTIFICATION <i>By RT-PCR</i>	Positive (RT-PCR method 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 (Enzymatic method performed on the three first batches manufactured from any new working seed lot)		

Export officiel non contrôlé
 Destinataire : A l'attention de l'ANSM
 Motif : Batch release procedure

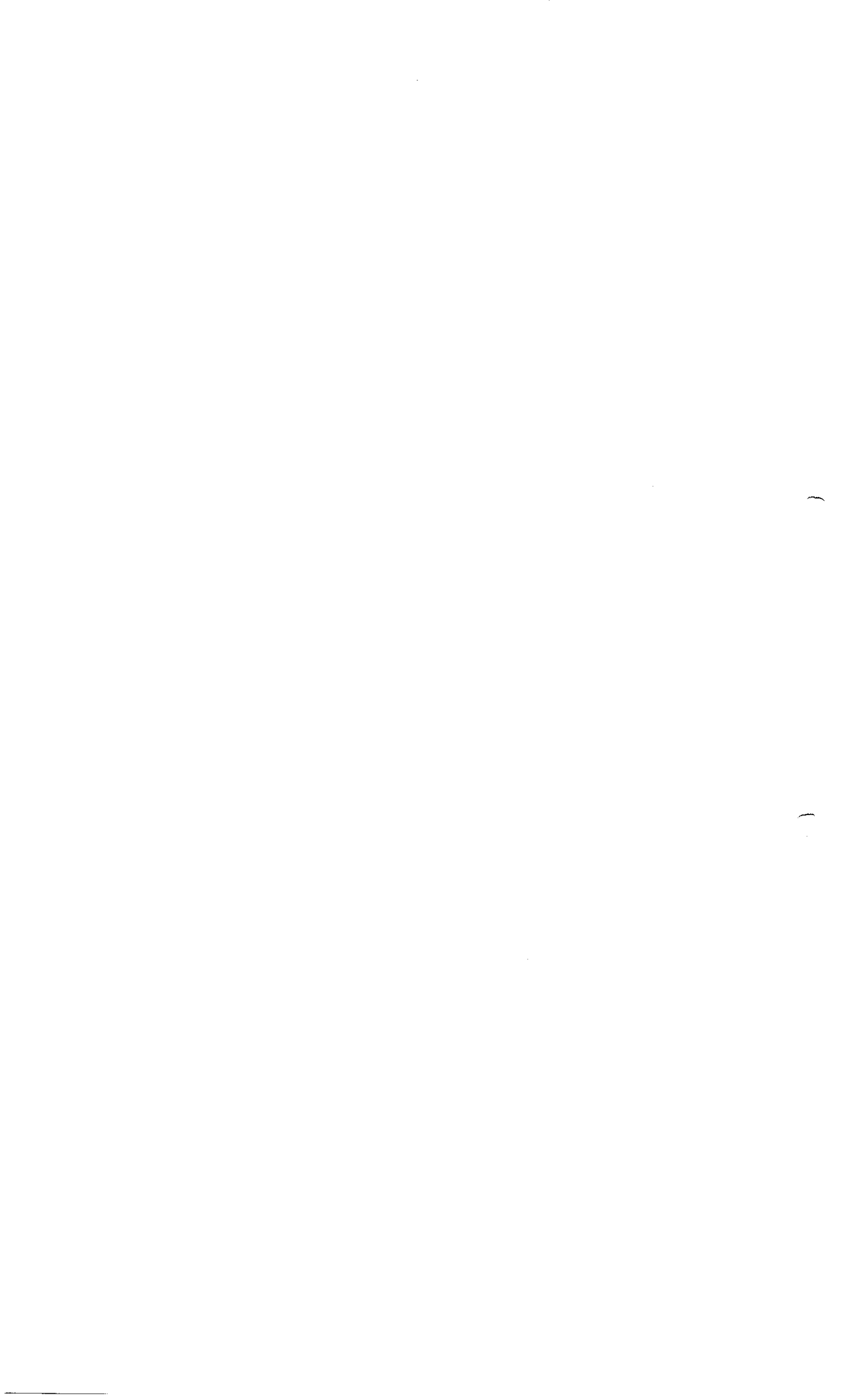
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Statut : Applicable

Numero : Q_0565202
Version : 2.0
Categorie : I





Additional information on lot - INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

Bacterial and Fungal Sterility

Method	Membrane filtration	
	Thioglycollate medium	Soybean Casein Digest medium
Media		
Temperatures	30-35°C	20-25°C
Volume tested	ml	
Inoculum per steritest	ml	ml
Volume of medium per steritest	100 ml	100 ml
Number of inoculated steritest	1	1
Test on		
Test off		
Result		

Residual Infectious Virus

Method	Research for live virus into embryonated chicken eggs
First inoculation	
Date	
Inoculated dilutions (log10)	pure, -1, -2
Volume inoculated by egg	mL
Number of inoculated eggs by dilution	
Incubation period and temperature	hours at °C
Date of egg cooling	
Date of harvest and mixture of allantoic fluids (AF) for each dilution	
Harvest storage	+5 +/-3°C
Second inoculation	
Date	
Volume of AF inoculated by egg	mL from each previous dilution

Destinataire : A l'attention de l'ANSM
 Export officiel non contrôlé
 Motif : Batch Release Production

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Statut : Applicable

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Version : 2.0
Catégorie : 1

