



Lot 110721
Page 23 of 42
Prot. 1056/11

Identity of neuraminidase (Specification: Positive for B strain)

Method ELISA
Date of test October 26, 2010
Result Positive for B strain

NI titre			
Antigen	Antiserum		
	[A(H1N1)] Anti-N1 NA A/California/7/2009 10/118	[A(H3N2)] Anti-N2 NA A/Perth/16/2009 10/182	[B] Anti-B NA B/Brisbane/60/2008 10/146
NYMC BX-35 Working seed Lot WS-093-01 dil. (10 ⁻⁵) 10 ⁻⁶	24	15	713

Identity of haemagglutinin (Specification: Positive for B strain)

Method Haemagglutination – inhibition test
Date of test October 26, 2010
Result Positive for B strain

HI titre			
Antigen	Antiserum		
	[A(H1N1)] X-181/10/118	[A(H3N2)] X-187/10/182	[B] BX-35/10/146
NYMC BX-35 Working seed Lot WS-093-01 dil. (10 ⁻⁵) 10 ⁻⁶	20	20	640

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MONOVALENT POOLED HARVEST LOT 1004/11

Production details of monovalent pooled harvest

Name and address of manufacturer	Novartis Vaccines and Diagnostics Srl Via Fiorentina, 1 - Siena (Italy)
B virus strain	NYMC BX-35 (B/ Brisbane/60/2008 - like virus)
Working seed lot used in manufacture	WS-093-01 dil. (10 ⁻⁵) 10 ⁻⁶
Date of inoculation:	
Monovalent lot : 110/11	January 16, 2011
Monovalent lot : 111/11	January 17, 2011
Added antibiotics	Kanamycin sulphate and neomycin sulphate
Date of harvesting:	
Monovalent lot : 110/11	January 20, 2011
Monovalent lot : 111/11	January 21, 2011
Method of inactivation	Treatment with formaldehyde
Date of inactivation:	
Monovalent lot : 110/11	January 20, 2011
Monovalent lot : 111/11	January 21, 2011
Concentration/purification procedure	Continuous zonal centrifugation in sucrose gradient, adsorption with barium sulphate and elution with sodium citrate solution

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Lot 110721
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Date of pooling of monovalent lots	January 24, 2011
Method of disruption	Treatment with Tween 80 and CTAB
Date of disruption	January 26, 2011
Date of sterile 0.2 µm final filtration	January 31, 2011
Volume of monovalent pooled harvest	37,181 mL
Storage conditions of monovalent pooled harvest	2 - 8°C

Tests on monovalent pooled harvest

Identity of neuraminidase (Specification: Positive for B strain)

Method	ELISA
Date of test	February 15, 2011
Result	Positive for B strain

Identity of haemagglutinin (Specification: Positive for B strain)

Method	SRID
Date of test	February 09, 2011
Result	Positive for B strain

Purity (Specification: Evidence of HA bands and absence or traces of NP and M components)

Method	SDS-PAGE, reducing conditions
Date of test	February 10, 2011
Result	Evidence of HA bands and absence or traces of NP and M components

Residual CTAB (Specification: ≤ 12 mcg/60 mcg HA)

Method	Colorimetric
Date of test	February 03, 2011
Result	< 3 mcg/60 mcg HA

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Lot 110721
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Residual barium (Specification: ≤ 1 mcg/mL)

Method	A. A. Spectrophotometry
Date of test	February 04, 2011
Result	< 1 mcg/mL

Residual sodium citrate (Specification: ≤ 1 mg/60 mcg HA)

Method	HPLC
Date of test	February 04, 2011
Result	< 0.02 mg/60 mcg HA

Residual Tween 80 (Specification: ≤ 300 mcg/mL)

Method	HPTLC
Date of test	February 03, 2011
Result	< 300 mcg/mL

Residual ovalbumin (Specification: Report result)

Method	ELISA
Date of test	February 03, 2011
Result	0.10 mcg/60 mcg HA

Residual formaldehyde (Specification: ≤ 1 mcg/60 mcg HA)

Method	Colorimetric
Date of test	February 08, 2011
Result	0.2 mcg/60 mcg HA

Sterility test (Specification: Sterile)

Method	Eur. Ph., membrane filtration
Media	FTM and SCDM
Volume tested	30 mL
Date of test	Jan. 31 – Feb. 14, 2011
Result	Sterile

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**SUMMARY PROTOCOL FOR PRODUCTION AND TESTING
OF INFLUENZA VACCINE (SUB - UNIT)**

NYMC BX-35 MONOVALENT POOLED HARVEST

Lot 1005/11

Summary

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- Seed virus:	
General information on seed virus	29
Tests on master seed	30
Tests on working seed	30
- Monovalent pooled harvest lot 1005/11:	
Production details of monovalent pooled harvest	32
Tests on monovalent pooled harvest	33

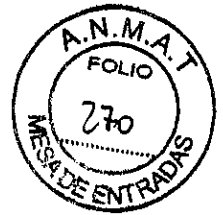
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Lot 110721
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Identity of neuraminidase (Specification: Positive for B strain)

Method ELISA
Date of test October 26, 2010
Result Positive for B strain

NI titre			
Antigen	Antiserum		
	[A(H1N1)] Anti-N1 NA A/California/7/2009 10/118	[A(H3N2)] Anti-N2 NA A/Perth/16/2009 10/182	[B] Anti-B NA B/Brisbane/60/2008 10/146
NYMC BX-35 Working seed Lot WS-093-01 dil. (10 ⁻⁵) 10 ⁻⁶	24	15	713

Identity of haemagglutinin (Specification: Positive for B strain)

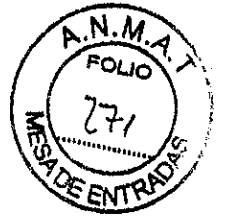
Method Haemagglutination – inhibition test
Date of test October 26, 2010
Result Positive for B strain

HI titre			
Antigen	Antiserum		
	[A(H1N1)] X-181/10/118	[A(H3N2)] X-187/10/182	[B] BX-35/10/146
NYMC BX-35 Working seed Lot WS-093-01 dil. (10 ⁻⁵) 10 ⁻⁶	20	20	640

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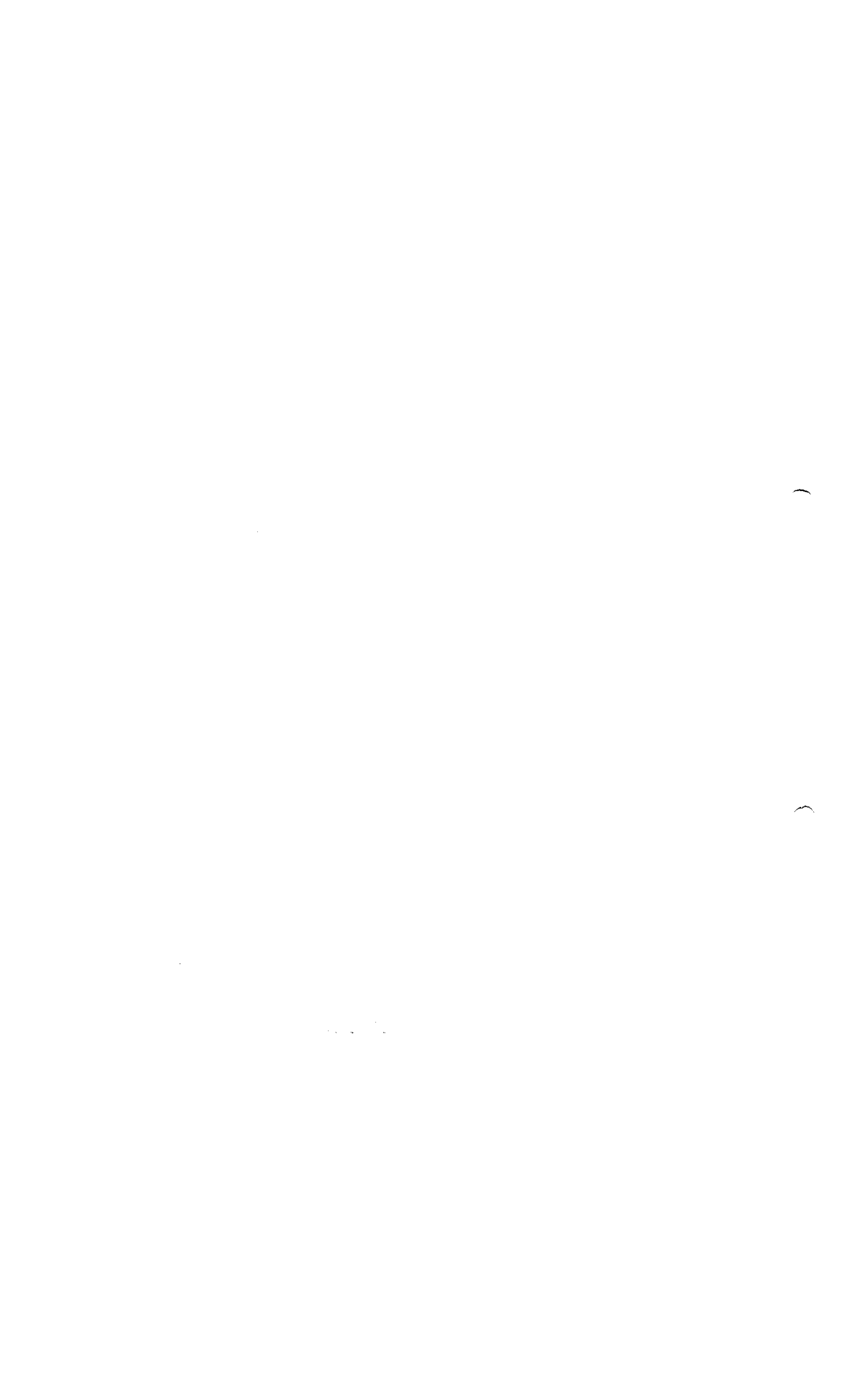
MONOVALENT POOLED HARVEST LOT 1005/11

Production details of monovalent pooled harvest

Name and address of manufacturer	Novartis Vaccines and Diagnostics Srl Via Fiorentina, 1 - Siena (Italy)
B virus strain	NYMC BX-35 (B/ Brisbane/60/2008 - like virus)
Working seed lot used in manufacture	WS-093-01 dil. (10 ⁻⁵) 10 ⁻⁶
Date of inoculation:	
Monovalent lot : 112/11	January 18, 2011
Monovalent lot : 113/11	January 19, 2011
Added antibiotics	Kanamycin sulphate and neomycin sulphate
Date of harvesting:	
Monovalent lot : 112/11	January 22, 2011
Monovalent lot : 113/11	January 23, 2011
Method of inactivation	Treatment with formaldehyde
Date of inactivation:	
Monovalent lot : 112/11	January 22, 2011
Monovalent lot : 113/11	January 23, 2011
Concentration/purification procedure	Continous zonal centrifugation in sucrose gradient, adsorption with barium sulphate and elution with sodium citrate solution

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Date of pooling of monovalent lots	January 26, 2011
Method of disruption	Treatment with Tween 80 and CTAB
Date of disruption	January 28, 2011
Date of sterile 0.2 µm final filtration	February 03, 2011
Volume of monovalent pooled harvest	42,831 mL
Storage conditions of monovalent pooled harvest	2 - 8°C

Tests on monovalent pooled harvest

Identity of neuraminidase (Specification: Positive for B strain)

Method	ELISA
Date of test	February 15, 2011
Result	Positive for B strain

Identity of haemagglutinin (Specification: Positive for B strain)

Method	SRID
Date of test	February 23, 2011
Result	Positive for B strain

Purity (Specification: Evidence of HA bands and absence or traces of NP and M components)

Method	SDS-PAGE, reducing conditions
Date of test	February 17, 2011
Result	Evidence of HA bands and absence or traces of NP and M components

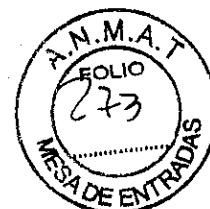
Residual CTAB (Specification: ≤ 12 mcg/60 mcg HA)

Method	Colorimetric
Date of test	February 08, 2011
Result	< 3 mcg/60 mcg HA

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Residual barium (Specification: ≤ 1 mcg/mL)

Method	A. A. Spectrophotometry
Date of test	February 04, 2011
Result	< 1 mcg/mL

Residual sodium citrate (Specification: ≤ 1 mg/60 mcg HA)

Method	HPLC
Date of test	February 14, 2011
Result	< 0.02 mg/60 mcg HA

Residual Tween 80 (Specification: ≤ 300 mcg/mL)

Method	HPTLC
Date of test	February 09, 2011
Result	< 300 mcg/mL

Residual ovalbumin (Specification: Report result)

Method	ELISA
Date of test	February 11, 2011
Result	0.18 mcg/60 mcg HA

Residual formaldehyde (Specification: ≤ 1 mcg/60 mcg HA)

Method	Colorimetric
Date of test	February 11, 2011
Result	0.2 mcg/60 mcg HA

Sterility test (Specification: Sterile)

Method	Eur. Ph., membrane filtration
Media	FTM and SCDM
Volume tested	30 mL
Date of test	Feb. 03 – Feb. 17, 2011
Result	Sterile

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Test for inactivation (Specification: Absence of live virus)

Method	Hemagglutination
Date of test	February 07, 2011
Result	Absence of live virus

Endotoxin content (Specification: < 100 IU/60 mcg HA)

Method	LAL test
Date of test	February 11, 2011
Result	< 1 IU/60 mcg HA

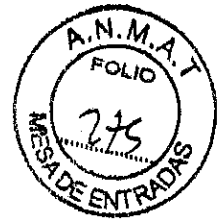
Haemagglutinin antigen content (Specification: Report result)

Method	SRID
Date of test	February 08, 2011
Result	231 mcg HA/mL

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Lot 110721
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**SUMMARY PROTOCOL FOR PRODUCTION AND TESTING
OF INFLUENZA VACCINE (SUB - UNIT)**

FINAL LOT 110721

Summary

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Tests on final bulk vaccine	39
- Final lot 110721:	
Production details of final lot	40
Tests on final lot	40

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Lot 110721
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FINAL BULK VACCINE LOT 1107

Information on blending

Name and address of manufacturer

Novartis Vaccines and Diagnostics Srl
Bellaria - Rosia, 53018 Sovicille - Siena (Italy)

Date of manufacturing

March 10, 2011

NYMC X-181 component

Monovalent pooled harvest lot
Concentration
Volume

1002/11
279 mcg HA/mL
28,441 mL

NYMC X-187 component

Monovalent pooled harvest lot
Concentration
Volume

1129/10
397 mcg HA/mL
19,987 mL

NYMC BX-35

Monovalent pooled harvest lot
Concentration
Volume

1004/11
228 mcg HA/mL
24,900 mL

Monovalent pooled harvest lot
Concentration
Volume

1005/11
231 mcg HA/mL
9,775 mL

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Buffer A solution


Nature	Buffered saline solution
Volume	145,430 mL


Buffer B solution

Nature	MgCl ₂ and CaCl ₂ in distilled water
Volume	1,470 mL

Final volume	230,000 mL
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Storage conditions of final bulk vaccine	2 - 8°C
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Tests on final bulk vaccine

Residual ovalbumin (Specification: ≤ 0.4 mcg/mL)

Method	ELISA
Date of test	March 14, 2011
Result	0.1 mcg/mL

Residual formaldehyde (Specification: ≤ 20 mcg/mL)

Method	Colorimetric
Date of test	March 16, 2011
Result	< 1 mcg/mL

Sterility test (Specification: Sterile)

Method	Eur. Ph., membrane filtration
Media	FTM and SCDM
Volume tested	30 mL (from each container)
Date of test	Mar. 11 – Mar. 25, 2011
Result	Sterile

Endotoxin content (Specification: < 100 IU/0.5 mL)

Method	LAL test
Date of test	March 16, 2011
Result	< 1 IU/0.5 mL

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Lot 110721
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Tests on final bulk vaccine

Residual ovalbumin (Specification: ≤ 0.4 mcg/mL)

Method	ELISA
Date of test	March 14, 2011
Result	0.1 mcg/mL

Residual formaldehyde (Specification: ≤ 20 mcg/mL)

Method	Colorimetric
Date of test	March 16, 2011
Result	< 1 mcg/mL

Sterility test (Specification: Sterile)

Method	Eur. Ph., membrane filtration
Media	FTM and SCDM
Volume tested	30 mL (from each container)
Date of test	Mar. 11 – Mar. 25, 2011
Result	Sterile

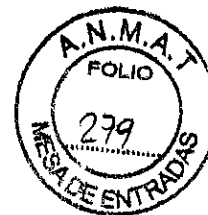
Endotoxin content (Specification: < 100 IU/0.5 mL)

Method	LAL test
Date of test	March 16, 2011
Result	< 1 IU/0.5 mL

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Lot 110721
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FINAL LOT 110721

Production details of final lot

Name and address of manufacturer	Novartis Vaccines and Diagnostics Srl Bellaria - Rosia, 53018 Sovicille - Siena (Italy)
Date of filling	March 18, 2011
Filled volume	0.545 mL
Type of container	Pre-filled syringe
No. of final containers	50,285
Expiry date	February 2012
Storage conditions of final product	2 - 8°C, do not freeze

Tests on final lot

Haemagglutinin antigens content (Specification: LCL (§) \geq 12 mcg HA/0.5 mL for each strain)

Method	SRID
Date of test	March 22, 2011
Result:	

Strain	mcg HA/0.5 mL	
	Mean	LCL (§)
NYMC X-181	16	15
NYMC X-187	16	15
NYMC BX-35	16	16

(§) - LCL = Lower Confidence Limit, $P = 0.95$

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Lot 110721
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Identity of haemagglutinin (Specification: Positive for A(H3N2), A(H1N1) and B strain)

Method	SRID
Date of test	March 22, 2011
Result	Positive for A(H3N2), A(H1N1) and B strain

pH (Specification: 6.9 - 7.7)

Method	Potentiometric
Date of test	March 29, 2011
Result	7.4

Appearance (Specification: Colourless clear liquid)

Method	Visual examination
Date of test	March 29, 2011
Result	Colourless clear liquid

Withdrawable content (Specification: ≥ 0.5 mL)

Method	Eur. Ph.
Date of test	March 25, 2011
Result	0.52 mL

Protein content less HA antigens (Specification: ≤ 120 mcg/0.5 mL)

Method	Micro Kjeldahl
Date of test	March 23, 2011
Result	43 mcg/0.5 mL

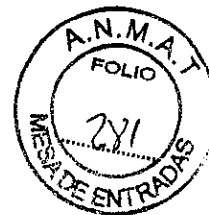
Endotoxin content (Specification: < 100 IU/0.5 mL)

Method	LAL test
Date of test	March 28, 2011
Result	< 1 IU/0.5 mL

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Lot 110721
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Sterility test (Specification: Sterile)

Method	Eur. Ph., membrane filtration
Media	FTM and SCDM
No. of containers tested	40
Date of test	Mar. 22 – Apr. 05, 2011
Result	Sterile

CERTIFICATION

I herewith certify that Final Lot No. 110721 of Influenza Vaccine (sub-unit) was manufactured and tested according to the procedures approved by competent authorities and complies with the quality requirements.

I also certify that no materials derived from ruminants (bovine, ovine, caprine), included within the scope of the current EMEA/CPMP "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via medicinal products", were used in the manufacture and/or formulation of the batch of product specified above.

Dr. Stefano Viti
Quality Assurance / Qualified Person

28 APR 11

Date

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Co-Directora Técnica - M.N. 15.576
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Istituto Superiore di Sanità
National Center for Immunobiologicals
Research and Evaluation

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 00161 ROMA
 TELEGRAMMI: ISTISAN ROMA
 TELEFONO 06 49901
 TELEFAX: 06 49387118
<http://www.iss.it>

Certificate n° 117/11-V/WHO

date of issue 10/05/2011

The following lot of Agrippal S1 vaccine filled in Pre-filled syringe produced by Novartis Vaccines and Diagnostics s.r.l., Sovicille Italy whose number appears on the labels of the final containers, meets all National Requirements and WHO Part A of Recommendations for the production and control of Influenza vaccine (inactivated), Annex III (TRS 927) and the Recommendation for good manufacturing practices and quality assurance for biological products.

LOT 110721	Expiry date	28/02/2012
	N° of containers:	50285
	N° of doses per container:	1

As a minimum, this certificate is based on an examination of the manufacturing protocol.

Dr. Carlo Pini
 Head, National Center for Immunobiologicals
 Research and Evaluation

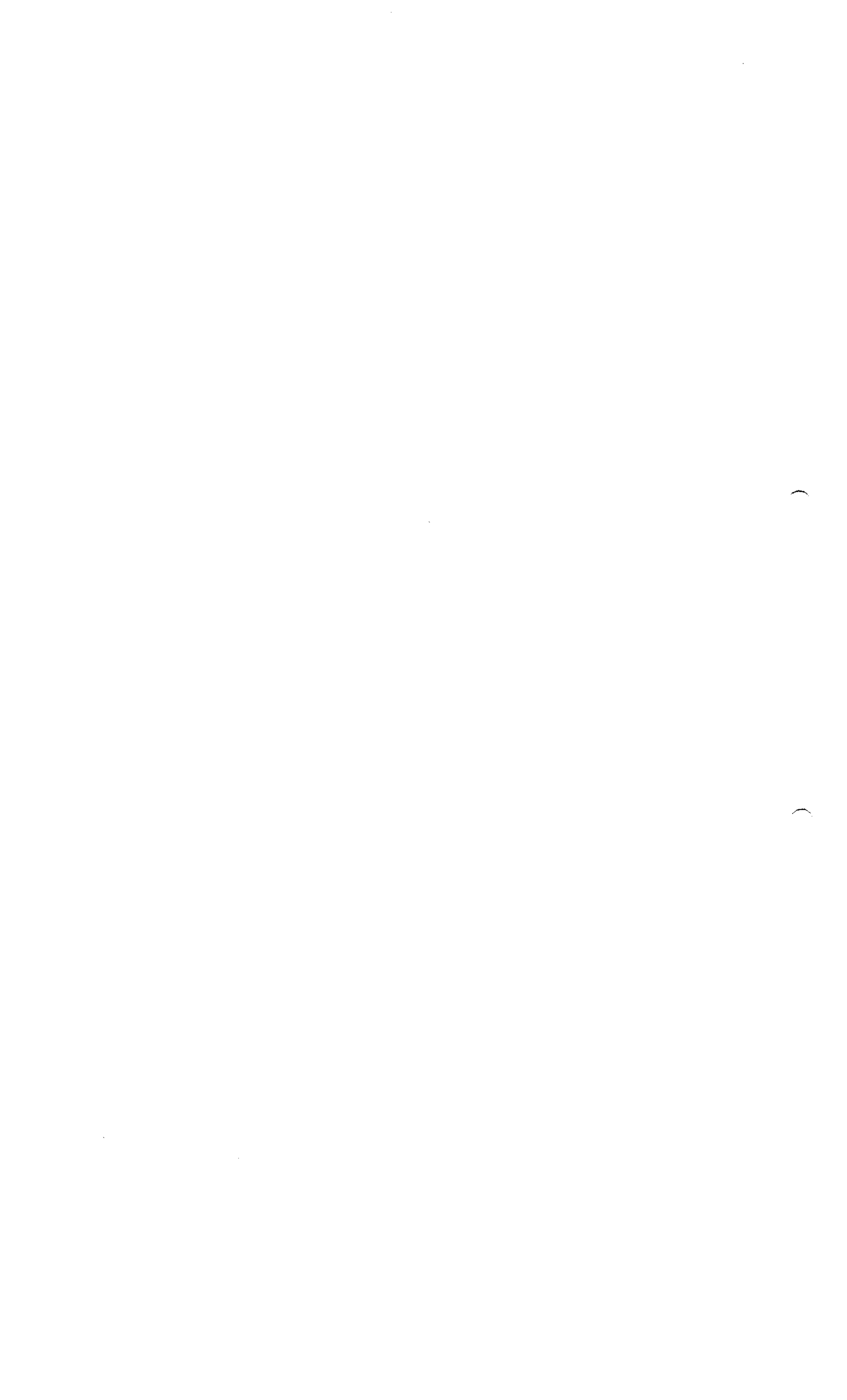


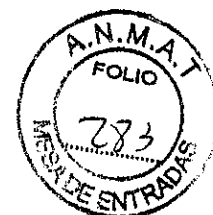
Novartis Argentina S.A.
 Farm. Elsa Crosal
 Directoría Técnica - M.N. 15.575
 sub. de Asuntos Regulatorios
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I.S.S. LAB. IMMUNOLOGIA

10. MAR. 2011 14:56

[Signature]
 Novartis Argentina S.A.
 Vacunas & Diagnóstico
 Ferrn. Adrián G. Jiménez
 Gte. Asuntos Regulatorios
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Lot 109901
Page 1 of 42
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**SUMMARY PROTOCOL FOR PRODUCTION AND TESTING
OF INFLUENZA VACCINE (SUB - UNIT)**

FINAL LOT 109901

Name and address of marketing authorization holder	Novartis Vaccines and Diagnostics Srl Via Fiorentina, 1 - Siena (Italy)
Proprietary name of product	INFLUPOZZI SUBUNITA' (pediatric)
Marketing authorisation number (Italy)	025984384
Final lot	109901
Type of container	Pre-filled syringe
No. of final containers	135,810
No. of doses per final container	One
Volume of single human dose	0.25 mL
Date of start period of validity	January 27, 2011
Expiry date	December 2011
Storage conditions of final product	2 - 8°C, do not freeze

Prescribed qualitative and quantitative strain composition per human dose:

- A(H1N1) strain	NYMC X-181 (A/California/7/2009 - like virus)	7.5 mcg HA/0.25 mL
- A(H3N2) strain	NYMC X-187 (A/Perth/16/2009 - like virus)	7.5 mcg HA/0.25 mL
- B strain	NYMC BX-35 (B/ Brisbane/60/2008 - like virus)	7.5 mcg HA/0.25 mL

(*) - Note: AGRIPPAL trademark is valid for all EU countries, except for Italy (AGRIPPAL S1), Austria (SANDOVAC), Portugal (CHIROFLU), Spain (CHIROFLU) and Germany (BEGRIPAL). The marketing authorisation holder for SANDOVAC is Novartis Pharma GmbH - Vienna, Austria.

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