



Lot ----
Page --of --
Prot. ---/--

N. MENINGITIDIS GROUP B STARTING MATERIAL

Production details of master seed

Name and address of manufacturer	Novartis Vaccines and Diagnostics Srl Bellaria - Rosia, 53018 Sovicille - Siena (Italy)
<i>N. meningitidis</i> group B strain	NZ 98/254
Master seed lot	-----
Date of manufacture of master seed	-----
Added preservatives in master seed	None
Storage conditions of master seed	Liquid nitrogen

Tests on master seed

Purity test (Specification: Absence of contaminants)


Method	Inoculation on plates and microscopic observation
Date of test	-----
Result	-----

Vitality tests (Specification: Confluent growth and $\geq 10^8$ CFU/mL)

Method	Inoculation on plates and visual examination
Date of test	-----
Result	-----

Method	Inoculation on plates and colony count
Date of test	-----
Result	--- x 10 ⁻⁻⁻ CFU/mL


Novartis Argentina S.A.
 Dr. Lucio Jeronic
 Director Técnico
 MN 14840


Novartis Argentina S.A.
 Farm. Sergio Imirtzian
 Gte. de Asuntos Regulatorios
 Codirector Técnico - M.N. 11521
 Apoderado

Template ID Number : 306168-03

CONFIDENTIAL

F11111111. 20 NOV 2010 17:44 011

Doc Number: 306168, Version: 3, Legacy Number: N/A



Lot ----
Page --of --
Prot. ----/--

Identity tests (Specification: Positive)

Method Immunoblotting
Date of test -----
Result -----

	Outer membrane proteins			LPS
	Class 1 (P1.4)	Class 3 (Serum type 4)	Class 5 (Opc)	3,7,9
Acceptance criteria	Present	Present	Present	Present
Strain NZ 98/254 Master seed	Present	Present	Present	Present

Method Agglutination
Date of test -----
Result -----

Method Dot blotting
Date of test -----
Result -----

Oxidase test (Specification: Positive)

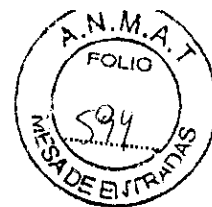
Method Dry slide oxidase kit
Date of test -----
Result -----

Maltose and glucose utilisation (Specification: Positive)

Method API-NH kit
Date of test -----
Result -----

Novartis Argentina S.A.
Dr. Lucio Jeroncio
Director Técnico
MN 14840

Novartis Argentina S.A.
Farm Sergio Imirtzian
Gte. de Asuntos Regulatorios
Codirector Técnico - M.N. 11521
Apoderado



Lot ----
Page --of --
Prot. ---/--

Production details of working seed

Name and address of manufacturer Novartis Vaccines and Diagnostics Srl
Bellaria - Rosia, 53018 Sovicille - Siena (Italy)

Lot of master seed used in manufacture -----

Working seed lot -----

Date of manufacture of working seed -----

Added preservatives in working seed None

Storage conditions of working seed - 80 ± 10°C

Tests on working seed


Purity test (Specification: Absence of contaminants)

Method Inoculation on plates and microscopic observation
Date of test -----
Result -----

Vitality tests (Specification: Confluent growth and $\geq 10^8$ CFU/mL)

Method Inoculation on plates and visual examination
Date of test -----
Result -----

Method Inoculation on plates and colony count
Date of test -----
Result ----- x 10⁻⁻⁻ CFU/mL


Novartis Argentina S.A.
Dr. Lucio Jeroncio
Director Técnico
MN 14840


Novartis Argentina S.A.
Farm. Sergio Imirtzian
Gte. de Asuntos Regulatorios
Codirector Técnico - M.N. 11521
Apoderado **CONFIDENTIAL**

Template ID Number : 306168-03

FOLIO 594

Doc Number: 306168, Version: 3, Legacy Number: N/A



Lot ----
Page --of--
Prot. ---/--

Identity tests (Specification: Positive)

Method Immunoblotting
Date of test -----
Result -----

	Outer membrane proteins			LPS
	Class 1 (P1.4)	Class 3 (Serum type 4)	Class 5 (Opc)	3,7,9
Acceptance criteria	Present	Present	Present	Present
Strain NZ 98/254 Working seed	Present	Present	Present	Present

Method Agglutination
Date of test -----
Result -----

Oxidase test (Specification: Positive)

Method Dry slide oxidase kit
Date of test -----
Result -----

Maltose and glucose utilization (Specification: Positive)

Method API-NH kit
Date of test -----
Result -----


Novartis Argentina S.A.
Dr. Lucio Jeronic
Director Técnico
MN 14840


Novartis Argentina S.A.
Farm. Sergio Imirtzian
Gle. de Asuntos Regulatorios
Codirector Técnico - M.N. 11521
Apoderado



Lot ----
Page --of --
Prot. ---/--

MEN B OMV NZ CONCENTRATED BULK LOT -----

Production details of Men B OMV NZ concentrated bulk

Name and address of manufacturer	Novartis Vaccines and Diagnostics Srl Bellaria - Rosia, 53018 Sovicille - Siena (Italy)
Lot of working seed used in manufacture	-----
Date of thawing of working seed for manufacture	-----
Date of inoculum	-----
Culture media used in fermentation	Catlin medium
Temperature of incubation	35 ± 1°C
Date of harvest	-----
Volume of harvest	----- Kg
Purification procedure	Ultrafiltration, ultracentrifugation and sonication
Date of manufacture	-----
Volume of purified Men B OMV concentrated bulk	----- mL
Date of sterile filtration	-----
Time of sterile filtration	-----
Expiry date	-----
Approved storage period	36 months
Storage conditions of purified Men B OMV concentrated bulk	2 – 8°C (protected from light)


Novartis Argentina S.A.
 Dr. Lucio Jeroncio
 Director Técnico
 MN 14840


Novartis Argentina S.A.
 Farm. Sergio Imirtzian
 Gte. de Asuntos Regulatorios
 Codirector Técnico - M.N. 11621
 Apoderado

Template ID Number : 306168-03

CONFIDENTIAL

FOLIO 596

Doc. Number: 306168, Version: 3, Legacy Number: N/A



Lot ----
Page --of --
Prot. ----/--

Test on Men B OMV NZ concentrated bulk

Total protein content (Specification: 450 - 1320 mcg/mL)

Method Lowry
Date of test -----
Result ----- mcg/mL

Purity test (Specification: Presence and percentage of OMV proteins confirmed)

Method SDS - PAGE
Date of test -----
Result -----

	Protein pattern							Total
	80 kD (Omp 85)	70 kD (FrpB)	Class 1	Class 3 + FpbA	Class 4	Class 5	NspA	
Acceptance criteria	1 - 4 %	presence ≤ 5 %	17 - 25 %	29 - 55 %	4 - 10 %	1 - 5 %	1 - 7 %	≥ 67 %
Men B OMV Concentrated bulk	----- %	----- ----- %	----- %	----- %	----- %	----- %	----- %	----- %

Identity test (Specification: Presence of OMV proteins confirmed)

Method Immunoblotting
Date of test -----
Result -----

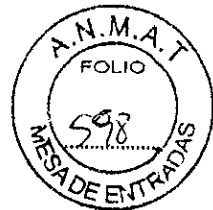
	Outer membrane proteins			LPS
	Class 1 (PorA P1.4)	Class 3 (Serotype 4)	Class 5 (Opc)	3,7,9
Acceptance criteria	presence	presence	presence	presence
Men B OMV Concentrated bulk	-----	-----	-----	-----

Template ID Number : 306168-03

Dr. Lucio Jeroncz
Novartis Argentina
Dr. Lucio Jeroncz
Director Técnico
MN 14840

Farm. Sergio Imirtzian
Novartis Argentina S.A.
Farm. Sergio Imirtzian
Eje. de Asuntos Regulatorios
Codirector Técnico - M.N. 11521
Apoderado

CONFIDENTIAL



Lot ---
Page --of --
Prot. ---/--

Appearance (Specification: Opalescent liquid, colourless to slightly yellow in colour, free from visible precipitate)

Method Visual examination
Date of test -----
Result -----

pH (Specification: 7.0 – 8.3)

Method Potentiometric
Date of test -----
Result -----

Residual DNA (Specification: ≤ 0.010 mcg/mcg protein)

Method Threshold total DNA assay system (ratio/protein)
Date of test -----
Result ----- mcg/ mcg protein

Deoxycholate content (Specification: 0.1 - 0.4 mcg/mcg protein)

Method Colorimetric
Date of test -----
Result ----- mcg/ mcg protein

Endotoxin content (Specification: < 1000 IU/mcg protein)

Method LAL test (ratio/protein)
Date of test -----
Result ----- IU/ mcg protein

Lipopolysaccharide content (Specification: 0.05 - 0.15 mcg/mcg protein)

Method RP-HPLC
Date of test -----
Result ----- mcg/mcg protein

Sucrose content (Specification: 2.7 - 4.1 %)

Method Spectrophotometric
Date of test -----
Result ----- %

Novartis Argentina S.A.
Dr. Lucio Jeroncio
Director Técnico
MN 14840

Novartis Argentina S.A.
Farm. Sergio Imirtzian
Gte. de Asuntos Regulatorios
Codirector Técnico - M.N. 11624
Apendice B
CONFIDENTIAL

Template ID Number : 306168-03

Printed: 20 NOV 2013 17:44 GMT

Doc Number: 306168, Version: 3, Legacy Number: N/A



Lot ---
Page --of--
Prot. ---/---

Sterility test (Specification: Sterile)

Method	Eur. Ph., membrane filtration
Media	FTM and SCDM
Volume tested	----- mL
Date of test	Record date beginning - date end
Result	-----

CERTIFICATION

I herewith certify that Men B OMV NZ Concentrated Bulk Lot No. ----- was manufactured and tested according to the procedures approved by competent authorities and complies with the quality requirements. This includes that, for any material 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 2001/83/EC and amending Directives 2003/63/EC and 2004/27/EC.

In addition the OMCL performing OCABR has been notified of all relevant approved variations that have an impact on product specifications or on data supplied in section 3 of this protocol as described in the EU administrative procedure for OCABR.

Dr. -----
Quality Operations / Qualified Person

Date

Novartis Argentina S.A.
Dr. Lucio Jerončić
Director Técnico
MN 14840

Novartis Argentina S.A.
Farm. Sergio Imirtzian
Gte. de Asuntos Regulatorios
Codirector Técnico - M.N. 1152
Aprobado

Template ID Number : 306168-03

CONFIDENTIAL

Printed: 26 Nov 2013 11:44 GMT

... 306168, Version: 3, Legacy Number: N/A

