

12^o CUERPO

22767-11-1



U0129866783
CLIENTE 748
DOCADEA 221785



Product Quality and Disposition Department

Diphtheria, tetanus, pertussis (acellular, component),
 hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus
 influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch)

20/180

TETANUS TOXOID
Lot n°FA265944

Strain	: 1472-C
Working seed-lot number	: FA121337
Storage temperature	: + 5°C ± 3°C
Approved storage period	: 112 days

Single harvests :

Medium used	: Massachussets
Date of reconstitution of seed lot ampoule(s)	: 29.01.07
Date of inoculation	: 01.02.07
Date of harvest	: 08.02.07

CONTROLS

Identity test

Method : tetanus flocculation
 Date : 22.03.07
 Result : positive

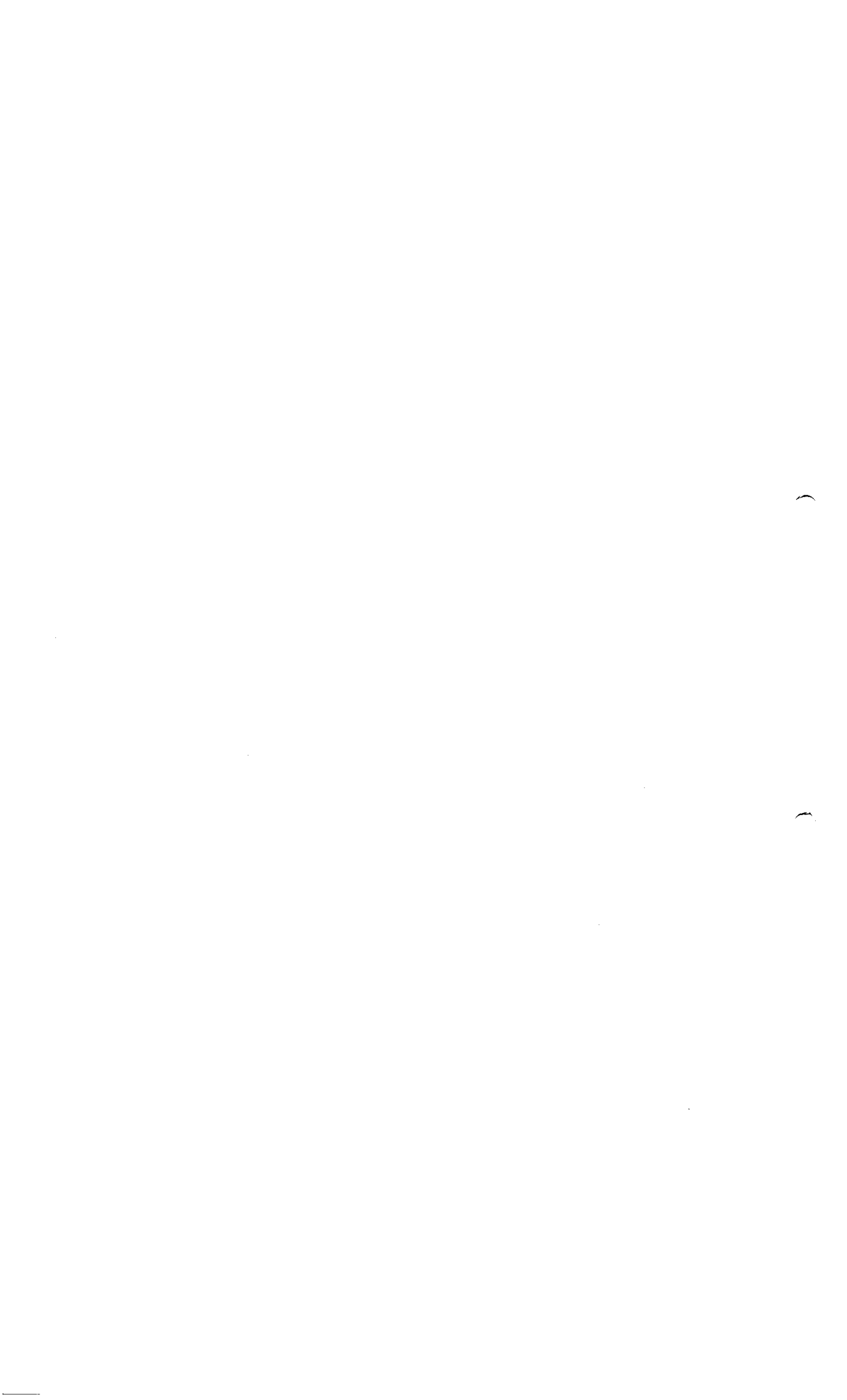
Bacterial purity

Method : Gram coloration
 Date: 07.02.07
 Result : conforms

Inactivation

Method : formaldehyde treatment
 Date of inactivation : 26.02.07

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21/180

TETANUS TOXOID
Lot n°FA271782

Strain : 1472-C
 Working seed-lot number : FA121337
 Storage temperature : + 5°C ± 3°C
 Approved storage period : 112 days

Single harvests :

Medium used : Massachussets
 Date of reconstitution of seed lot ampoule(s) : 02.04.07
 Date of inoculation : 05.04.07
 Date of harvest : 12.04.07

CONTROLS

Identity test


Method : tetanus flocculation
 Date : 15.05.07
 Result : positive

Bacterial purity


Method : Gram coloration
 Date: 11.04.07
 Result : conforms

Inactivation

Method : formaldehyde treatment
 Date of inactivation : 30.04.07



 ROXANA MONTEMILONE
 DIRECTORA TÉCNICA
 SANOFI PASTEUR S.A.



 CHRISTIAN DOMÍNGUEZ
 SUPERVISOR
 SANOFI PASTEUR S.A.



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22/180

TETANUS TOXOID
Lot n°FA274931

Strain	: 1472-C
Working seed-lot number	: FA121337
Storage temperature	: + 5°C ± 3°C
Approved storage period	: 112 days

Single harvests :

Medium used	: Massachussets
Date of reconstitution of seed lot ampoule(s)	: 16.04.07
Date of inoculation	: 19.04.07
Date of harvest	: 26.04.07

CONTROLS

Identity test



Method : tetanus flocculation
 Date : 25.06.07
 Result : positive

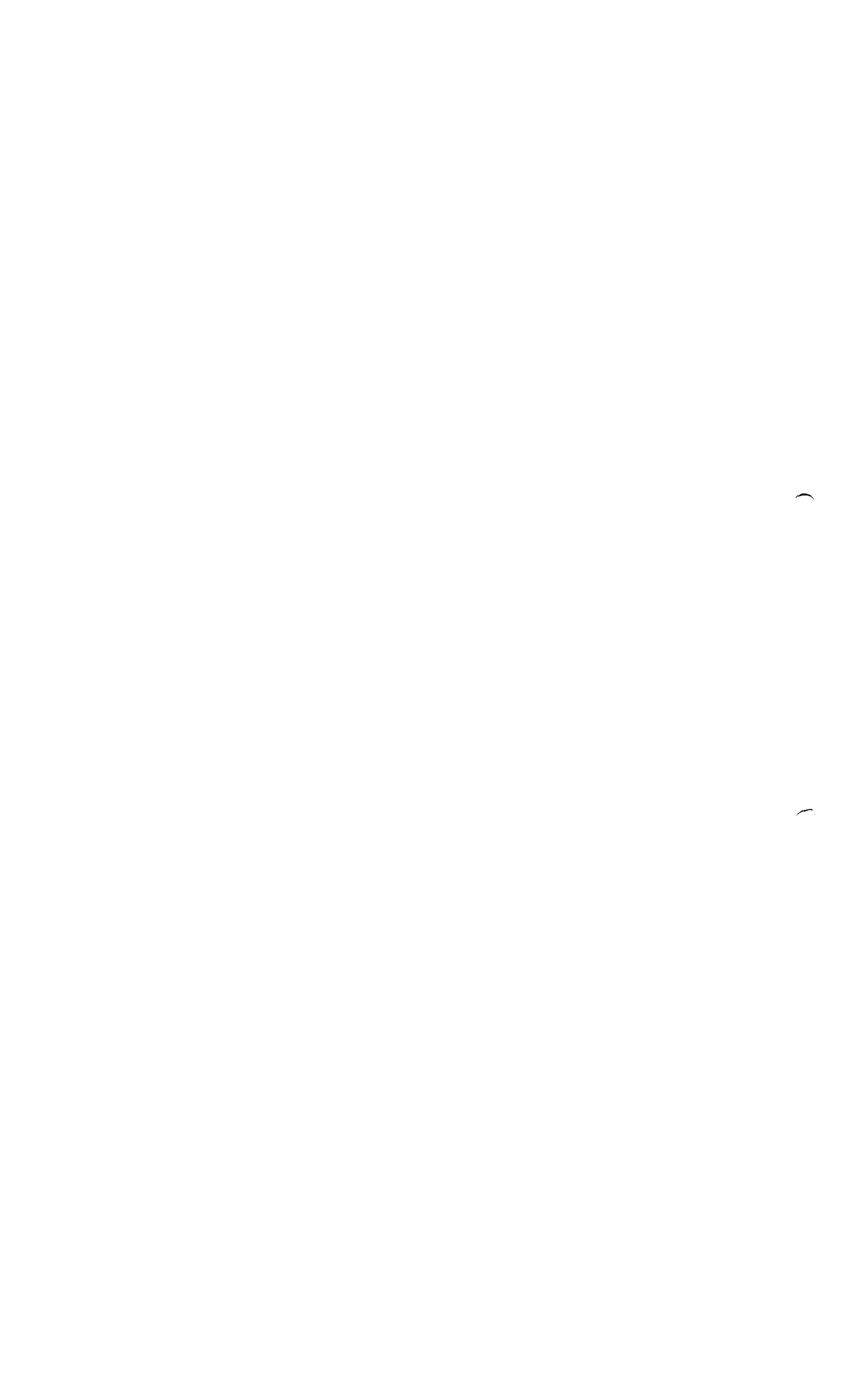
Bacterial purity

Method : Gram coloration
 Date: 25.04.07
 Result : conforms

Inactivation

Method : formaldehyde treatment
 Date of inactivation : 14.05.07

 ROXANA MONTMILONE DIRECTORA TÉCNICA SANOFI PASTEUR S.A.	 CHRISTIAN DOMINGUEZ GERENTE SANOFI PASTEUR S.A.
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Diphtheria, tetanus, pertussis (acellular, component),
hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus
influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch) 23/180

TETANUS TOXOID
Lot n°FA274933

Strain : 1472-C
Working seed-lot number : FA121337
Storage temperature : + 5°C ± 3°C
Approved storage period : 112 days

Single harvests :


Medium used : Massachussets
Date of reconstitution of seed lot ampoule(s) : 23.04.07
Date of inoculation : 26.04.07
Date of harvest : 03.05.07


CONTROLS

Identity test
Method : tetanus flocculation
Date : 08.06.07
Result : positive

Bacterial purity
Method : Gram coloration
Date: 02.05.07
Result : conforms

Inactivation
Method : formaldehyde treatment
Date of inactivation :21.05.07


ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.


CHRISTIAN DOMÍNGUEZ
GERENTE
SANOFI PASTEUR S.A.



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24/180

**PURIFIED TETANUS TOXOID
FA276217**

TESTS	SPECIFICATIONS
PROTEIN NITROGEN CONTENT	For antigenic purity calculation
FREE FORMALDEHYDE CONTENT	For formulation (used for formulation in final bulk product where appropriate)
FLOCCULATING TITER	For antigenic purity calculation
ANTIGENIC PURITY	≥ 1000 Lf/mg of protein nitrogen
BACTERIAL AND FUNGAL STERILITY	No microbial growth
ABSENCE OF TOXIN (SPECIFIC TOXICITY) AND IRREVERSIBILITY OF TOXOID	No tetanus symptom and at least 93 % of survival


 ROXANA MONTEMILONE
 DIRECTORA TÉCNICA
 SANOFI PASTEUR S.A.


 CHRISTIAN DOMINGUEZ
 ACCERADO
 SANOFI PASTEUR S.A.



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PURIFIED TETANUS TOXOID
Lot n° FA276217

Working seed Lot n° : FA121337

Tetanus toxoid Lot number :	FA265944	FA271782	FA274931	FA274933
Volume used (liters) :	261.45	156.35	192.05	195.55

Volume : 39 liters
 Storage temperature : + 5°C ± 3°C
 Date of manufacture : 04.06.07
 Expiry date : 04 JUNE 2010
 Approved storage period : 3 years

CONTROLS

Protein nitrogen content

Method : Kjeldahl after trichloroacetic acid precipitation
 Date : 18.06.07
 Result : 4.91 mg/ml

Free formaldehyde content


Method : Nash
 Date : 11.06.07
 Result : 62.62 µg/ml

Flocculating titer

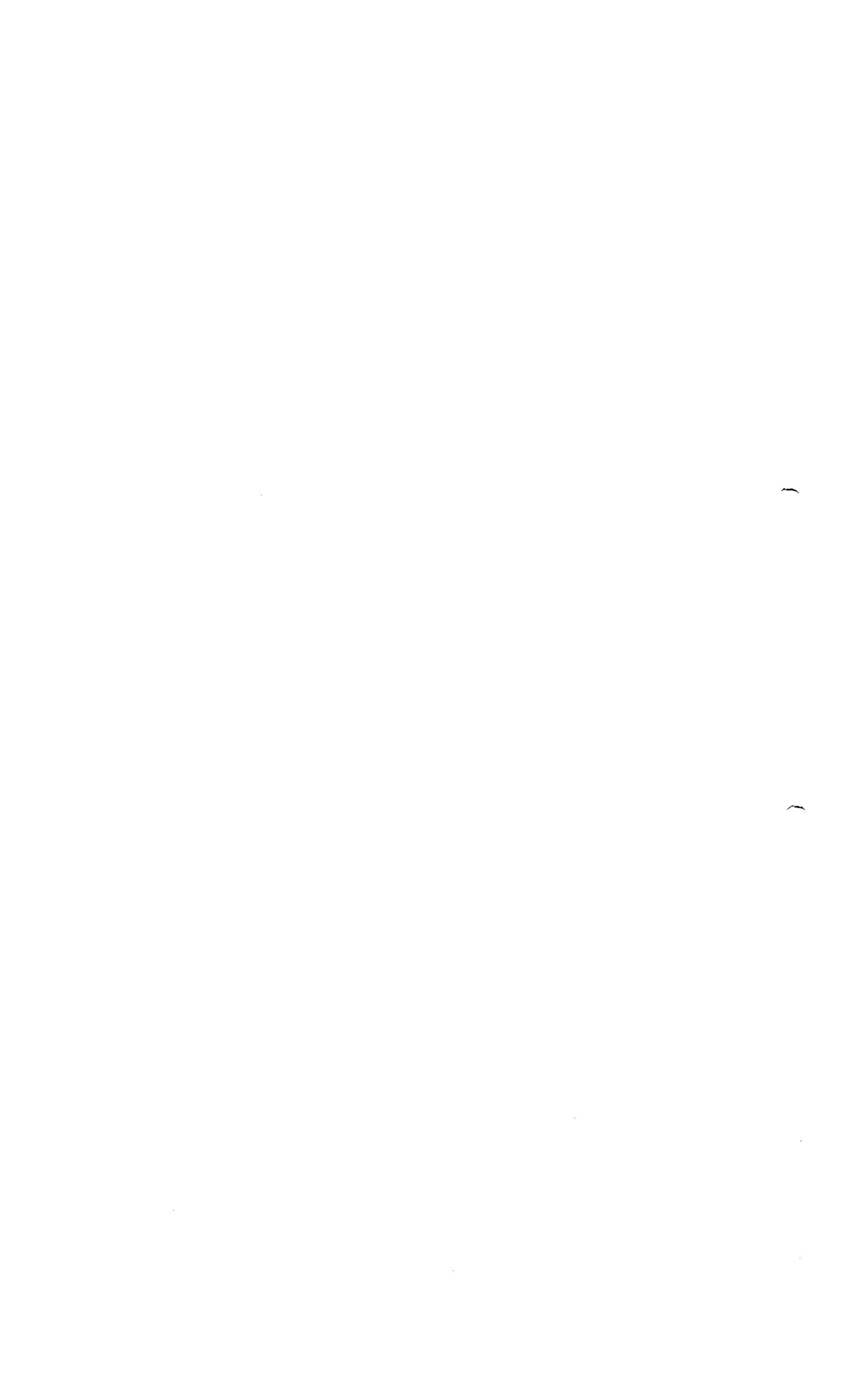
Method : Flocculation in comparison with in house reference
 Date : 07.06.07
 Result : 5 000 Lf/ml

Antigenic purity

Date : 04.07.07
 Result : 1018 Lf/mg of protein nitrogen - **Conforms**



 RUXANA MONTEMILONE CHRISTIAN DOMINGUEZ
 DIRECTORA TÉCNICA GERENTE
 SANOFI PASTEUR S.A. SANOFI PASTEUR S.A.



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Bacterial and fungal sterility

Method	:	Membrane filtration	
Media	:	Thioglycollate	Soybean casein digest
Temperatures	:	30-35°C	20-25°C
Volume tested	:	20 ml	
Inoculum per Steritest	:	10 ml	10 ml
Volume of medium per Steritest	:	100 ml	100 ml
Number of inoculated Steritest	:	1	1
Test on	:	06.06.07	
Test off	:	20.06.07	
Result	:	No microbial growth - Conforms	

Absence of toxin (specific toxicity)



Animals	:	Guinea-pigs
Number of animals	:	5
Lf of toxoid injected per animal	:	2000
Route of injection	:	Subcutaneous
Test on	:	04.07.07
Test off	:	25.07.07
Result	:	No tetanus symptom and at least 93% of survival - Conforms

Irreversibility of toxoid

Concentration of the toxoid solution	:	20 Lf/ml	20 Lf/ml
Incubation period	:	5°C ± 3°C	
Temperatures	:	5°C ± 3°C	37°C
Date of beginning	:	19.06.07	
Date of end	:	31.07.07	

Test in animals

Number of guinea pigs injected	:	5	5
Route	:	Subcutaneous	
Volume injected	:	5 ml	5 ml
Date of inoculation	:	31.07.07	
Date of end of observation	:	21.08.07	
Result	:	No tetanus symptom and at least 93% of survival - Conforms	



 ROXANA MONTEMILONE CHRISTIAN DOMINGUEZ
 DIRECTORA TÉCNICA APODERADO
 SANOFI PASTEUR S.Á. SANOFI PASTEUR S.Á.

