

sanofi pasteur



The vaccines division of sanofi-aventis group

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)

27/180

- C - 2 COMPONENT ACELLULAR PERTUSSIS

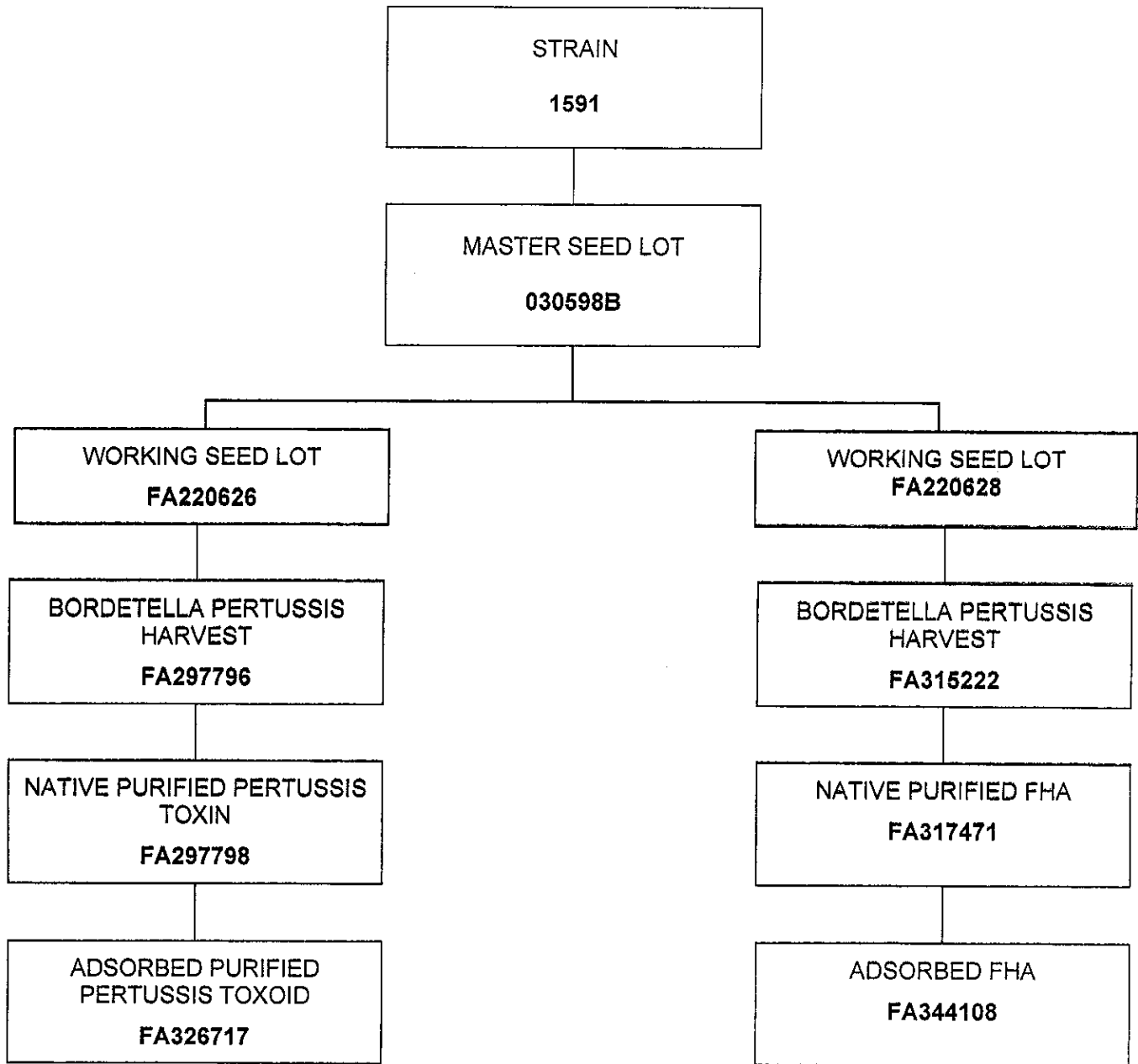
	
ROXANA MONTEMILONE DIRECTORA TÉCNICA SANOFI PASTEUR S.A.	CHRISTIAN DOMÍNGUEZ GERENTE SANOFI PASTEUR S.A.



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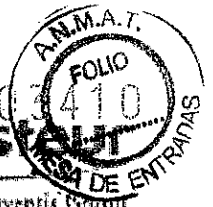


PRODUCTION FLOW SHEET


 ROXANA MONTEMILONE
 DIRECTORA TÉCNICA
 SANOFI PASTEUR S.A.


 CHRISTIAN DOMÍNGUEZ
 GERENTE
 SANOFI PASTEUR S.A.





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BORDETELLA PERTUSSIS
Strain : Bordetella pertussis 1591

STRAIN


Name : Pillemer 134
Origin : Dr N.W. Preston
University of Manchester
England
Received : 07.03.69
Institut Mérieux number : IM 1591


BORDETELLA PERTUSSIS
Master seed lot n°030598B

Strain : IM 1591
Preparation date : 03.05.98
Release date : 16.10.98

CONTROLS

- Purity
Identification
- Morphology
 - Growth characteristics
 - Biochemical characteristics
 - Antigenic characteristics


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30/180

BORDETELLA PERTUSSIS
Working seed lot n° FA220626

Master seed lot : 030598B
Preparation date : 30.09.05
Release date : 07.12.05

CONTROLS

- Purity
- Identification
 - Morphology
 - Growth characteristics
 - Biochemical characteristics
 - Antigenic characteristics

The tests results show that working seed lot has the same characteristics as the master seed lot.


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CHRISTIAN DOMINGUEZ
SECRETARIO
SANOFI PASTEUR S.A.





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31/180

BORDETELLA PERTUSSIS
Working seed lot n° FA220628

Master seed lot : 030598B
Preparation date : 07.10.05
Release date : 28.12.05

CONTROLS

Purity

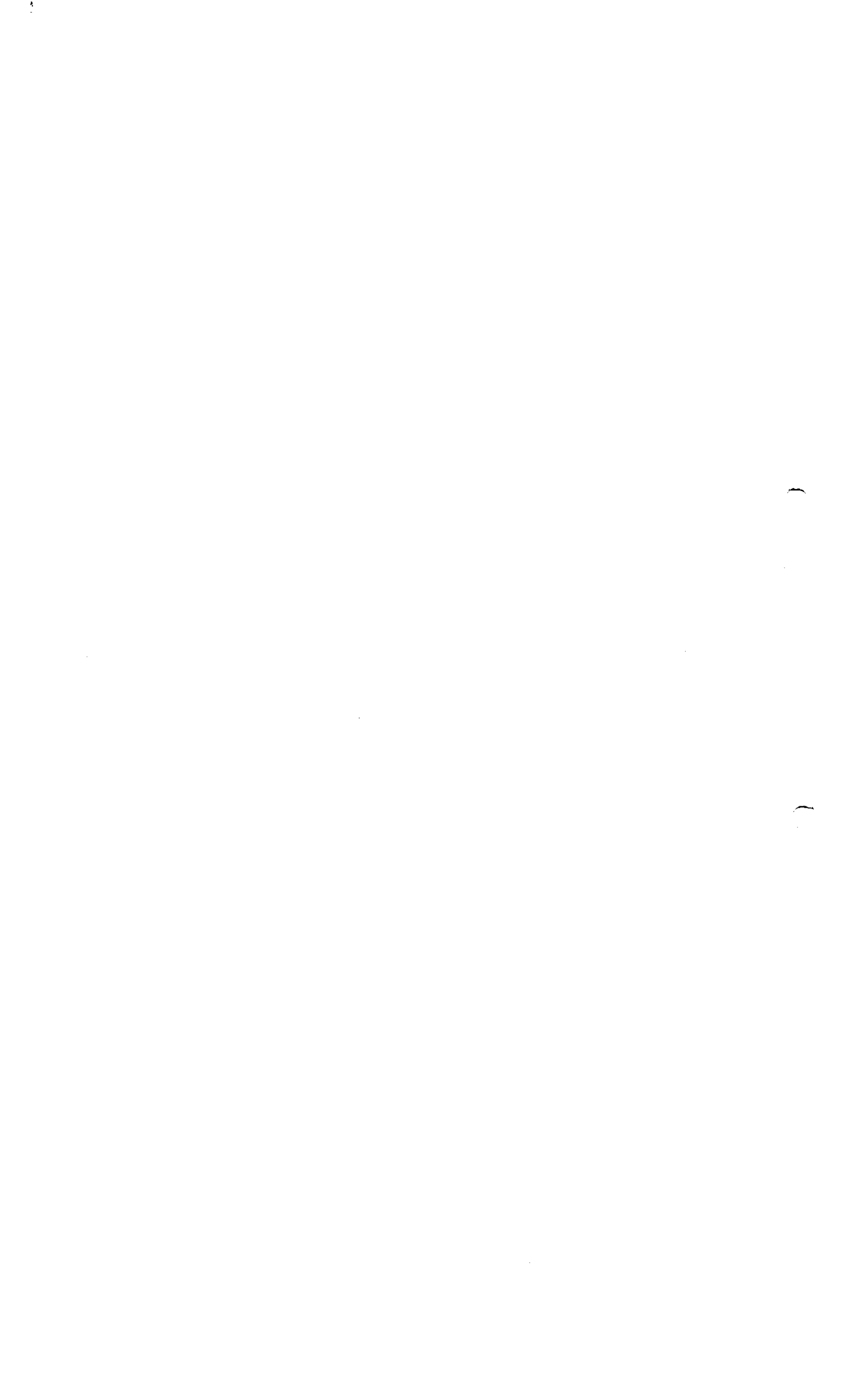
Identification

- Morphology
- Growth characteristics
- Biochemical characteristics
- Antigenic characteristics

The tests results show that working seed lot has the same characteristics as the master seed lot.

[Signature]
ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.

[Signature]
CHRISTIAN DOMINGUEZ
ANAGERADO
SANOFI PASTEUR S.A.





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Bordetella pertussis harvest
Lot n° FA297796

Strain : 1591
Working seed lot number : FA220626
Date of reconstitution of working seed lot ampoules: 11.01.08
Medium used : SS-SAT
Temperature incubation : 36°C +/- 1°C

Harvest
Date of inoculation : 16.01.08
Date of harvest : 18.01.08
Volume : 1234 liters

CONTROLS

Bacterial purity

Method : Gram staining
Result : Gram negative bacilli

Bordetella pertussis harvest
Lot n° FA315222

Strain : 1591
Working seed lot number : FA220628
Date of reconstitution of working seed lot ampoules: 20.06.08
Medium used : SS-SAT
Temperature incubation : 36°C +/- 1°C

Harvest
Date of inoculation : 25.06.08
Date of harvest : 27.06.08
Volume : 1238 liters

CONTROLS

Bacterial purity

Method : Gram staining
Result : Gram negative bacilli

352_CC5_SPI_AE.dot /19.09.11

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APODERADO
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NATIVE PURIFIED PERTUSSIS TOXIN

TESTS	SPECIFICATIONS
PROTEIN CONTENT	For calculation
SDS-PAGE	Electrophoresis profile comparable to the profile of the reference (5 bands between 30 and 14 kDa)
PERTUSSIS TOXIN IDENTIFICATION	Positive
CLUSTERING ACTIVITY ON CHO CELLS	Cytopathic activity (CPU/ μ g of protein) \geq lower confidence limit (P = 0.95) of cytopathic activity of the reference.
HAEMAGGLUTINATING ACTIVITY	20 000 – 500 000 HAU/mg of protein IHA with cholesterol : \leq 20 %


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