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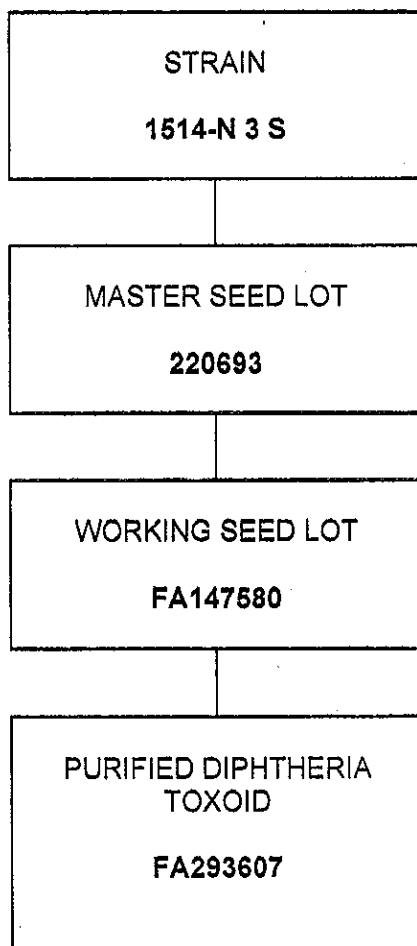
The vaccines division of sanofi-aventis Group

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° S4312 (clinical batch)

7/229

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**PRODUCTION FLOW SHEET**

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SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ  
MODERADO  
SANOFI PASTEUR S.A.





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8/229

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**DIPHTHERIA STRAIN**  
**Corynebacterium diphtheriae 1514-N-3S**

**STRAIN**


Name : Utrecht CN 2000 MSM III  
Origin : Rijks Institut (RIV), Bilthoven  
Hollande  
Received : 01.12.69  
Institut Mérieux number : 1514-N-3S

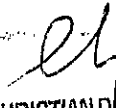
**DIPHTHERIA MASTER SEED LOT**  
**Lot n°220693**

Strain number : 1514-N-3S  
Preparation date : 22.06.93  
Release date : 06.06.95

**CONTROLS**

- Purity  
Identification
- Morphology
  - Growth characteristics
  - Biochemical characteristics

  
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9/229

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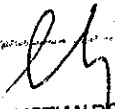
**DIPHTHERIA WORKING SEED LOT**  
**Lot n°FA147580**

Master seed Lot n° : 220693  
Preparation date : 09.04.03  
Release date : 11.07.03

**CONTROLS**

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

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


  
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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° S4312 (clinical batch) 10/229  
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**DIPHTHERIA TOXOID**  
 Lot n°FA285657

Strain	: 1514-N-3S
Working seed-lot number	: FA147580
Storage temperature	: + 5°C ± 3°C
Approved storage period	: 112 days

**Single harvests :**

Medium used	: IMD (Pope and Linggood)
Date of reconstitution of seed lot ampoule(s)	: 16.09.07
Date of inoculation	: 22.09.07
Date of harvest	: 24.09.07

**CONTROLS**

**Identity test**

Method : diphtheria flocculation  
 Date : 13.11.07  
 Result : positive

**Bacterial purity**



Method : Gram coloration  
 Date: 23.09.07  
 Result : conforms

**Detoxification**

Method : formaldehyde  
 Date of inactivation : 25.09.07

**CONTROLS**

Inactivation test (intradermic test) : conforms

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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° S4312 (clinical batch)

11/229

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**DIPHTHERIA TOXOID**  
**Lot n°FA285658**

Strain : 1514-N-3S  
Working seed-lot number : FA147580  
Storage temperature : + 5°C ± 3°C  
Approved storage period : 112 days

**Single harvests :**

Medium used : IMD (Pope and Linggood)  
Date of reconstitution of seed lot ampoule(s) : 20.09.07  
Date of inoculation : 26.09.07  
Date of harvest : 28.09.07

**CONTROLS**


**Identity test**  
Method : diphtheria flocculation  
Date : 20.11.07  
Result : positive


**Bacterial purity**  
Method : Gram coloration  
Date: 27.09.07  
Result : conforms

**Detoxification**  
Method : formaldehyde  
Date of inactivation : 29.09.07

**CONTROLS**

Inactivation test (intradermic test) : conforms

  
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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° S4312 (clinical batch)

12/229

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DIPHTHERIA TOXOID  
Lot n°FA285659

Strain : 1514-N-3S  
Working seed-lot number : FA147580  
Storage temperature : + 5°C ± 3°C  
Approved storage period : 112 days

Single harvests :

Medium used : IMD (Pope and Linggood)  
Date of reconstitution of seed lot ampoule(s) : 23.09.07  
Date of inoculation : 29.09.07  
Date of harvest : 01.10.07

CONTROLS

**Identity test**

Method : diphtheria flocculation  
Date : 16.11.07  
Result : positive

**Bacterial purity**


Method : Gram coloration  
Date: 30.09.07  
Result : conforms

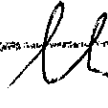
**Detoxification**

Method : formaldehyde  
Date of inactivation : 02.10.07

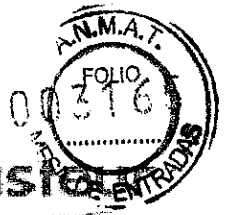
CONTROLS

Inactivation test (intradermic test) : conforms

  
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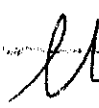
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Influenzae type b conjugate vaccine (adsorbed) lot n° S4312 (clinical batch)

13/229

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PURIFIED DIPHTHERIA TOXOID  
FA293607

TESTS	SPECIFICATIONS
PROTEIN NITROGEN CONTENT	For purity calculation
RESIDUAL FORMALDEHYDE CONTENT	For formulation
FLOCCULATING TITER	For purity calculation
ANTIGENIC PURITY	≥ 1500 Lf/mg of protein nitrogen
BACTERIAL AND FUNGAL STERILITY	No microbial growth
SPECIFIC TOXICITY	Negative
IRREVERSIBILITY OF TOXOID	Negative


  
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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° S4312 (clinical batch) 14/229

**PURIFIED DIPHTHERIA TOXOID**  
**Lot n° FA293607**

Working seed Lot n° : FA147580

Diphtheria toxoid Lot number :	<b>FA285657</b>	<b>FA285658</b>	<b>FA285659</b>
Volume used (liters) :	<b>540</b>	<b>400</b>	<b>530</b>

Volume : 108.1 liters  
 Storage temperature : + 5°C ± 3°C  
 Date of manufacture : 03.12.2007  
 Expiry date : 03 DECEMBER 2010  
 Approved storage period : 3 years

**CONTROLS**

**Protein nitrogen content**

Method : Kjeldahl after trichloroacetic acid precipitation  
 Date : 11.12.07  
 Result : 3.27 mg/ml

**Residual formaldehyde content**

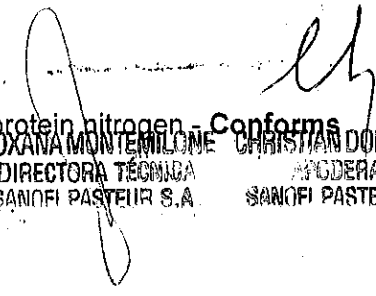
Method : Nash  
 Date : 05.12.07  
 Result : 24.78 µg/ml

**Flocculating titer**

Method : Flocculation in comparison with in house  
 reference  
 Date : 11.12.07  
 Result : 5500 Lf/ml

**Antigenic purity**

Date : 19.12.07  
 Result : 1682 Lf/mg of protein nitrogen - **Conforms**

  
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