

**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)

80/180

**CONTROLS ON CELLS:**

**Observation**



Method	: Studied through a microscope
Cells	: Vero, 142 <sup>nd</sup> passage
Number of cells tested	: 320*10 <sup>6</sup> cells
Test on	: 21.01.08
Test off	: 04.02.08
Result	: Absence of cytopathic effect

**Test for haemadsorbing viruses**

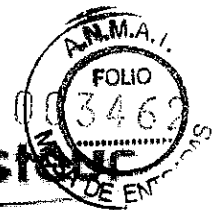
Method	: visual inspection
Number of vials tested	: 8
Type of red blood cells	: Guinea-pig
Incubation	: 4 vials, 30 minutes at 5°C ± 3°C
	: 4 vials, 30 minutes at 20-25°C
Date	: 04.02.08
Result	: Absence of hemadsorption

**Simian cells identification**

Method	: Isoenzymes analysis by IsoElectric Focusing
Iso-enzymes analysed	: Lactate DeHydrogenase Phospho Gluconate Dehydrogenase Glucose Phosphate Isomerase
Reference cells	: Vero, MRC5, WI38, Hep 2
Date	: 30.06.08
Result	: Positive identification

	
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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)

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CONTROLS ON SUPERNATANTS:

Test for extraneous agents

Vero cells

Method	: Studied through a microscope
Type of cells	: Vero
Volume tested	: 10 ml
Temperature of incubation	: 36 ± 1° C
Test on	: 10.03.08
Test off	: 25.03.08
Result	: Absence of cytopathic effect

Human diploid cells

Method	: Studied through a microscope
Type of cells	: MRC5
Volume tested	: 10 ml
Temperature of incubation	: 36 ± 1° C
Test on	: 11.03.08
Test off	: 08.04.08
Result	: Absence of cytopathic effect

Primary monkey kidney cells

Method	: Studied through a microscope
Type of cells	: Vervet Monkey Cells
Volume tested	: 10 ml
Temperature of incubation	: 36 ± 1° C
Test on	: 12.02.08
Test off	: 26.02.08
Result	: Absence of cytopathic effect

  
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influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch)

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**Test for Mycoplasma by culture method**

Method	: Agar culture
Volume tested	: 34 ml
Media used	: Hayflick solid Hayflick semi-solid B.O.B. solid B.O.B. semi-solid
Temperature of incubation	: 36 ± 1° C
Positive controls	: <i>M. pneumoniae</i> and <i>M. orale</i> and <i>A. laidlawii</i>
<i>Primary test</i>	
Test on	: 28.10.08
Test off	: 12.11.08
<i>Subculture at 3<sup>rd</sup> day</i>	
Test on	: 31.10.08
Test off	: 14.11.08
<i>Subculture at 7<sup>th</sup> day</i>	
Test on	: 04.11.08
Test off	: 18.11.08
<i>Subculture at 14<sup>th</sup> day</i>	
Test on	: 12.11.08
Test off	: 26.11.08
<i>Subculture at 21<sup>th</sup> day</i>	
Test on	: 18.11.08
Test off	: 25.11.08
Result	: No growth of Mycoplasma

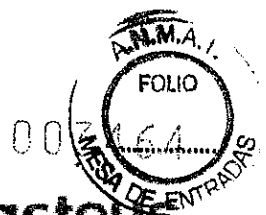
**Test for Mycoplasma by epifluorescence in cell culture**

Method	: DNA fluorescence staining
Cell used	: Vero, 152 <sup>nd</sup> passage
Volume tested	: 4 ml
Temperature of incubation	: 36 ± 1° C
Positive control	: <i>M. hyorhinitis</i> and <i>M. orale</i>
Test on	: 20.05.08
Test off	: 27.05.08
Result	: No Mycoplasma detected by epifluorescence in cell culture

  
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**CONTROLS ON SINGLE VIRUS HARVEST:**

**Polio virus identification**

Method	: Cytopathogenic effect neutralization
Cell strain used	: Hep 2
Antiserum	: MAHONEY type 1
Test on	: 23.07.08
Test off	: 30.07.08
Result	: Positive

**Polio virus concentration**

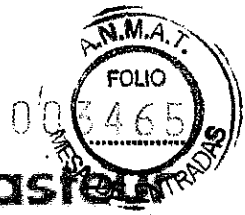
Method	: Cytopathogenic effect on sensitive cells
Cell strain used	: Hep 2
Test on	: 23.07.08
Test off	: 30.07.08
Virus concentration	: 10 <sup>9.07</sup> CCID <sub>50</sub> /ml
Result	: Conforms

**Bacterial and fungal sterility**

Method used	:	Membrane filtration	:
Media	:	Thioglycollate medium	: Soybean Casein Digest medium
Temperatures	:	30-35° C	: 20-25° C
Volume tested	:	10 ml	: 10 ml
Inoculum per Steritest	:	100 ml	: 100 ml
Volume of medium per Steritest	:	100 ml	: 100 ml
Test on	:	30.01.08	:
Test off	:	13.02.08	:
Result	:	No microbial growth	:

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Test for Mycoplasma by culture method

Method : Agar culture  
 Volume tested : 34 ml  
 Media used : Hayflick solid  
                   Hayflick semi-solid  
                   B.O.B. solid  
                   B.O.B. semi-solid  
 Temperature of incubation : 36 ± 1° C  
 Positive controls : M. pneumoniae and M. orale and A. laidlawii

Primary test  
 Test on : 28.10.08  
 Test off : 12.11.08  
 Subculture at 3<sup>rd</sup> day  
 Test on : 31.10.08  
 Test off : 14.11.08  
 Subculture at 7<sup>th</sup> day  
 Test on : 04.11.08  
 Test off : 18.11.08  
 Subculture at 14<sup>th</sup> day  
 Test on : 12.11.08  
 Test off : 26.11.08  
 Subculture at 21<sup>th</sup> day  
 Test on : 18.11.08  
 Test off : 25.11.08  
 Result : No growth of Mycoplasma

  
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hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus  
Influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch)

85/180

**CONTROLS ON CONCENTRATED PURIFIED VIRAL SUSPENSION :**

**Protein content**

Method : Spectrophotometry  
Date : 12.02.08  
Result : 96.75 µg/ml

**D Antigen content**

Method : ELISA  
Reference standard : 28.1.99  
Date : 04.02.08  
Result : 10 327 D Antigen U/ml

**Bacterial and fungal sterility**

Method used	:	Membrane filtration
Media	:	Thioglycollate medium      Soybean Casein Digest medium
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
Test on	:	04.02.08
Test off	:	18.02.08
Result	:	No microbial growth

**Purity**

Result : 0.009 µg of protein / D Antigen U


  
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influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch)

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SINGLE HARVEST - Type : 1  
Lot Number : FA296701

**CELL:**

Working Cell Bank : FA106611  
Date of thawing ampoule of WCB : 20.12.07  
Thawing ampoule amount : One ampoule

**VIRUS:**

Virus Working Seed lot : FA159761  
Date of inoculation : 14.01.08  
Date of virus harvest : 17.01.08

**CRUDE HARVEST:**

Storage : from 18.01.08 to 21.01.08  
Volume : 1 490 L  
Storage temperature : +5°C ± 3°C

**SINGLE HARVEST:**

Date of single harvest : 21.01.08

**CONCENTRATION AND PURIFICATION OF THE SINGLE HARVEST**

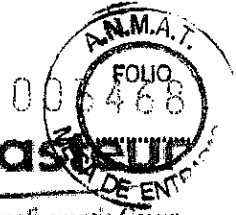
DEAE Spherodex large column : Ion exchange chromatography on 22.01.08  
CL-6-B Sepharose column : Gel filtration on 23.01.08  
DEAE Sphérodex small column : Ion exchange chromatography on 23.01.08

**CONCENTRATED PURIFIED VIRAL SUSPENSION :**

Manufacture date : 23.01.08  
Volume : 19 500 ml  
Storage temperature : +5°C ± 3°C

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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) 87/180  
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**CONTROLS ON CELLS:**

**Observation**


Method : Studied through a microscope  
Cells : Vero, 142<sup>nd</sup> passage  
Number of cells tested : 320\*10<sup>6</sup> cells  
Test on : 14.01.08  
Test off : 28.01.08  
Result : Absence of cytopathic effect


**Test for haemadsorbing viruses**

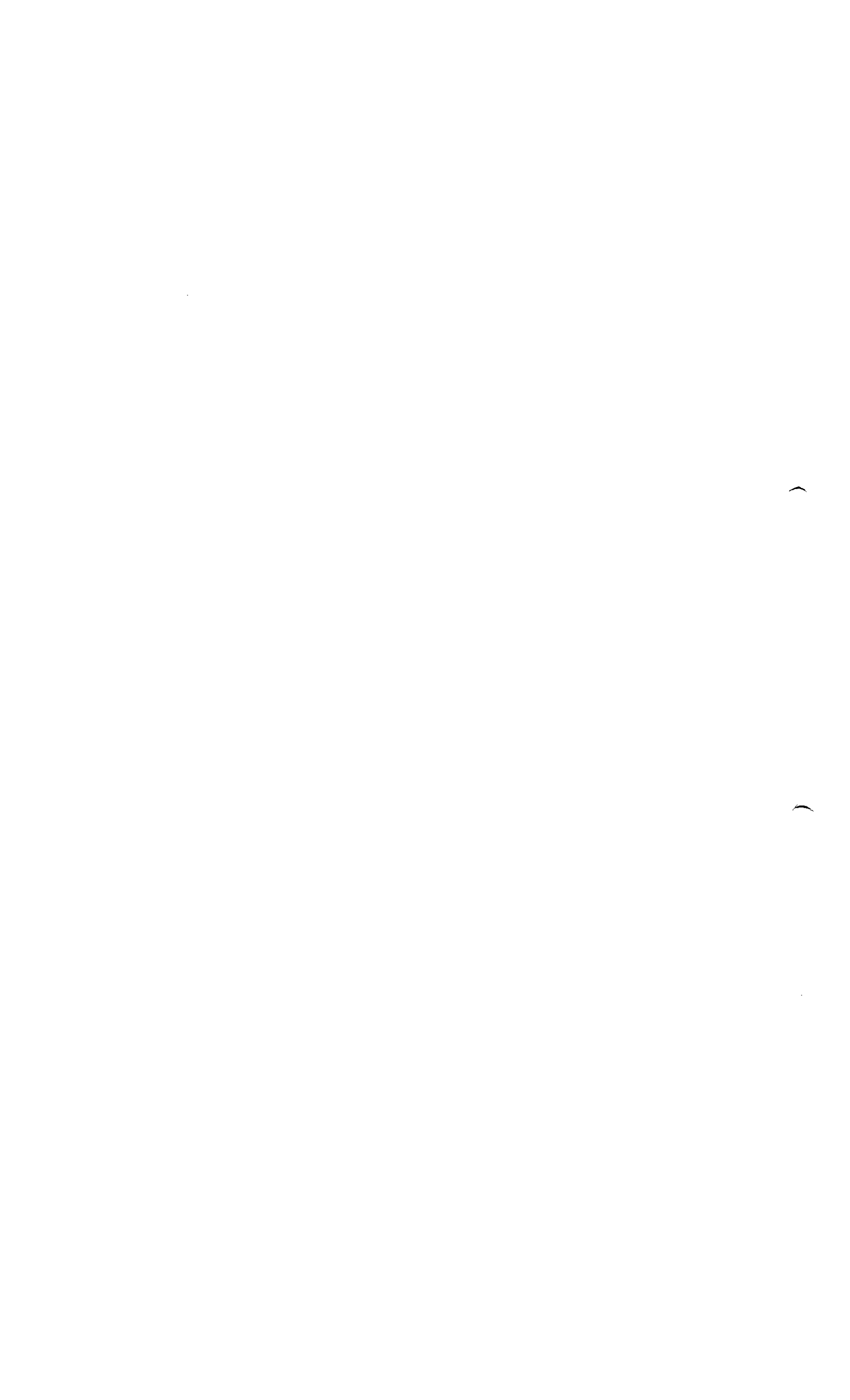
Method : visual inspection  
Number of vials tested : 8  
Type of red blood cells : Guinea-pig  
Incubation : 4 vials, 30 minutes at 5°C ± 3°C  
: 4 vials, 30 minutes at 20-25°C  
Date : 28.01.08  
Result : Absence of hemadsorption

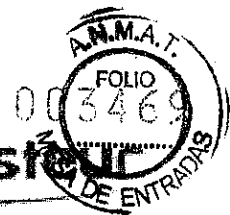
**Simian cells identification**

Method : Isoenzymes analysis by IsoElectric Focusing  
Iso-enzymes analysed : Lactate DeHydrogenase  
Phospho Gluconate Dehydrogenase  
Glucose Phosphate Isomerase  
Reference cells : Vero, MRC5, WI38, Hep 2  
Date : 03.04.08  
Result : Positive identification

  
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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° S4313 (clinical batch) 88/180  
\*\*\*\*\*

**CONTROLS ON SUPERNATANTS:**

**Test for extraneous agents**

*Vero cells*

Method : Studied through a microscope  
Type of cells : Vero  
Volume tested : 10 ml  
Temperature of incubation : 36 ± 1° C  
Test on : 29.01.08  
Test off : 12.02.08  
Result : **Absence of cytopathic effect**

*Human diploid cells*

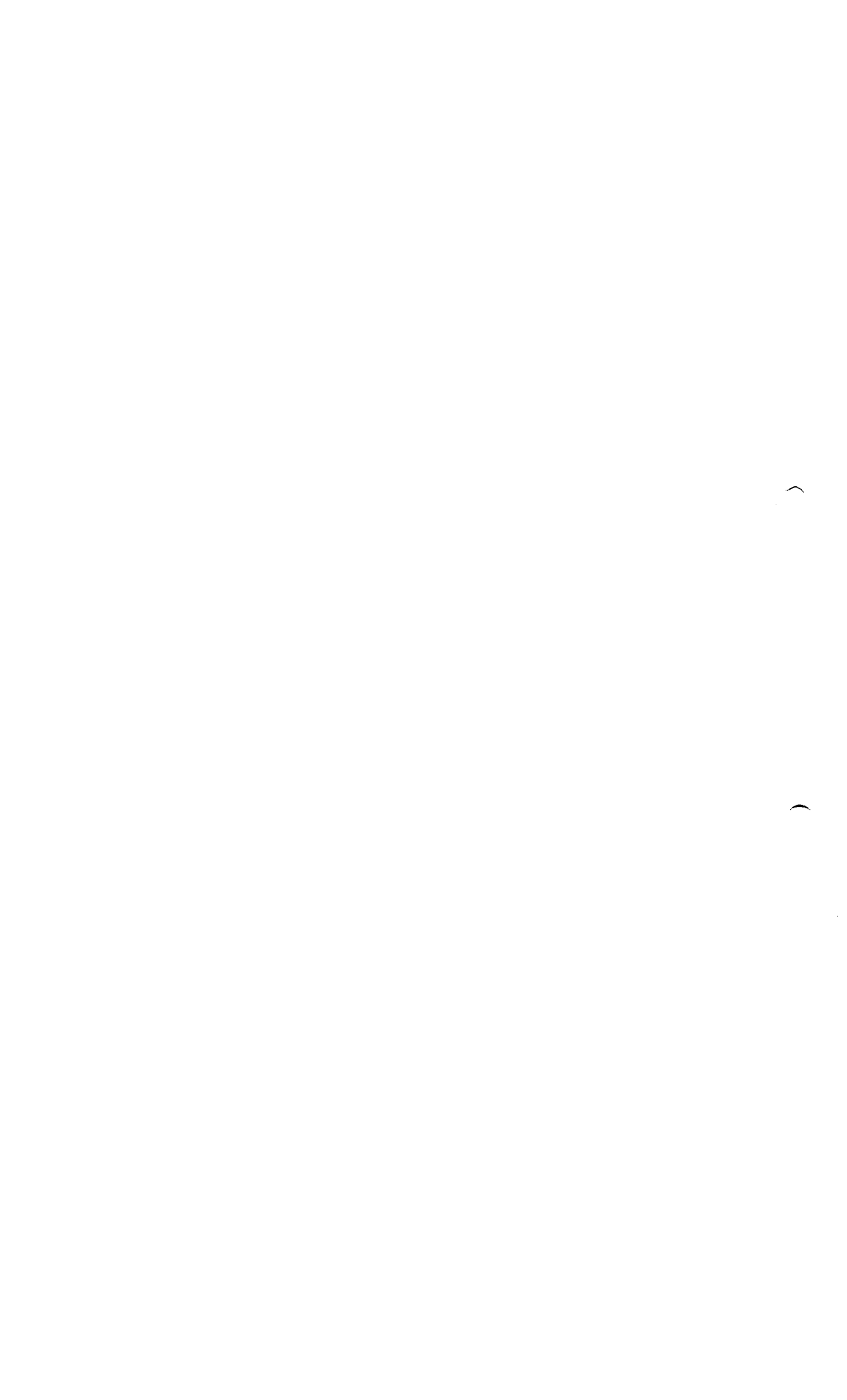
Method : Studied through a microscope  
Type of cells : MRC5  
Volume tested : 10 ml  
Temperature of incubation : 36 ± 1° C  
Test on : 20.02.08  
Test off : 19.03.08  
Result : **Absence of cytopathic effect**

*Primary monkey kidney cells*

Method : Studied through a microscope  
Type of cells : Vervet Monkey Cells  
Volume tested : 10 ml  
Temperature of incubation : 36 ± 1° C  
Test on : 12.02.08  
Test off : 26.02.08  
Result : **Absence of cytopathic effect**

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influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch)

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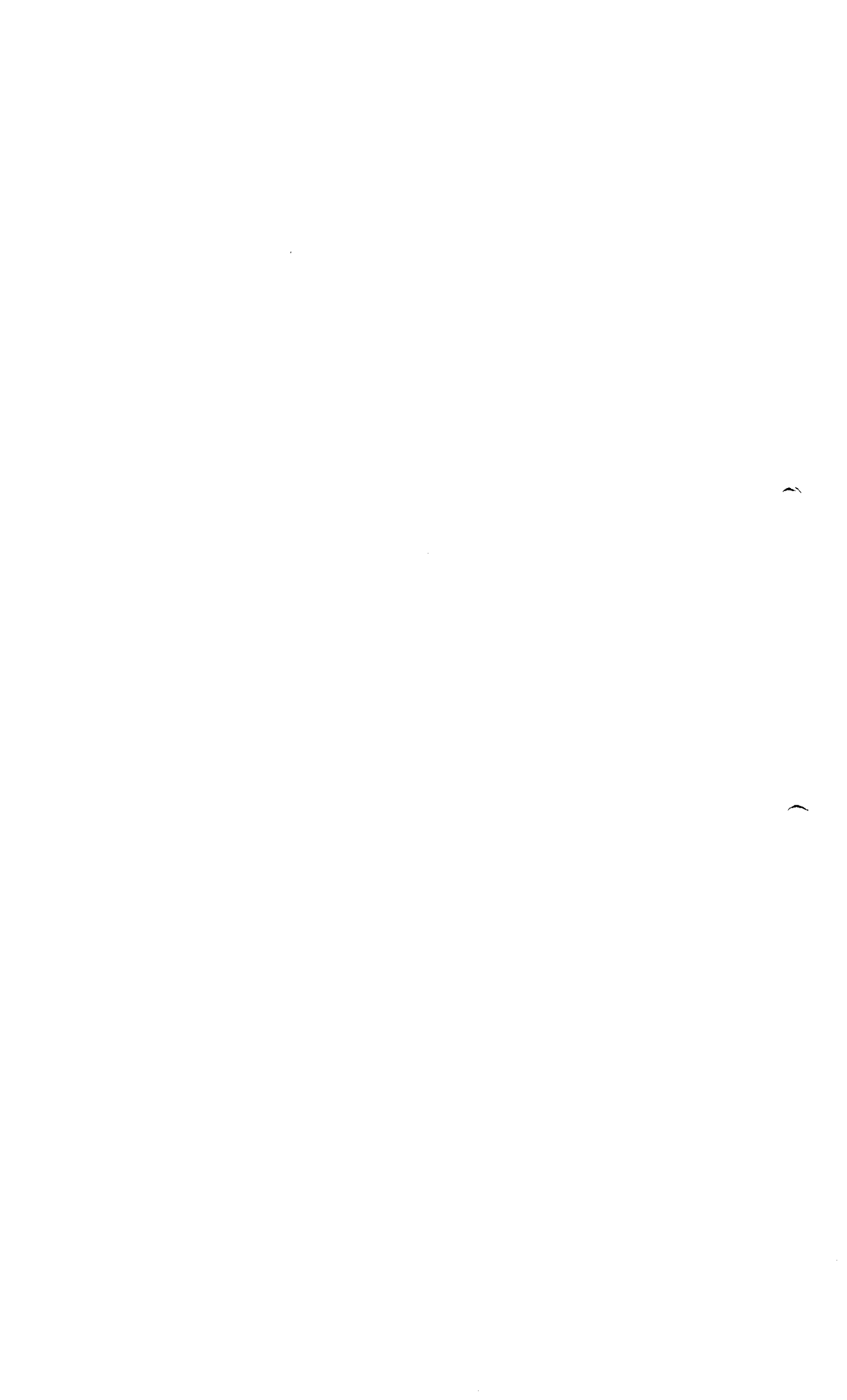
**Test for Mycoplasma by culture method**

Method	: Agar culture
Volume tested	: 34 ml
Media used	: Hayflick solid Hayflick semi-solid B.O.B. solid B.O.B. semi-solid
Temperature of incubation	: 36 ± 1° C
Positive controls	: <i>M. pneumoniae</i> and <i>M. orale</i> and <i>A. laidlawii</i>
 <i>Primary test</i>	
Test on	: 20.10.08
Test off	: 03.11.08
<i>Subculture at 3<sup>rd</sup> day</i>	
Test on	: 23.10.08
Test off	: 06.11.08
<i>Subculture at 7<sup>th</sup> day</i>	
Test on	: 27.10.08
Test off	: 12.11.08
<i>Subculture at 14<sup>th</sup> day</i>	
Test on	: 03.11.08
Test off	: 17.11.08
<i>Subculture at 21<sup>th</sup> day</i>	
Test on	: 10.11.08
Test off	: 17.11.08
Result	: No growth of Mycoplasma

**Test for Mycoplasma by epifluorescence in cell culture**

Method	: DNA fluorescence staining
Cell used	: Vero, 146 <sup>th</sup> passage
Volume tested	: 1 ml
Temperature of incubation	: 36 ± 1° C
Positive control	: <i>M. hyorhinis</i> and <i>M. orale</i>
Test on	: 29.04.08
Test off	: 06.05.08
Result	: No Mycoplasma detected by epifluorescence in cell culture

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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° S4313 (clinical batch) 90/180  
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**CONTROLS ON SINGLE VIRUS HARVEST:**

**Polio virus identification**

Method : Cytopathogenic effect neutralization  
 Cell strain used : Hep 2  
 Antiserum : MAHONEY type 1  
 Test on : 23.07.08  
 Test off : 30.07.08  
 Result : Positive

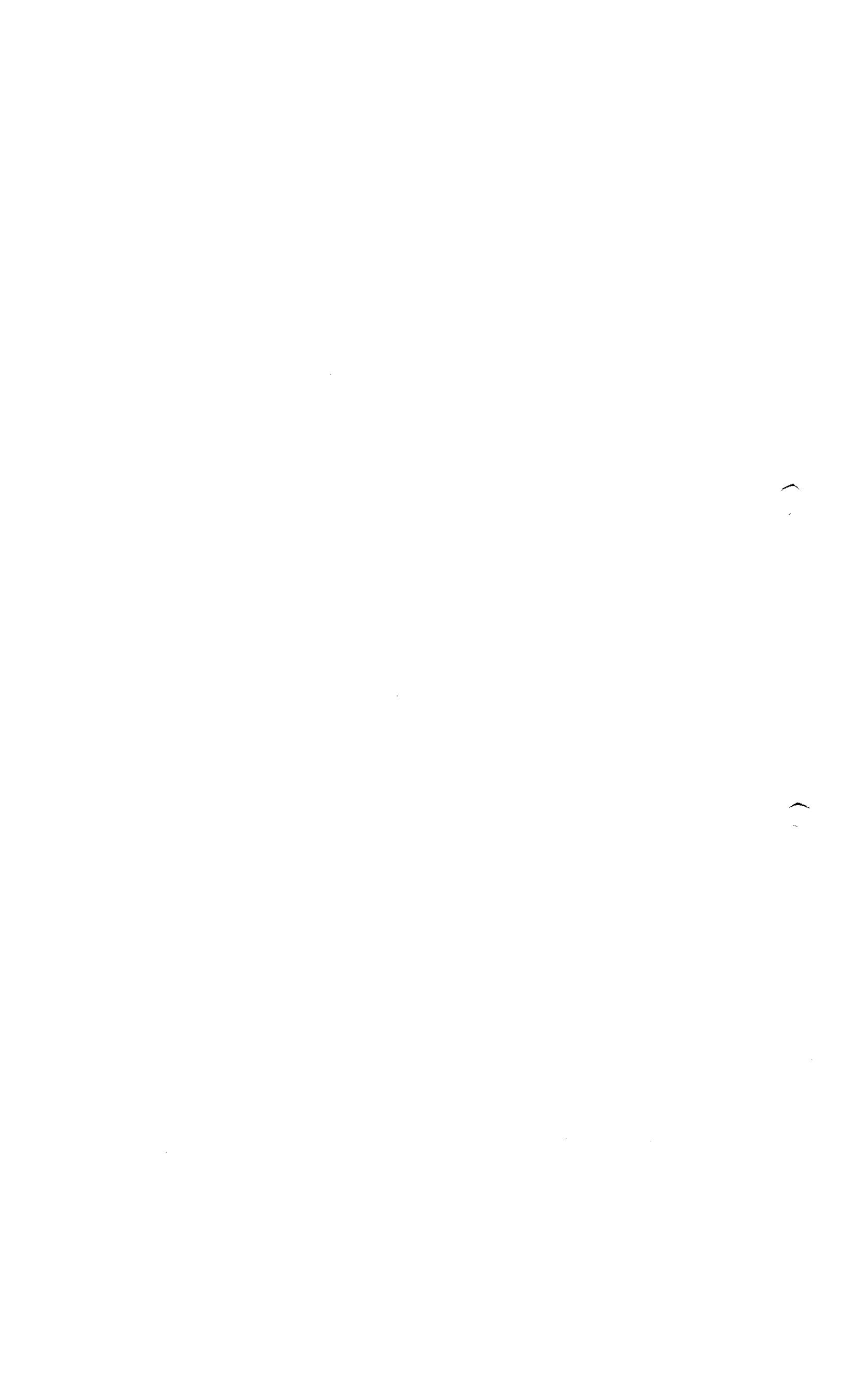
**Polio virus concentration**

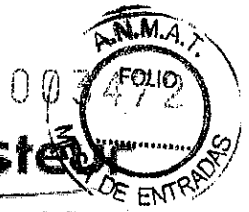
Method : Cytopathogenic effect on sensitive cells  
 Cell strain used : Hep 2  
 Test on : 23.07.08  
 Test off : 30.07.08  
 Virus concentration :  $10^{8.93}$  CCID<sub>50</sub>/ml  
 Result : Conforms

**Bacterial and fungal sterility**

Method used	: Membrane filtration	
Media	: Thioglycollate medium	: Soybean Casein Digest medium
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
Test on	: 23.01.08	
Test off	: 06.02.08	
Result	: No microbial growth	


  
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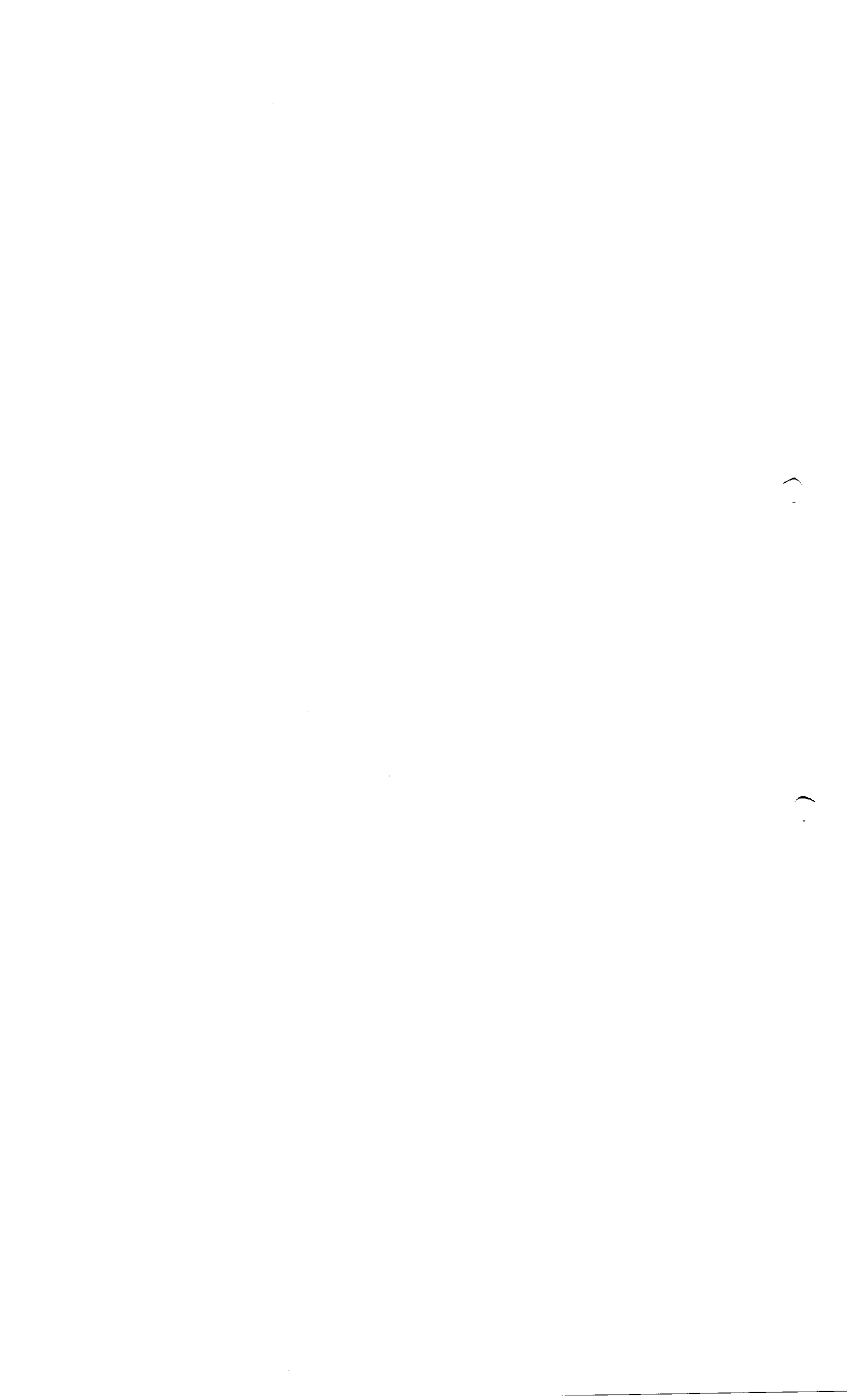
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Test for Mycoplasma by culture method

Method	: Agar culture
Volume tested	: 34 ml
Media used	: Hayflick solid Hayflick semi-solid B.O.B. solid B.O.B. semi-solid
Temperature of incubation	: 36 ± 1° C
Positive controls	: <i>M. pneumoniae</i> and <i>M. orale</i> and <i>A. laidlawii</i>
<i>Primary test</i>	
Test on	: 20.10.08
Test off	: 03.11.08
<i>Subculture at 3<sup>rd</sup> day</i>	
Test on	: 23.10.08
Test off	: 06.11.08
<i>Subculture at 7<sup>th</sup> day</i>	
Test on	: 27.10.08
Test off	: 12.11.08
<i>Subculture at 14<sup>th</sup> day</i>	
Test on	: 03.11.08
Test off	: 17.11.08
<i>Subculture at 21<sup>th</sup> day</i>	
Test on	: 10.11.08
Test off	: 17.11.08
Result	: No growth of Mycoplasma

  
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92/180

CONTROLS ON CONCENTRATED PURIFIED VIRAL SUSPENSION :

Protein content

Method : Spectrophotometry
Date : 19.02.08
Result : 119.35 µg/ml

D Antigen content

Method : ELISA
Reference standard : 28.1.99
Date : 29.01.08
Result : 13 282 D Antigen U/ml

Bacterial and fungal sterility

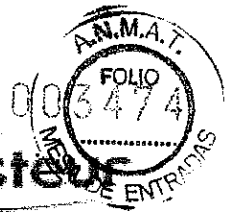
Method used : Membrane filtration
Media : Thioglycollate medium, Soybean Casein Digest medium
Temperatures : 30-35° C, 20-25° C
Volume tested : 20 ml
Inoculum per Steritest : 10 ml, 10 ml
Volume of medium per Steritest : 100 ml, 100 ml
Test on : 28.01.08
Test off : 11.02.08
Result : No microbial growth

Purity

Result : 0.009 µg of protein / D Antigen U

Handwritten signatures and printed names: ROXANA MONTEMILONE, DIRECTORA TÉCNICA, SANOFI PASTEUR S.A.; CHRISTIAN DOMÍNGUEZ, GERENTE, SANOFI PASTEUR S.A.





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93/180

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SINGLE HARVEST - Type : 1  
Lot Number : FA297937

**CELL:**

Working Cell Bank : FA106611  
Date of thawing ampoule of WCB : 03.01.08  
Thawing ampoule amount : One ampoule

**VIRUS:**

Virus Working Seed lot : FA159761  
Date of inoculation : 28.01.08  
Date of virus harvest : 30.01.08

**CRUDE HARVEST:**

Storage : from 01.02.08 to 04.02.08  
Volume : 1 505 L  
Storage temperature : +5°C ± 3°C

**SINGLE HARVEST:**


Date of single harvest : 04.02.08


**CONCENTRATION AND PURIFICATION OF THE SINGLE HARVEST**

DEAE SpheroDex large column : Ion exchange chromatography on 05.02.08  
CL-6-B Sepharose column : Gel filtration on 06.02.08  
DEAE SpheroDex small column : Ion exchange chromatography on 06.02.08

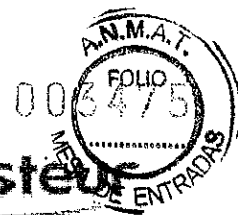
**CONCENTRATED PURIFIED VIRAL SUSPENSION :**

Manufacture date : 06.02.08  
Volume : 19 400 ml  
Storage temperature : +5°C ± 3°C

  
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influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch) 94/180  
\*\*\*\*\*

**CONTROLS ON CELLS:**

**Observation**



Method : Studied through a microscope  
Cells : Vero, 142<sup>nd</sup> passage  
Number of cells tested : 320\*10<sup>6</sup> cells  
Test on : 28.01.08  
Test off : 11.02.08  
Result : Absence of cytopathic effect

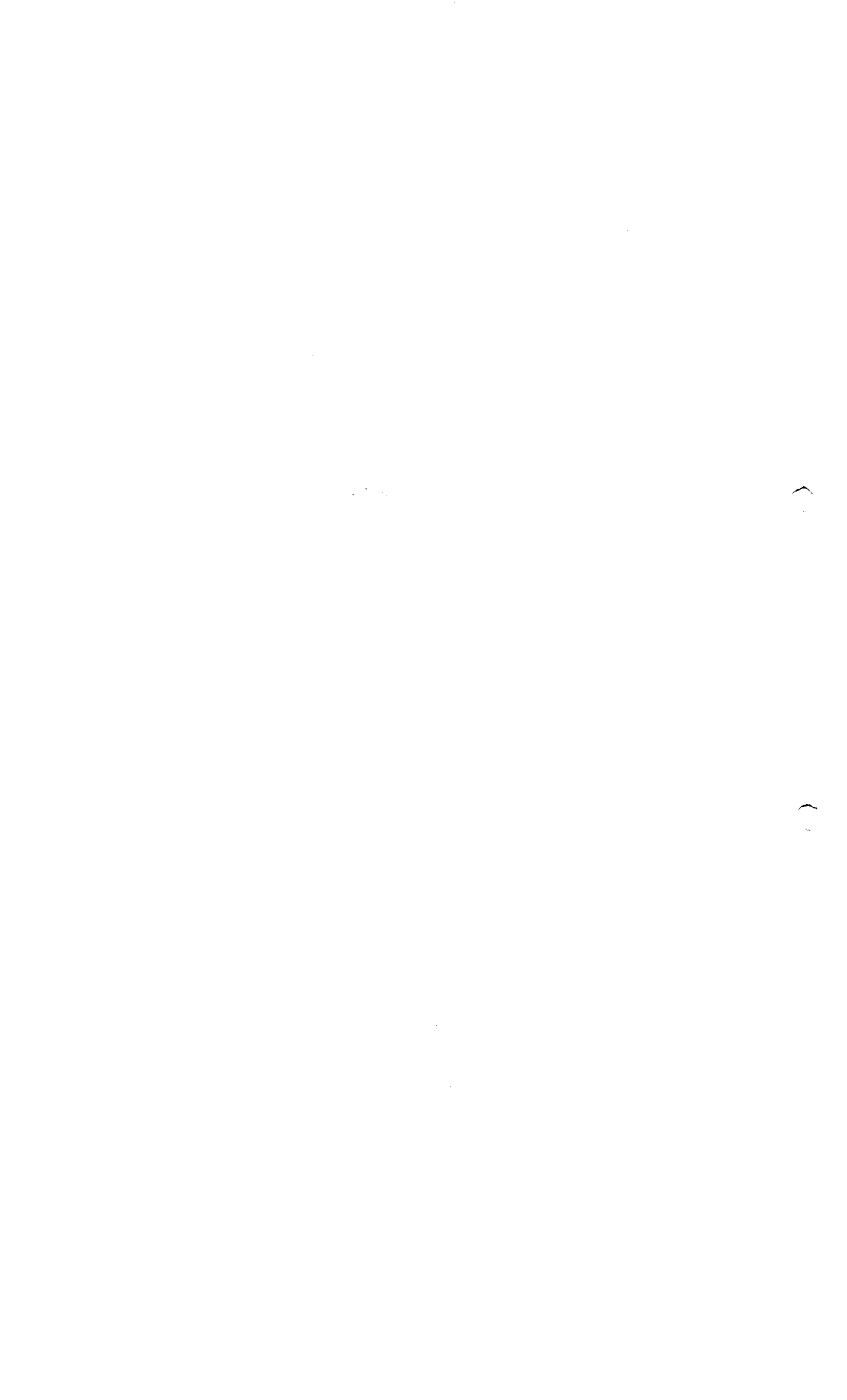
**Test for haemadsorbing viruses**

Method : visual inspection  
Number of vials tested : 8  
Type of red blood cells : Guinea-pig  
Incubation : 4 vials, 30 minutes at 5°C ± 3°C  
: 4 vials, 30 minutes at 20-25°C  
Date : 11.02.08  
Result : Absence of hemadsorption

**Simian cells identification**

Method : Isoenzymes analysis by IsoElectric Focusing  
Iso-enzymes analysed : Lactate DeHydrogenase  
Phospho Gluconate Dehydrogenase  
Glucose Phosphate Isomerase  
Reference cells : Vero, MRC5, WI38, Hep 2  
Date : 03.09.08  
Result : Positive identification

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





**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)

95/180

**CONTROLS ON SUPERNATANTS:**

**Test for extraneous agents**

*Vero cells*

Method	: Studied through a microscope
Type of cells	: Vero
Volume tested	: 10 ml
Temperature of incubation	: 36 ± 1° C
Test on	: 10.03.08
Test off	: 25.03.08
Result	: <b>Absence of cytopathic effect</b>


*Human diploid cells*

Method	: Studied through a microscope
Type of cells	: MRC5
Volume tested	: 10 ml
Temperature of incubation	: 36 ± 1° C
Test on	: 11.03.08
Test off	: 08.04.08
Result	: <b>Absence of cytopathic effect</b>

*Primary monkey kidney cells*

Method	: Studied through a microscope
Type of cells	: Vervet Monkey Cells
Volume tested	: 10 ml
Temperature of incubation	: 36 ± 1° C
Test on	: 12.02.08
Test off	: 26.02.08
Result	: <b>Absence of cytopathic effect</b>

  
 ROXANA MONTEMILONE  
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