



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° S4314 (clinical batch)

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**

CONTROLS ON CELLS:

Observation

Method : Studied through a microscope
 Cells : Vero, 142nd passage
 Number of cells tested : 320*10⁶ cells
 Test on : 02.07.07
 Test off : 16.07.07
 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 : 16.07.07
 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 : 04.10.07
 Result : Positive identification



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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	: 23.08.07
Test off	: 06.09.07
Result	: Absence of cytopathic effect

Human diploid cells

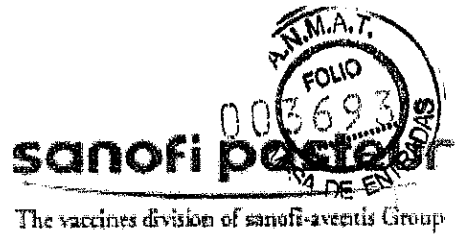
Method	: Studied through a microscope
Type of cells	: MRC5
Volume tested	: 10 ml
Temperature of incubation	: 36 ± 1° C
Test on	: 30.08.07
Test off	: 27.09.07
Result	: Absence of cytopathic effect

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	: 18.09.07
Test off	: 02.10.07
Result	: Absence of cytopathic effect

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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	: 12.02.08
Test off	: 26.02.08
<i>Subculture at 3rd day</i>	
Test on	: 15.02.08
Test off	: 29.02.08
<i>Subculture at 7th day</i>	
Test on	: 19.02.08
Test off	: 04.03.08
<i>Subculture at 14th day</i>	
Test on	: 26.02.08
Test off	: 11.03.08
<i>Subculture at 21th day</i>	
Test on	: 04.03.08
Test off	: 11.03.08
Result	: No growth of Mycoplasma

Test for Mycoplasma by epifluorescence in cell culture

Method	: DNA fluorescence staining
Cell used	: Vero, 150 th passage
Volume tested	: 1 ml
Temperature of incubation	: 36 ± 1° C
Positive control	: <i>M. hyorhinis</i> and <i>M. orale</i>
Test on	: 06.12.07
Test off	: 13.12.07
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 : LEPINE type 3
 Test on : 24.07.07
 Test off : 31.07.07
 Result : Positive

Polio virus concentration

Method : Cytopathogenic effect on sensitive cells
 Cell strain used : Hep 2
 Test on : 24.07.07
 Test off : 31.07.07
 Virus concentration : $10^{8.60}$ CCID₅₀/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	: 12.07.07	
Test off	: 26.07.07	
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	: <i>M. pneumoniae</i> and <i>M. orale</i> and <i>A. laidlawii</i>
 <i>Primary test</i>	
Test on	: 12.02.08
Test off	: 26.02.08
<i>Subculture at 3rd day</i>	
Test on	: 15.02.08
Test off	: 29.02.08
<i>Subculture at 7th day</i>	
Test on	: 19.02.08
Test off	: 04.03.08
<i>Subculture at 14th day</i>	
Test on	: 26.02.08
Test off	: 11.03.08
<i>Subculture at 21th day</i>	
Test on	: 04.03.08
Test off	: 11.03.08
Result	: No growth of Mycoplasma



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CONTROLS ON CONCENTRATED PURIFIED VIRAL SUSPENSION:

Protein content

Method : Spectrophotometry
 Date : 23.07.07
 Result : 55.67 µg/ml

D Antigen content



Method : ELISA
 Reference standard : 28.1.99
 Date : 16.07.07
 Result : 3 990 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	: 16.07.07	
Test off	: 30.07.07	
Result	: No microbial growth	

Purity

Result : 0.014 µg of protein / D Antigen U



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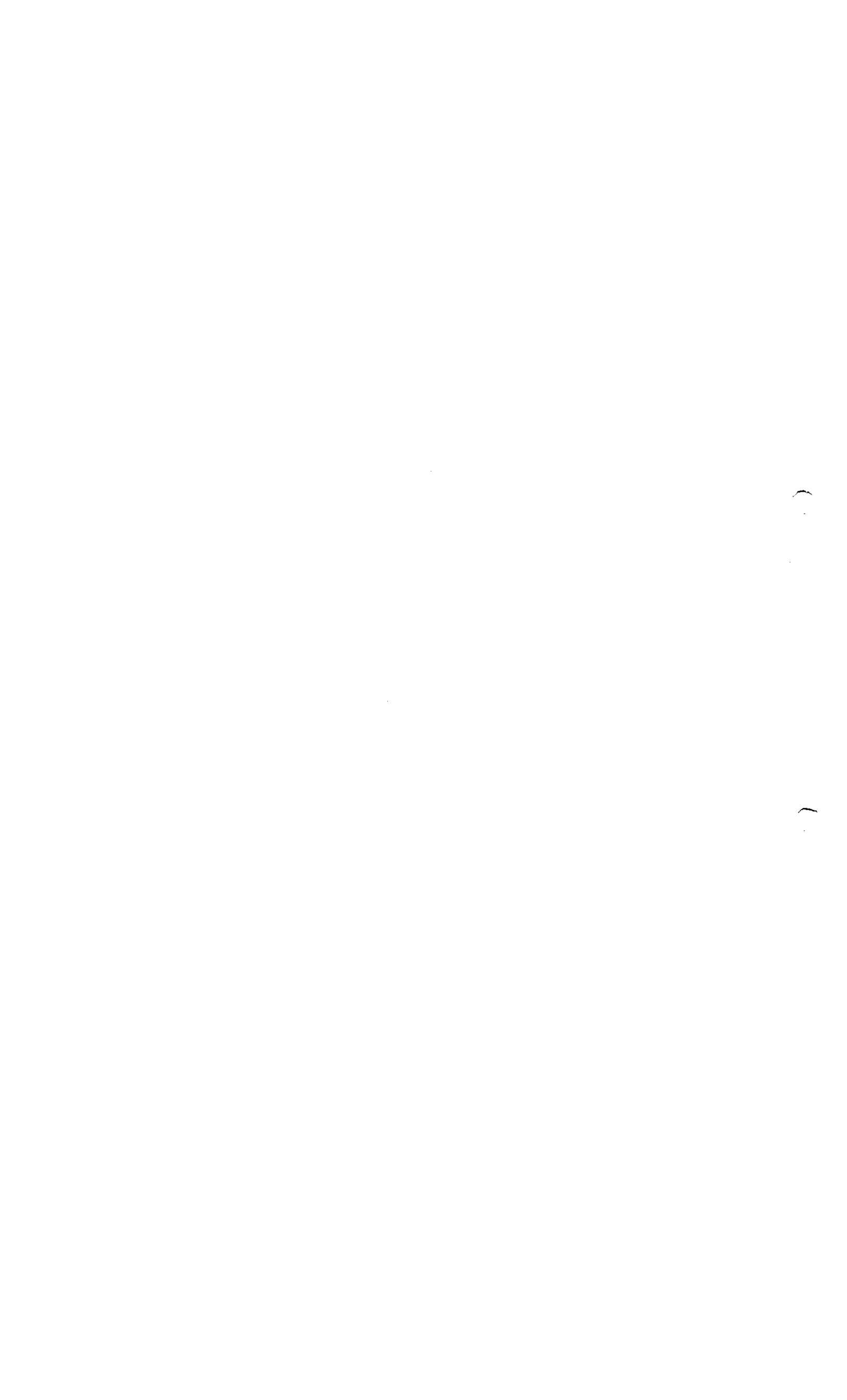
 **

MONOVALENT BULK (TYPE 1, 2 AND 3)

TESTS	ACCEPTANCE CRITERIA
RESIDUAL FORMALDEHYDE CONTENT	80 ± 30 µg/ml
PROTEIN CONTENT	For purity calculation
D ANTIGEN CONTENT	For purity calculation
PURITY	≤ 50 ng of protein/D antigen unit
BACTERIAL AND FUNGAL STERILITY TEST	No microbial growth
KINETICS OF INACTIVATION DAY 0 DAY 24H DAY 48H DAY 72H DAY 96H SLOPE CALCULATION (D0, D0+24H, D0+48H)	The infectious titer drops in linear mode Type 1 : within -0.1187 and -0.1758 Type 2 : within -0.0955 and -0.1890 Type 3 : within -0.1090 and -0.1933
TEST FOR EFFECTIVE INACTIVATION : DAY 9 DAY 12	No cytopathic effect during amplification process No cytopathic effect during amplification process


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**

MONOVALENT BULK - Type : 1
 Lot Number : FA291505

Single harvest used : FA285883 – FA285976
 Date of inactivation : 19.11.07
 Inactivation method : 0.88% (w/v) Formaldehyde, 37°C, 12 days
 Date of manufacture : 19.11.07
 Volume : 250 300 ml
 Storage temperature : +5°C ± 3°C
 Monovalent bulk period of validity : 3 years
 Expiry date : 19 NOVEMBER 2010

CONTROLS:

Residual formaldehyde content

Method : Spectrophotometry
 Date : 29.11.07
 Result : 89.04 µg/ml - **Conforms**

Protein content

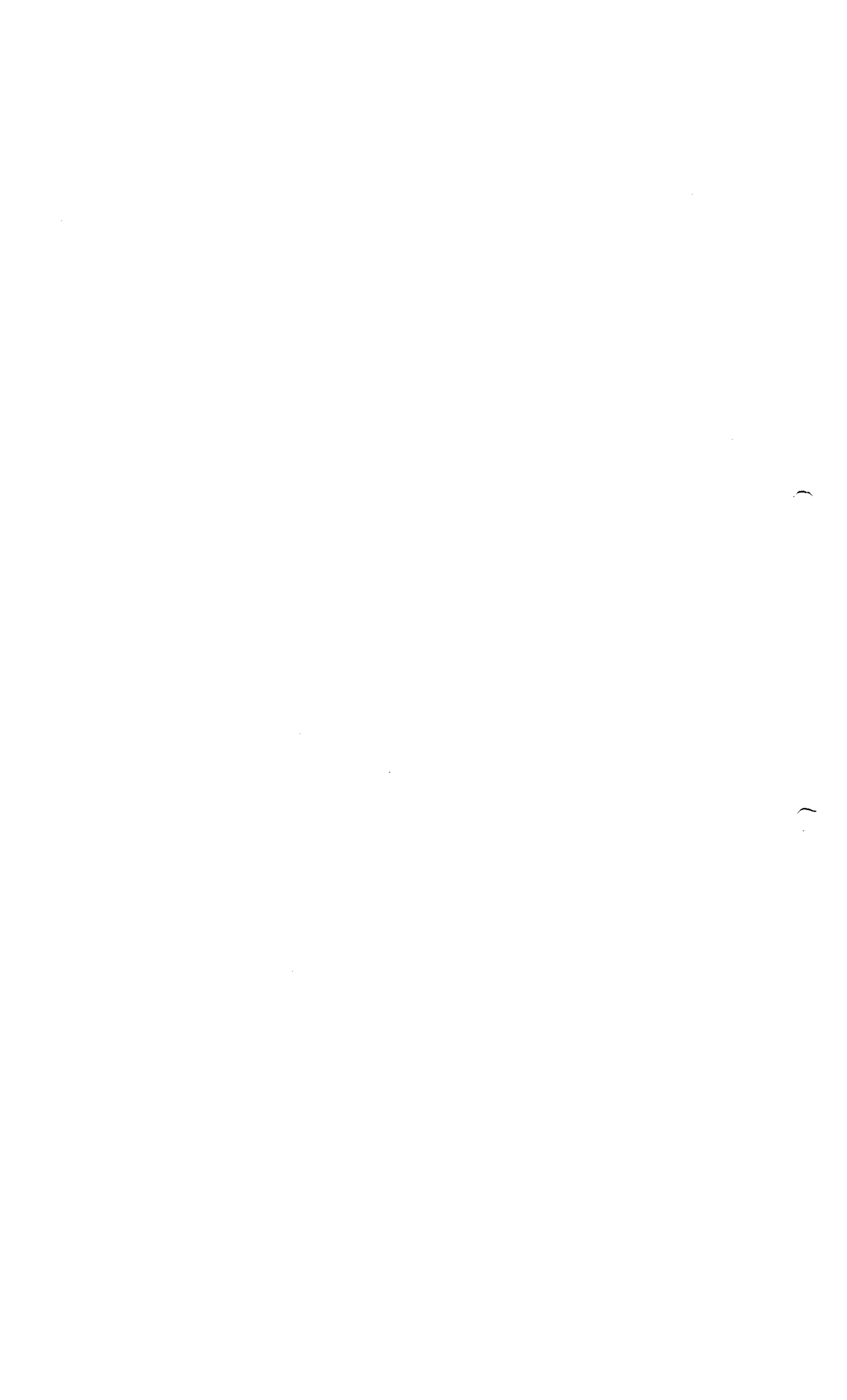
Method : Spectrophotometry
 Date : 04.12.07
 Result : 22.99 µg/ml

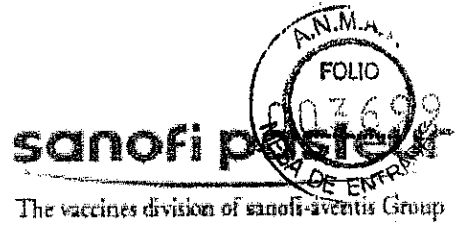
D Antigen content

Method : ELISA
 Reference standard : 28.1.99
 Date : 03.12.07
 Result : 1 420 D Antigen U/ml

Purity

Result : 16.187 ng of protein / D Antigen U - **Conforms**





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**

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	:	21.11.07
Test off	:	05.12.07
Result	:	No microbial growth

Inactivation Kinetics

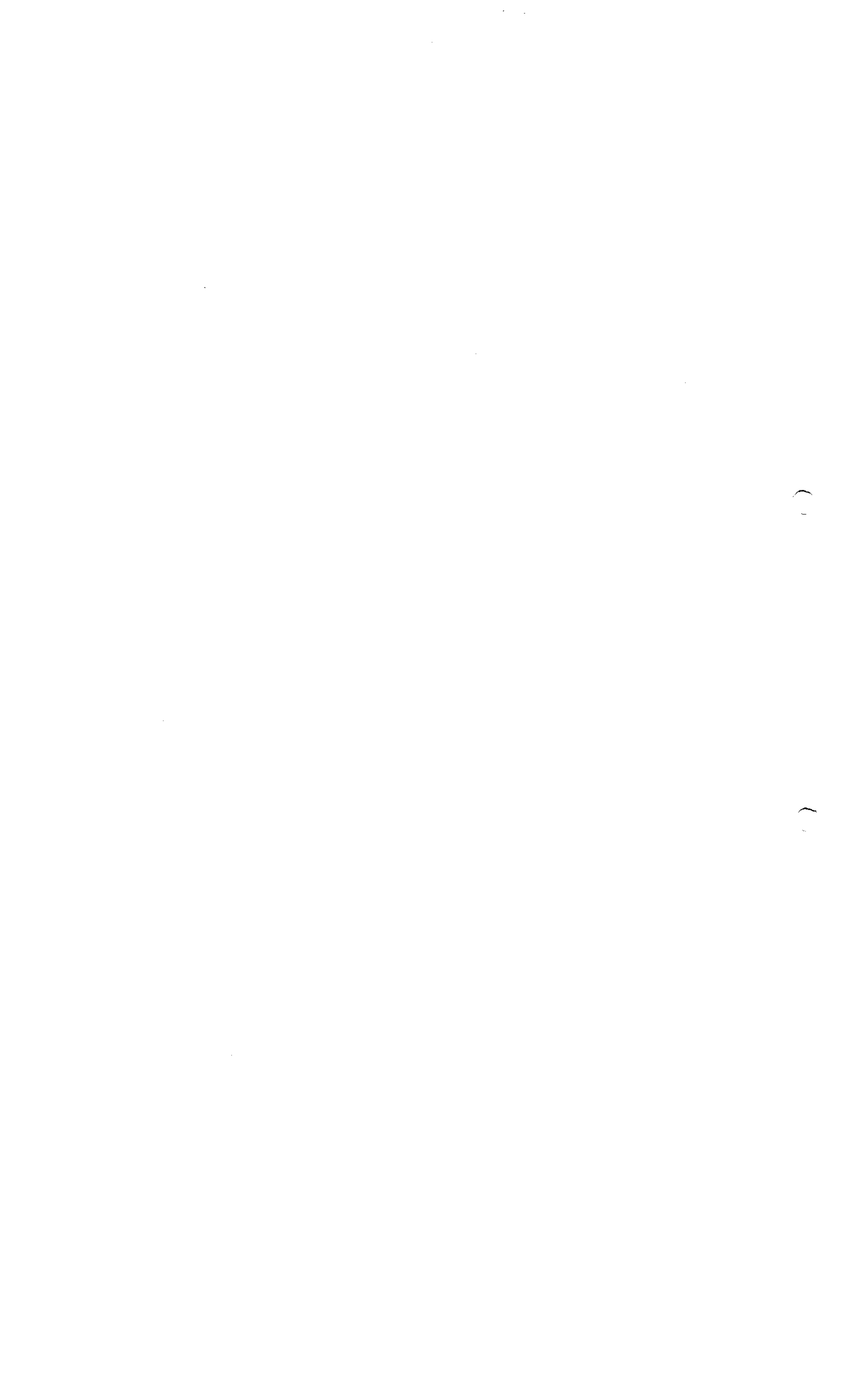
Method	:	viral titration of pollo cytopathogenic effect on sensitive cells
Cell strain used	:	Hep 2
Temperature of incubation	:	36 ± 1°C
Test on	:	07.12.07
Test off	:	14.12.07

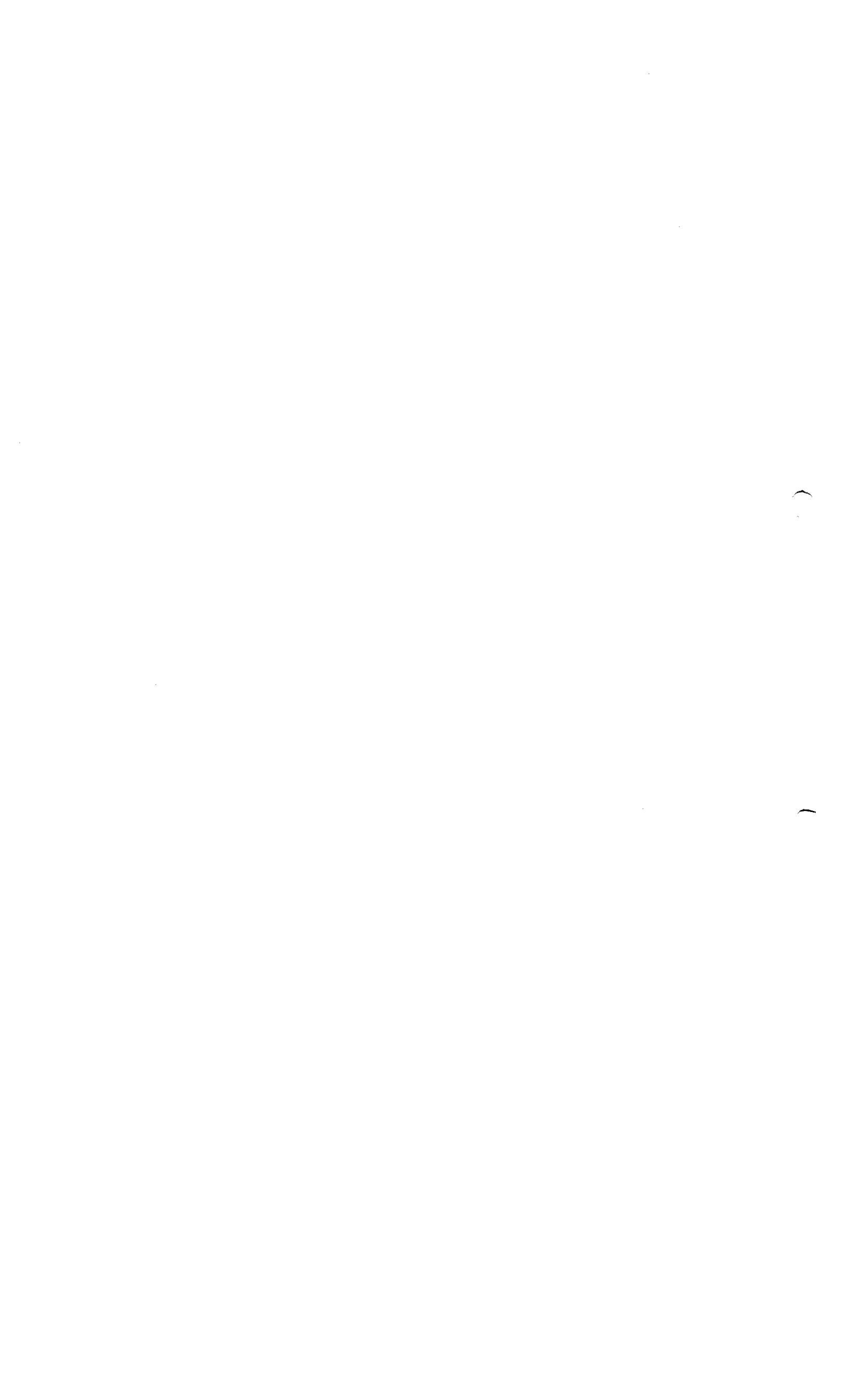
TIME	D0	D0 + 24H	D0 + 48H	D0 + 72H	D0 + 96H
Titer (CCID ₅₀ /ml)	10 ^{9.20}	10 ^{4.90}	≤10 ^{2.10}	≤10 ^{1.30}	≤10 ^{1.30}

Slope calculation : - 0.1479, Conforms

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**

MONOVALENT BULK - Type : 1
Lot Number : FA304026

Single harvest used	: FA296701 – FA297937
Date of inactivation	: 31.03.08
Inactivation method	: 0.88% (w/v) Formaldehyde, 37°C, 12 days
Date of manufacture	: 31.03.08
Volume	: 254 200 ml
Storage temperature	: +5°C ± 3°C
Monovalent bulk period of validity	: 3 years
Expiry date	: 31 MARCH 2011

CONTROLS:

Residual formaldehyde content

Method	: Spectrophotometry
Date	: 10.04.08
Result	: 88.18 µg/ml - Conforms

Protein content

Method	: Spectrophotometry
Date	: 15.04.08
Result	: 21.00 µg/ml

D Antigen content

Method	: ELISA
Reference standard	: 28.1.99
Date	: 03.04.08
Result	: 1 364 D Antigen U/ml

Purity

Result	: 15.396 ng of protein X D Antigen U - Conforms
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 **

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	:	04.04.08
Test off	:	18.04.08
Result	:	No microbial growth

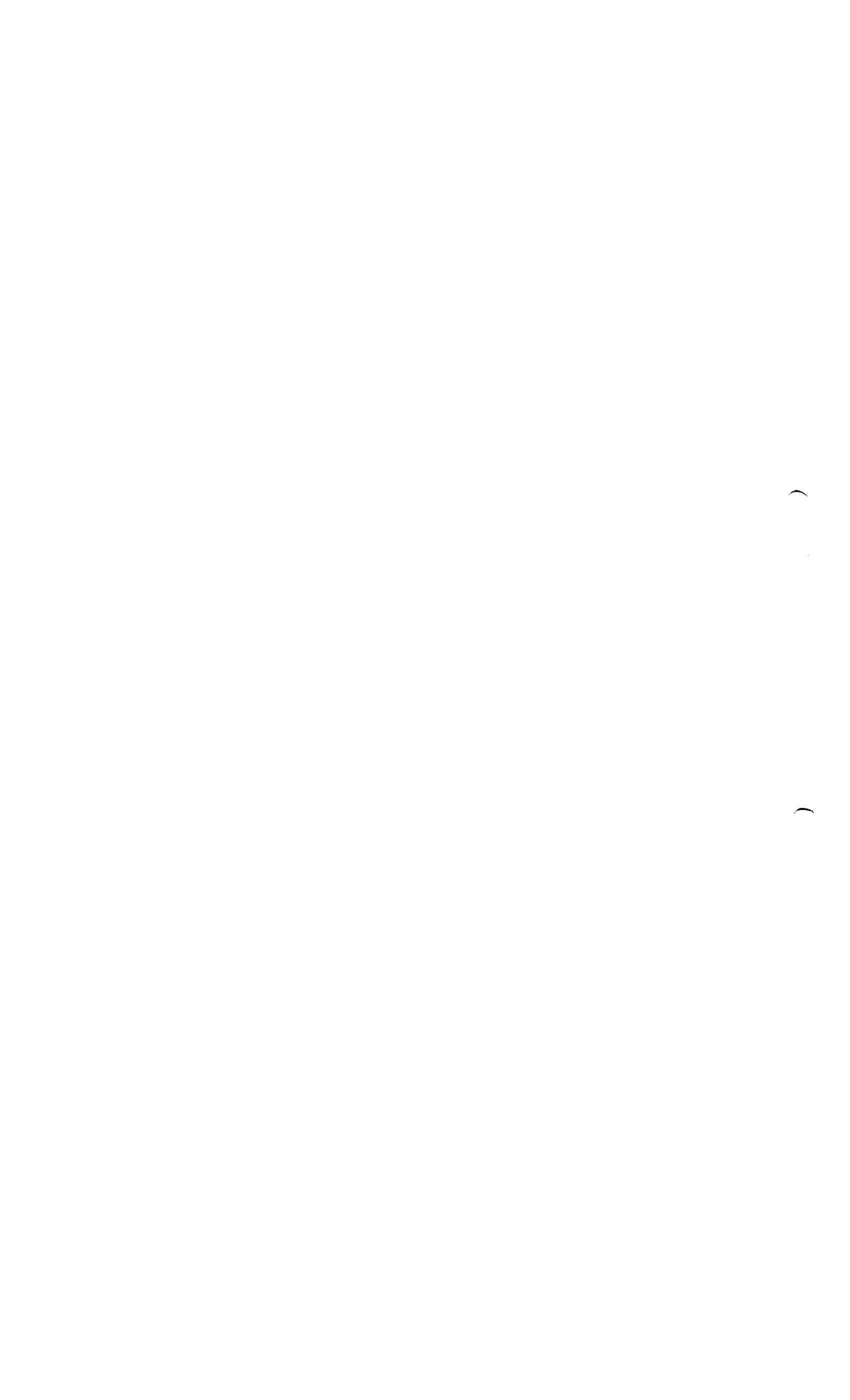
Inactivation kinetics

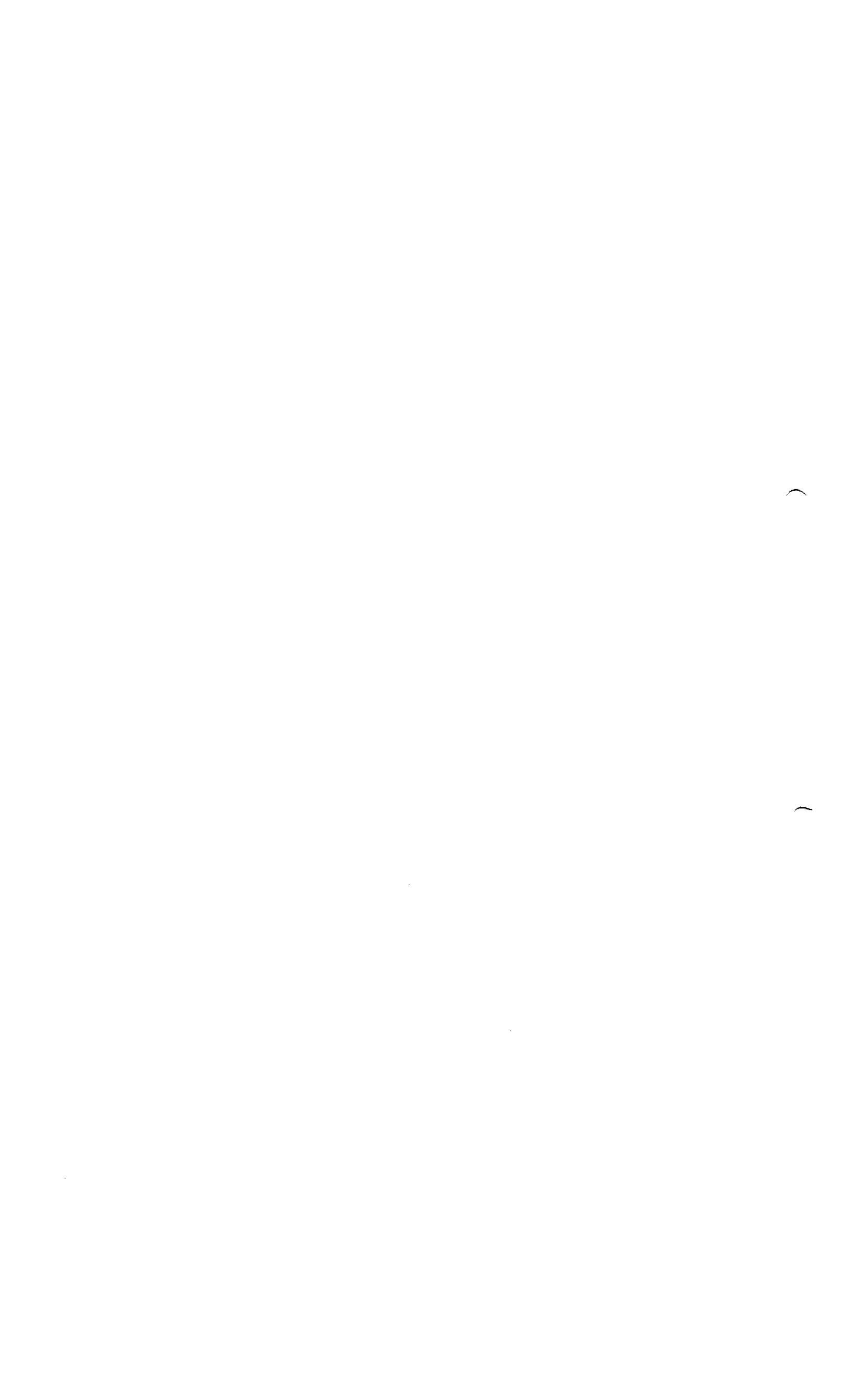
Method	:	viral titration of polio cytopathogenic effect on sensitive cells
Cell strain used	:	Hep 2
Temperature of incubation	:	36 ± 1° C
Test on	:	04.04.08
Test off	:	11.04.08

TIME	D0	D0 + 24H	D0 + 48H	D0 + 72H	D0 + 96H
Titer (CCID ₅₀ /ml)	10 ^{9.30}	10 ^{5.00}	≤10 ^{2.20}	≤10 ^{1.30}	≤10 ^{1.30}

Slope calculation : - 0.1479, Conforms



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Diphtheria, tetanus, pertussis (acellular, component),
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 influenzae type b conjugate vaccine (adsorbed) lot n° S4314 (clinical batch)

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 **

MONOVALENT BULK - Type : 2
 Lot Number : FA293397

Single harvest used : FA286930 – FA287531
 Date of inactivation : 17.12.07
 Inactivation method : 0.88% (w/v) Formaldehyde, 37°C, 12 days

 Date of manufacture : 17.12.07
 Volume : 96 800 ml
 Storage temperature : +5°C ± 3°C
 Monovalent bulk period of validity : 3 years
 Expiry date : 17 DECEMBER 2010

CONTROLS:

Residual formaldehyde content

Method : Spectrophotometry
 Date : 10.01.08
 Result : 86.59 µg/ml - **Conforms**

Protein content

Method : Spectrophotometry
 Date : 08.01.08
 Result : 30.54 µg/ml

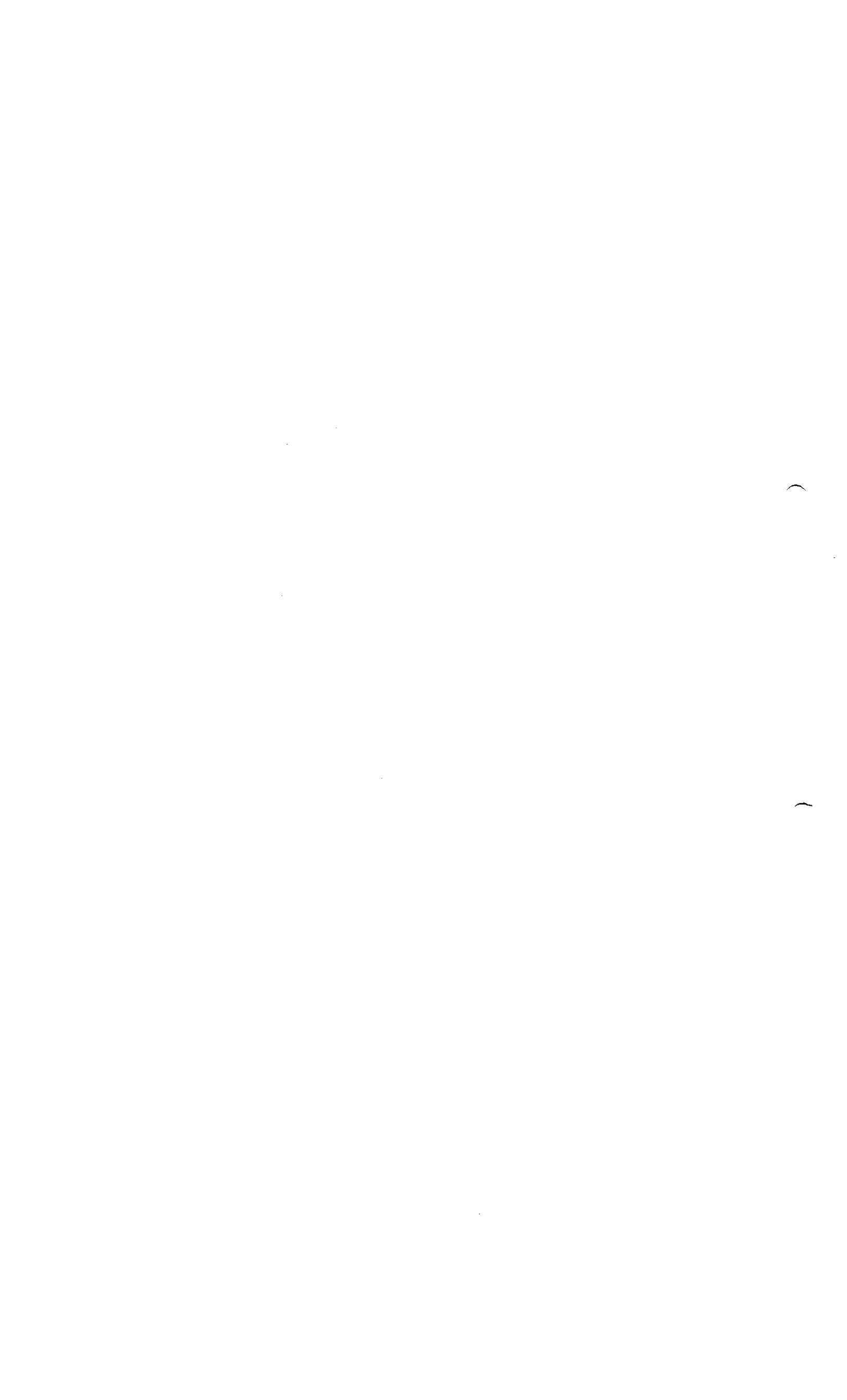
D Antigen content

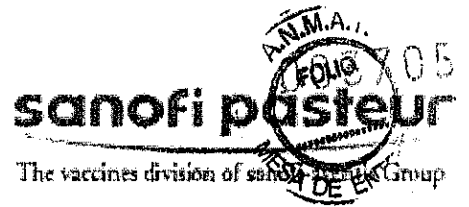
Method : ELISA
 Reference standard : 28.1.99
 Date : 14.01.08
 Result : 843 D Antigen U/ml

Purity

Result : 36.2301 ng of protein / D Antigen U - **Conforms**

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Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed) lot n° S4314 (clinical batch) 144/211

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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	:	20.12.07	
Test off	:	03.01.08	
Result	:	No microbial growth	

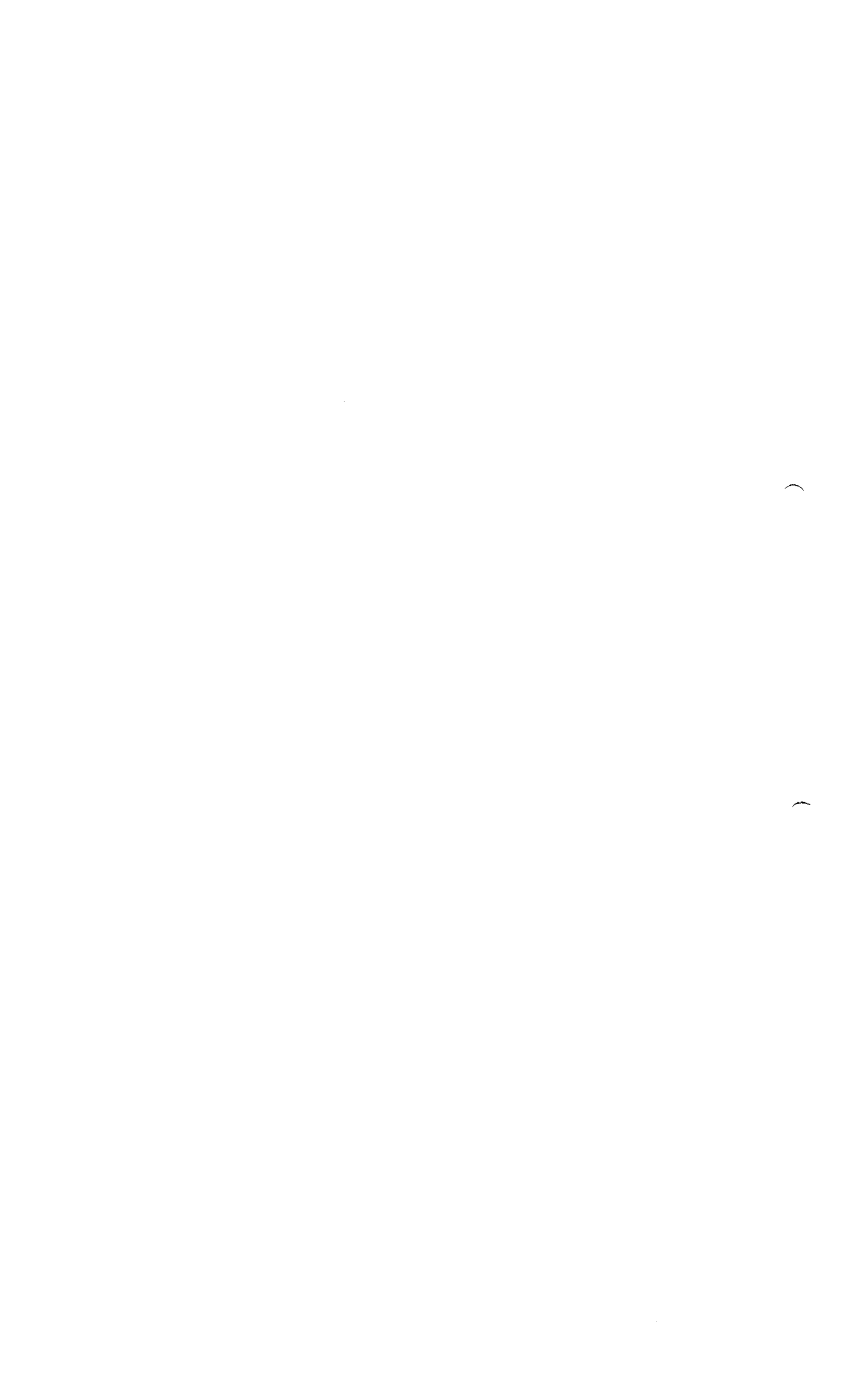
Inactivation kinetics

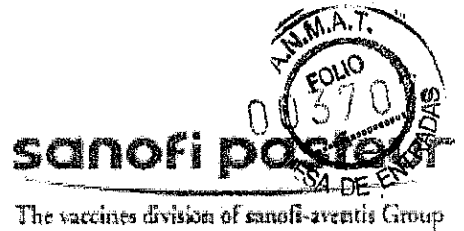
Method	:	viral titration of polio cytopathogenic effect on sensitive cells
Cell strain used	:	Hep 2
Temperature of incubation	:	36 ± 1°C
Test on	:	11.01.08
Test off	:	18.01.08

TIME	D0	D0 + 24H	D0 + 48H	D0 + 72H	D0 + 96H
Titer (CCID ₅₀ /ml)	10 ^{9.60}	10 ^{6.50}	10 ^{3.30}	≤10 ^{1.30}	≤10 ^{1.30}

Slope calculation : - 0.1313, Conforms



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**

MONOVALENT BULK - Type : 3
 Lot Number : FA300586

Single harvest used	: FA290835 – FA292974
Date of inactivation	: 25.02.08
Inactivation method	: 0.88% (w/v) Formaldehyde, 37°C, 12 days
Date of manufacture	: 25.02.08
Volume	: 207 500 ml
Storage temperature	: +5°C ± 3°C
Monovalent bulk period of validity	: 3 years
Expiry date	: 25 FEBRUARY 2011

CONTROLS:

Residual formaldehyde content

Method	: Spectrophotometry
Date	: 03.03.08
Result	: 85.93 µg/ml - Conforms

Protein content



Method	: Spectrophotometry
Date	: 04.03.08
Result	: 22.67 µg/ml

D Antigen content

Method	: ELISA
Reference standard	: 28.1.99
Date	: 28.02.08
Result	: 1 053 D Antigen U/ml

Purity

Result	: 21.527 ng of protein / D. Antigen U - Conforms
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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	:	27.02.08
Test off	:	12.03.08
Result	:	No microbial growth


Inactivation kinetics

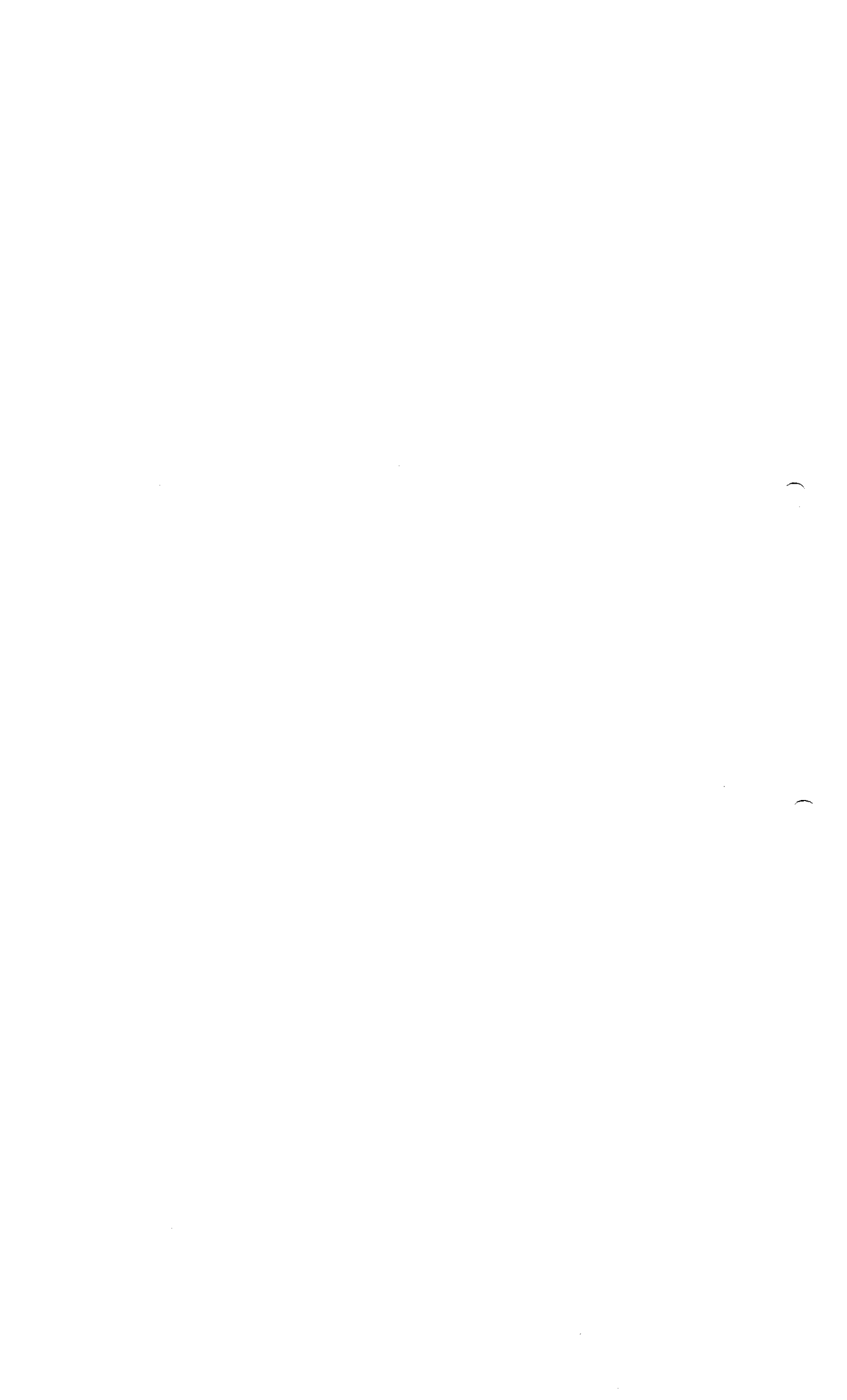
Method	:	viral titration of polio cytopathogenic effect on sensitive cells
Cell strain used	:	Hep 2
Temperature of incubation	:	36 ± 1°C
Test on	:	29.02.08
Test off	:	07.03.08

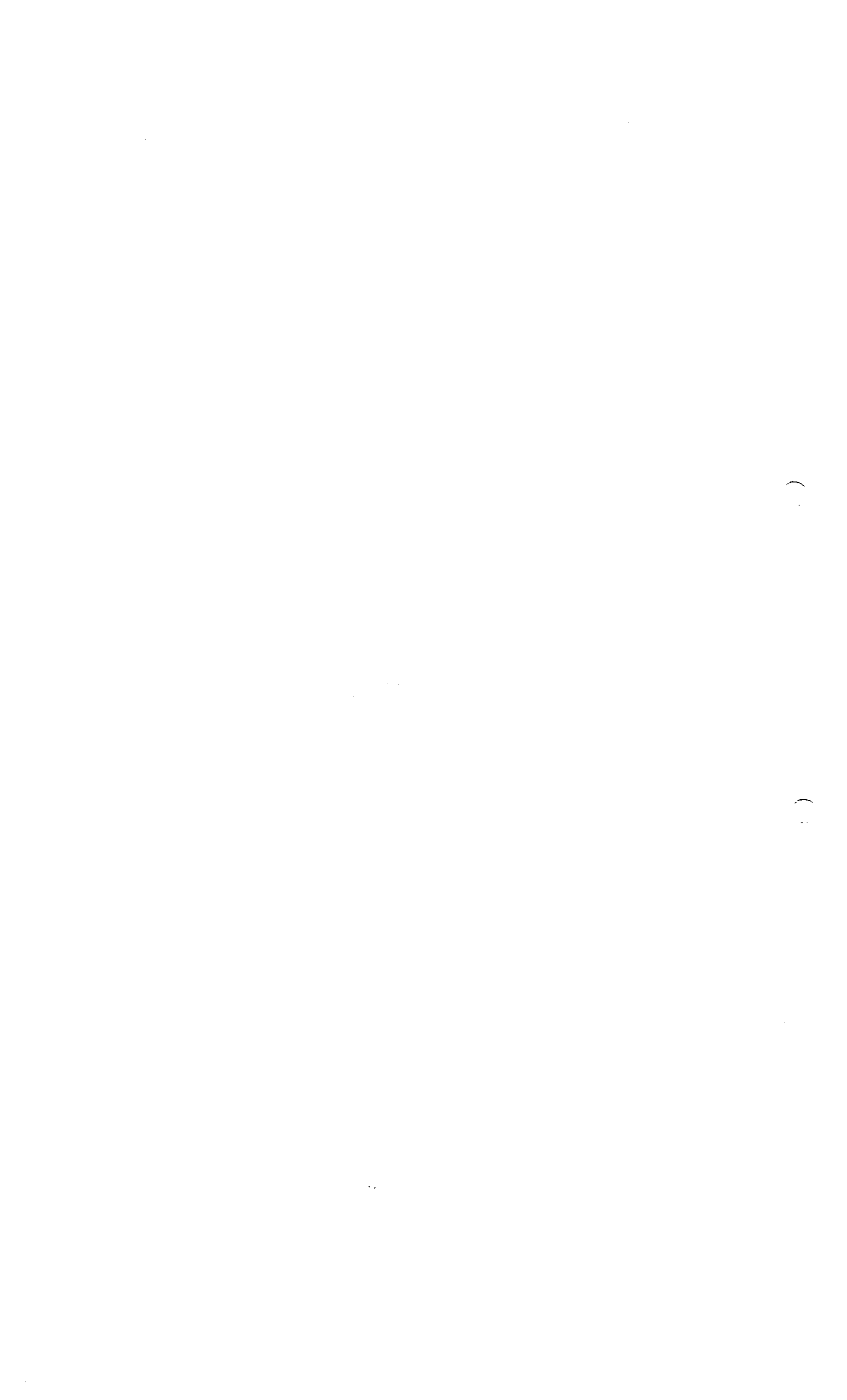
TIME	D0	D0 + 24H	D0 + 48H	D0 + 72H	D0 + 96H
Titer (CCID ₅₀ /ml)	10 ^{9.20}	10 ^{5.30}	≤10 ^{2.00}	≤10 ^{1.30}	≤10 ^{1.30}

Slope calculation : - 0.1500, Conforms


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**

MONOVALENT BULK - Type : 3
Lot Number : FA288122

Single harvest used : FA279494
Date of inactivation : 15.10.07
Inactivation method : 0.88% (w/v) Formaldehyde, 37°C, 12 days

Date of manufacture : 15.10.07
Volume : 63 640 ml
Storage temperature : +5°C ± 3°C
Monovalent bulk period of validity : 3 years
Expiry date : 15 OCTOBER 2010

CONTROLS:

Residual formaldehyde content

Method : Spectrophotometry
Date : 25.10.07
Result : 90.39 µg/ml - **Conforms**

Protein content

Method : Spectrophotometry
Date : 25.10.07
Result : 22.04 µg/ml

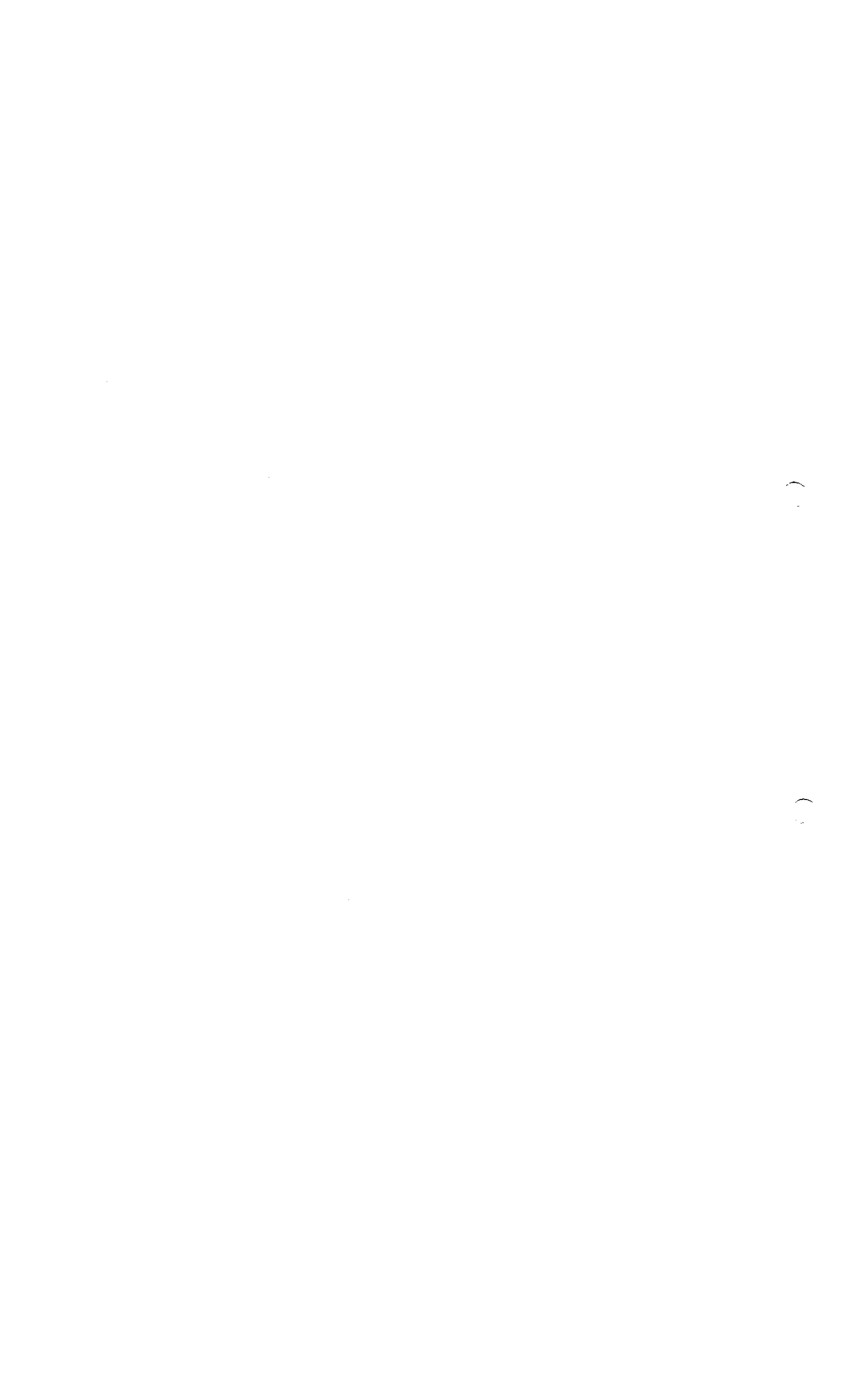
D Antigen content

Method : ELISA
Reference standard : 28.1.99
Date : 27.11.07
Result : 1 260 D Antigen U/ml

Purity

Result : 17.495 ng of protein / D Antigen U - **Conforms**

[Signatures]
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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° S4314 (clinical batch) 150/211

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	:	17.10.07
Test off	:	31.10.07
Result	:	No microbial growth


Inactivation kinetics

Method	:	viral titration of polio cytopathogenic effect on sensitive cells
Cell strain used	:	Hep 2
Temperature of incubation	:	36 ± 1°C
Test on	:	19.10.07
Test off	:	26.10.07

TIME	D0	D0 + 24H	D0 + 48H	D0 + 72H	D0 + 96H
Titer (CCID ₅₀ /ml)	10 ^{9.60}	10 ^{5.90}	≤10 ^{2.20}	≤10 ^{1.30}	≤10 ^{1.30}

Slope calculation : - 0.1542, Conforms


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