

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)

59/211

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**HEPATITIS B SURFACE ANTIGEN**

**Lot number : AC013**

Date of manufacture	: May 12 <sup>th</sup> , 2008
Storage temperature	: + 5°C ± 3°C
Expiry date	: April 2011 (shelf life used at the time of the release of the batch)
Quantity:	: 3,00097 g of proteins

**CONTROLS :**

**Appearance**

Method	: Visual inspection
Date	: May 26 <sup>th</sup> , 2008
Result	: Opalescent, slightly cloudy and yellowish

**solution**

**pH**

Method	: Glass electrode
Date	: May 27 <sup>th</sup> ,
Result	: 6,9 - Conforms

**Protein content**

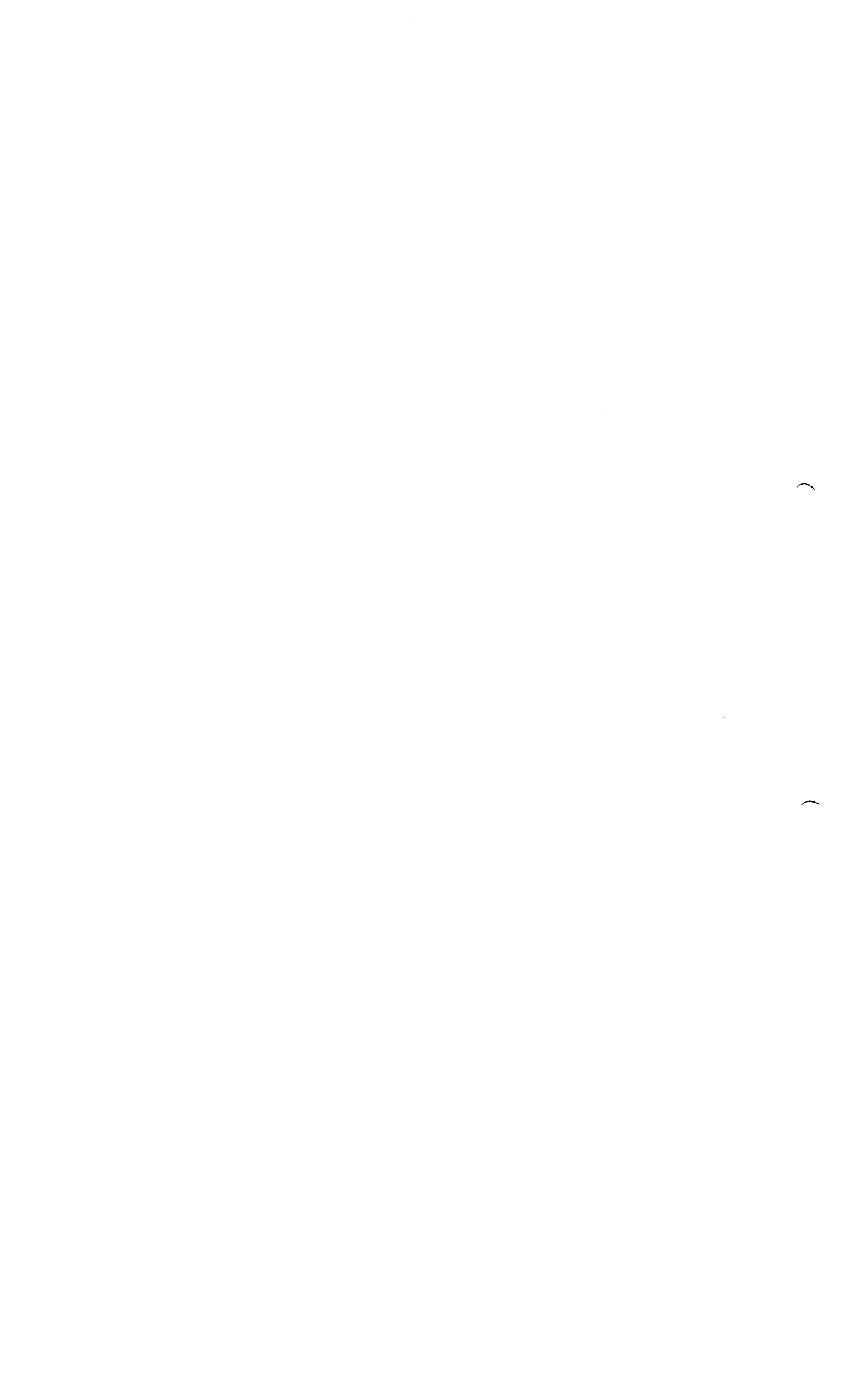
Method	: Lowry
Date	: June 19 <sup>th</sup> , 2008
Result	: 1,51 mg/ml - Conforms

**Identification of HBsAg**

Method	: ELISA
Date	: August 30 <sup>th</sup> , 2008
Result	: <b>Positive</b>

Method	: SDS - PAGE
Date	: August 30 <sup>th</sup> , 2008
Result	: <b>Conforms</b>

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**HBsAg Content**

Method : ELISA  
 Date : August 30<sup>th</sup>, 2008  
 Result : 1,2 mg/mg of total proteins – **Conforms**

**Carbohydrates Content**

Method : Colorimetric assay  
 Date : August 30<sup>th</sup>, 2008  
 Result : 34 µg/mg of total proteins – **Conforms**

**Lipids Content**

Method : Colorimetric assay  
 Date : August 30<sup>th</sup>, 2008  
 Result : 0,7 mg/mg of total proteins – **Conforms**

**Purity Content**

Method : SDS - PAGE  
 Date : August 30<sup>th</sup>, 2008  
 Result : 97 %

**Percentage of HBsAg free monomer**



Method : SDS - PAGE  
 Date : August 30<sup>th</sup>, 2008  
 Result : Less than 3 % - **Conforms**

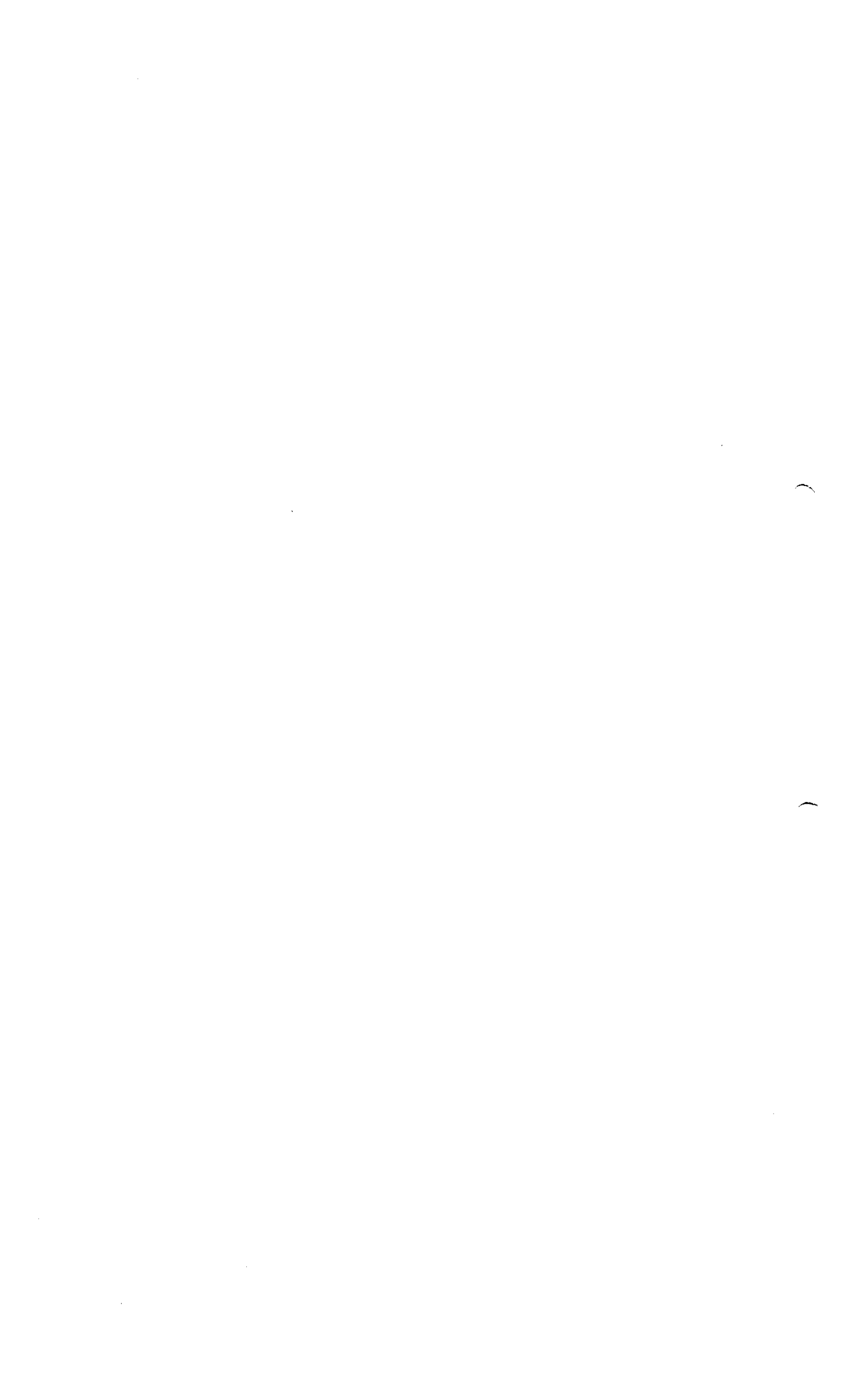
**Bacterial and fungal sterility**

Method	:	Membrane filtration	
Media	:	Thioglycollate medium	Soybean-Casein Digest medium
Temperature	:	30-35° C	20-25° C
Inoculum per Steritest	:	10 ml	10 ml
Volume of medium per Steritest	:	100 ml	100 ml
Test on	:	May 13th, 2008	
Test off	:	May 27th, 2008	
Result	:	No microbial growth - <b>Conforms</b>	

**Bacterial Endotoxins**

Method : LAL – Gel clot  
 Date : Not Available  
 Result : <1 EU/10µg of proteins- **Conforms**

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61/211

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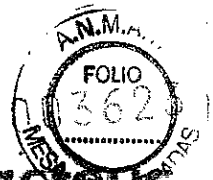
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**- E - INACTIVATED POLIOMYELITIS TRIVALENT**

  
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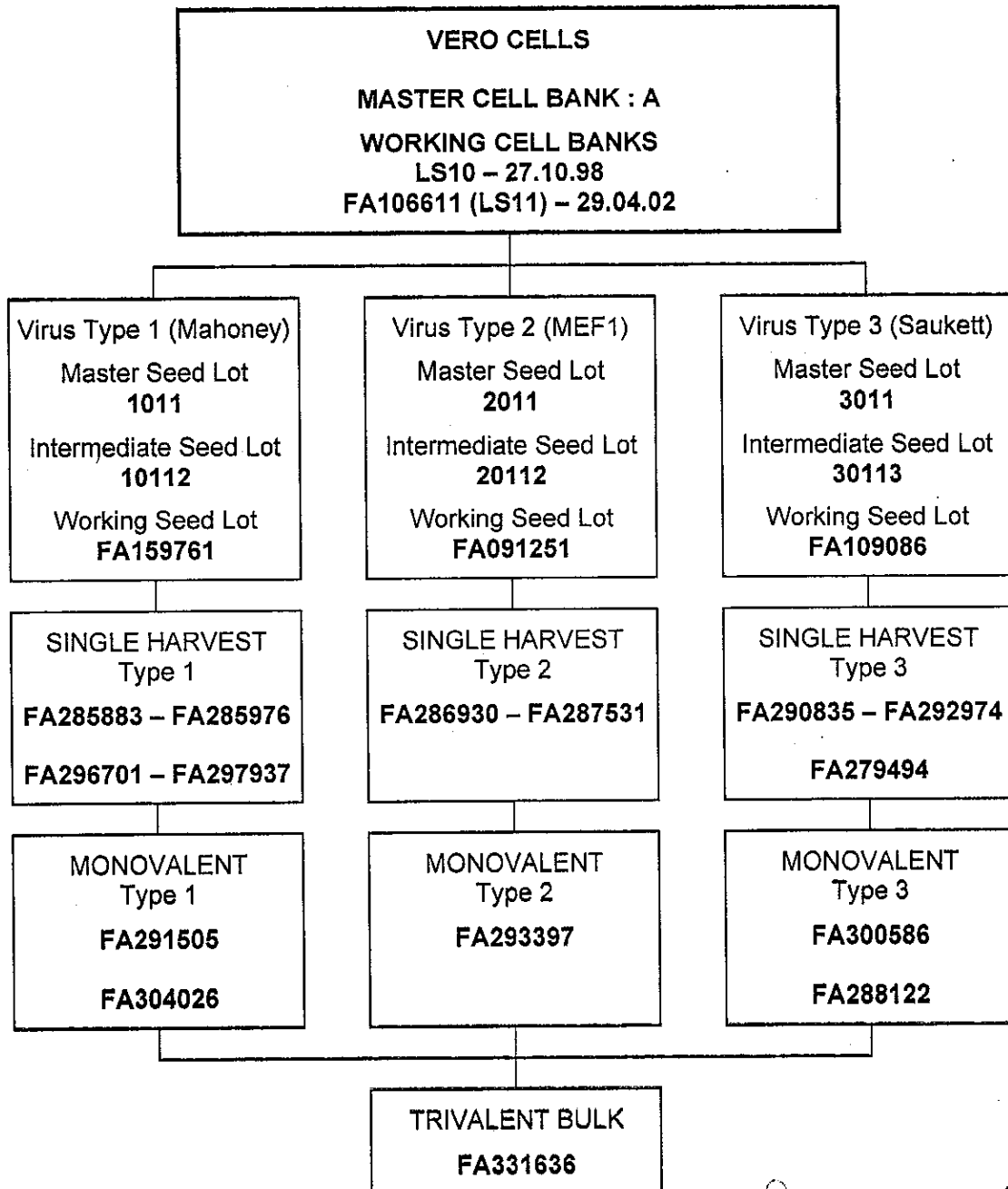
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62/211

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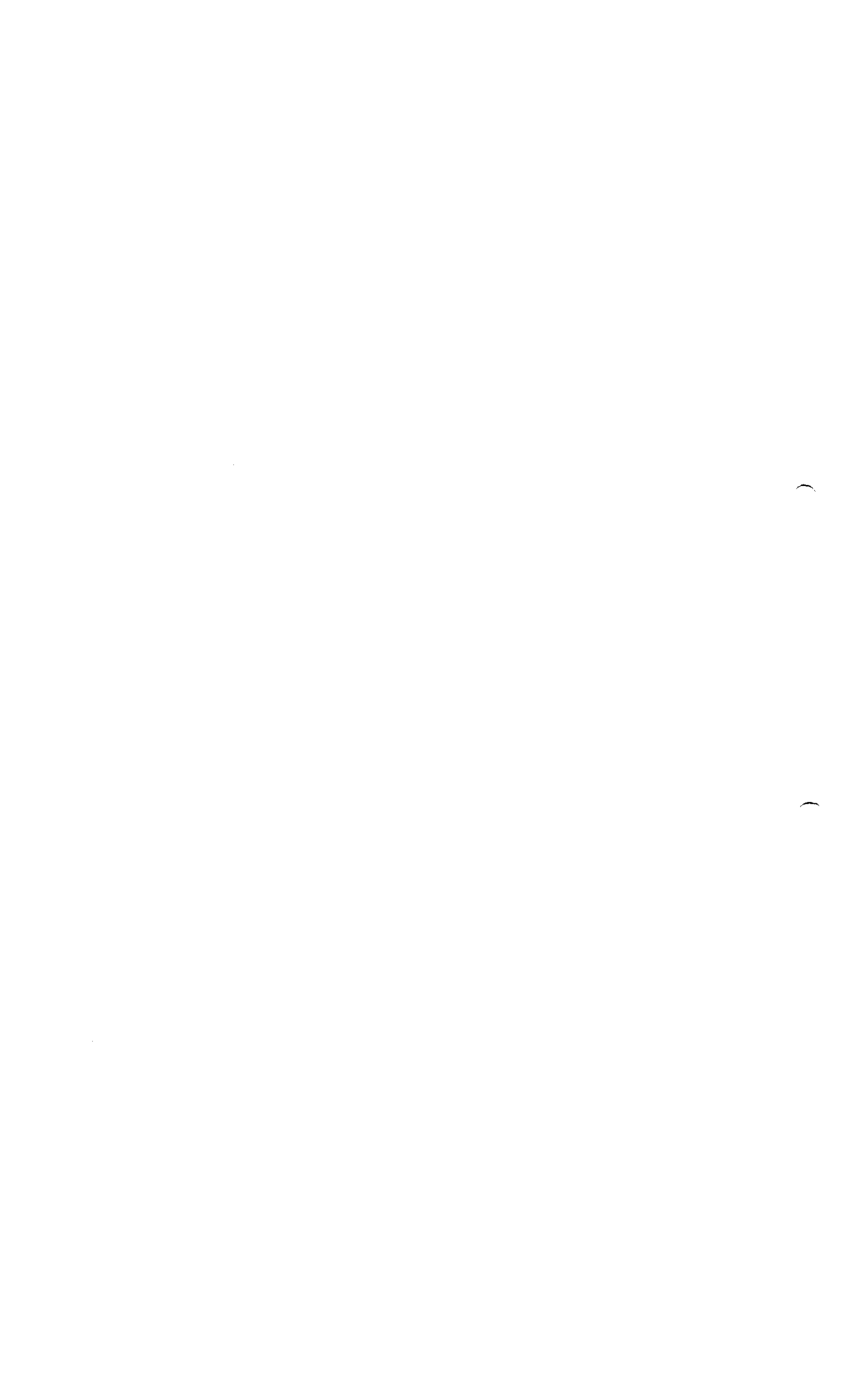
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**PRODUCTION FLOW SHEET**



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63/211

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POLIOMYELITIS VACCINE (INACTIVATED)  
MASTER CELL BANK -VERO CELLS-  
Lot Number : A

**Strain Cell** : Cercopithecus aethiops kidney cells.  
**Supplier** : American Type Culture Collection  
**Reference** : ATCC-CCL 81 at 124<sup>th</sup> passage  
**Received** : 22.05.79  
**Aventis Pasteur reference** : ATCC-CCL 81 VERO F1415

**Master Cell Bank:**

**Aventis Pasteur reference** : Cell Bank A at 129<sup>th</sup> passage  
**Preparation date** : 21.06.79  
**Storage temperature** : liquid nitrogen

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64/211

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POLIOMYELITIS VACCINE (INACTIVATED)  
WORKING CELL BANK -VERO CELLS-  
Lot Number : LS10

Master Cell Bank

: Cell Bank A at 129<sup>th</sup> passage

Working Cell Bank :

Aventis Pasteur reference  
Preparation date  
Release date  
Storage temperature

: LS10 at 137<sup>th</sup> passage  
: 27.10.98  
: 18.12.00  
: liquid nitrogen

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65/211

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POLIOMYELITIS VACCINE (INACTIVATED)  
WORKING CELL BANK -VERO CELLS-  
Lot Number : FA106611 (LS11)

Master Cell Bank

: Cell Bank A at 129<sup>th</sup> passage

Working Cell Bank :

Aventis Pasteur reference

: FA106611 (LS11) at 137<sup>th</sup> passage

Preparation date

: 29.04.02

Release date

: 26.03.08

Storage temperature

: liquid nitrogen

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POLIOMYELITIS VACCINE (INACTIVATED)  
MASTER VIRUS SEED LOT - Type 1  
Lot Number 1011

Virus strain : MAHONEY type 1  
Original strain : 74/3-B3 - Pitman and Moore Company  
Supplier : RIJKS Instituut Voor de Volksgezondheid (RIV)  
Bilthoven - Netherlands  
Received from supplier : 04.02.77  
Cells used : Primary Monkey kidney cells of Erythrocebus  
Patas  
Preparation date : 09.03.77  
Release date : 02.09.77

POLIOMYELITIS VACCINE (INACTIVATED)  
INTERMEDIATE VIRUS SEED LOT - Type 1  
Lot Number 10112

Master seed lot : 1011  
Cells used : Primary Monkey kidney cells of Erythrocebus  
Patas  
Preparation date : 17.05.79  
Release date : 26.09.79

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67/211

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POLIOMYELITIS VACCINE (INACTIVATED)  
MASTER VIRUS SEED LOT - Type 2  
Lot Number 2011

Virus strain : MEF 1 type 2  
Original strain : 68/2-B3 - Statens Serum Institute, Copenhagen  
Supplier : RIJKS Instituut Voor de Volksgezondheid (RIV)  
Bilthoven - Netherlands  
Received from supplier : 04.02.77  
Cells used : Primary Monkey kidney cells of Erythrocebus  
Patás  
Preparation date : 09.03.77  
Release date : 02.09.77

POLIOMYELITIS VACCINE (INACTIVATED)  
INTERMEDIATE VIRUS SEED LOT - Type 2  
Lot Number 20112

Master seed lot : 2011  
Cells used : Primary Monkey kidney cells of Erythrocebus  
Patás  
Preparation date : 07.05.79  
Release date : 26.09.79

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68/211

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<p>POLIOMYELITIS VACCINE (INACTIVATED)</p> <p>MASTER VIRUS SEED LOT - Type 3</p> <p>Lot Number 3011</p>
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Virus strain	: SAUKETT type 3
Original strain	: 74/2-B2 - Statens Serum Institute, Copenhagen
Supplier	: RIJKS Instituut Voor de Volksgezondheid (RIV) Bilthoven - Netherlands
Received from supplier	: 04.02.77
Cells used	: Primary Monkey kidney cells of <b>Erythrocebus</b>
<b>Patas</b>	
Preparation date	: 09.03.77
Release date	: 03.11.77

<p>POLIOMYELITIS VACCINE (INACTIVATED)</p> <p>INTERMEDIATE VIRUS SEED LOT - Type 3</p> <p>Lot Number 30113</p>
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Master seed lot	: 3011
Cells used	: Primary Monkey kidney cells of <b>Erythrocebus</b>
<b>Patas</b>	
Preparation date	: 18.05.79
Release date	: 15.10.79

  
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69/211

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POLIOMYELITIS VACCINE (INACTIVATED)

WORKING VIRUS SEED LOT - Type : 1

Lot Number : FA159761

Working Cell Bank : LS10

Intermediate seed lot : 10112

Working seed lot : FA159761

Cell amplification from 137<sup>th</sup> to 142<sup>nd</sup> passage : 07.08.03 to 28.08.03


Number of passage between PSL and WSL : 2

Preparation date : 09.09.03

Release date : 16.04.04

Storage temperature : ≤ -35°C

  
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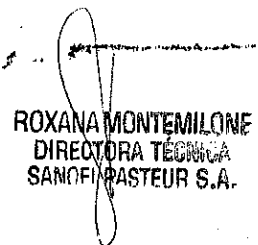

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POLIOMYELITIS VACCINE (INACTIVATED)  
 WORKING VIRUS SEED LOT - Type : 2  
 Lot Number : FA091251

<u>Working Cell Bank</u>	: LS10
<u>Intermediate seed lot</u>	: 20112
<u>Working seed lot</u>	: FA091251
Cell amplification from 137 <sup>th</sup> to 142 <sup>nd</sup> passage	: 13.09.01 to 04.10.01
Number of passage between PSL and WSL	: 2
Preparation date	: 16.10.01
Release date	: 30.05.02
Storage temperature	: ≤ -35°C

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71/211

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POLIOMYELITIS VACCINE (INACTIVATED)  
WORKING VIRUS SEED LOT - Type : 3  
Lot Number : FA109086

Working Cell Bank : LS10

Intermediate seed lot : 30113

Working seed lot : FA109086  
Cell amplification from 137<sup>th</sup> to 142<sup>nd</sup> passage : 14.03.02 to 03.04.02  
Number of passage between PSL and WSL : 2  
Preparation date : 17.04.02  
Release date : 09.01.03  
Storage temperature : ≤ -35°C

  
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72/211

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**SINGLE HARVEST (TYPE 1, 2 AND 3)**

TESTS	ACCEPTANCE CRITERIA
<b>ON CELLS</b>	
OBSERVATION	Absence of cytopathic effect due to extraneous agents
TEST FOR HAEMADSORBING VIRUSES	Absence of hemadsorption
SIMIAN CELLS IDENTIFICATION	Positive identification
<b>ON SUPERNATANT</b>	
TEST FOR EXTRANEIOUS AGENTS USING CELLS . VERO CELLS . HUMAN DIPLOID CELLS . PRIMARY MONKEY KIDNEY CELLS	Absence of cytopathic effect for each cell type
TEST FOR MYCOPLASMA BY CULTURE METHOD	No growth of mycoplasma
TEST FOR MYCOPLASMA BY EPIFLUORESCENCE IN CELL CULTURE	No mycoplasma detected by epifluorescence in cell culture
<b>SINGLE VIRUS HARVEST</b>	
POLIO VIRUS IDENTIFICATION	Positive
POLIO VIRUS CONCENTRATION	$\geq 10^7$ CCID <sub>50</sub> /ml
BACTERIAL AND FUNGAL STERILITY	No microbial growth
TEST FOR MYCOPLASMA BY CULTURE METHOD	No growth of mycoplasma
<b>CONCENTRATED PURIFIED VIRAL SUSPENSION</b>	
PROTEIN CONTENT	For purity ratio calculation
D ANTIGEN CONTENT	For purity ratio calculation
BACTERIAL AND FUNGAL STERILITY	No microbial growth
PURITY (SPECIFIC ACTIVITY)	Type 1 : < 0.027 µg of protein/D antigen unit Type 2 : < 0.0875 µg of protein/D antigen unit Type 3 : < 0.030 µg of protein/D antigen unit



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73/211

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SINGLE HARVEST - Type : 1  
 Lot Number : **FA285883**

**CELL:**

Working Cell Bank : **FA106611**  
 Date of thawing ampoule of WCB : **16.08.07**  
 Thawing ampoule amount : **One ampoule**

**VIRUS:**

Virus Working Seed lot : **FA159761**  
 Date of inoculation : **10.09.07**  
 Date of virus harvest : **13.09.07**

**CRUDE HARVEST:**

Storage : from **14.09.07** to **17.09.07**  
 Volume : **1 500 L**  
 Storage temperature : **+5°C ± 3°C**

**SINGLE HARVEST:**

Date of single harvest : **17.09.07**

**CONCENTRATION AND PURIFICATION OF THE SINGLE HARVEST**

DEAE Spherodex large column : Ion exchange chromatography on **18.09.07**  
 CL-6-B Sepharose column : Gel filtration on **19.09.07**  
 DEAE Sphérodex small column : Ion exchange chromatography on **19.09.07**

**CONCENTRATED PURIFIED VIRAL SUSPENSION :**

Manufacture date : **19.09.07**  
 Volume : **19 600 ml**  
 Storage temperature : **+5°C ± 3°C**

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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 : 10.09.07  
 Test off : 24.09.07  
 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 : 24.09.07  
 Result : Absence of hemadsorption

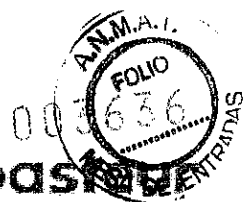
**Simian cells identification**

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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75/211

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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	: 26.09.07
Test off	: 10.10.07
Result	: <b>Absence of cytopathic effect</b>


*Human diploid cells*

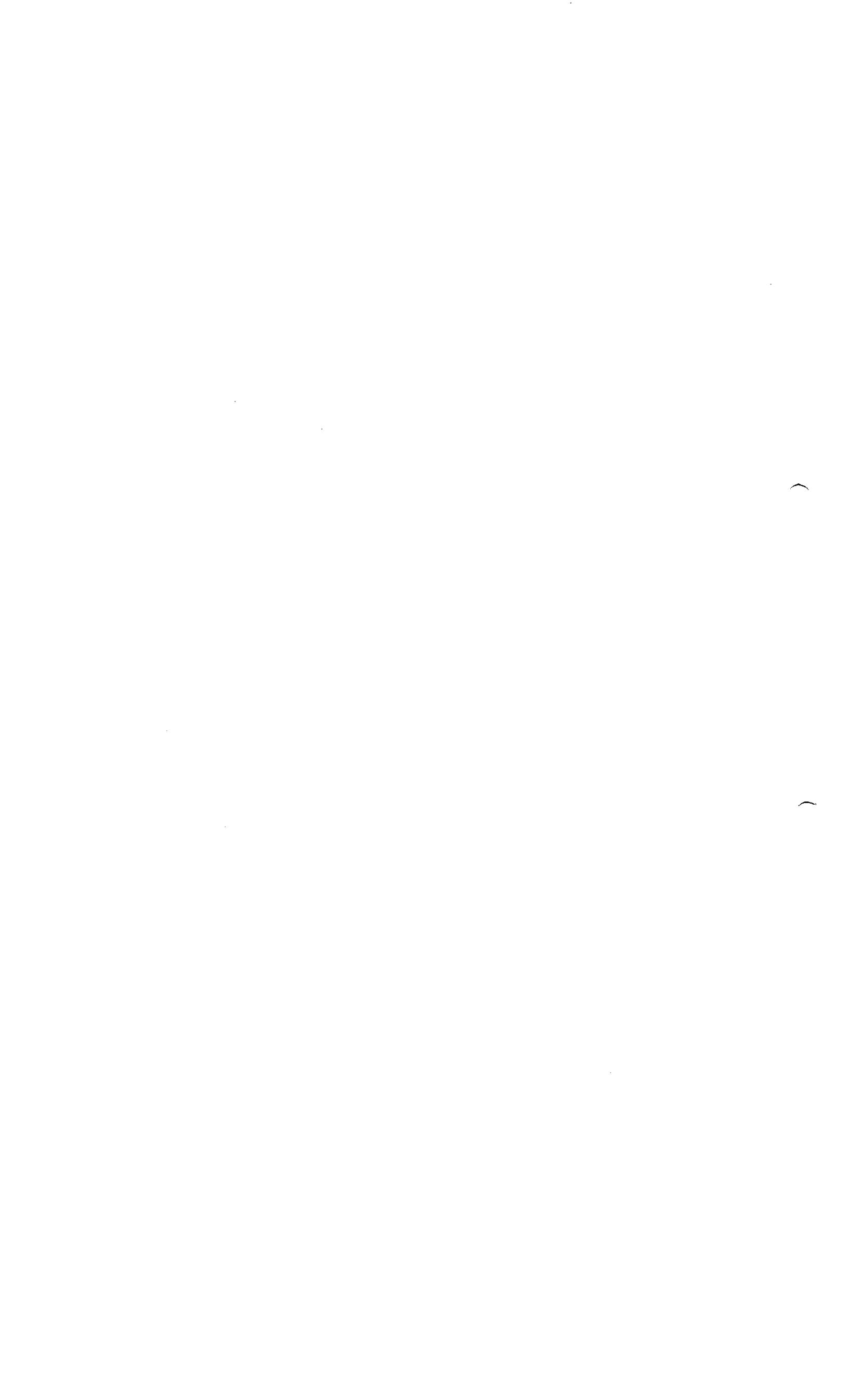
Method	: Studied through a microscope
Type of cells	: MRC5
Volume tested	: 10 ml
Temperature of incubation	: 36 ± 1° C
Test on	: 15.01.08
Test off	: 12.02.08
Result	: <b>Absence of cytopathic effect</b>

*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	: 30.10.07
Test off	: 13.11.07
Result	: <b>Absence of cytopathic effect</b>

  
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76/211


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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	: 28.03.08
Test off	: 11.04.08
<i>Subculture at 3<sup>rd</sup> day</i>	
Test on	: 31.03.08
Test off	: 14.04.08
<i>Subculture at 7<sup>th</sup> day</i>	
Test on	: 04.04.08
Test off	: 18.04.08
<i>Subculture at 14<sup>th</sup> day</i>	
Test on	: 11.04.08
Test off	: 25.04.08
<i>Subculture at 21<sup>th</sup> day</i>	
Test on	: 18.04.08
Test off	: 25.04.08
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	: 1 ml
Temperature of incubation	: 36 ± 1° C
Positive control	: <i>M. hyorhinis</i> and <i>M. orale</i>
Test on	: 13.12.07
Test off	: 20.12.07
Result	: No Mycoplasma detected by epifluorescence in cell culture

  
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