

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) 62/180

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 124th passage
Received : 22.05.79
Aventis Pasteur reference : ATCC-CCL 81 VERO F1415

Master Cell Bank:

Aventis Pasteur reference : Cell Bank A at 129th passage
Preparation date : 21.06.79
Storage temperature : liquid nitrogen

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

Master Cell Bank


: Cell Bank A at 129th passage

Working Cell Bank :

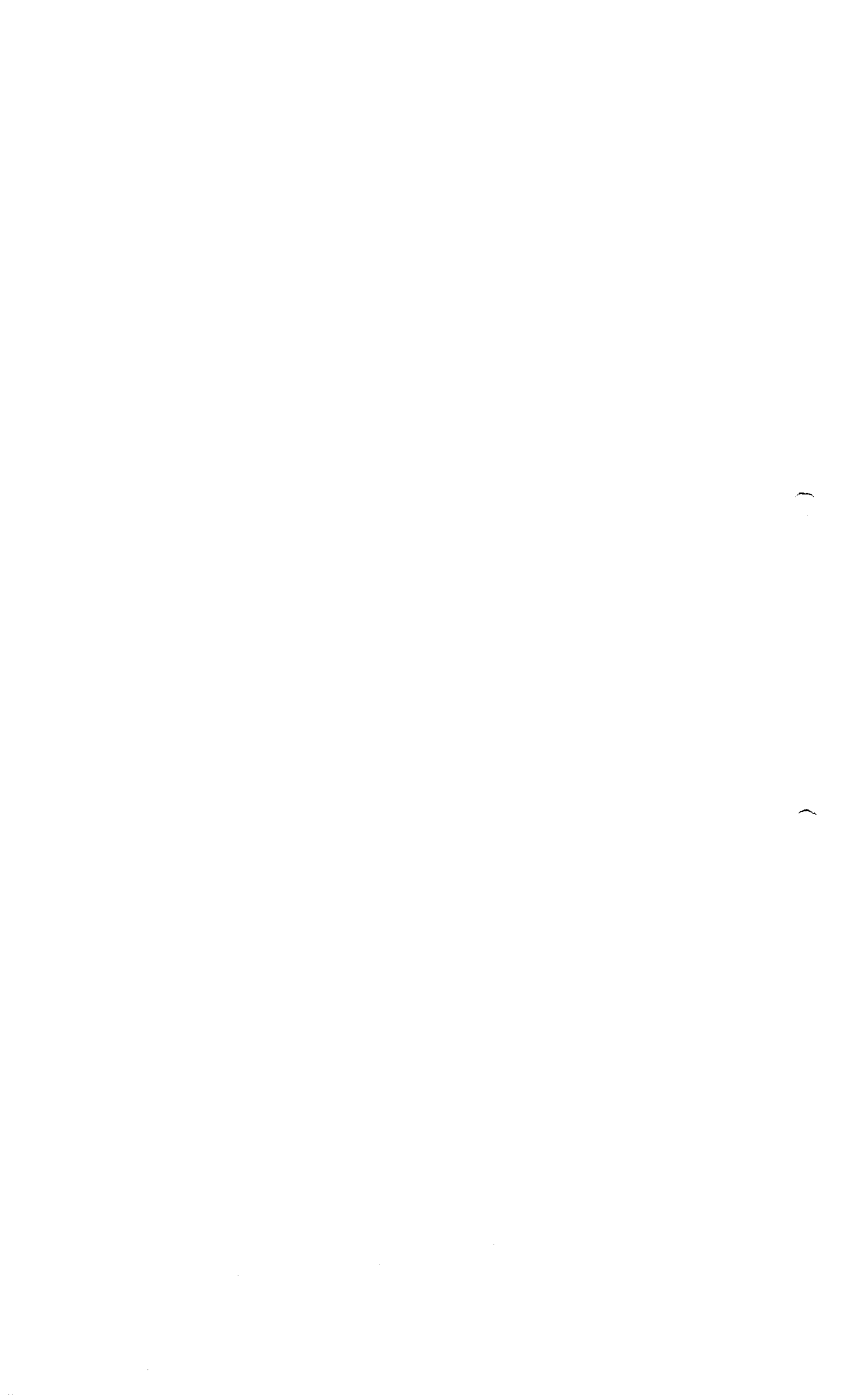
Aventis Pasteur reference
Preparation date
Release date
Storage temperature

: LS10 at 137th passage
: 27.10.98
: 18.12.00
: liquid nitrogen

352_CC5_SPL_AE.dot /19.09.11


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

Master Cell Bank

: Cell Bank A at 129th passage

Working Cell Bank :

Aventis Pasteur reference

: FA106611 (LS11) at 137th passage

Preparation date

: 29.04.02

Release date

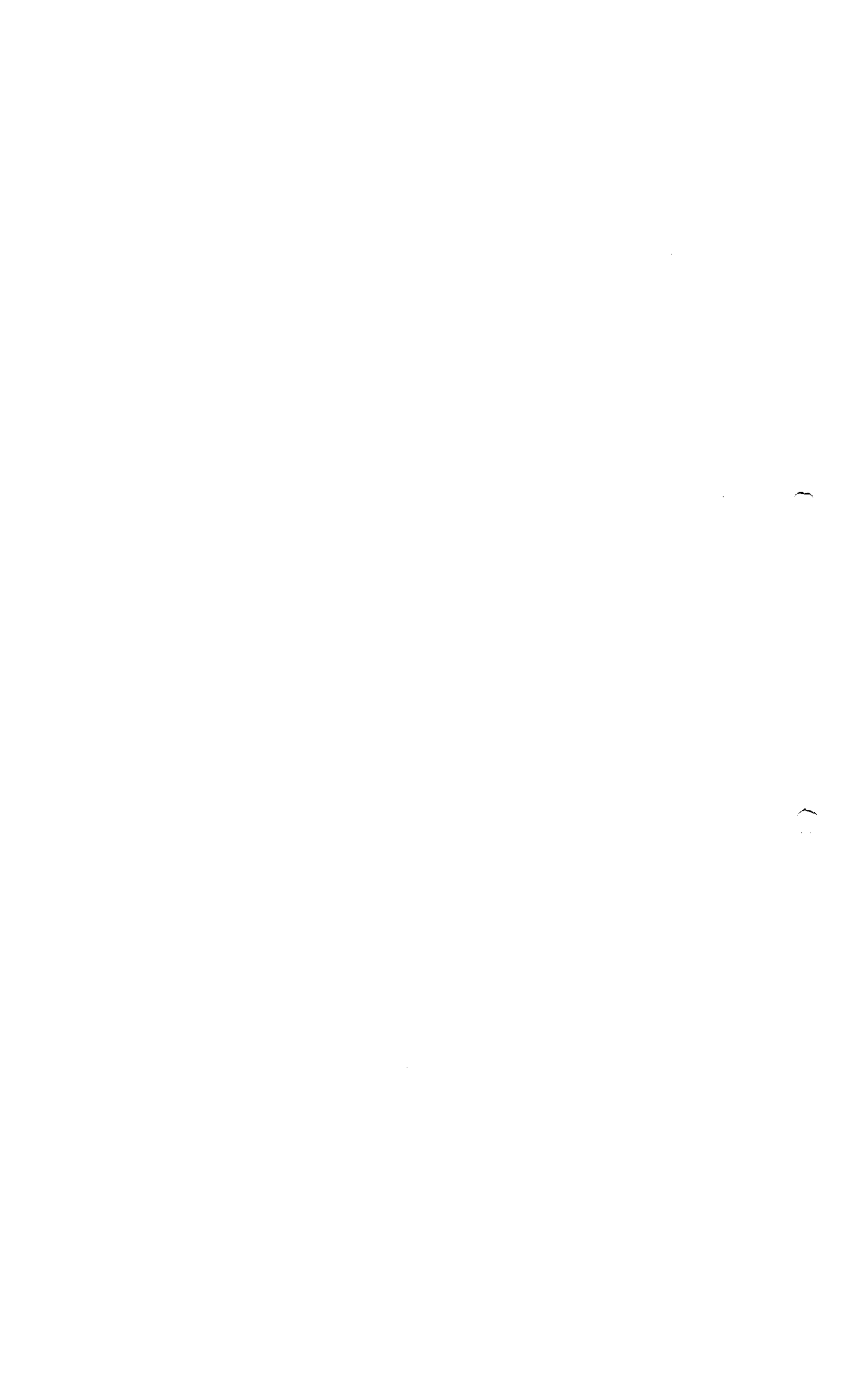
: 26.03.08

Storage temperature

: liquid nitrogen


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

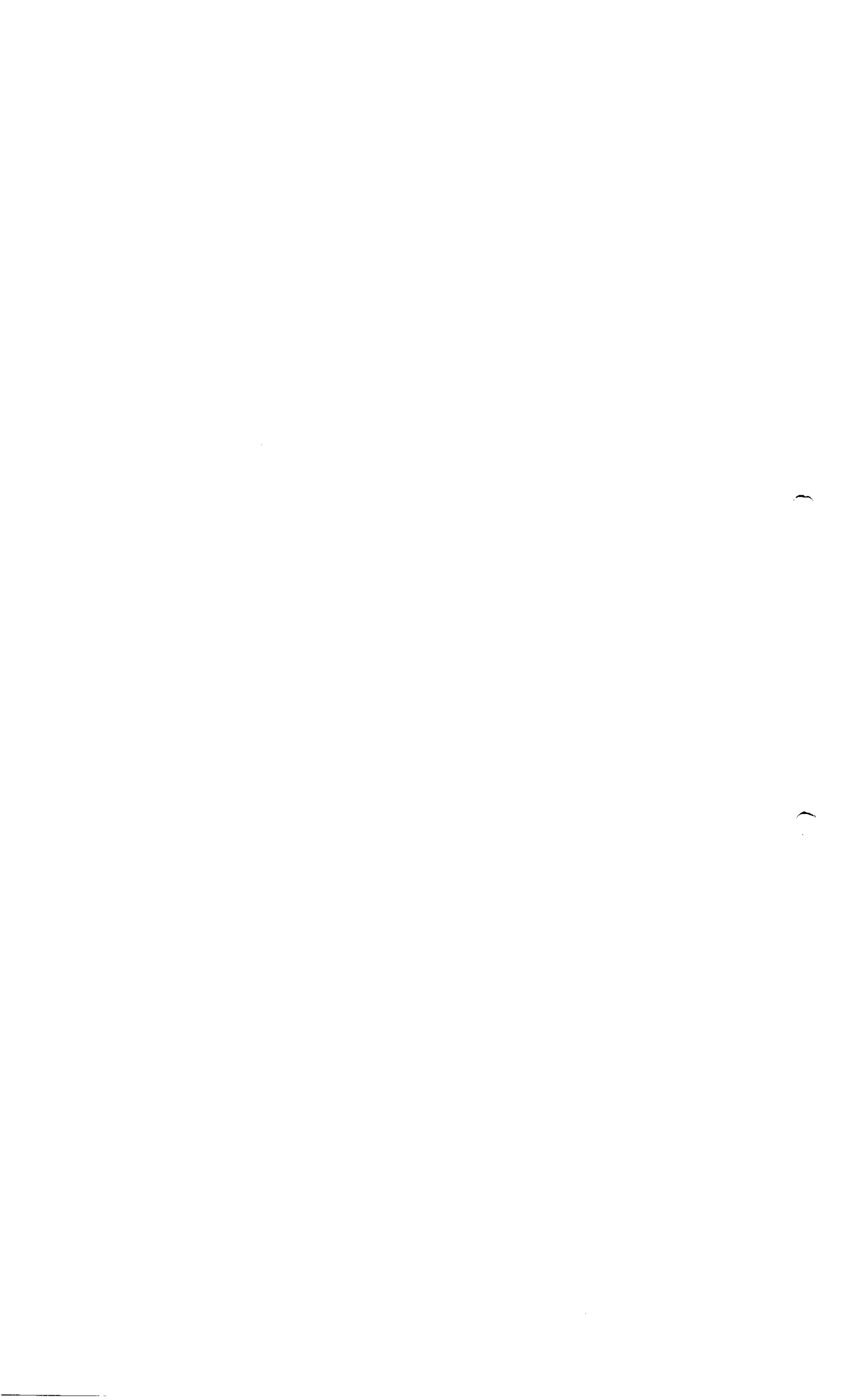
Virus strain : MAHONEY type 1
Original strain : 74/3-B3 - Pitman and Moore Company
Supplier : RIJKS Instituut Voor de Volksgezondheid (RIV)
Bilthoven - Netherlands
Received from supplier : 04.02.77
Cells used : Primary Monkey kidney cells of **Erythrocebus Patas**
Preparation date : 09.03.77
Release 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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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 Patas**
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 Patas**
Preparation date : 07.05.79
Release date : 26.09.79

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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) 67/180

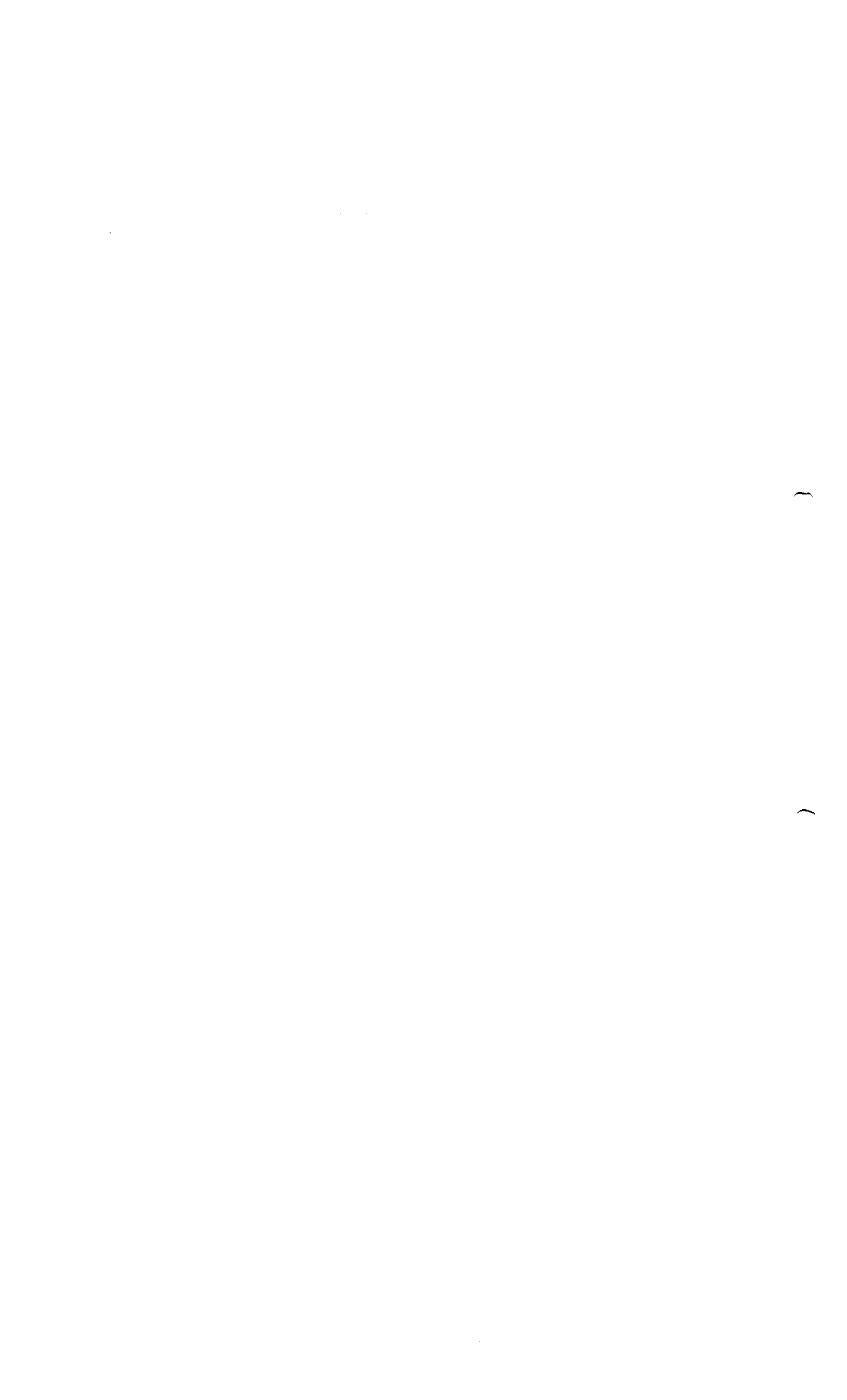
POLIOMYELITIS VACCINE (INACTIVATED)
 MASTER VIRUS SEED LOT - Type 3
 Lot Number 3011

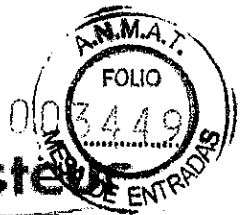
Virus strain	: SAUKETT type 3
Original strain	: 74/2-B2 - Statens Serum Institute, Copenhagen
Supplier	: RIJKS Instituut Voor de Volksgezondheid (RIV) Bilthoven - Netherlands
Received from supplier	: 04.02.77
Cells used	: Primary Monkey kidney cells of Erythrocebus Patas
Preparation date	: 09.03.77
Release date	: 03.11.77

POLIOMYELITIS VACCINE (INACTIVATED)
 INTERMEDIATE VIRUS SEED LOT - Type 3
 Lot Number 30113

Master seed lot	: 3011
Cells used	: Primary Monkey kidney cells of Erythrocebus Patas
Preparation date	: 18.05.79
Release date	: 15.10.79

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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 137th to 142nd passage : 07.08.03 to 28.08.03

Number of passage between PSL and WSL : 2

Preparation date : 09.09.03

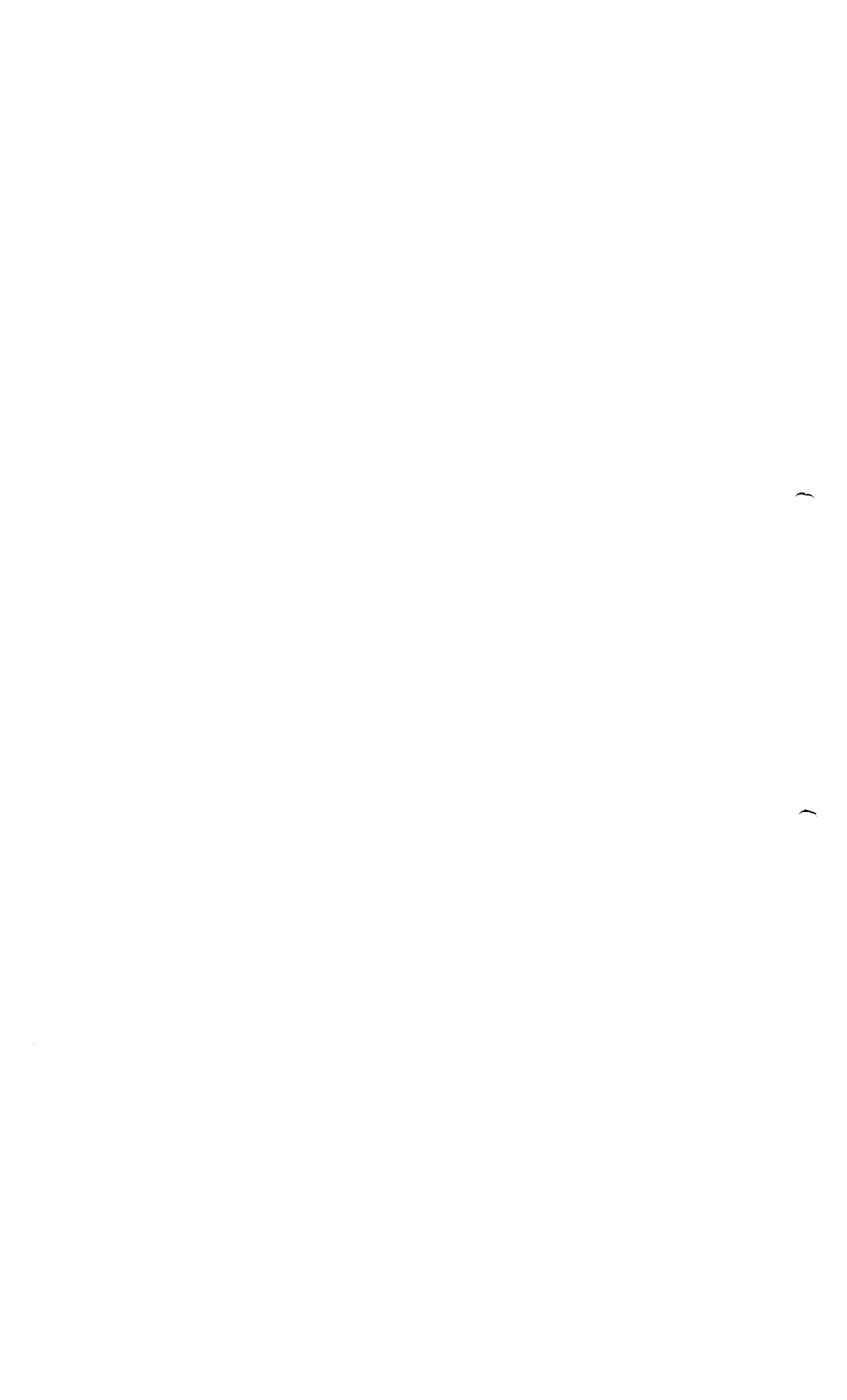
Release date : 15.04.04

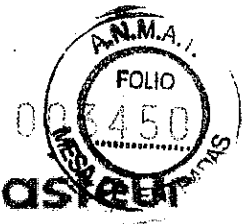
Storage temperature : ≤ -35°C

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

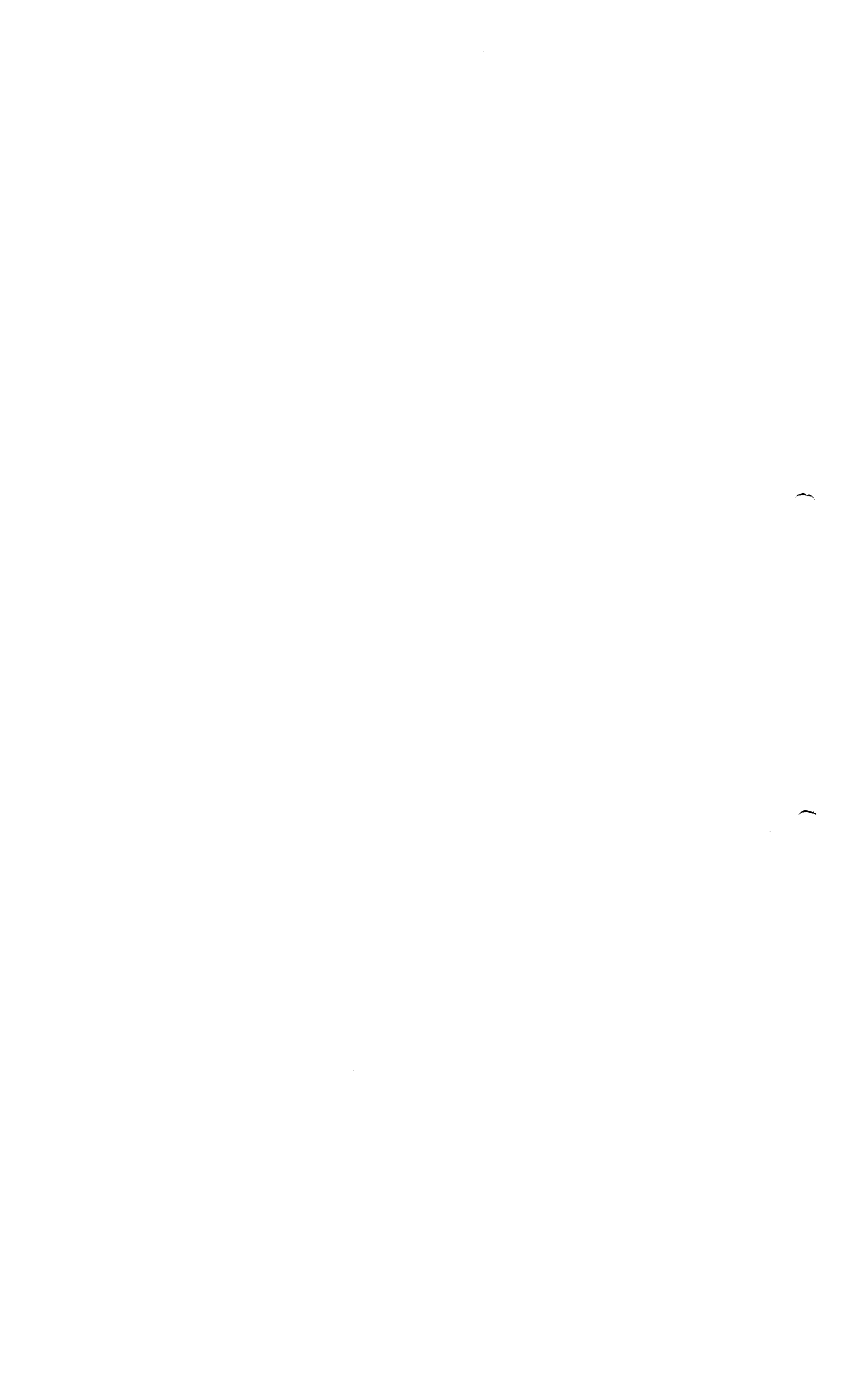
Working Cell Bank : LS10

Intermediate seed lot : 20112

Working seed lot : FA091251
Cell amplification from 137th to 142nd 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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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 137th to 142nd passage : 14.03.02 to 03.04.02

Number of passage between PSL and WSL : 2

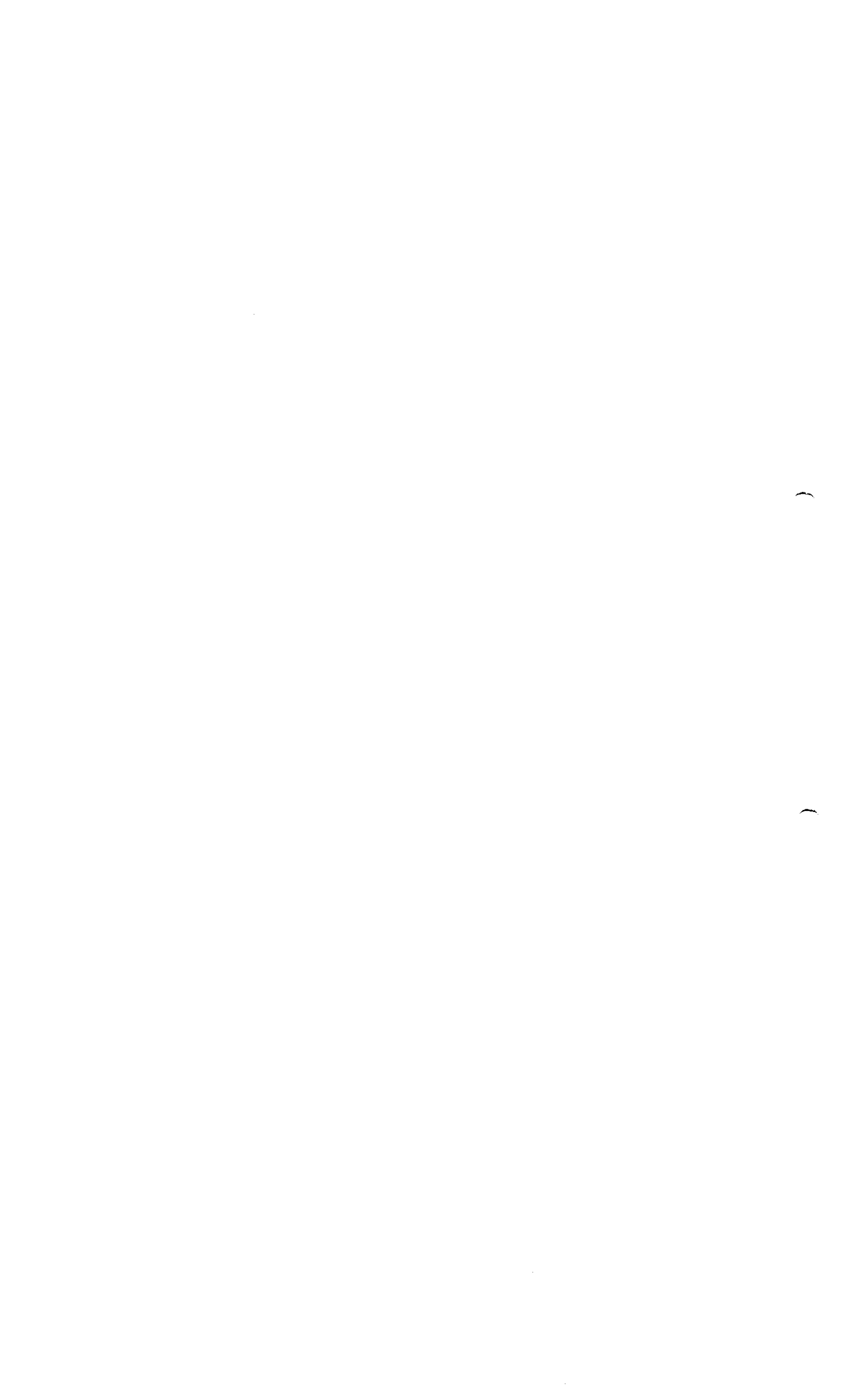
Preparation date : 17.04.02

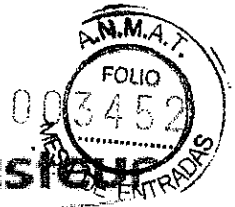
Release date : 09.01.03

Storage temperature : ≤ -35°C

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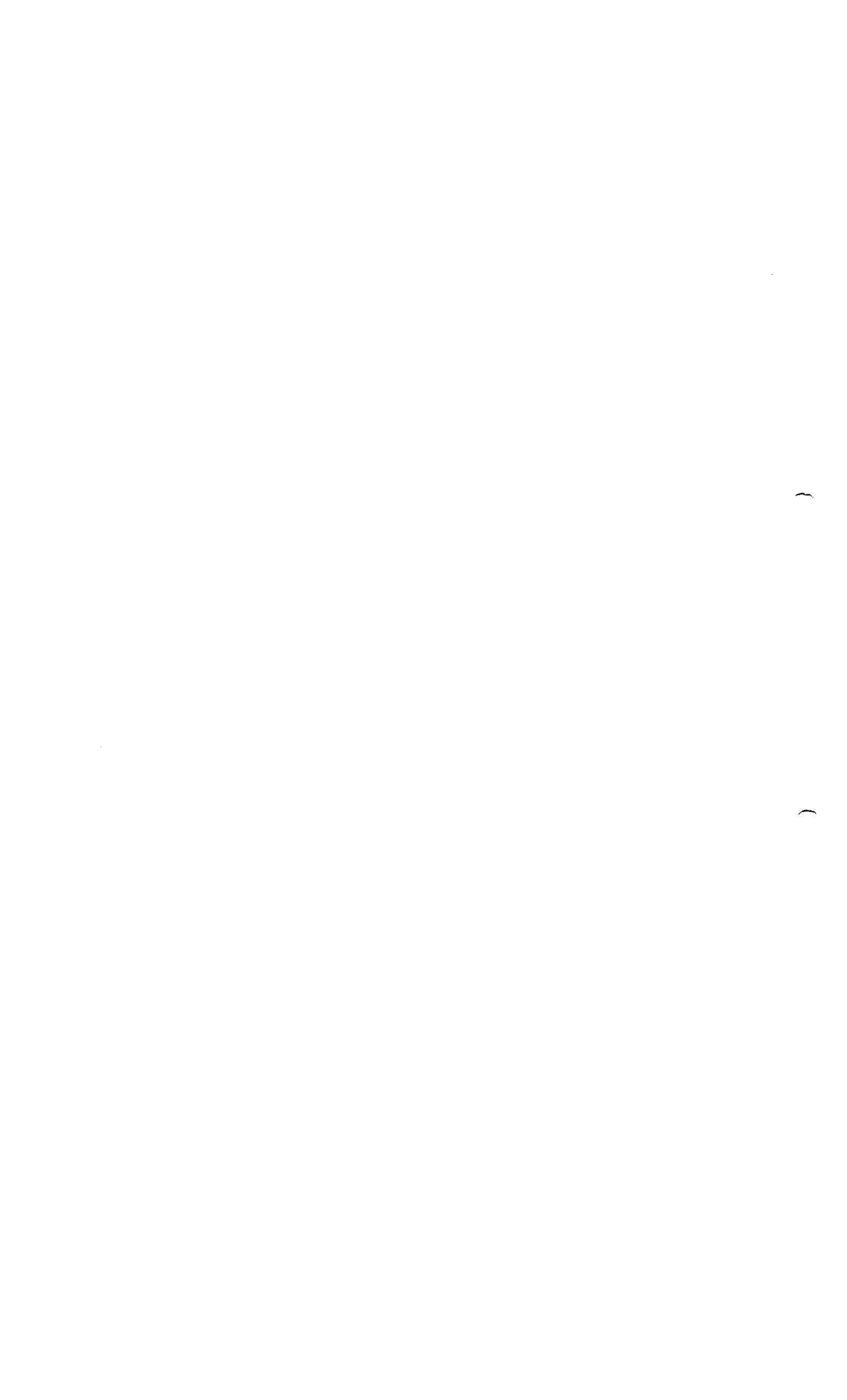
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SINGLE HARVEST (TYPE 1, 2 AND 3)

TESTS	ACCEPTANCE CRITERIA
ON CELLS	
OBSERVATION	Absence of cytopathic effect due to extraneous agents
TEST FOR HAEMADSORBING VIRUSES	Absence of hemadsorption
SIMIAN CELLS IDENTIFICATION	Positive identification
ON SUPERNATANT	
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
SINGLE VIRUS HARVEST	
POLIO VIRUS IDENTIFICATION	Positive
POLIO VIRUS CONCENTRATION	$\geq 10^7$ CCID ₅₀ /ml
BACTERIAL AND FUNGAL STERILITY	No microbial growth
TEST FOR MYCOPLASMA BY CULTURE METHOD	No growth of mycoplasma
CONCENTRATED PURIFIED VIRAL SUSPENSION	
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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SINGLE HARVEST - Type : 1
Lot Number : FA295889

CELL:

Working Cell Bank : FA106611
Date of thawing ampoule of WCB : 13.12.07
Thawing ampoule amount : One ampoule

VIRUS:

Virus Working Seed lot : FA159761
Date of inoculation : 07.01.08
Date of virus harvest : 09.01.08

CRUDE HARVEST:

Storage : from 11.01.08 to 14.01.08
Volume : 1 493 L
Storage temperature : +5°C ± 3°C

SINGLE HARVEST:


Date of single harvest : 14.01.08


CONCENTRATION AND PURIFICATION OF THE SINGLE HARVEST

DEAE Spherodex large column : Ion exchange chromatography on 15.01.08
CL-6-B Sepharose column : Gel filtration on 16.01.08
DEAE Sphérodex small column : Ion exchange chromatography on 16.01.08

CONCENTRATED PURIFIED VIRAL SUSPENSION :

Manufacture date : 16.01.08
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 nd passage
Number of cells tested	: 320*10 ⁶ cells
Test on	: 07.01.08
Test off	: 21.01.08
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	: 21.01.08
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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CONTROLS ON SUPERNATANTS:

Test for extraneous agents

Vero cells

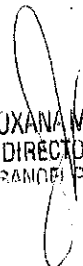

Method	: Studied through a microscope
Type of cells	: Vero
Volume tested	: 10 ml
Temperature of incubation	: 36 ± 1° C
Test on	: 29.01.08
Test off	: 12.02.08
Result	: Absence of cytopathic effect

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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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 3rd day</i>	
Test on	: 23.10.08
Test off	: 06.11.08
<i>Subculture at 7th day</i>	
Test on	: 27.10.08
Test off	: 12.11.08
<i>Subculture at 14th day</i>	
Test on	: 03.11.08
Test off	: 17.11.08
<i>Subculture at 21th 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, 152 nd passage
Volume tested	: 1 ml
Temperature of incubation	: 36 ± 1° C
Positive control	: <i>M. hyorhinis</i> and <i>M. orale</i>
Test on	: 10.04.08
Test off	: 17.04.08
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

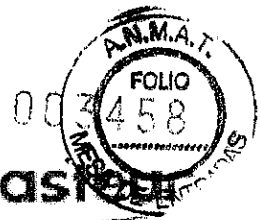
Method : Cytopathogenic effect on sensitive cells
Cell strain used : Hep 2
Test on : 23.07.08
Test off : 30.07.08
Virus concentration : 10^{8.97} CCID₅₀/ml
Result : Conforms

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	:	16.01.08	
Test off	:	30.01.08	
Result	:	No microbial growth	

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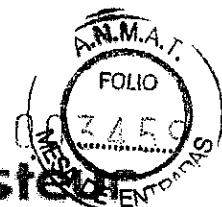
Test for Mycoplasma by culture method

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	: <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 3rd day</i>	
Test on	: 23.10.08
Test off	: 06.11.08
<i>Subculture at 7th day</i>	
Test on	: 27.10.08
Test off	: 12.11.08
<i>Subculture at 14th day</i>	
Test on	: 03.11.08
Test off	: 17.11.08
<i>Subculture at 21th day</i>	
Test on	: 10.11.08
Test off	: 17.11.08
Result	: No growth of Mycoplasma


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CONTROLS ON CONCENTRATED PURIFIED VIRAL SUSPENSION :

Protein content

Method : Spectrophotometry
Date : 12.02.08
Result : 105.90 µg/ml

D Antigen content

Method : ELISA
Reference standard : 28.1.99
Date : 21.01.08
Result : 11 915 D Antigen U/ml

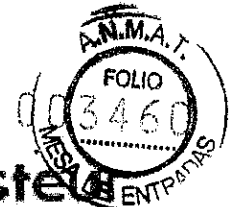
Bacterial and fungal sterility

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 : 21.01.08
Test off : 04.02.08
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, SANOFI PASTEUR S.A.



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influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch) 79/180

SINGLE HARVEST - Type : 1
Lot Number : FA297421

CELL:

Working Cell Bank : FA106611
Date of thawing ampoule of WCB : 27.12.07
Thawing ampoule amount : One ampoule

VIRUS:

Virus Working Seed lot : FA159761
Date of inoculation : 21.01.08
Date of virus harvest : 23.01.08

CRUDE HARVEST:

Storage : from 25.01.08 to 28.01.08
Volume : 1 486 L
Storage temperature : +5°C ± 3°C

SINGLE HARVEST:

Date of single harvest : 28.01.08

CONCENTRATION AND PURIFICATION OF THE SINGLE HARVEST

DEAE Spherodex large column : Ion exchange chromatography on 29.01.08
CL-6-B Sepharose column : Gel filtration on 30.01.08
DEAE Sphérodex small column : Ion exchange chromatography on 30.01.08

CONCENTRATED PURIFIED VIRAL SUSPENSION :

Manufacture date : 30.01.08
Volume : 19 400 ml
Storage temperature : +5°C ± 3°C

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

