


3.2.P.6

**Certificate of Analysis - Pertussis Immunogenicity Reference**

  
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## Ph. Eur. Reference Standard - LEAFLET

### **BORDETELLA PERTUSSIS MOUSE ANTISERUM BRP batch 1**

*Bordetella pertussis* mouse antiserum BRP batch 1 is intended for use in the serological potency assay of acellular pertussis vaccine components according to the Ph. Eur. General Chapter 2.7.16 *Assay of pertussis vaccine (acellular)*. The BRP consists of freeze-dried mouse serum. The BRP is presented in vials with an assigned activity of:

Anti-pertussis toxin	19.5 ELU <sup>1</sup> per vial
Anti-filamentous haemagglutinin	69 ELU per vial
Anti-pertactin	17 ELU per vial
Anti fimbrial 2 and 3 antigens	28 ELU per vial

### STORAGE

Keep vials unopened at -20 °C. Do not store at lower temperatures to avoid deterioration of the rubber stoppers.

### USE

- Allow the vial and content to reach room temperature.
- Tap vial gently to collect material at the bottom.
- Using an appropriate syringe reconstitute the reference preparation by injecting 500 µl of water for injections R or milliQ water
- Use as soon as possible after reconstitution. Do not freeze or store for subsequent use.

### CAUTION

*Bordetella pertussis* mouse antiserum BRP batch 1 is not appropriate for administration to humans and/or to animals. This preparation must be handled according to the appropriate QA system for biological testing laboratories. Please refer to the

<sup>1</sup> ELU : ELISA Unit



\* 0 0 B 1 1 4 2 0 0 0 5 . 0 \*

Catalogue code: B1142000

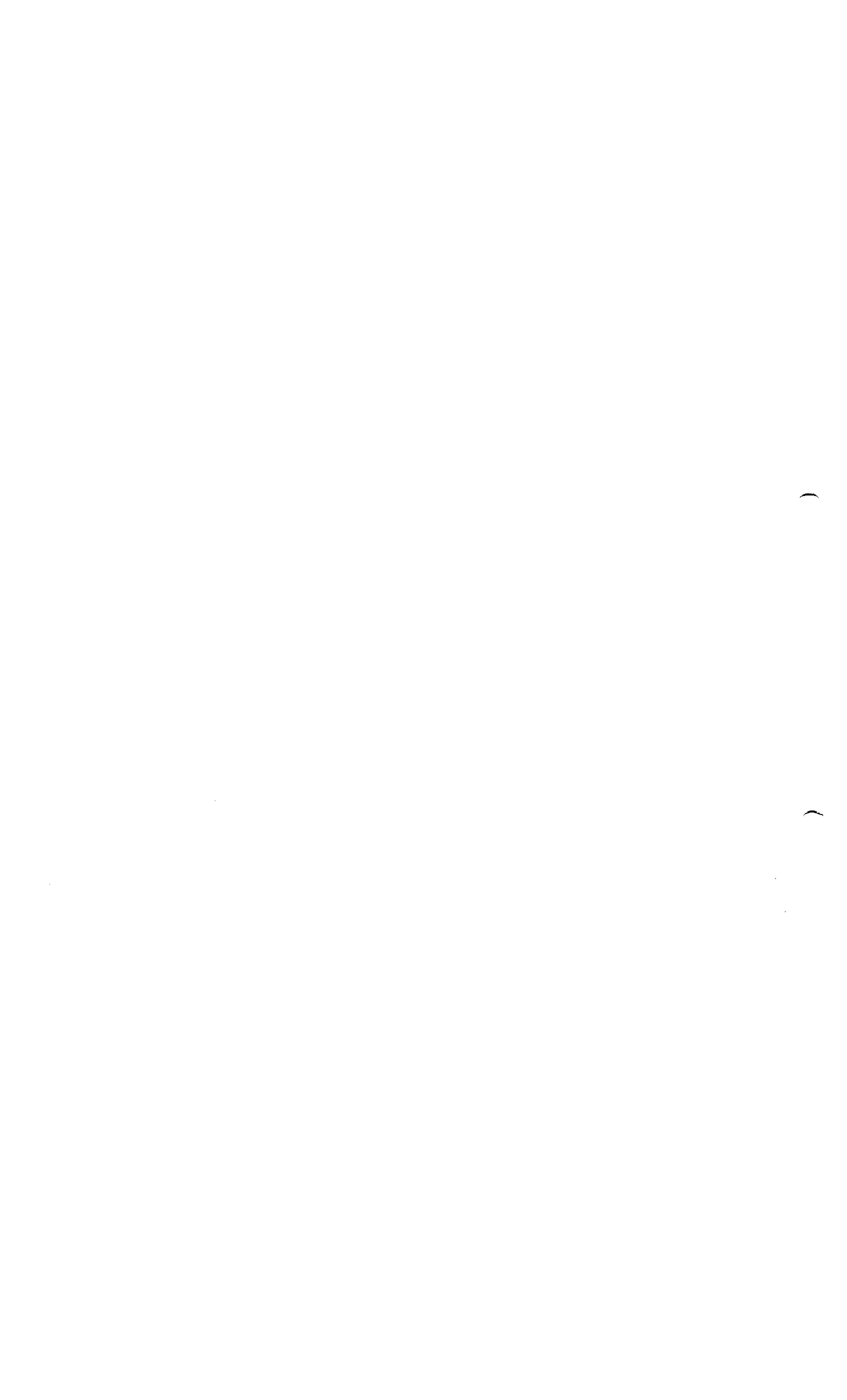
Revision 05

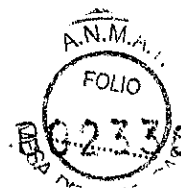
Date of issue: 27/10/2008

1/2

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corresponding safety data sheet, which can be downloaded from the internet web site of the EDQM (<http://www.edqm.eu>) or is delivered upon request.

**LITERATURE**

Fuchs, R. Dobbelaer. *Collaborative study for the establishment of a European Pharmacopoeia Biological Reference Preparation for Bordetella pertussis mouse antiserum for serological potency testing of acellular pertussis vaccines.* Pharmeuropa Bio 2001-2, 25-42, 2001.



\* 0 0 1 1 4 2 0 0 0 5 . 0 \*

Catalogue code: B1142000

Revision 05

Date of issue: 27/10/2008

2/2

  
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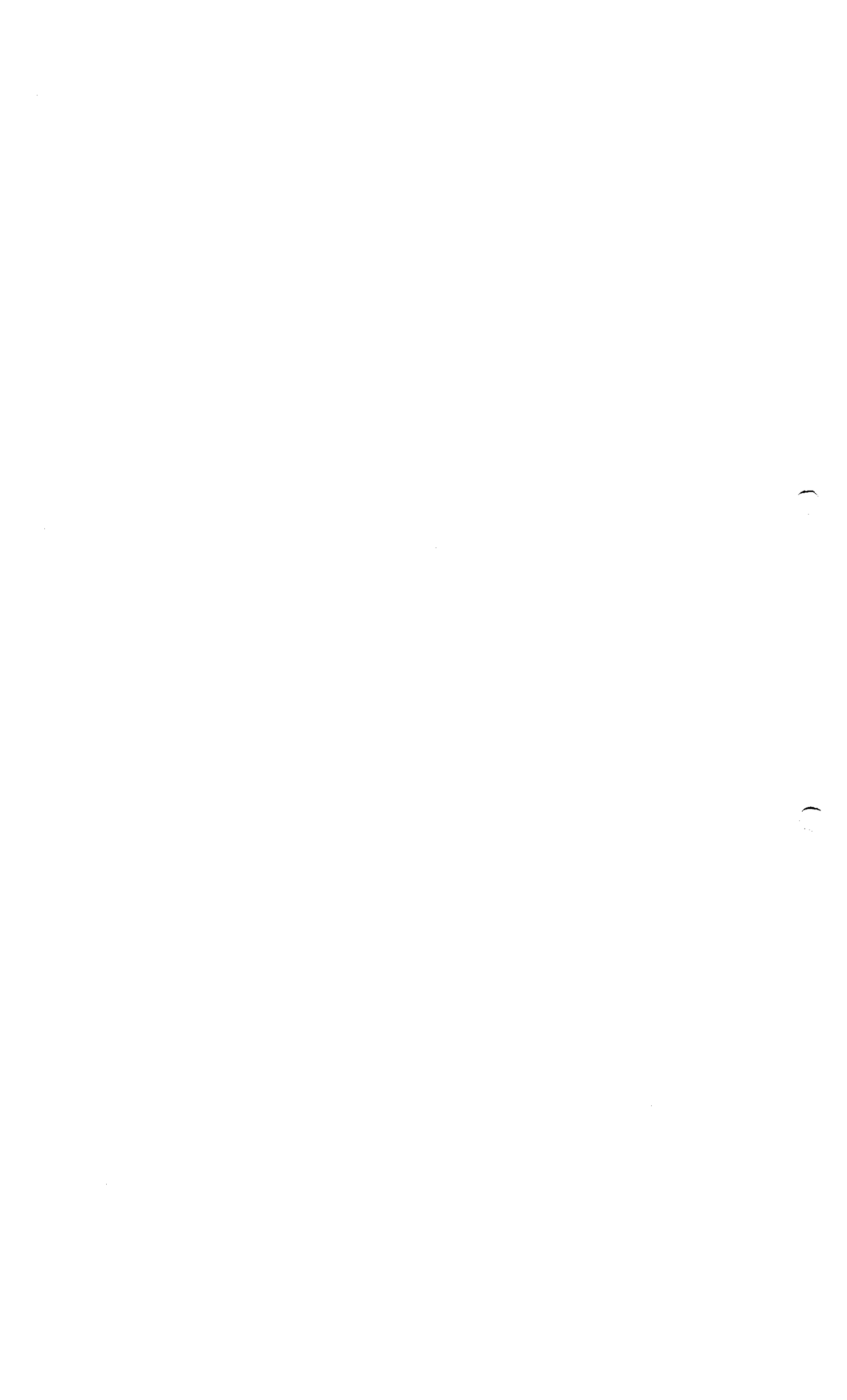


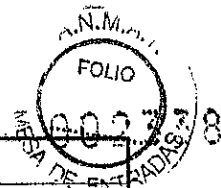


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**Certificate of Analysis - Pertussis Immunogenicity Reference Vaccine**

	
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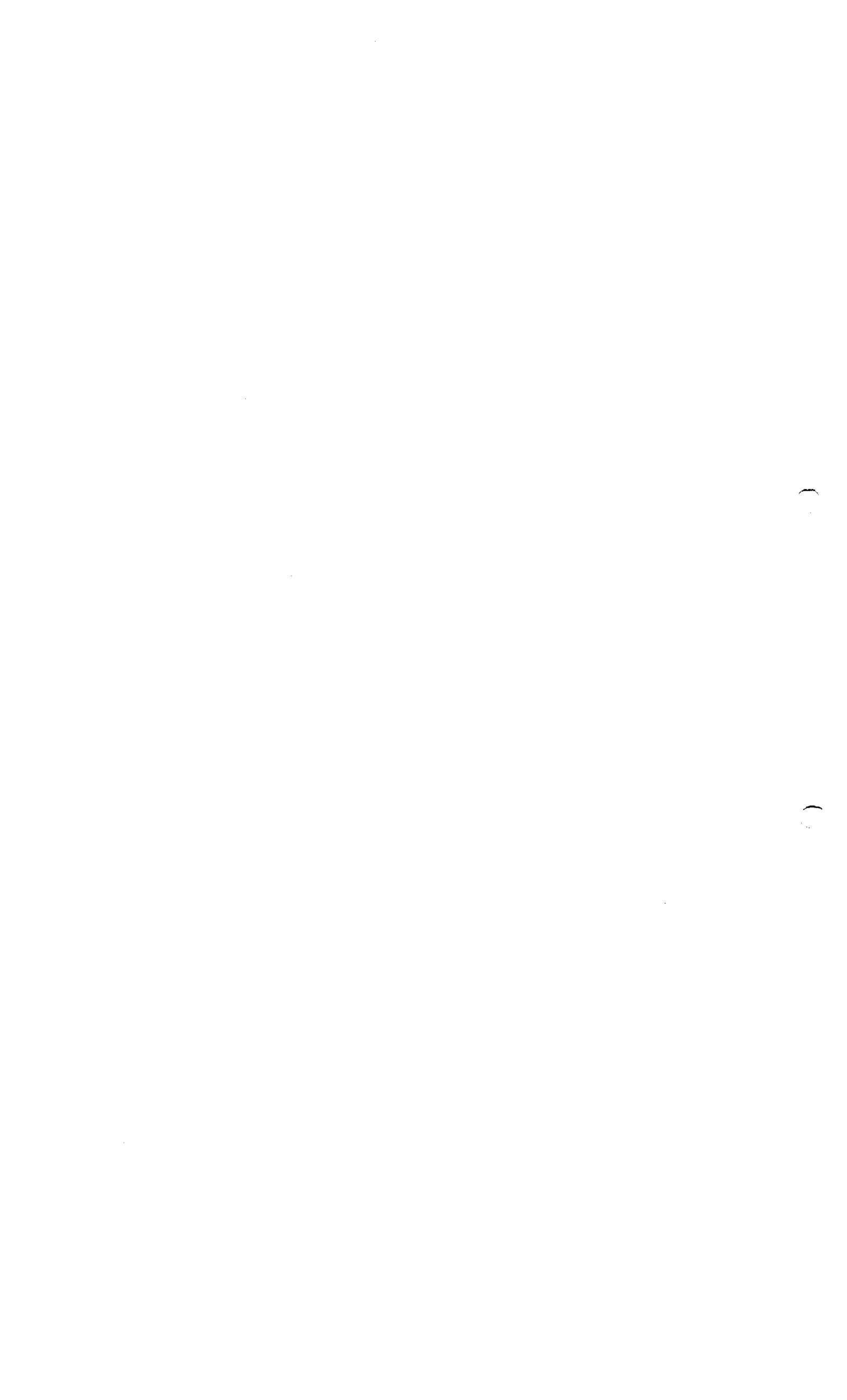
<b>Aventis Pasteur SA</b>	RECORD	
<b>QUALITY CONTROL</b>	<b>QUALITY CONTROL CERTIFICATE</b> <b>352 AL2I VACCINE</b> <b>FILLED PRODUCT</b>	Page 1 of 2
		<b>APPENDIX</b>

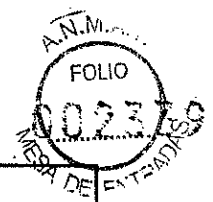
Batch N° : FA61003-03

Date of Production : 24 / 06 / 2004

TESTS	TEST REFERENCE.	SOP	SPECIFICATION	SPECIFICATION REFERENCE	RESULTS
Aspect	Technique AvP	ABC 20080	Whitish and cloudy suspension	Internal specification	Comply
Extractable Volume	F.E. 2.9.17	ABC 20072	≥Nominal Volume	Internal specification	Comply
Aluminium Content	F.E. 2.5.13	ABC 20108.	0,80 - 1,60 mg/ml	Internal specification	1,20 mg/ml
Diphtheria Identification	F.E. 2.7.1	ABC 20118	Positive	-----	Comply
Tetanus Identification	F.E. 2.7.1	ABC 20118	Positive	-----	Comply
Haemophilus Identification	F.E. 2.7.1	ABC 20128	Positive	-----	Comply
Pertussis: FHA & Pertussis toxoid Identification	F.E. 2.7.1	001326 (B002981/06)	Positive	-----	Comply
Hepatitis B Identification	F.E. 2.7.1	ABC 20075	Positive	-----	Comply
Polio Identification	F.E. 2.7.1	ABC 20160	Positive	-----	Comply


  
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 DIRECTORA TÉCNICA      DIRECTOR  
 SANOFI PASTEUR S.A.      SANOFI PASTEUR S.A.





<b>Aventis Pasteur SA</b>	<b>REGISTRO</b>	
<b>QUALITY CONTROL</b>	<b>QUALITY CONTROL CERTIFICATE</b> <b>352 AL2I VACCINE</b> <b>FILLED PRODUCT</b>	Page 2 of 2
		<b>APPENDIX</b>

Batch N°: PFA61003-03

Date of Production: 24 / 06 / 2004


TESTS	TEST REFERENCE.	SOP	SPECIFICATION	SPECIFICATION REFERENCE	RESULTS
Bacterial Endotoxines	F.E. 2.6.14	ABC 20037	For Information	-----	63 < END L25 <sup>US</sup> / <sub>dos</sub>
Pyrogens Test (100)	F.E. 2.6.8	PTB37-03 Lab. IAE	Conform	F.E.	Comply
Abnormal Toxicity	F.E. 2.6.9	I-TA.30.303 Lab. BIOL	Conform	F.E.	Comply
Bacterial and Fungal Sterility	F.E. 2.6.1	ABC 20039	Conform	F.E.	Comply

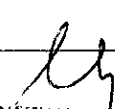
**APPROVAL OF RESULTS**

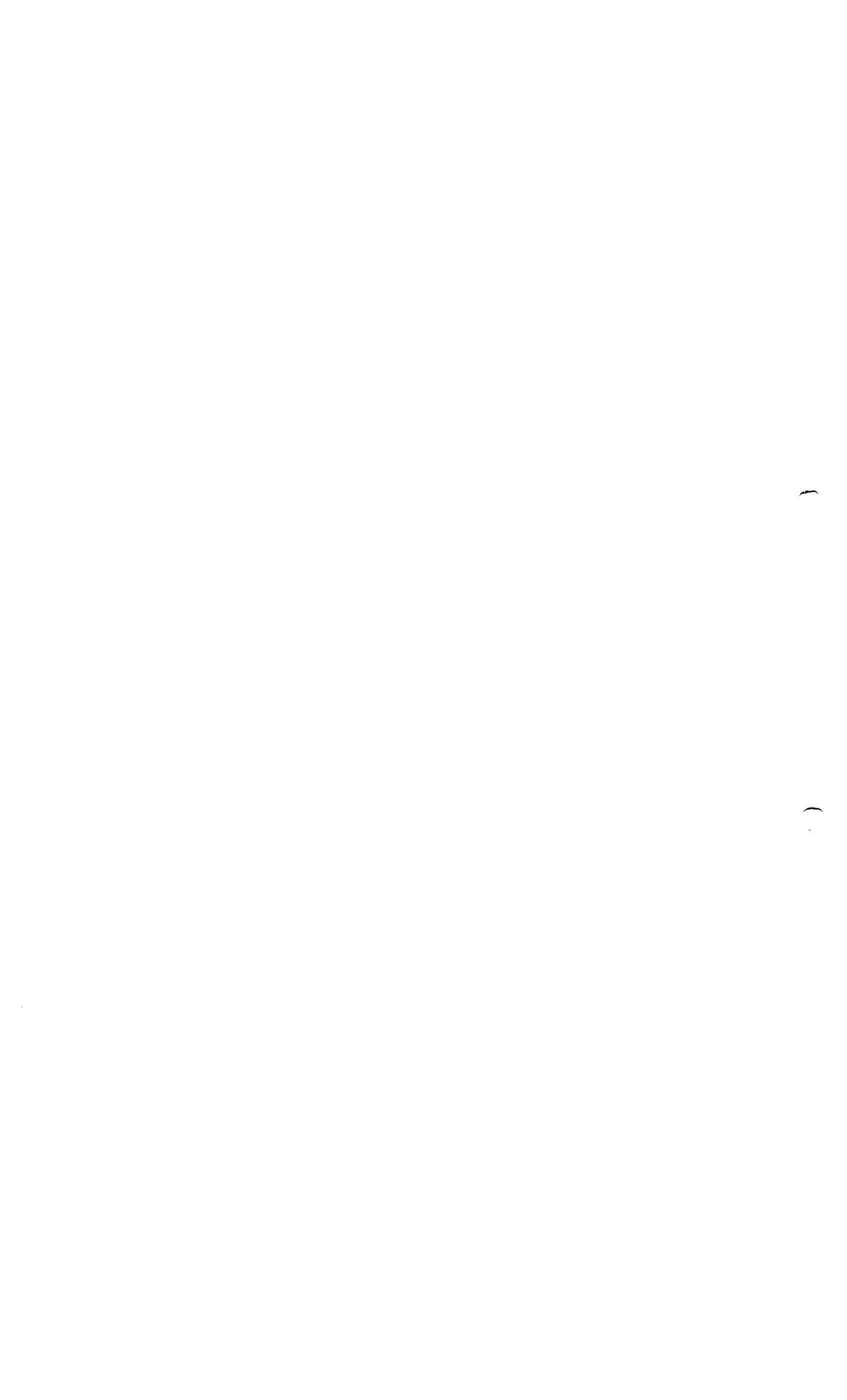
**CONCLUSION:**

*This batch complies with all the specifications established for AL2I filled product.*

<b>Quality Control Manager:</b>	MARTA I. GRINBERG
<b>Signature / date</b>	<i>[Signature]</i> 18-03-2005
<b>Comments:</b>	NA



  
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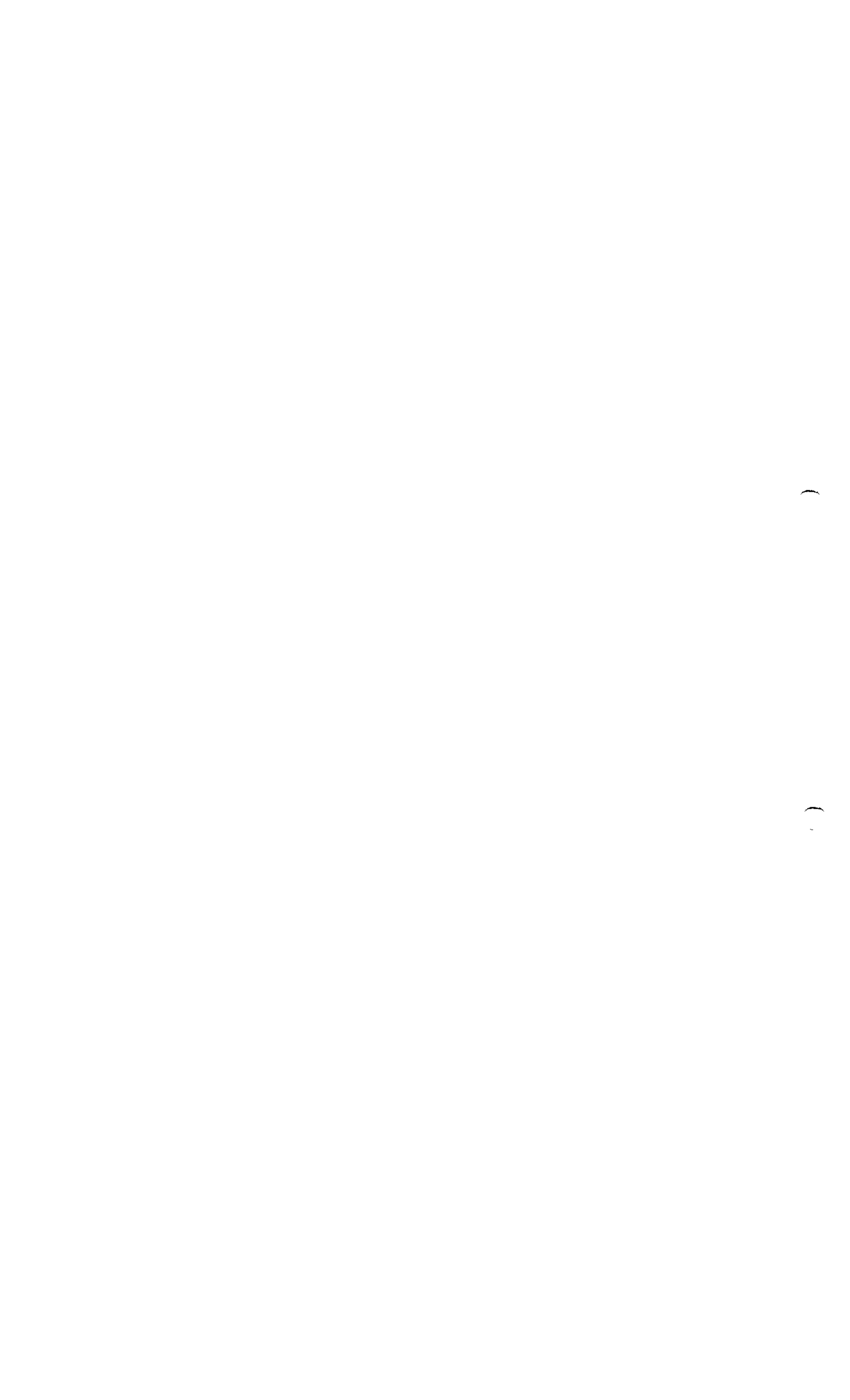
  
 CHRISTIAN DUMÉNIL  
 JEFE DE LABORATORIO  
 SANOFI PASTEUR S.A.



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**Certificate of Analysis - D-Antigen Content Reference**

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**Certificate of analysis: Poliomyelitis in-house reference**  
**Batch N°11-07-07 for D-antigen titration**

**Manufacturing**

- Vero cell  
142th passage for bulk production
- Concentration of the product on Biomax Pellicon II (trivalent step) on the 11-07-07
- Filtration of concentrated product on Millidisk MCGL on the 11-07-07 and stored at +5°C.
- Filling on the 16.07.07 and stored at +5°C
- Freezing at -70°C on the 24.07.2007 after controls.

**Controls**


- D Antigen titer serotype 1 (parallel lines method) → **1149** UD/ml
- D Antigen titer serotype 2 (parallel lines method) → **269** UD/ml
- D Antigen titer serotype 3 (parallel lines method) → **1016** UD/ml

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06/07/2010  


Page 1 sur 1

  
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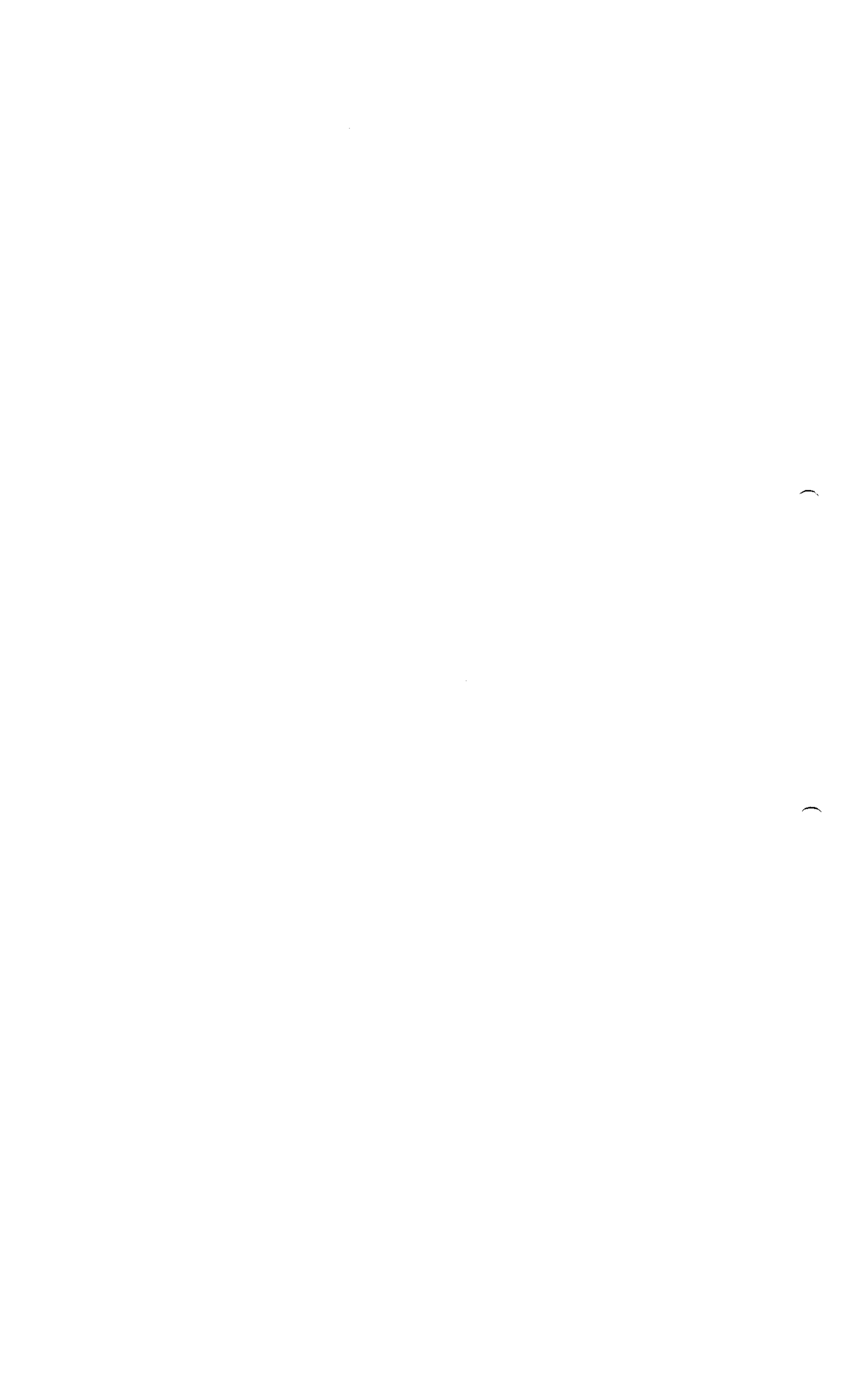


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**Certificate of Analysis - Aluminum Content External Reference**

  
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# Certificate of Analysis

Material : 23174.233  
Batch : 10E250018

Cuivre (II) sulfate pentahydraté AnalAR NORMAPUR  
Expires end of 04/2015

CHARACTERISTICS	SPECIFICATIONS	MEASURED VALUES
Titre	99,0 --> 100,5 %	99,1 %
Insolubilité dans l'eau	Max. 50 ppm	Max. 50 ppm
N total (Azote)	Max. 10 ppm	Max. 10 ppm
Cl (Chlorure)	Max. 5 ppm	Max. 5 ppm
Ca (Calcium)	Max. 50 ppm	2 ppm
Fe (Fer)	Max. 30 ppm	Max. 30 ppm
K (Potassium)	Max. 10 ppm	1 ppm
Mg (Magnésium)	Max. 50 ppm	2 ppm
Na (Sodium)	Max. 50 ppm	3 ppm
Ni (Nickel)	Max. 50 ppm	Max. 50 ppm
Pb (Plomb)	Max. 50 ppm	Max. 50 ppm
Zn (Zinc)	Max. 0,03 %	Max. 0,03 %

We certify that this batch conforms to the specifications listed above.  
BDL : Below detected limit.

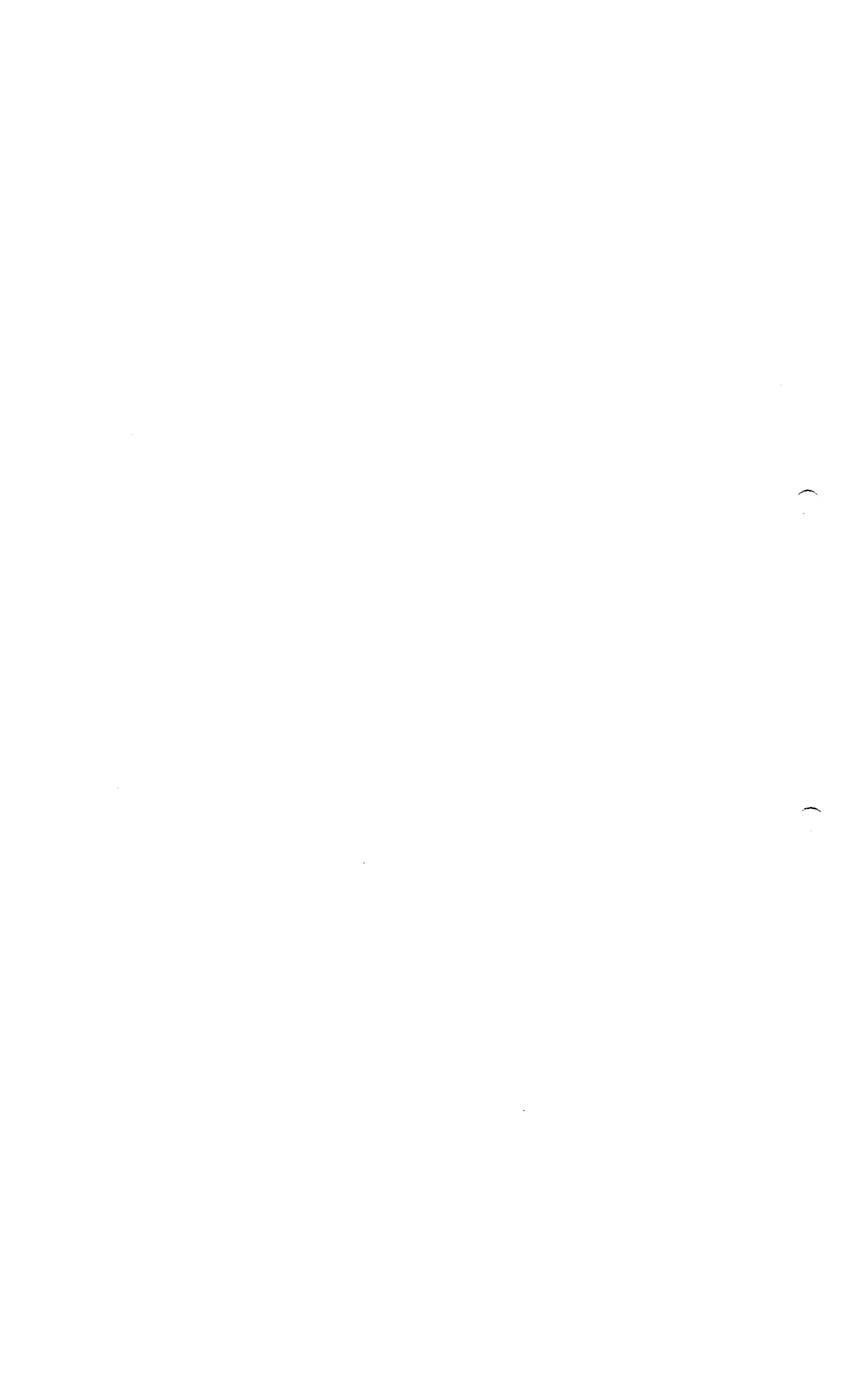
Wendy Mathues Head of laboratory - Haasrode  
VWR International  
Document printed on 09/2010

*This document has been produced electronically and is valid without a signature.*

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**Certificate of Analysis - Diphtheria Identity Reference**

  
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sanofi pasteur

The vaccines division of sanofi-aventis Group

Product Quality and Disposition Department

**QUALITY CONTROL RELEASE**  
**PURIFIED DIPHTHERIA TOXOID**

Lot number : FA024245

Protein nitrogen content : 2.33 mg/ml  
Residual formaldehyde content : 15.37 µg/ml  
Toxoid content : 4750 Lf/ml  
Antigenic purity : 2039 Lf/mg of protein nitrogen  
Bacterial and fungal sterility : Conforms  
Specific toxicity : Conforms  
Irreversibility of toxoid : Conforms

Expiry date : OCTOBER 2002

**GENERAL CONCLUSION : Conforms**

Release date : 17.02.2000

Product Quality and Disposition Department

Anne LAMOTTE

ADP\_OC2\_HSP.dot/20.07.2010

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**Certificate of Analysis - Tetanus Identity Reference**



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**QUALITY CONTROL RELEASE**  
**PURIFIED TETANUS TOXOID**

Lot number : FA063251

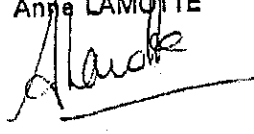
Protein nitrogen content : 4.32 mg/ml  
Residual formaldehyde content : 70.18 µg/ml  
Toxoid content : 4725 Lf/ml  
Antigenic purity : 1094 Lf/mg of protein nitrogen  
Bacterial and fungal sterility : Conforms  
Specific toxicity : Conforms  
Irreversibility of toxoid : Conforms

EXPIRY DATE : DECEMBER 2003

GENERAL CONCLUSION : Conforms

Release date : 06.03.2001

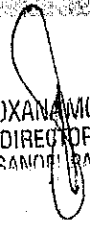
Product Quality and Disposition Department  
Anne LAMOTTE



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3.2.P.6

**Certificate of Analysis - Pertussis Identity (PT) Reference**

  
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**Certificate of Analysis - Pertussis Identity (FHA) Reference**

  
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