



Certificate of Analysis

Material : 20913.294
Batch : 09C270014

Formaldéhyde 37 % Ph.Eur.
Expires end of 03/2012


CHARACTERISTICS	SPECIFICATIONS	MEASURED VALUES
Titre	34,5 → 38,0 %	37,4 %
Aspect	Liquide limpide incolore	Liquide limpide incolore
Identification A	Conforme	Conforme
Identification B	Conforme	Conforme
Identification C	Conforme	Conforme
Identification D	Conforme	Conforme
Solution S	Conforme	Conforme
Aspect de la solution	Conforme	Conforme
Acidité	Conforme	Conforme
Méthanol (V/V)	9,0 → 15,0 %	14,6 %
Cendres sulfuriques	Max. 0,1 %	Max. 0,1 %
Solvants résiduels	Conforme	Conforme


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

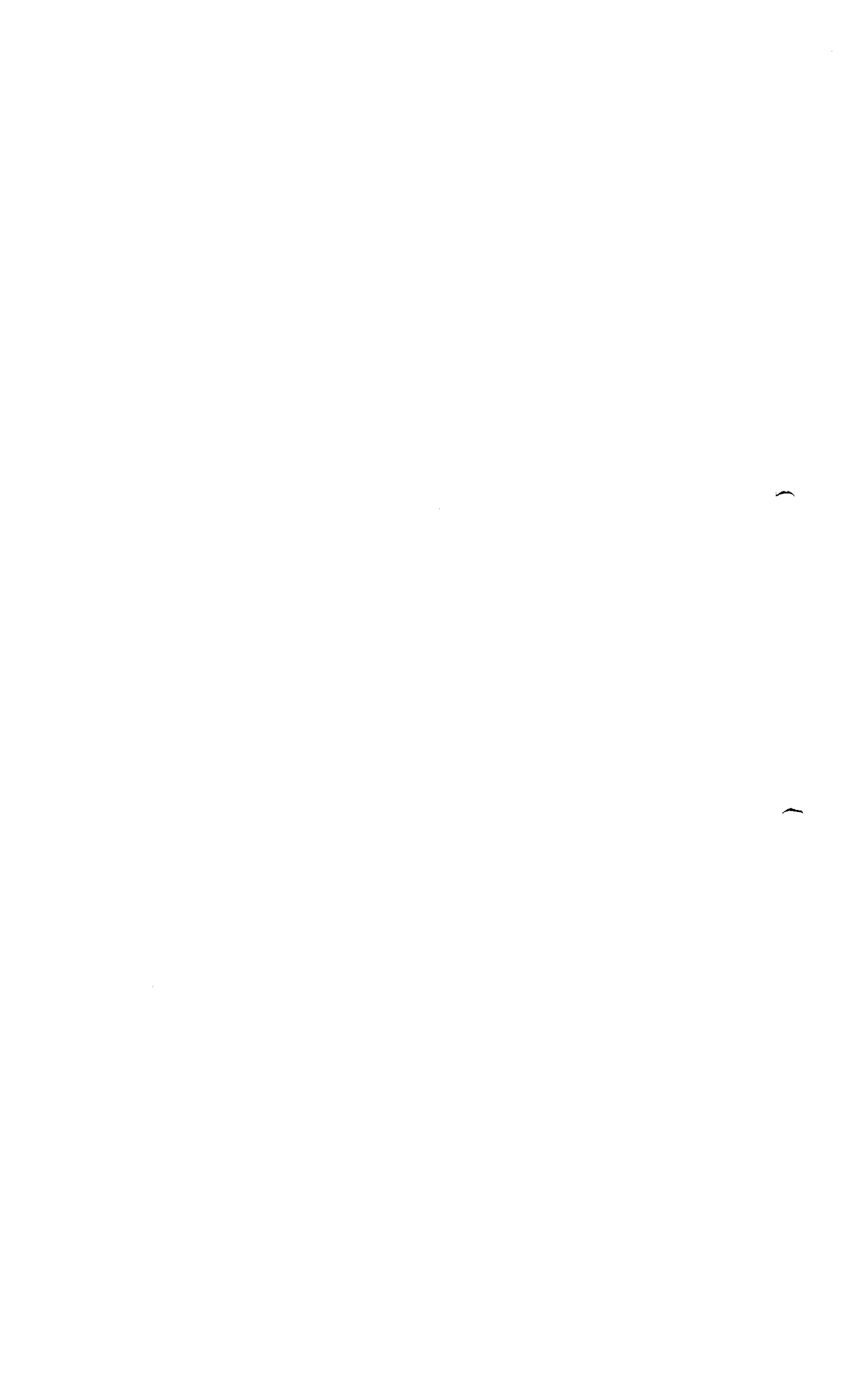
Wendy Mathues Head of laboratory - Haasrode
VWR International
Document printed on 17.06.2010

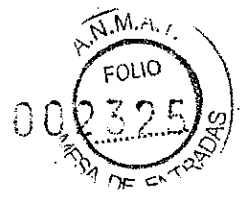
This document has been produced electronically and is valid without a signature.

VWR International bvba/spri
Haasrode Research Park Zone 3
Geldenaaksebaan 464
B-3001 Leuven
Tel: +32 (0)16 385 011


ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SAMPEL PASTEUR S.A.


CHRISTIAN DUMORTIER
GERENTE
SAMPEL PASTEUR S.A.



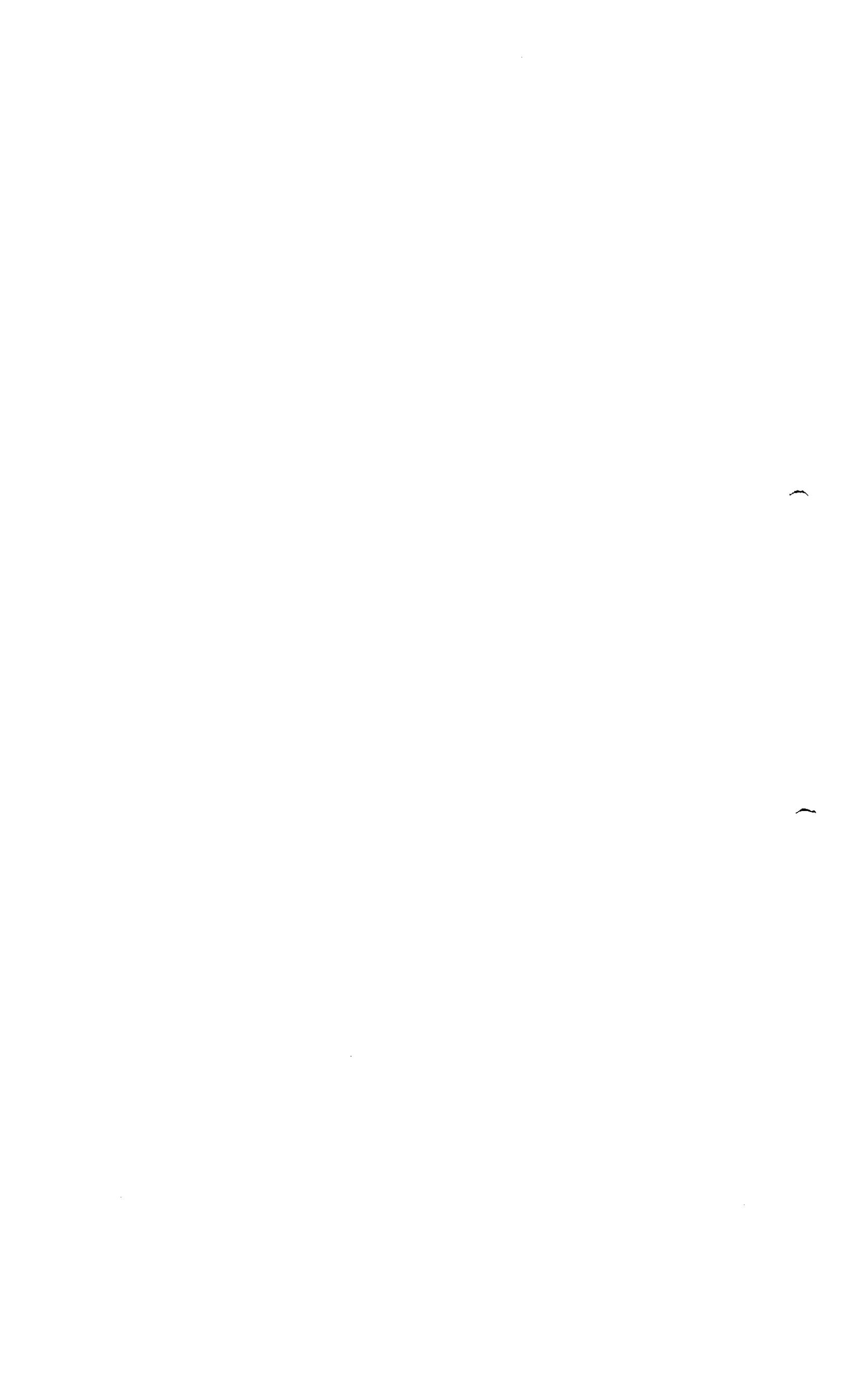


3.2.P.6

Certificate of Analysis - Non Adsorbed and Depolymerized PRP Reference


ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANGRE PASTEUR S.A.


CHRISTIAN DOMÍNGUEZ
COORDINADOR
SANGRE PASTEUR S.A.





sano fi pasteur

Product Quality and Disposition Department

The vaccines division of sano fi-aventis Group

QUALITY CONTROL RELEASE
HAEMOPHILUS POLYSACCHARIDE CONJUGATE
(CONCENTRATED BULK)

Lot number : FA314017

pH : 6.99

Phosphorus content : 15.7 µg/ml

Haemophilus polysaccharide content : 186.90 µg/ml

Sucrose content : 79.25 g/l

Protein/Polysaccharide ratio : 2.4

Residual EDAC content
(Ethyl-Dimethylaminopropyl-Carbodiimide) : <10 µmol/l

Residual phenol content : <1.00 µg/ml

Free polysaccharide content : <4.1 %

Molecular size distribution
Percentage of polysaccharide eluted
before K_d 0.20 : 79.2 %

Free carrier protein content : <1 %

Tetanus identification : Positive

Haemophilus identification : Positive

Bacterial and fungal sterility : Conforms

Date of manufacture : 04.06.08

GENERAL CONCLUSION : Conforms

Release date : 23.10.08

Batch Release Department

Caroline CAUDAL

095-Proc.dot /20/07/2010

This document is intended for health authority biological release purposes only

ROXANA MONTEMILONE
 DIRECTORA TÉCNICA
 SANO FI PASTEUR S.A

CHRISTIAN DIMAS CORDERO
 GERENTE
 SANO FI PASTEUR S.A



3.2.P.6

Certificate of Analysis - Percent Adsorption Hepatitis B and IVRP Reference



ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANJEL PASTERIR S.A.



CHRISTIAN DUMINEZ
REGISTRADO
SANJEL PASTERIR S.A.



sanofi pasteur

La division vaccins du Groupe sanofi-aventis.

CERTIFICATE OF ANALYSIS

Product name : DTaP-IPV-HB-PRP-T
Batch: S4114
Prior batch: FDNC0005
Predecessor conform on: May 16. 2006

QUALITY CONTROL TESTS	ACCEPTANCE CRITERIA	RESULTS
Appearance	Cloudy whitish suspension	Cloudy whitish suspension
Extractable volume	≥ 0.5 ml for each of the 5 vials tested	0.52 ml – 0.53 ml – 0.54 ml – 0.53 ml – 0.53 ml
Aluminium content	0.40 – 0.80 mg/dose	0.63 mg/dose
Diphtheria identification	Positive	Positive
Tetanus identification	Positive	Positive
Haemophilus identification	Positive	Positive
HBs antigen identification	Positive	Positive
Pertussis identification :		
- Pertussis toxoid	Positive	Positive
- FHA	Positive	Positive
D antigen content	Type 1 : 20 – 43 DU/dose Type 2 : 5 – 9 DU/dose Type 3 : 17 – 36 DU/dose	Type 1 : 28.6 DU/dose Type 2 : 5.9 DU/dose Type 3 : 25.3 DU/dose
Bacterial and fungal sterility	No microbial growth	Conforms
Bacterial endotoxins	For information only	110.50 IU/dose
Pyrogens (1/100)	Conforms to EP	0°09 – 0°39 – 0°25 = 0°73
Abnormal toxicity	No clinical sign or death within 7 days after inoculation	Conforms

- The batch S4114 has been controlled according to the specifications described in the Specifications 102 464/2.0
- The results conform to the acceptance criteria above and approved in the specification N° 102 464/2.0
- The results are as expected based on prior manufacturing stages and processes.

Head of ARD EU

D. PÉTRÉ

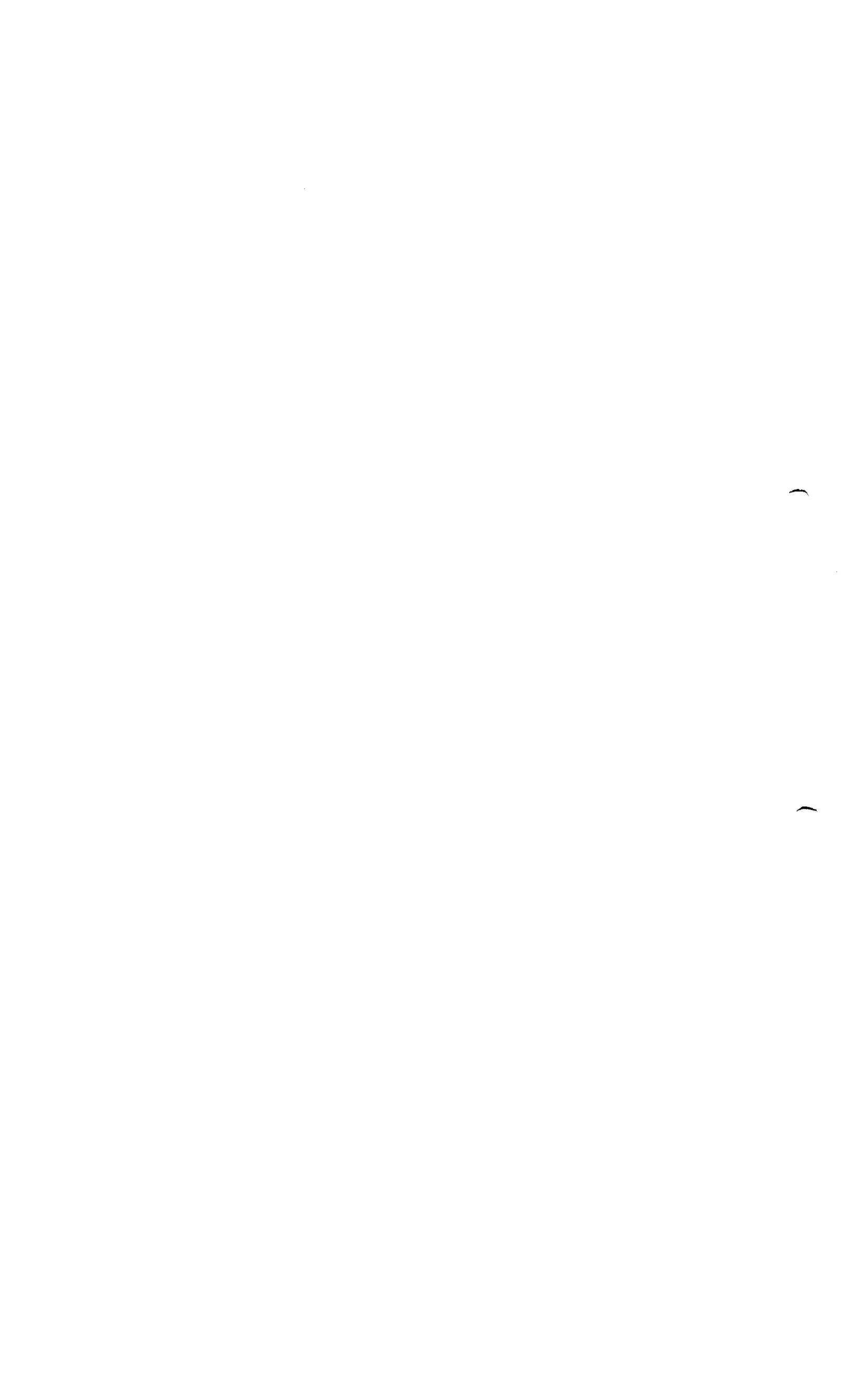
Name

Signature

30 juillet 2010

Date


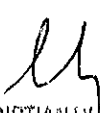
ROXANA MONTEMILONE CHRISTIAN DUNNIN
 DIRECTORA TÉCNICA GERENTE
 SANOFI PASTEUR S.A. SANOFI PASTEUR S.A.

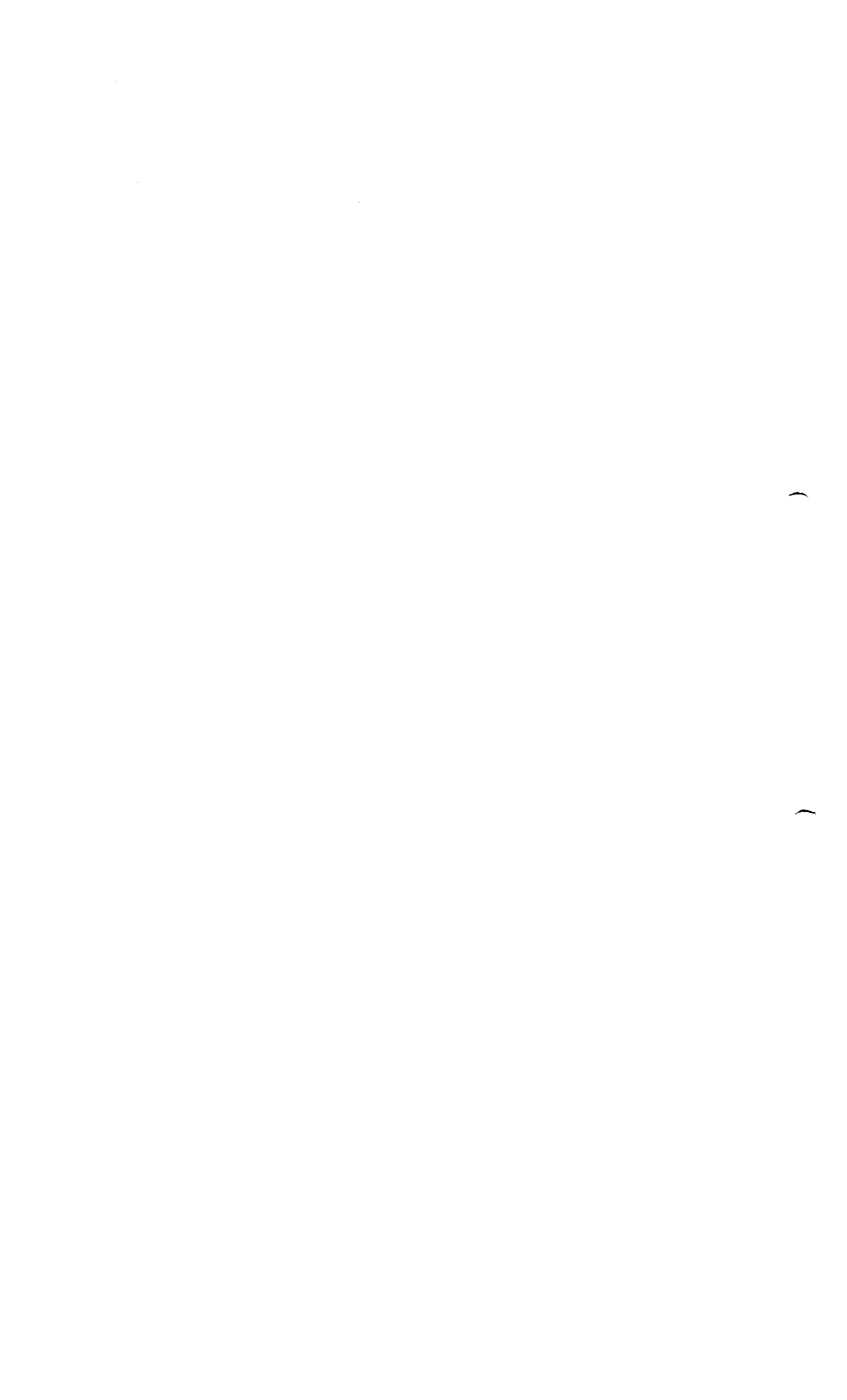


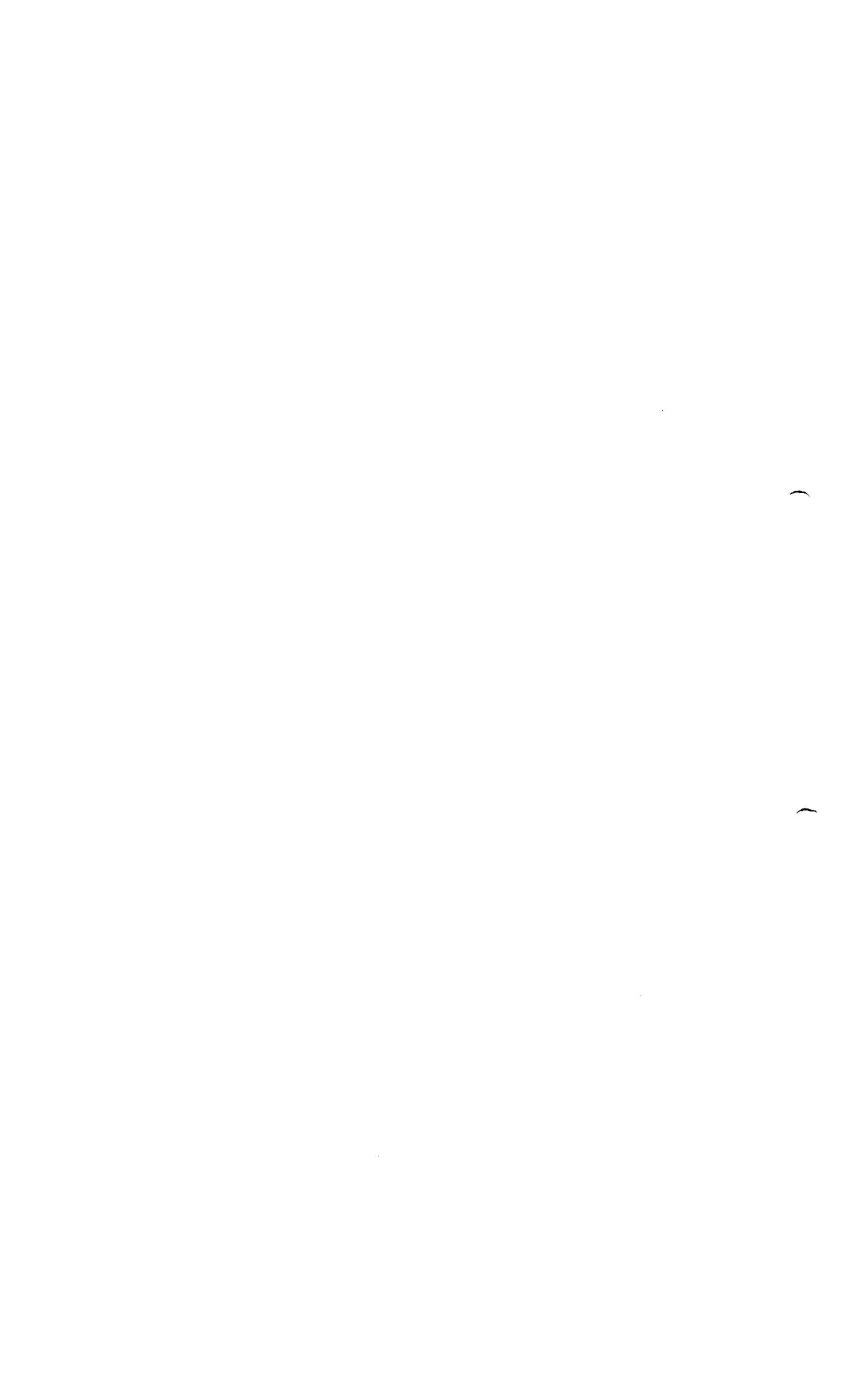


3.2.P.6

Certificate of Analysis - Diphtheria Potency External Reference

	
ROXANA MONTEMILONE DIRECTORA TÉCNICA SANGRE PASTEUR S.A	CHRISTIAN DOMINGUEZ GERENTE SANGRE PASTEUR S.A




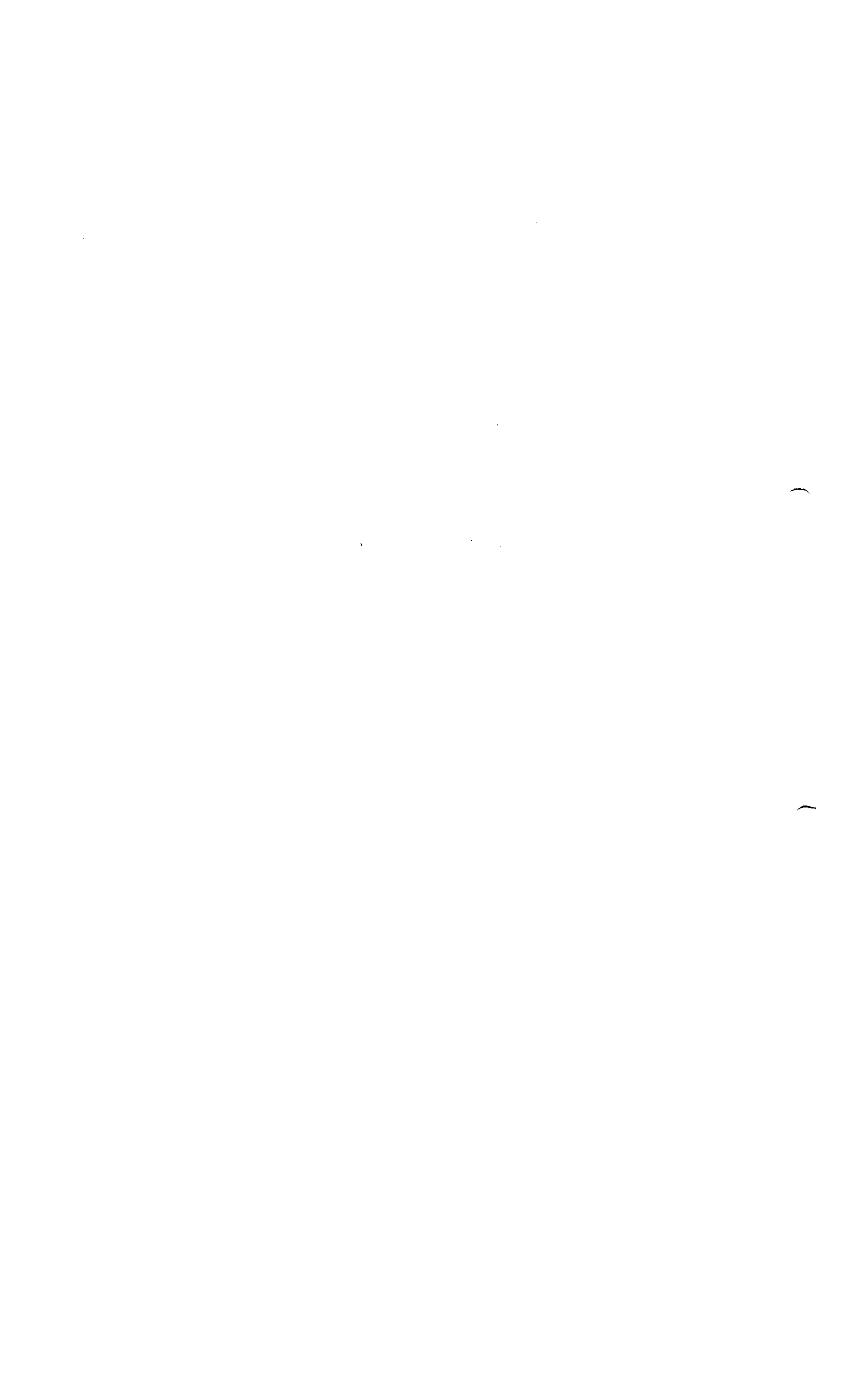


3.2.P.6

Certificate of Analysis - Tetanus Potency External Reference

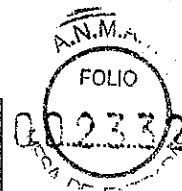

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANO PASTEUR S.A.


CHRISTIAN DOMINGUEZ
GERENTE
SANO PASTEUR S.A.





European Directorate for the
Quality of Medicines & HealthCare



European Directorate for the Quality of Medicines & HealthCare
European Pharmacopoeia (Ph. Eur.)
7, Allée Kastner CS 30026, F-67081 Strasbourg (France)
Tel. +33 (0)3 88 41 20 35 Fax. + 33 (0)3 88 41 27 71
For any question: www.edqm.eu (HelpDesk)

Ph. Eur. Reference Standard - LEAFLET

TETANUS VACCINE (ADSORBED) BRP batch 2

Tetanus vaccine (adsorbed) BRP batch 2 is intended for use in the assay of adsorbed tetanus vaccine as described in the Ph. Eur. General Chapter 2.7.8. The preparation consists of freeze-dried tetanus toxoid, adsorbed on $AlPO_4$, presented in ampoules. It does not contain a preservative. Each ampoule contains 10 mg of trehalose as stabiliser. The Al^{3+} content is equal to 1 mg/ampoule. The assigned potency is

469 IU/ampoule for assays in guinea-pigs
496 IU/ampoule for assays in mice

STORAGE

Keep ampoules unopened at $-20\text{ }^{\circ}\text{C}$. Do not store at lower temperatures to avoid deterioration of the rubber stoppers.

USE

- Allow the ampoule and content to reach room temperature.
- Tap ampoule gently to collect material at the bottom.
- Open ampoule in an appropriate way and reconstitute the freeze-dried material by adding an accurately measured suitable volume of *water for injections Ph. Eur. 0169* (for example 0.5 ml). Carefully mix and stir very gently, avoiding spuming.
- Use the suspension as soon as possible after reconstitution. Do not freeze or store for subsequent use.

RESULTS OBTAINED WITH TETANUS VACCINE (ADSORBED) BRP batch 2

Please be aware that any switch from your in-house standards to the tetanus vaccine (adsorbed) BRP batch 2 might lead to differences in potency estimates of the assayed tetanus vaccine. Re-calibration of your in-house standard against the tetanus vaccine BRP batch 2 is thus strongly recommended, as well as a thorough validation of your SOP.

ROXANA MONTMILONE
DIRECTORA TÉCNICA
SANDOZ PASTEUR S.A.

CHRISTIAN DUMAS
GERENTE
SANDOZ PASTEUR S.A.



CAUTION

Tetanus Vaccine (adsorbed) BRP batch 2 is not appropriate for administration to humans. This preparation must be handled according to the QA system for biological testing laboratories. Please refer to the corresponding safety data sheet, which can be downloaded from the Internet site of the EDQM (<http://www.edqm.eu>) or is delivered upon request.

LITERATURE

D. Sesardic, R. Winsnes, P. Rigsby, R. Gaines Das. Collaborative study for the establishment of tetanus vaccine (adsorbed) third International Standard and European Pharmacopoeia Biological Reference Preparation Batch no. 2. Pharmeuropa Bio 2001-1, 43-72, 2001.


ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANGRE PASTEUR S.A.


CHRISTIAN DOMÍNGUEZ
SECRETARIO
SANGRE PASTEUR S.A.

