Table 1. Certified Bovine Serum Albumin Concentration by Amino Acid Analysis[a]

BSA Concentration: 65.41 g/L ± 0.82 g/L

[a] The certified value is the equally weighted mean of results obtained from two chemically independent methods (see "Analytical Methods"). The expanded uncertainty in the certified concentration is calculated as $U = ku_c$. The quantity u_c is the combined standard uncertainty calculated based on a Bayesian approach in [5] and ISO and NIST Guides [6]. The coverage factor, $k = 2$, represents an approximate 95 % level of confidence.

Table 2. Reference Total Protein Concentration by the Biuret Method[a]

Protein Concentration: 70.10 g/L ± 0.74 g/L

[a] Because only a single method was used, the results do not meet the NIST criteria for a certified value [7]. Therefore this method specific result is considered a reference value. The expanded uncertainty in the reference concentration is calculated as $U = ku_c$. The uncertainty u_c is based upon quadratically combining the measurement uncertainty with the uncertainty in SRM 927c, which served as the external standard for the measurements. The major component in the uncertainty for SRM 927d is the uncertainty in the concentration of SRM 927c. The coverage factor, $k = 2$, represents an approximate 95 % confidence interval.

Table 3. Reference Values for Various Properties of SRM 927d

Mean Fill Volume:	2.245 mL	±	0.006 mL
pH:	6.70	±	0.01
Density:	1.0178 g/mL	±	0.0003 g/mL

Spectral Properties		Absorbance		
Ultraviolet (A_{252}/A_{279} ratio @ 1.0 g/L)		0.467	±	0.002
Soret Band (Visible)	A_{405}	0.140	±	0.002
	A_{500}	0.0320	±	0.0021
	A_{600}	0.0187	±	0.0024

Major molecular forms of BSA in decreasing order of abundance

Relative Molecular Mass		
66 432	±	7
66 549	±	12
66 473	±	14
66 593	±	11
66 344	±	13
66 222	±	14
66 389	±	14

Theoretical BSA relative molecular mass from Amino Acid Sequence [8]: 66 399

The uncertainties in the reference values are calculated as $U = ku_c$. The quantity u_c is the combined standard uncertainty calculated according to the ISO and NIST Guides [6], where u_c is intended to represent the measurement error at the level of one standard deviation. The coverage factor, $k = 2$, represents an approximate 95 % confidence interval.

Table 4. Information Value for Optical Absorbance

Optical Absorbance @ 279 nm for 1 g/L [9]	0.667

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[1] NCCLS Approved Standard ACS-1; *Specification for Standardized Protein Solution (Bovine Serum Albumin)*, 2nd ed.; National Committee for Clinical Laboratory Standards: Villanova, PA (1979).

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[7] May, W.; Parris, R.; Beck, C.; Fassett, J.; Greenberg, R.; Guenther, F.; Kramer, G; Wise, S.; Gills, T.; Colbert, J.; Gettings, R.; MacDonald, B.; *Definitions of Terms and Modes Used at NIST for Value-Assignment of Reference Materials for Chemical Measurements*; NIST Special Publication 260-135; U.S. Government Printing Office: Washington, DC (2000); available at http://www.cstl.nist.gov/nist839/NIST_special_publications.htm.

[8] Swiss-Prot database, Swiss Institute for Bioinformatics (http://us.expasy.org/sprot/sprot-top.html).

[9] *All About Albumin: Biochemistry, Genetics, and Medical Applications*; Peters, T., Jr.; Academic Press Inc.: San Diego, CA, p. 25 (1995).

Users of this SRM should ensure that the certificate in their possession is current. This can be accomplished by contacting the SRM Program at: telephone (301) 975-6776; fax (301) 926-4751; e-mail srminfo@nist.gov; or via the Internet at http://www.nist.gov/srm

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3.2.S.5

Certificate of Analysis - Standard Batch 11/07/07 - IPV

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Certificat of analysis : Poliomyelitis in-house reference Batch N°11-07-07 for Dantigen 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 (sigmoid method) → **1448** UD/ml
  D Antigen titer serotype 2 (sigmoid method) → **325** UD/ml
  D Antigen titer serotype 3 (sigmoid method) → **1123** UD/ml

Confidential 28/04/2009

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3.2.S.5

Certificate of Analysis - Formaldehyde - IPV

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VWR

BDH PROLABO

Certificate of Analysis

Material : 20913.294
Batch : 06L140015

Formaldéhyde 37 %
Expires end of 11/2009

CHARACTERISTICS	*SPECIFICATIONS*	*MEASURED VALUES*
Titre	34,5 --> 38,0 %	37,2 %
spect	Liquide limpide incolore	Liquide limpide incolore
Identification A	Conforme	Conforme
Identification B	Conforme	Conforme
Identification C	Conforme	Conforme
ıtification D	Conforme	Conforme
Solution S	Conforme	Conforme
Aspect de la solution	Conforme	Conforme
Acidité	Conforme	Conforme
Méthanol (V/V)	9,0 --> 15,0 %	13,1 %
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.

Ingrid Dewolf Head of laboratory - Haasrode
VWR International
Document printed on 04/2007

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

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sanofi pasteur

La division vaccins du Groupe sanofi-aventis

CONTROL CERTIFICATE

PRODUCT : **FORMALDEHYDE SOLUTION (600160)**

BATCH N° : **FA 274243**

Supplier Batch n° : **06 L 140015**

CONTROLS :	**RESULTS :**	**SPECIFICATIONS :**
CHARACTERS		
Appearance	: Pass	Liquid
Colour	: Pass	Colourless
Miscibility	: Pass	Pass
IDENTIFICATION	: Pass	Pass
TESTS		
Appearance (aqueous solution 20% V/V)	: Pass	Colourless
Acidity	: Pass	Pass
Methanol	: 12.7 % V/V	9.0 to 15.0% V/V
Sulphated ash	: 0.0% w/w	≤ 0.1% w/w
ASSAY	: 36.5 % w/w	34.5 to 38.0% w/w

REFERENCES : - European Pharmacopoeia
- SOP n°030 840

CONCLUSION : **PASS**

Release Date : 26/04/2007 (DD/MM/YY)

SIGNATURE : K. CHAZELLE
Raw Material Laboratory Manager
Quality Control

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3.2.S.5

Certificate of Analysis - Endotoxin Standard - IPV

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Council of Europe

EUROPEAN DIRECTORATE FOR
THE QUALITY OF MEDICINES

EUROPEAN PHARMACOPOEIA COMMISSION

ENDOTOXIN STANDARD BRP batch 4

1. AMPOULE CONTENTS

Each vial contains the residue after freeze-drying of 1.0 ml of a solution that contained:

E. coli 0113: H10: K-endotoxin	1µg
Lactose	10 mg
Polyethylene glycol	1 mg

2. ASSIGNED CONTENT

10 000 International Units per vial.

3. RECONSTITUTION AND USE OF VIALS

Add 5ml of sterile water LAL to the vial. Reconstitute by mixing intermittently for 30 min, using a vortex mixer. The resulting solution of 2 000 IU per ml is to be used as a stock solution for preparing serial dilutions. For economy of use, the stock solution may be divided into aliquots immediately after reconstitution and the aliquots stored at - 40°C or below. Alternatively, the stock solution may be stored in a refrigerator for not more than 14 days. Aliquots of the stock solution are to be taken (for preparing serial dilutions) after vigorous mixing for 3 minutes. Subsequent dilutions are to be mixed for not less than 30 seconds.

Suitable precautions should be taken in the use and disposal of the vial and its contents.

4. STORAGE

Unopened vials are to be stored at - 20°C (long term storage).

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Estándares o Materiales de Referencia - PRP-T

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Sección 3.2.S.5 - Estándares o materiales de referencia

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