9º CUERPO

22767-11-1

Analytical measurements were performed by D.W. Bearden, K.W. Phinney, C.A. Rimmer, M.M. Schantz, L.T. Sniegoski, and T.W. Vetter of the NIST Analytical Chemistry Division, and D.K. Hancock and B.E. Lang of the NIST Biochemical Science Division.

Statistical analyses were provided by N.F. Zhang of the NIST Statistical Engineering Division.

Support aspects involved in the issuance of this SRM were coordinated through the NIST Measurement Services Division.

NOTICE AND WARNING TO USERS

Storage and Use: The SRM should be stored in its original bottle at temperatures between approximately 20 °C and 25 °C. With proper storage and handling, this material will not require drying prior to use. It must be tightly re-capped after usage and protected from excessive moisture and light.

SOURCE, PREPARATION, AND ANALYSIS[1]

Source of Material: The material used for this SRM was provided by the California and Hawaiian Sugar Company (Crockett, CA).

Preparation of a Normal Sugar Solution: For very accurate measurements, solutions of the SRM should be freshly prepared under sterile conditions using pure sterilized water. A "normal sugar solution" is defined as 26.0160 g of "pure" sucrose weighed in vacuum, dissolved in pure water, and diluted to 100.000 cm^3 at 20.00 °C. This is equivalent to 23.7018 g of sucrose per 100.000 g of aqueous solution. Therefore, weigh out 23.7018 g of SRM 17f and add pure sterile water to a total mass of 100.000 g. Additional information on the preparation of a normal sugar solution can be found in reference 3. In practice, one can accurately weigh an amount that differs from 23.7018 g and multiply the observed rotation by the ratio of 23.7018 to the actual mass to compare results with the reference values in Table 2a.

Analyses: Analyses for value assignment of the optical rotation of SRM 17f provided in Table 2a were performed at NIST, JASCO, Inc. (Easton, MD), and ATS Analytics (Fairfield, CT). Measurements at 546.2271 nm were made at JASCO and ATS Analytics. Measurements at 589.4400 nm were made at NIST, JASCO, and ATS Analytics.

The optical rotation of a normal solution of SRM 17f, provided in Table 2b, is based on the International Sugar Scale, which became effective July 1, in 1988. The 100 °Z point of the International Sugar Scale Based corresponds to the optical rotation caused by normal solution of pure sucrose at the wavelength of 546.2271 nm in a 200.000 mm polariscope tube at 20.00 °C [3].

Additional Analyses: Table 1 provides the elemental analysis results of SRM 17f and the theoretical percentages calculated for $C_{12}H_{22}O_{11}$. Thus, the comparison shows that the theoretical composition is well within the uncertainty of the elemental analysis measurements.

Table 1. Theoretical Composition and Elemental Analysis of $C_{12}H_{22}O_{11}$ for SRM 17f

Element	SRM 17f Results (%)	Theoretical Calculation (%)
C	42.22 ± 0.18	42.10
H	6.47 ± 0.15	6.48

Karl Fischer titration yielded a moisture content of approximately 0.097 mg/g. Results of nuclear magnetic resonance (NMR) analysis were consistent with a purity > 99 %, and additional supporting analyses indicated that there was no significant contribution from other saccharides.

[1]Certain commercial equipment, instruments, or materials are identified in this certificate to specify adequately the experimental procedure. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology, nor does it imply that the materials or equipment identified are necessarily the best available for the purpose.

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ICUMSA Equation: Using the rotatory dispersion equation below, given by the ICUMSA [4], values for the optical rotation at 632.9914 nm and 882.6 nm were calculated from the measured values at 546.2271 nm. These values are shown in Table 2a. This equation was also used to calculate a value for the optical rotation at 589.4400 nm. This value agreed to within 0.2 % of the average measured rotation for this SRM at 589.4400 nm.

$$\frac{\alpha_\lambda}{\alpha_{0.5462271}} = \frac{1}{a_0 + a_1 \cdot \lambda^2 + a_2 \cdot \lambda^4 + a_3 \cdot \lambda^6}$$

a_0 = –0.075047659000

a_1 = 3.588221904585

a_2 = 0.051946178300

a_3 = –0.006515194377

λ = wavelength (μm)

Table 2a. Reference Values for the Optical Rotation and Associated Uncertainties[a] of a "Normal Sugar Solution" of SRM 17f at 20.00 °C ± 0.01 °C

Wavelength	100.00 mm cell Optical Rotation		200.00 mm cell Optical Rotation	
(*in vacuo*, nm)	(mrad)	(degrees)	(mrad)	(degrees)
546.2271	355.68 ± 0.05	20.379 ± 0.003	711.36 ± 0.10	40.758 ± 0.006
589.4400	301.50 ± 0.42	17.275 ± 0.048	603.01 ± 0.84	34.550 ± 0.096
632.9914[b]	259.51 ± 0.08	14.869 ± 0.004	519.02 ± 0.16	29.737 ± 0.008
882.60[b]	129.41 ± 0.04	7.414 ± 0.002	258.81 ± 0.08	14.828 ± 0.004

Table 2b. Reference Value and Associated Uncertainty[a,c] for °Z at 546.2271 nm of a "Normal Sugar Solution" of SRM 17f at 20.00 °C ± 0.01 °C

°Z = 99.950 ± 0.012

Table 2c. Reference Value for the Specific Rotation $[\alpha]_D^{20}$ and Associated Uncertainty[a] at 589.4400 nm

Specific Rotation, $[\alpha]_D^{20}$: 66.512 ± 0.025

[a] The uncertainties in the reference values are expressed as expanded uncertainties, U, at the 95 % level of confidence, and are calculated according to the method described in the ISO Guide and NIST Guidelines [2]. The expanded uncertainty is calculated as $U = ku_c$, where u_c is intended to represent, at the level of one standard deviation, the combined effects of method differences, within-method variation, and material inhomogeneity. The coverage factor k is determined from the Student's t-distribution corresponding to the appropriate degrees of freedom and approximately 95 % confidence.

[b] The optical rotation values for 632.9914 nm and 882.60 nm are calculated based upon the measurements at 546.2271 nm (see section entitled "ICUMSA Equation").

[c] The uncertainty for the °Z value also includes a component for uncertainty in the 100 °Z value [3].

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REFERENCES

[1] May, W.E.; Gills, T.E.; Parris, R.; Beck, II, C.M.; Fassett, J.D.; Gettings, R.J.; Greenberg, R.R.; Guenther, F.R.; Kramer, G.; MacDonald, B.S.; Wise, S.A.; *Definitions of Terms and Modes Used at NIST for Value-Assignment of Reference Materials for Chemical Measurements*; NIST Special Publication 260–136 (2000); available at http://ts.nist.gov/MeasurementServices/ReferenceMaterials/PUBLICATIONS.cfm.

[2] ISO; *Guide to the Expression of Uncertainty in Measurement*, ISBN 92-67-10188-9, 1st ed.; International Organization for Standardization: Geneva, Switzerland (1993); see also Taylor, B.N.; Kuyatt, C.E.; *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*; NIST Technical Note 1297, U.S. Government Printing Office: Washington, DC (1994); available at http://physics.nist.gov/Pubs/.

[3] ICUMSA – Methods Book, Method GS2/3-1; The Braunschweig Method for the Polarization of White Sugar by Polarimetry; ICUMSA Publication Department: Norwich Research Park NR4 7UB, England (1994).

[4] ICUMSA Proceedings 1998, 22nd Session; Bartens: Berlin, Germany; p. 209 (1998).

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) 975-2200; fax (301) 926-4751; e-mail srminfo@nist.gov; or via the Internet http://www.nist.gov/srm.

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3.2.S.5

Certificate of Analysis - Olive Oil Reference standard - HBsAg

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SIGMA DIAGNOSTICS

SIGMA DIAGNOSTICS, INC.
P.O. BOX 14508 ST. LOUIS, MO 63178 USA
Technical Service: 800-325-0250
or call collect 314-286-7880
To Order: 800-325-3010 or call collect 314-771-5750
http://www.sigma.sial.com/diagnostics.html

CERTIFICATE OF ANALYSIS

PRODUCT NAME: OLIVE OIL

CATALOG NUMBER: O-1500

LOT NUMBER: 012K6042

This product meets all of Sigma Diagnostics quality specifications and performs as outlined in the product insert.

08/13/02

o1500a.cos

Sigma Diagnostics, Inc. Manufactures Diagnostic Kits, Reagents and Instrumentation for Clinical Laboratories Worldwide.

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O1500 Olive oil

Sigma suitable for substrate for lipase

This product number has been discontinued but a similar product may be available. Please select the recommended replacement product below (if a direct replacement is available) or use the links to "similar products" or "related product categories" to see other possible replacement products.

Recommended Products

Replaced by O1514, Olive oil

Price and Availability

Click For Pricing and Availability

CAS Number	8001-25-0
EG/EC Number	2322770
MDL number	MFCD00131764

xpand/Collapse All

Descriptions

Linkage	Also see Sigma lipase substrate, an olive oil emulsion, for the determination of serum lipase.
Quality	Highly refined; low acidity

Properties

density	0.91 g/mL at 25 °C(lit.)
suitability	suitable for substrate for lipase

Safety

WGK Germany	-
RTECS	RK4300000
F	8-9-23

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28/02/2007

SIGMA-ALDRICH

Certificate of Analysis

Product Name	Olive oil
Product Number	O1514
Product Brand	SIGMA
CAS Number	8001-25-0
Molecular Formula	
Molecular Weight	

TEST	SPECIFICATION	LOT 014K6007 RESULTS
APPEARANCE		CLEAR FAINT YELLOW LIQUID
SPECIFIC GRAVITY		0.913
ACID VALUE		0.04
IODINE VALUE		81
SAPONIFICATION VALUE		191
C16:0		9.8%
C16:1		0.7%
C18:0		3.2%
C18:1		77.3%
C18:2		7.1%
C18:3		0.6%
C20:0		0.5%
C20:1		0.4%
IR SPECTRUM		CONSISTENT WITH STRUCTURE
QC ACCEPTANCE DATE		NOVEMBER 2003

Lori Schulz, Manag
Analytical Service
St. Louis, Missouri

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SIGMA-ALDRICH

A.N.M.A.T. FOLIO 002508 ENTRADO

Sigma-Aldrich
de Argentina S.A.
Estomba 835 - (C1427COS)
Buenos Aires, Argentina

Buenos Aires, 05 de octubre de 2004

SIGMA
Biochemicals and Reagents for Life Science Research

Aventis-Pasteur S.A.
Sra. Valeria Padin
S / D:

Por medio de la presente certificamos según los lineamientos de nuestra Corporación, que el producto **O1514 lot# 014K6007** goza de **5 años de vigencia** a partir de la fecha en la que el mismo es recepcionado por vuestra empresa.

ALDRICH
Organics and Biochemicals for Chemical Synthesis

Sigma-Aldrich de Argentina S.A. asegura la elaboración, almacenamiento, empaque y el correspondiente transporte en condiciones adecuadas de todos sus productos hasta que los mismos llegan a manos de nuestros clientes.

Sin otro particular, aprovechamos la presente para saludarla muy atentamente.

Fluka
Specialty Chemicals and Analytical Reagents for Research

Sigma-Aldrich de Argentina S.A.

[redacted]
Laboratory Chemicals and Reagents for Research and Analysis

SUPELCO
Chromatography Products for Analysis and Purification

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SIGMA-ALDRICH®

SIGMA

Industriestrasse 25, CH-9471 Buchs (SG), Switzerland
Tel: +41 81 755 2511 Fax: +41 81 756 5449

Certificate of Analysis

Product Name:	OLIVE OIL highly refined, low acidity
Product Number:	O1514
Product Brand:	Sigma
Molecular Formula:	
Molecular Mass:	
CAS Number:	8001-25-0

TEST	**LOT 1423657 RESULTS**
APPEARANCE	CLEAR YELLOW LIQUID
REMARKS ON GC	C16:0 = 10.0 % C18:2 = 7.2 % C18:3 = 0.5 %
DENSITY D20/4	0.912
INFRARED SPECTRUM	CONFORMS
SAPONIFICATION VALUE	192
QC RELEASE DATE	13/MAR/09

E. Schwärzler

Edeltraud Schwärzler, Manager
Quality Control
Buchs, Switzerland

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3.2.S.5

Certificate of Analysis - Low Molecular Weight Marker Reference Material - HBsAg

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GE Healthcare

A.N.M.A.T. FOLIO 0025111 MESA DE ENTRADAS

Certificate of Analysis

Part Number: 17044601

Name: Amersham Low Molecular Weight Calibration Kit for Electrophoresis

Lot No:	**382576**	**Date of Manufacture:**	**October 2009**	**Test Date:**	**October 2009**	**Expiry Date**	**04 January 2012**

Analytical information

Each vial contains a lyophilized mixture of protein standards. When reconstituted with 100 µl of electrophoresis buffer, the solution will contain approximately 25% sucrose, allowing direct application to an electrophoresis gel.

Quality control

Reconstitution of the vial with 100 µl of electrophoresis buffer and application to an 8-25% PhastGel™ yielded the results listed below.

Protein	R_f Value	Specification
Phosphorylase b	0.35	0.32-0.40
Bovine Serum Albumin	0.43	0.39-0.47
Ovalbumin	0.51	0.46-0.56
Carbonic Anhydrase	0.62	0.58-0.70
Trypsin Inhibitor	0.73	0.66-0.80
αLactalbumin	0.83	0.75-0.91

Band intensity : Pass
Band Appearance : Pass
48 hour stability at 37 °C : Pass

Package & storage conditions:

Store at 2-8 °C.
Ship at ambient.

John Dunn
Proteomics Team Leader

Version AA 10/2009

imagination at work

www.gelifesciences.com
GE Healthcare UK Limited
Amersham Place Little Chalfont

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3.2.S.5

Certificate of Analysis - Endotoxins Reference Material - HBsAg

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charles river
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A.N.M.A.T. FOLIO 002513

CERTIFICATE OF ANALYSIS

VIAL CONTENTS: Endosafe® Control Standard Endotoxin is prepared from *E. coli* strain 055:B5. Each vial contains 500 ng of purified Lipopolysaccharide, freeze dried in a stabilized matrix.

RSE/CSE RATIO: The potency of this standard in Endotoxin units, (EU) has been determined to be 22 EU/ng by the method described in Appendix C (***Gel-clot Technique***) of the GUIDELINE ON VALIDATION OF THE LIMULUS AMEBOCYTE LYSATE TEST AS AN END PRODUCT ENDOTOXIN TEST FOR HUMAN AND ANIMAL PARENTERAL DRUGS, BIOLOGICAL PRODUCTS, AND MEDICAL DEVICES, published by the U.S Food and Drug Administration.

CSE Lot: EM04972 LAL Reagent Lot: B4352L RSE Lot: EC-6-3

RSE/CSE Ratio: 22 EU/ng Vial contents: 11,000 EU/vial

Geometric Mean Sensitivity with RSE: 0.03 EU/mL

IS/CSE RATIO: The Expert Committee on Biological Standardization of WHO has assigned a potency of the IS as 10,000 IU per vial of IS, so that 1 IU = 1 EU. The potency of this endotoxin standard in International (Endotoxin) Units, IU, has been designated as 22 IU/ng.

DIRECTIONS FOR USE: Reconstitute the lyophilized material with 5.5 mL of LAL reagent grade water to obtain 2000 EU/mL or 2000 IU/mL. Vortex mix vigorously for at least 5 minutes after rehydration, and for at least 1 minute immediately prior to each use.

STORAGE: Store rehydrated material at 2-8°C for up to 4 weeks. Store lyophilized material at controlled room temperature or refrigerated as preferred. Diluted endotoxin should not be stored except under validated conditions.

CAUTION: DO NOT FREEZE ENDOTOXIN SOLUTIONS

Signature: Cynthia Raeh Date: 21st Apr 2010

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CA-GC500-02

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CERTIFICATE OF ANALYSIS (1/2)

Product name : 352 AL2i
Batch: FDNC0491
Prior batch: FDV01398-3
Predecessor conform on: June 29. 2010

FILLED PRODUCT

QUALITY CONTROL TESTS	ACCEPTANCE CRITERIA	RESULTS
Appearance	Whitish and cloudy suspension	Conforms
Extractable volume	≥ 0.5 mL for each of the 5 individual syringes tested	Conforms
Aluminium content	0.40 – 0.80 mg/dose	0.61 mg/dose
pH measurement	6.5 – 7.5	7.27
Diphtheria identity (Ouchterlony)	***For information***	***Positive***
Tetanus identity (Ouchterlony)	***For information***	***Positive***
Haemophilus identity (Ouchterlony)	***For information***	***Positive***
Pertussis identity (Ouchterlony) • *FHA* • *PT*	***For information***	***Positive***
Hepatitis B Identity (ELISA)	***For information***	***Positive***
Polio Identity (ELISA – D Antigen)	***For information***	***Positive***
Identity of each valence : Haemophilus, Hepatitis B, Pertussis, Diphtheria, Tetanus, Polio (Luminex)	Positive for each valence	***Positive***
Bacterial and fungal sterility test	Free from growth when tested for bacterial and fungal contamination	Conforms

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CERTIFICATE OF ANALYSIS (2/2)

Product name : 352 AL2i
Batch: FDNC0491
Prior batch: FDV01398-3
Predecessor conform on: June 29. 2010

FILLED PRODUCT

QUALITY CONTROL TESTS	ACCEPTANCE CRITERIA	RESULTS
Pyrogen test	Conforms	0°00 – 0°00 – 0°05 = 0°05 Conforms
Abnormal toxicity test	No sign of death or illness within 7 days after inoculation	Conforms
Endotoxin content by rFC	***For information***	***< 10.0 IU/mL***

- The batch FDNC0491 has been controlled according to the specifications described in the DSC N°GQ_001712/1.0
- The results conform to the acceptance criteria above and approved in the DSC N° GQ_001712/1.0
- The results are as expected based on prior manufacturing stages and processes.

Head of ARD EU D. PÉTRÉ (Name) — D Petré (Signature) — 4 nov 2010 (Date)

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CERTIFICATE OF ANALYSIS (1/2)

Product name : 352 AL2i
Batch: FDNC0504
Prior batch: FDV01416-3
Predecessor conform on: June 29. 2010

FILLED PRODUCT

QUALITY CONTROL TESTS	ACCEPTANCE CRITERIA	RESULTS
Appearance	Whitish and cloudy suspension	Conforms
Extractable volume	≥ 0.5 mL for each of the 5 individual syringes tested	Conforms
Aluminium content	0.40 – 0.80 mg/dose	0.61 mg/dose
pH measurement	6.5 – 7.5	7.17
Diphtheria identity (Ouchterlony)	***For information***	***Positive***
Tetanus identity (Ouchterlony)	***For information***	***Positive***
Haemophilus identity (Ouchterlony)	***For information***	***Positive***
Pertussis identity (Ouchterlony) • *FHA* • *PT*	***For information***	***Positive***
Hepatitis B Identity (ELISA)	***For information***	***Positive***
Polio Identity (ELISA – D Antigen)	***For information***	***Positive***
Identity of each valence : Haemophilus, Hepatitis B, Pertussis, Diphtheria, Tetanus, Polio (Luminex)	**Positive for each valence**	***Positive***
Bacterial and fungal sterility test	**Free from growth when tested for bacterial and fungal contamination**	**Conforms**

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CERTIFICATE OF ANALYSIS (2/2)

Product name : 352 AL2i
Batch: FDNC0504
Prior batch: FDV01416-3
Predecessor conform on: June 29. 2010

FILLED PRODUCT

QUALITY CONTROL TESTS	ACCEPTANCE CRITERIA	RESULTS
Pyrogen test	**Conforms**	**0°00 – 0°23 – 0°00 = 0°23 Conforms**
Abnormal toxicity test	**No sign of death or illness within 7 days after inoculation**	**Conforms**
Endotoxin content by rFC	***For information***	***< 10.0 IU/mL***

- The batch FDNC0504 has been controlled according to the specifications described in the DSC N°GQ_001712/1.0
- The results conform to the acceptance criteria above and approved in the DSC N° GQ_001712/1.0
- The results are as expected based on prior manufacturing stages and processes.

Head of ARD EU D. PÉTRÉ (Name) — D. Pétré (Signature) — 4 nov 2010 (Date)

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CERTIFICATE OF ANALYSIS (1/2)

Product name : 352 AL2i
Batch: FDNC0505
Prior batch: FDV01420-3
Predecessor conform on: June 29. 2010

FILLED PRODUCT

QUALITY CONTROL TESTS	ACCEPTANCE CRITERIA	RESULTS
Appearance	Whitish and cloudy suspension	Conforms
Extractable volume	≥ 0.5 mL for each of the 5 individual syringes tested	Conforms
Aluminium content	0.40 – 0.80 mg/dose	0.59 mg/dose
pH measurement	6.5 – 7.5	7.19
Diphtheria identity (Ouchterlony)	***For information***	***Positive***
Tetanus identity (Ouchterlony)	***For information***	***Positive***
Haemophilus identity (Ouchterlony)	***For information***	***Positive***
Pertussis identity (Ouchterlony) • *FHA* • *PT*	***For information***	***Positive***
Hepatitis B Identity (ELISA)	***For information***	***Positive***
Polio Identity (ELISA – D Antigen)	***For information***	***Positive***
Identity of each valence : Haemophilus, Hepatitis B, Pertussis, Diphtheria, Tetanus, Polio (Luminex)	Positive for each valence	***Positive***
Bacterial and fungal sterility test	Free from growth when tested for bacterial and fungal contamination	Conforms

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CERTIFICATE OF ANALYSIS (2/2)

Product name : 352 AL2i
Batch: FDNC0505
Prior batch: FDV01420-3
Predecessor conform on: June 29. 2010

FILLED PRODUCT

QUALITY CONTROL TESTS	ACCEPTANCE CRITERIA	RESULTS
Pyrogen test	Conforms	0°25 – 0°31 – 0°12 = 0°68 Conforms
Abnormal toxicity test	No sign of death or illness within 7 days after inoculation	Conforms
Endotoxin content by rFC	***For information***	***< 10.0 IU/mL***

- The batch FDNC0505 has been controlled according to the specifications described in the DSC N°GQ_001712/1.0
- The results conform to the acceptance criteria above and approved in the DSC N° GQ_001712/1.0
- The results are as expected based on prior manufacturing stages and processes.

Head of ARD EU D. PÉTRÉ (Name) — D. Pétré (Signature) — 4 nov 2011 (Date)

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QUALITY CONTROL CERTIFICATE

NAME OF THE PRODUCT	:	**DTaP-IPV-HepB-PRP~T**
LOT N°	:	**S4312**
PRESENTATION	:	Vial 1 dose (0.5 mL)
FINAL BULK N°	:	FDV01398-1
DATE OF MANUFACTURE	:	08 February 2010

CONTROLS	SPECIFICATIONS	RESULTS
Appearance	Whitish and cloudy suspension	**Conforms**
Extractable volume	≥ 0.5 mL for each of the 5 individual vials tested	**Conforms**
Aluminium content	0.40 – 0.80 mg/dose	**0.62** mg/dose
pH	6.5 – 7.5	**7.29**
Identity of each valence : Haemophilus, Hepatitis B, Pertussis, Diphtheria, Tetanus, Polio	Positive for each valence	**Positive**
Bacterial and fungal sterility	Free from growth when tested for bacterial and fungal contamination	**Conforms**
Pyrogens	Conforms	**0°13 – 0°13 – 0°10 = 0°36 Conforms**
Abnormal toxicity	No sign of death or illness within 7 days after inoculation	**Conforms**

Batch released on: 22 July 2010

01. Oct. 10

Alice PADIEU-SEQUEIRA
R&D QA Manager - Clinical Batch Release

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ
APODERADO
SANOFI PASTEUR S.A

sanofi pasteur

La division vaccins du Groupe sanofi-aventis.

QUALITY CONTROL CERTIFICATE

NAME OF THE PRODUCT	:	**DTaP-IPV-HepB-PRP~T**
LOT N°	:	**S4313**
PRESENTATION	:	Vial 1 dose (0.5 mL)
FINAL BULK N°	:	FDV01416-1
DATE OF MANUFACTURE	:	09 February 2010

CONTROLS	SPECIFICATIONS	RESULTS
Appearance	Whitish and cloudy suspension	**Conforms**
Extractable volume	≥ 0.5 mL for each of the 5 individual vials tested	**Conforms**
Aluminium content	0.40 – 0.80 mg/dose	**0.60** mg/dose
pH	6.5 – 7.5	**7.18**
Identity of each valence : Haemophilus, Hepatitis B, Pertussis, Diphtheria, Tetanus, Polio	Positive for each valence	**Positive**
Bacterial and fungal sterility	Free from growth when tested for bacterial and fungal contamination	**Conforms**
Pyrogens	Conforms	**0°14 – 0°40 – 0°09 = 0°63 Conforms**
Abnormal toxicity	No sign of death or illness within 7 days after inoculation	**Conforms**

Batch released on: 22 July 2010

Alice PADIEU- SEQUEIRA 01-oct-10
R&D QA Manager - Clinical Batch Release

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A.N.M.A.T. FOLIO 002522 FECHA DE ENTRADA

sanofi pasteur

La division vaccins du Groupe sanofi-aventis.

QUALITY CONTROL CERTIFICATE

NAME OF THE PRODUCT	:	**DTaP-IPV-HepB-PRP~T**
LOT N°	:	**S4314**
PRESENTATION	:	Vial 1 dose (0.5 mL)
FINAL BULK N°	:	FDV01420-1
DATE OF MANUFACTURE	:	10 February 2010

CONTROLS	SPECIFICATIONS	RESULTS
Appearance	Whitish and cloudy suspension	**Conforms**
Extractable volume	≥ 0.5 mL for each of the 5 individual vials tested	**Conforms**
Aluminium content	0.40 – 0.80 mg/dose	**0.62** mg/dose
pH	6.5 – 7.5	**7.20**
Identity of each valence : Haemophilus, Hepatitis B, Pertussis, Diphtheria, Tetanus, Polio	Positive for each valence	**Positive**
Bacterial and fungal sterility	Free from growth when tested for bacterial and fungal contamination	**Conforms**
Pyrogens	Conforms	**0°22 – 0°10 – 0°13 = 0°44* Conforms**
Abnormal toxicity	No sign of death or illness within 7 days after inoculation	**Conforms**

* The total temperature increase provided is not issued from the rounded values provided by the excel file, but from actual individual results.

Batch released on: 22 July 2010

01-Oct-10

Alice PADIEU-SEQUEIRA
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A.N.M.A.T. FOLIO 0252 MESA DE ENTRADAS

3.2.P.5.3

Validación de los Procedimientos Analíticos

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Sección 3.2.P.5.3 - Validación de los procedimientos analíticos

Índice

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