Thymine

Specification	Requirement
Identity	
Infrared	Match > 70
Chemical tests	
Content	≥ 97.0 %
Microbiological properties	
-	

Uracil

Specification	Requirement
Identity	
Infrared	Match > 70
Chemical tests	
Total ash	≤ 0.1 %
Melting point	≥ 300 °C and ≤ 330 °C
Content	≥ 99.0 %
Microbiological properties	
-	

Xanthine

Specification	Requirement
Identity	
Infrared	Match > 70
Chemical tests	
Content	≥ 99.0 %
Microbiological properties	
-	

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Dra. Bernarda Belay
Co-Directora Tecnica
M.N. 15.146

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Compañia Argentina de Investigaciones Farmacéuticas, S.A.
Dra. María Bernarda Belay
Apoderada
DNI 20378925

Donor Bovine Serum, gamma irradiated, 25 kGy

This specification is based on internal specification: SPC-20412 version 6

Product origin

Origin: Animal
Animal species: Bovine
Tissue: blood
Country of Origin: Canada (closed herd), New Zealand
TSE certificate: CEP2001-184 (Bodinco BV PAA) and CEP2000-341 (PERBIO-Hyclone)
Steps in Production process that reduce possible microbial contaminations:

- Aseptic purchase of blood, filtration and gamma irradiated at 25 – 40 kGy

Other information:

Donor Bovine Serum , gamma irradiated, 25 kGy complies with the general rules for minimizing the TSE-risk EP 5.2.8. The bovine serum also complies also with the current EMEA Note for Guidance (EMEA/410/01) for minimizing the TSE-risk via human and veterinary products.
The animals should not be vaccinated. The serum is taken from animals with an age ≤ 36 months. The country of origin is free of the following diseases or free since 1989: foot-and-mouth disease, vesicular stomatitis, contagious bovine pleurapneumoniae, rinderpest, pest of small ruminants, rift valley fever, Q-fever. The animals are free of tuberculosis, leptospirose, brucellose, blue tongue, bovine leukaemia.

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DNI 29778925

Donor Bovine Serum, gamma irradiated, 25 kGy

Quality

Donor Bovine Serum , gamma irradiated, 25 kGy complies with Ph.eur. monograph 2262 for Bovine Serum. Serum is the liquid, colourless to light-yellow component of blood, without fibrin. The following tests are performed on non-irradiated serum.

Specification	Requirement
Identity	
Immuno-electrophorese	Electrophoretic pattern corresponds to that of cow serum
Chemical tests	
Osmolality	240 – 340 mOs/kg
Total protein	≥ 35 mg/ml
Haemoglobin	≥ 4 mg/ml
pH	For information purposes only
Specific density	For information purposes only
Bilirubine	For information purposes only
Cholesterol	For information purposes only
Creatinine	For information purposes only
LDH	For information purposes only
SAST (SGOT)	For information purposes only
SALT (SGPT)	For information purposes only
Albumin	For information purposes only
Ureum	For information purposes only
Globulin	For information purposes only
Calcium	For information purposes only
Glucose	For information purposes only
Phosphorous	For information purposes only
Potassium	For information purposes only
Sodium	For information purposes only
Microbiological properties	
Absence of Bovine Polyoma virus	No BPV is demonstrated
Bacteria and fungi	Not present
Mycoplasma	No mycoplasma is demonstrated
Endotoxin	≤ 10 IU/ml
Growth quality#	Conform (Adequate cell growth on Vero cells)
Absence of polio antibodies#	Antibodies against polio type 1, 2 or 3 are not

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Donor Bovine Serum, gamma irradiated, 25 kGy

	present
Blue tongue	Not present
Bovine adeno virus	Not present
Bovine parvo virus	Not present
Bovine RSV	Not present
Bovine viral diarrhoea virus °	Not present
Rabies	Not present
Para-influenza virus type 3	Not present
Bovine leukosis virus	Not present
Reovirus type 3	Not present
Bovine herpes virus type 1 (=IBR, 2 and 4)	Not present

These tests are performed on the radiated serum

°If BDVD is not demonstrated, a comparing titration with a reference serum should be performed, to demonstrate that the serum does not contain BVDV-antibodies

The inacctivated serum sample may not have a significant inhibiting effect (< 2 log) on the growth of the BVDV reference stam, in comparison with an earlier controlled an treated reference serum.

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PAA LABORATORIES INC.

145 BETHRIDGE ROAD, ETOBICOKE, ONTARIO, CANADA, M9W 1N4

CERTIFICATE OF ORIGIN

LOT # SD70404

DONOR BOVINE SERUM

ORIGIN: CANADA

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Co-Directora Tecnica
M.N. 15.148

CAIF
Compañia Argentina de Investigaciones Farmacéuticas
Dra. María Bernarda Belay
Apoderada
DNI 29.575.925

THE UNDERSIGNED HAS EXAMINED THE MANUFACTURER'S INVOICE OR SHIPPER'S AFFIDAVIT CONCERNING THE ORIGIN OF THE MERCHANDISE AND DEEMS IT TO BE TRUE AND CORRECT TO THE BEST OF HIS/HER KNOWLEDGE AND BELIEF.

VIVIAN BAO, a Commissioner etc.
City of Toronto, for PAA Laboratories Inc.
Expires January 26, 2010

Vivian Bao, a Commissioner, etc.,
City of Toronto, for PAA Laboratories Inc.
Expires January 26, 2010

ADUANA FOLIO

REF# TMAM-2007-2374

Government of Canada
Canadian Food Inspection Agency

VETERINARY CERTIFICATE

FOR PRODUCTS TO BE USED FOR TECHNICAL PURPOSES INCLUDING PHARMACEUTICALS, IN VITRO DIAGNOSIS AND LABORATORY REAGENTS, BUT EXCLUDING SERUM OF EQUIDAE, INTENDED FOR DISPATCH TO THE EUROPEAN COMMUNITY

Note for the Importer: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

1. CONSIGNOR (NAME AND FULL ADDRESS) PAA LABORATORIES INC. 145 BETHRIDGE ROAD ETOBICOKE ONTARIO CANADA M9W 1N4	2. VETERINARY CERTIFICATE NO.(1) TMAM-2007- 2374 ORIGINAL 3. ORIGIN OF THE BLOOD PRODUCTS 3.1 COUNTRY: CANADA 3.2 CODE OF TERRITORY: CA-01
2. CONSIGNEE (NAME AND FULL ADDRESS) NVI -VACCIN ANThONIE VAN LEEUWENHOEKLAAN 9 3720 BA BILTHOVEN HOLLAND	4. COMPETENT AUTHORITY CANADIAN FOOD INSPECTION AGENCY GOVERNMENT OF CANADA
5. DESTINATION OF THE BLOOD PRODUCTS 5.1 EU MEMBER STATE: HOLLAND 5.2 NAME AND ADDRESS OF THE DESTINATION: AS CONSIGNEE ABOVE	6. PLACE OF LOADING 145 BETHRIDGE ROAD ETOBICOKE, ONTARIO CANADA
7. MEANS OF TRANSPORT AND CONSIGNMENT IDENTIFICATION 7.1 AIRCRAFT(3)	7.4 NATURE OF PACKAGING: PLASTIC BOTTLES 7.5 NUMBER OF PACKAGES: 1 X 500ML AND 1 X 500ML GI
7.2 NUMBER OF SEAL (IF APPLICABLE):	7.6 NET WEIGHT: 1.2 KG
7.3 REGISTRATION NUMBER, SHIP NAME OR FLIGHT NUMBER	7.7 LOT/BATCH PRODUCTION REFERENCE NUMBER: SD70404
8. IDENTIFICATION OF THE BLOOD PRODUCTS	
8.1 NATURE OF THE BLOOD PRODUCTS: DONOR BOVINE SERUM, DONOR BOVINE SERUM GAMMA IRRADIATED	
8.2 SPECIES OF ANIMALS FROM WHICH THE BLOOD PRODUCTS DERIVE: BOVINE	
8.3 ADDRESS AND REGISTRATION NUMBER OF THE APPROVED ESTABLISHMENT: PAA LABORATORIES INC. 145 BETHRIDGE ROAD, ETOBICOKE ONTARIO CANADA M9W 1N4 REGISTRATION NUMBER: BPT-02	

HA2110 (JUNE 10, 2004)

Canada

CANADIAN FOOD INSPECTION AGENCY Government of Canada Canada Gouvernement du Canada AGENCE CANADIENNE D'INSPECTION DES ALIMENTS

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Co-Directora Tecnica
M.N. 15.148

CAIF
Compañía Argentina de Investigaciones Farmacéuticas S.A.
Dra. María Bernarda Belay
Apoderada
DNI 29378925

REF# TMAM-2007- 2374

9. HEALTH ATTESTATION

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002[1] and certify that the blood products described above:

9.1 consist of blood products that satisfy the health requirements below;

9.2 consist exclusively of blood products not intended for human or animal consumption;

9.3 have been prepared exclusively with the following animal by-products:

[2] either - ~~blood of slaughtered animals, which is fit for human consumption in accordance with community legislation, but is not intended for human consumption for commercial reasons;~~

[2] and/or - ~~blood of slaughtered animals, which is rejected as unfit for human consumption but is not affected by any signs of diseases communicable to human or animals, derived from carcasses that are fit for human consumption in accordance with Community legislation;~~

[3] and/or - ~~blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;~~

[3] and/or - ~~blood and blood products derived from the production of products intended for human consumption;~~

[3] and/or - blood and blood products originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals;

9.4 [3] either - In the case of blood products derived from ruminant animals they originate in a third country or regions where:

[3] either - ~~the animals and products come from a region where no case of foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever and bluetongue[4] has been recorded for 12 months and in which vaccination has not been carried out against these diseases for at least 12 months and from which imports of ruminant animals are authorized pursuant to community legislation. The blood from which such products are manufactured must have been collected:~~

[3] either - ~~in slaughterhouses approved in accordance with Community legislation,~~

[3] or - ~~from live animals in facilities approved in accordance with community legislation;~~

[3] or - ~~in slaughterhouses approved and supervised by the competent authority of the third country; in this case the Commission and Member States must be notified of the address and approval number of such slaughterhouse and the certificate shall indicate this information.~~

~~Address:~~ _____

~~Approval number:~~ _____

[3] or - the products have undergone one of the following treatments, guaranteeing the absence of pathogens of the ruminant diseases foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever and bluetongue[4]

[3] either - ~~heat treatment at a temperature of 55°C for at least three hours, followed by an effectiveness check;~~

[3] or - irradiation at 2,5 megarads or by gamma rays, followed by an effectiveness check;

[3] or - ~~change in pH to pH 5 for two hours, followed by an effectiveness check;~~

[3] or - ~~heat treatment of at least 90°C throughout their substance, followed by an effectiveness check;~~.

[3] or - ~~sero-positive bluetongue animals are present, and the blood and blood products are intended for technical purposes including pharmaceuticals, in vitro diagnosis and laboratory reagents, to be processed in the approved~~

~~plants [approval number]~~ _____ in

~~[Member State]~~ _____ [5]

[3] or - ~~in the case of blood products derived from animals excluding ruminants they originate in a third country or regions where:~~

[3] either - ~~the animals and the products come from a region where no case of foot and mouth disease, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease, or avian influenza has been recorded for 12 months in the susceptible species and in which vaccination has not been carried out against these diseases for at least 12 months. The health certificate shall follow the model according to the species of animal from which the blood products are derived;~~

[3] or - ~~the products have undergone a heat treatment at a temperature of 55°C for at least three hours, followed by an effectiveness check, guaranteeing the absence of pathogens of the following diseases: foot and mouth disease, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease or avian influenza in the susceptible species;~~

HA2110 (JUNE 10, 2004)

Canada

CANADIAN FOOD INSPECTION AGENCY
Government of Canada
Canada
AGENCE CANADIENNE D'INSPECTION DES ALIMENTS
Gouvernement du Canada

CAIF SA
Dra. Bernarda Bolay
Co-Directora Tecnica
M.N. 19.160

CAIF
Compañía Argentina de Investigaciones Farmaceuticas S.A.
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Apoderada
DNI 29378925

REF# TMAM-2007-2374

9.5the end product was:

[3] either - packed in new or sterilized bags,

[3] ~~or transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,~~

and which bears labels indicating 'NOT FOR HUMAN OR ANIMAL CONSUMPTION';

9.6 the end product was stored in enclosed storage;

9.7 the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Done at MARKHAM, on JUNE 01, 2007

Signature of Official Veterinarian[7]

Canadian Food Inspection Agency

Government of Canada

Gary Boose - DVM
Canadian Food Inspection Agency
145 Renfrew Drive
Suite #160
Markham, ONT
L3R 9R6

GARY BOOSE-DVM

(Name, qualification and title, in capital letters)

Official Export Stamp[7]

(1) Issued by the competent authority.

(2) For goods vehicles, the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

(3) Delete as appropriate

(4) OJ L 273, 10.10.2002, p. 1.

(5) In the case of countries in which bluetongue sero-positive ruminant animals are present, blood products have been treated or the animals have been tested seronegative.

(6) This must be the same Member State of first entry of the product into the Community.

(7) The signature and stamp must be in colour different to that of the printing.

HA2110 (JUNE 10, 2004)

Canada

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STERIS®

CERTIFICATE OF PROCESSING

CUSTOMER	IRRADIATION LOT NUMBER	PO NUMBER
PAA International Inc.	1435	N/A

PRODUCT CODE NUMBER	PRODUCT LOT NUMBER	NUMBER OF CASES
Fetal Bovine Serum	SF70216	167
Fetal Bovine Serum	SF70216/SF51201	1
Donor Bovine Serum	SD70404	1

TOTAL MINIMUM DOSE DELIVERED: 26.6 kGy
TOTAL MAXIMUM DOSE DELIVERED: 38.2 kGy

PAA	
Q.C. MANAGER	
DATE	APR 12 2007
APPROVED	

IRRADIATION START TIME & DATE:	1952	4/11/2007
IRRADIATION FINISH TIME & DATE:	2245	4/11/2007

REMARKS: There was no process interruption time logged for this run.

MINIMUM SPECIFIED DOSE:	25.0 kGy	MINIMUM DELIVERED DOSE:	26.6 kGy
MAXIMUM SPECIFIED DOSE:	N/A kGy	MAXIMUM DELIVERED DOSE:	N/A kGy

Q.A. APPROVED	TITLE	DATE
L. Samson	QS/RC Analyst	April 12, 2007

Isomedix Corporation • 184 Crown Court • Whitby • Ontario • L1N 7B1

Dra. Bernarda Belay
Directora Técnica

CAIF
Compañía Argentina de Investigaciones Farmacéuticas S.A.
Dra. María Bernarda Belay
Apoderada
DNI 29378965

16/4/2007

HyClone®
New Zealand

Certificate of Analysis

Preliminary

Product: Donor Bovine Serum Custom Made for SVM
New Zealand Sourced
0.2µm Sterile Filtered

Catalogue Number: SH3A1246

Lot Number: DNA0106 **Manufacturing Date:** January 2003

Total Batch Volume: 1140.8L **Expiration Date:** January 2006

Test/Method	Specification	Units	Result
Endotoxin Limulus Amoebocyte Lysate	≤ 5	EU/ml.	<0.06
Sterility (USP) Bacteria and Fungi	No Growth		No Growth
Virus Testing (9CFR) Fluorescent Antibody			
Bluetongue	Not Detected		Not Detected
Bovine Adenovirus	Not Detected		Not Detected
Bovine Parvovirus	Not Detected		Not Detected
Bovine Respiratory Syncytial Virus	Not Detected		Not Detected
Bovine Viral Diarrhoea	Not Detected		Not Detected
Rabies	Not Detected		Not Detected
Reovirus	Not Detected		Not Detected
Cytopathogenic Agents - e.g. IBR	Not Detected		Not Detected
Haemadsorbing Agents - e.g. PI3	Not Detected		Not Detected
Mycoplasma (Large Volume Direct Culture)	Not Detected		Not Detected
(Hoechst DNA Stain)	Not Detected		Not Detected
Irradiation Dose	25 – 35 kGy	kGy	To be Performed

The raw material used to produce this batch of serum has been sourced exclusively from clinically healthy cattle which were born and maintained in a country which is officially recognised as being free from Bovine Spongiform Encephalopathy (BSE), namely New Zealand.

The raw material used was not derived from animals:

- Which have died on the farm, including newborn animals or foetuses,
- Which have been killed to eradicate epizootic diseases,
- Showing any clinical signs and/or lesions of contagious diseases for humans, or for reasons of residues, were declared unfit for human consumption.

This is a preliminary Certificate of Analysis. As of the 28th April 2003, this product has not been released.

Collected and Processed in NZ HyClone Sold

Caroline Newcombe
QA/QC Manager

CAIF SA
Dra. Bernarda Belay
Co-Directora Tecnica
M.N. 1448

Omokoroa Farm P O Box 694, Tauranga New Zealand Telephone +64 7 548 0225 Facsimile +64 7 548 1295 Email hyclone@hyclone.com Internet www.hyclone.com

Parent office of
HyClone AB
P O Box Knarrbunken 34
S 252 78 Helsingborg
SWEDEN

Public Company
Corporate Identity No.
1158396-5295

PERBIC

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Compañía Argentina de Investigaciones Farmacéuticas S.A.
Dra. María Bernarda Belay
Apoderada
DNI 29378925

GEWAARMERKTE COPIE
POUR COPIE CONFORME
CERTIFIED COPY

NEW ZEALAND FOOD SAFETY AUTHORITY
Ministry of Agriculture and Forestry

Certificate number / Referentienummer van het certificaat NZL2007/HYCLONE1/7523

Animal Health Certificate[1] / Diergezondheidscertificaat[1]

16.1 Processed blood and blood products for pharmaceutical or technical use - cattle sheep, goats, pigs

Name and address of consignor / Naam en adres van de afzender: HYCLONE1, Hyclone Aktiebolag, Omokoroa Farm, 441 Old Highway, TAURANGA, NEW ZEALAND	**Exporting country** / Land van verzending NEW ZEALAND **Competent authority** / Bevoegde instantie FOOD SAFETY AUTHORITY
Name and address of consignee / Naam en adres van degene voor wie de zending is bestemd: Perbio Science NV, Industriezone 111, Industrielaan 27, 9320 Erembodegem - Aalst, BELGIUM	

Place and Country of Destination / Plaats en land van bestemming: Brussels, Belgium	**Departure Date** / Verschepingsdatum: 6-Oct-2007
Means of transport / Per vervoermiddel: Air, Singapore Airlines, SQ286	**Port of Loading** / plaats van lading: Auckland [AUK]
Port of Inspection / Inspectiehaven: Zaventem [VBR]	**Port of Discharge** / Ontschepinghaven: Zaventem [VBR]

Item / Eenheid	Number and kind of packages / Aantal en soort verpakkingen	Description of product / Productomschrijving	Net weight / Nettogewicht
1	2 Bottles	Frozen Filtered New Zealand Donor Bovine Serum, 500mL bottles, SH3A1248.02, DSE0289	1 ltr
2	24 Bottles	Frozen Filtered New Zealand Foetal Bovine Serum, 1000mL bottles, SH30406.03, DSG0297	24 ltr
	26 Packages in Total / Pakketten in totaal	Total Weight / Totaal gewicht:	25 ltr

ORIGINAL

Species / Diersoort: (1,2) Bovine	**Identification Marks** / Merktekens ter identificatie: Not Applicable	**Container (& Seal) Numbers** / Container & (Zegel) nummers: Not Applicable
Processing Premises / Verwerkingsplaatsen: (1,2) BBP7 Hyclone Aktiebolag, TAURANGA, NEW ZEALAND		
Production Date(s) / Productiedatum/a: (1) 1-Jun-2007 (2) 1-Aug-2007		

Health Attestation / Gezondheidsverklaring

1. **The animal products herein described, comply with the relevant New Zealand animal health standards and requirements which have been recognised as equivalent to the European Community standards and requirements as prescribed in Council Decision 97/132/EC. Specifically in accordance with the Animal Products Act 1999.** / Die hierin beschreven dierlijke producten voldoen aan de desbetreffende normen en voorschriften van Nieuw-Zeeland op het gebied van de diergezondheid die als gelijkwaardig zijn erkend aan de normen en voorschriften van de Europese Gemeenschap die zijn vastgesteld in Besluit 97/132/EG van de Raad. Zij moeten met name voldoen aan de Animal Products Act van 1999.
2. **the animal by-product does not contain and is not derived from bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a negligible BSE risk.** / Het dierlijke bijproduct geen materiaal van runderen, schapen en geiten bevat en daar niet van is afgeleid, met uitzondering van materiaal dat afkomstig is van dieren die geboren, ononderbroken gehouden en geslacht zijn in een land of gebied dat, overeenkomstig artikel 5, lid 2, is ingedeeld als land of gebied met een verwaarloosbaar BSE-risico.

1. This health certificate is for veterinary purposes only. The official health certificate must accompany the consignment until it reaches the border inspection post or when the official certificate is issued after departure of the consignment, it must be available in the border inspection post at arrival and the eligibility document statement must be completed. / Dit gezondheidscertificaat is uitsluitend bestemd voor veterinaire doeleinden. Het officiële gezondheidscertificaat moet de zending vergezellen tot in de grensinspectiepost of moet, wanneer het wordt afgegeven nadat de zending reeds is vertrokken, beschikbaar zijn in de grensinspectiepost bij aankomst van de zending en in dat geval moet Eligibility Document verklaring zijn ingevuld

Done at / Gedaan te MT MAUNGANUI, New Zealand

On / op 4-Oct-2007

NEW ZEALAND FOOD SAFETY AUTHORITY — Official Veterinarian 0340

Signature of official veterinarian, New Zealand Government / Handtekening ambtelijke veearts van de Nieuw-Zeelandse regering

J King BVSc

Name, title and qualifications / Naam, titel en kwalificaties

Dra. Bernarda ... Directora Tecnica
Compañía Argentina de Investigaciones Farmacéuticas
Dra. María Bernarda Belzy, Apoderada, DNI 23778925

AP639.5

Sterigenics.

13 -11- 2007

CERTIFICAT D'IRRADIATION N° 98466
BEWIJS VAN BESTRALING Nr
CERTIFICATE OF IRRADIATION N°

STERIGENICS Belgium (Fleurus) s.a. Zoning industriel B-6220 certifie avoir traité dans ses installations par rayonnement gamma (cobalt-60) sur base de l'autorisation d'exploitation délivrée en application de l'A.R. du 12 mars 2002 par l'Agence Fédérale de Contrôle Nucléaire et en conformité avec les normes EN 552 et ISO 11137.

STERIGENICS Belgium (Fleurus) n.v. Zoning industriel B-6220 verklaart door middel van gammastralen (cobalt-60) te hebben behandeld in haar inrichtingen waarvoor een uitbatingsvergunning werd bekomen in toepassing van het K.B. van 12 maart 2002 door het Federaal Agentschap voor Nucleaire Controle en overeenkomstig met normen EN 552 en ISO 11137.

STERIGENICS Belgium (Fleurus) s.a. Zoning industriel B-6220 certifies the treatment by gamma irradiation (cobalt-60) at its plant according to the licence delivered in compliance to the Belgian Royal Decree of March 12, 2002 by the Federal Agency for Nuclear Control and in accordance with norms EN 552 and ISO 11137.

Pour le compte de : PERBIO
Voor rekening van :
For the account of :

"Produit maintenu à l'état congelé pendant l'irradiation – Product kept frozen during irradiation"

Les colis suivants : nombre : 1 carton donor bovine serum
De volgende colli : aantal :
Following parcels : quantity :

Réf. STERIGENICS: 9073

Identification suivant déclaration du client : SH 3A1248.02/NVI
Identificatie volgens verklaring van de klant : Product Lot N°: DSE0289
Identification following the declaration of the customer : 500 ml

Répartis dans les unités de traitement numérotées : 421183
Verdeeld in de genummerde behandelingseenheden :
Divided into the numbered treated units :

Date d'irradiation :
Bestralingsdatum : 07/11/07
Irradiation date :

Fleurus, le 9 novembre 2007

Dose garantie : 28,67 kGy min
Gewaarborgde dosis : 33,75 kGy max
Guaranteed dose of :

G. BOUXIN
Ingénieur Assurance Qualité

P. QUERTINMONT
Contrôle Qualité

Dra. Bernarda Belay
Co-Directora Tecnica
M.N. 15.148

Sterigenics Belgium (Fleurus) S.A.
Zoning Industriel ▫ B-6220 Fleurus
Tel +32 71 81 00 84 ▫ Fax +32 71 81 63 53 ▫ www.sterigenics.com

TVA BE 0442 042 064 ▫ RPM Charleroi
Fortis 230-0080250-51
IBAN BE75230006025051 ▫ Swift code GEBABEBB
Crédit du Nord 30076-04205-0003220400-05

Compañía Argentina de Investigaciones Farmacéuticas S.A.
Dra. María Bernarda Belay
Apoderada
DNI 29378925

Foetal Bovine Serum, gamma irradiated, 25 kGy

This specification is based on internal specification: SPC-20414 version 6

Product origin

Origin: Animal
Animal species: Bovine
Tissue: blood
Country of Origin: Canada, New Zealand
TSE certificate: CEP 2000-093 (PAA)
Steps in Production process that reduce possible microbial contaminations:
- Aseptic purchase of blood, filtration and gamma irradiated at 25 – 40 kGy

Other information:
Foetal Bovine Serum , gamma irradiated, 25 kGy complies with the general rules for minimizing the TSE-risk EP 5.2.8. The Foetal Bovine Serum also complies also with the current EMEA Note for Guidance (EMEA/410/01) for minimizing the TSE-risk via human and veterinary products. The dams may be vaccinated in accordance with the national or regional veterinary vaccination scheme. The serum is taken from normal fetuses, from healthy cows, suitable for human consumption. The country of origin is free of the following diseases or free since 1989: foot-and-mouth disease, vesicular stomatitis, contagious bovine pleurapneumoniae, rinderpest, pest of small ruminants, rift valley fever, Q-fever.

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Dra. María Bernarda Belay
Apoderada
DNI 29378925

Foetal Bovine Serum, gamma irradiated, 25 kGy

Quality

Foetal Bovine Serum , gamma irradiated, 25 kGy complies with Ph.Eur. monograph 2262 for Bovine Serum. The following tests are performed on the non-irradiated serum.

Specification	Requirement
Identity	
Immuno-electrophorese	Electrophoretic pattern corresponds to that of cow serum
Chemical tests	
Osmolality	280 – 365 mOs/kg
Total protein	30- 45 mg/ml
Haemoglobin	≥ 4 mg/ml
pH	For information purposes only
Specific density	For information purposes only
Bilirubine	For information purposes only
Cholesterol	For information purposes only
Creatinine	For information purposes only
LDH	For information purposes only
SAST (SGOT)	For information purposes only
SALT (SGPT)	For information purposes only
Albumin	For information purposes only
Ureum	For information purposes only
Globulin	For information purposes only
Calcium	For information purposes only
Glucose	For information purposes only
Phosphorus	For information purposes only
Potassium	For information purposes only
Sodium	For information purposes only
Microbiological properties	
Absence of Bovine Polyoma virus	No BPV is demonstrated
Bacteria and fungi	Not present
Mycoplasma	No mycoplasma is demonstrated
Endotoxin	≤ 25 IU/ml
Growth quality#	Conform (Adequate cell growth on Vero cells
Absence of polio antibodies#	Antibodies against polio type 1, 2 or 3 are not present

Foetal Bovine Serum, gamma irradiated, 25 kGy

Blue tongue	Not present
Bovine adeno virus	Not present
Bovine parvo virus	Not present
Bovine RSV	Not present
Bovine viral diarrhoea virus °	Not present
Rabies	Not present
Para-influenza virus type 3	Not present
Bovine leukosis virus	Not present
Reovirus type 3	Not present
Bovine herpes virus type 1 (=IBR, 2 and 4)	Not present

These tests are performed on the radiated serum

° If BDVD is not demonstrated, a comparing titration with a reference serum should be performed, to demonstrate that the serum does not contain BVDV-antibodies
The inacctivated serum sample may not have a significant inhibiting effect (< 2 log) on the growth of the BVDV reference stam, in comparison with an earlier controlled an treated reference serum.

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Co-Directora Tecnica
M.N. 15.148

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Compañía Argentina de Investigaciones Farmacéuticas S.A.
Dra. María Bernarda Belay
Apoderada
DNI 29378925

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PAA LABORATORIES INC.

145 BETHRIDGE ROAD, ETOBICOKE, ONTARIO, CANADA, M9W 1N4

CERTIFICATE OF ORIGIN

LOT # A70306-7117

FETAL BOVINE SERUM G.I.

ORIGIN: CANADA

THE UNDERSIGNED HAS EXAMINED THE MANUFACTURER'S INVOICE OR SHIPPER'S AFFIDAVIT CONCERNING THE ORIGIN OF THE MERCHANDISE AND DEEMS IT TO BE TRUE AND CORRECT TO THE BEST OF HIS/HER KNOWLEDGE AND BELIEF.

Vivian Bad, a Commissioner etc.
City of Toronto, for PAA Laboratories Inc.
Expires January 26, 2010

CAIF SA
Dra. Bernarda Belay
Co-Directora Tecnica
M.N. 18.148

Comprador Intermediario de Productos Farmacéuticos S.A.
Dra. María Bernarda Belay
Apoderada
DNI 93.378.825

Rx datum/tijd 11-DEC-2007(DIN) 17:37 66
11-DEC-2007 18:00 FROM BODINCO ALKMAAR TO 00302250610

12/06/2007 11:08 905-433-2129 STERIS PAGE 02

STERIS®

CERTIFICATE OF PROCESSING

CUSTOMER	IRRADIATION LOT NUMBER	PO NUMBER
PAA Laboratories Inc.	1451	N/A
PRODUCT CODE NUMBER	**PRODUCT LOT NUMBER**	**NUMBER OF CASES**
Fetal Bovine Serum	SR71123 A70308-7117	1

PAA
Q.C. MANAGER
DATE
APPROVED

TOTAL MINIMUM DOSE DELIVERED: 28.6 kGy
TOTAL MAXIMUM DOSE DELIVERED: 36.[illegible] kGy

IRRADIATION START TIME & DATE: [illegible] 12/5/2007
IRRADIATION FINISH TIME & DATE: 1708 12/5/2007

REMARKS: There was no process interruption time logged for this run.

MINIMUM SPECIFIED DOSE: 25.0 kGy MINIMUM DELIVERED DOSE: 14.3 kGy
MAXIMUM SPECIFIED DOSE: N/A kGy MAXIMUM DELIVERED DOSE: N/A kGy

Q.A. APPROVED	TITLE	DATE
R. Franco	QS/RC Manager	December 6, 2007

Isomedix Corporation • 104 Crown Court • Whitby • Ontario • L1N 7B1
Isomedix Corporation operates under a quality system that is in compliance with the ISO 13485:2003 quality standard.
Isomedix Corporation adheres to requirements provided through ANSI/AAMI/ISO 11137 and EN 552

Form 200067.1
Revision: 1
Effective Jun. 09, 06

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Compañía Argentina de Investigaciones Farmacéuticas S.A.
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TOTAL P. 11

REF#: TMAM-2007- 540

Government of Canada
Canadian Food Inspection Agency

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VETERINARY CERTIFICATE

FOR PRODUCTS TO BE USED FOR TECHNICAL PURPOSES INCLUDING PHARMACEUTICALS, IN VITRO DIAGNOSIS AND LABORATORY REAGENTS, BUT EXCLUDING SERUM OF EQUIDAE, INTENDED FOR DISPATCH TO THE EUROPEAN COMMUNITY

Note for the importer: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

1. CONSIGNOR (NAME AND FULL ADDRESS) PAA LABORATORIES INC. 145 BETHRIDGE ROAD ETOBICOKE ONTARIO CANADA M9W 1N4	2. VETERINARY CERTIFICATE NO.(1) TMAM-2007- ORIGINAL 3. ORIGIN OF THE BLOOD PRODUCTS 3.1 COUNTRY: CANADA 3.2 CODE OF TERRITORY: CA-01
2. CONSIGNEE (NAME AND FULL ADDRESS) NVI – VACCIN DEPT LCB-GBE. H1 ANTONIE VAN LEEUWENHOEKLAAN 9 3720 BA BILTHOVEN THE NETHERLANDS	4. COMPETENT AUTHORITY CANADIAN FOOD INSPECTION AGENCY GOVERNMENT OF CANADA
5. DESTINATION OF THE BLOOD PRODUCTS 5.1 EU MEMBER STATE: HOLLAND 5.2 NAME AND ADDRESS OF THE DESTINATION: AS CONSIGNEE ABOVE	6. PLACE OF LOADING 145 BETHRIDGE ROAD ETOBICOKE ONTARIO CANADA
7. MEANS OF TRANSPORT AND CONSIGNMENT IDENTIFICATION 16 16 16	7.4 NATURE OF PACKAGING: PLASTIC BOTTLES
7.1 ~~LORRY, RAIL, SHIP OR~~ AIRCRAFT(3)	7.5 NUMBER OF PACKAGES: 4 X 500ML
7.2 NUMBER OF SEAL (IF APPLICABLE):	7.6 NET WEIGHT: 2.4KGS
7.3 REGISTRATION NUMBER, SHIP NAME OR FLIGHT NUMBER INPUT	7.7 LOT/BATCH PRODUCTION REFERENCE NUMBER: A70106-7117 AND A70306-7117GI
8. IDENTIFICATION OF THE BLOOD PRODUCTS	
8.1 NATURE OF THE BLOOD PRODUCTS: FETAL BOVINE SERUM AND FETAL BOVINE SERUM GI	
8.2 SPECIES OF ANIMALS FROM WHICH THE BLOOD PRODUCTS DERIVE: BOVINE	
8.3 ADDRESS AND REGISTRATION NUMBER OF THE APPROVED ESTABLISHMENT: PAA LABORATORIES INC. 145 BETHRIDGE ROAD, ETOBICOKE ONTARIO CANADA M9W 1N4 REGISTRATION NUMBER: BPT-02	

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REF#: TMAM-2007- 5409

9. HEALTH ATTESTATION

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002[4] and certify that the blood products described above:

9.1 consist of blood products that satisfy the health requirements below;

9.2 consist exclusively of blood products not intended for human or animal consumption;

9.3 have been prepared exclusively with the following animal by-products:

[3] either - blood of slaughtered animals, which is fit for human consumption in accordance with community legislation, but is not intended for human consumption for commercial reasons;

[3] and/or - blood of slaughtered animals, which is rejected as unfit for human consumption but is not affected by any signs of diseases communicable to human or animals, derived from carcasses that are fit for human consumption in accordance with Community legislation;

[3] and/or - blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;

[3] and/or - blood and blood products derived from the production of products intended for human consumption;

[3] and/or - blood and blood products originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals;

9.4 [3] either - in the case of blood products derived from ruminant animals they originate in a third country or regions where:

[3] either - the animals and products come from a region where no case of foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever and bluetongue[5] has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months and from which imports of ruminant animals are authorized pursuant to community legislation. The blood from which such products are manufactured must have been collected:

[3] either - in slaughterhouses approved in accordance with Community legislation,

[3] or - from live animals in facilities approved in accordance with community legislation,

[3] or - in slaughterhouses approved and supervised by the competent authority of the third country. In this case the Commission and Member States must be notified of the address and approval number of such slaughterhouse and the certificate shall indicate this information.

Address: _____

_____

Approval number: _____

[3] or - the products have undergone one of the following treatments, guaranteeing the absence of pathogens of the ruminant diseases foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever and bluetongue[5]

[3] either - heat treatment at a temperature of 65°C for at least three hours, followed by an effectiveness check,

[3] or - Irradiation at 2,5 megarads or by gamma rays, followed by an effectiveness check,

[3] or - change in pH to pH 5 for two hours, followed by an effectiveness check,

[3] or - heat treatment of at least 90°C throughout their substance, followed by an effectiveness check,

[3] or - sero-positive bluetongue animals are present, and the blood and blood products are intended for technical purposes including pharmaceuticals, in vitro diagnosis and laboratory reagents, to be processed in the approved

plants [approval number] _____ in

[Member State] _____[6]

[3] or - In the case of blood products derived from animals excluding ruminants they originate in a third country or regions where:

[3] either - the animals and the products come from a region where no case of foot-and-mouth disease, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease, or avian influenza has been recorded for 12 months in the susceptible species and in which vaccination has not been carried out against these diseases for at least 12 months. The health certificate shall follow the model according to the species of animal from which the blood products are derived;

[3] or - the products have undergone a heat treatment at a temperature of 65°C for at least three hours, followed by an effectiveness check, guaranteeing the absence of pathogens of the following diseases: Foot and-mouth disease, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease or avian influenza in the susceptible species;

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REF#: TMAM-2007-

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9.5 the end product was:

(3) either - packed in new or sterilized bags,

(3) ~~or transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,~~

and which bears labels indicating 'NOT FOR HUMAN OR ANIMAL CONSUMPTION';

9.6 the end product was stored in enclosed storage;

9.7 the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Done at MARKHAM, on DEC 19 2007

Signature of Official Veterinarian(7)

Canadian Food Inspection Agency

Government of Canada

CANADIAN FOOD INSPECTION AGENCY Government of Canada Canada Official Export Stamp(7) Gouvernement du Canada AGENCE CANADIENNE D'INSPECTION DES ALIMENTS

[illegible] DVM
CANADIAN FOOD INSPECTION AGENCY
145 RENFREW DR. UNIT# 160
MARKHAM ONT.
L3R 9R6 905-513-2850

(Name, qualification and title, in capital letters)

(1) Issued by the competent authority.

(2) For goods vehicles, the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

(3) Delete as appropriate

(4) OJ L 273, 10.10.2002, p. 1.

(5) In the case of countries in which bluetongue sero-positive ruminant animals are present, blood products have been treated or the animals have been tested seronegative.

(6) This must be the same Member State of first entry of the product into the Community.

(8) The signature and stamp must be in colour different to that of the printing.

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HA2110 (JUNE 10, 2004)

Cytodex

The specification is based on internal specification: SPC-21078 version 1

Product origin:

Origin: Animal

Animal species: Bovine

Tissue: Bovine milk

Country of origin: USA

TSE certificate: not applicable

Steps in Production process that reduce possible microbial contaminations:

- Ethanol 40 % during 32 hours
- Treatment with pH = 1.3 during 10 hours at 85 °C
- Spray dry treatment at 230 °C

Cytodex

Quality

Cytodex is a white powder.

Specification	Requirement
Identity	
Growth curve of cell line IMR-90	≥ 0.8 (quotient of the slope of the growth curve)
Particle size distribution	≥ 70 % (dry particles with a size between 60 and 87 µm)
Density	≤ 1.045 $g.ml^{-1}$
Chemical tests	
Ione exchange capacity	≥ 1.40 and ≤ 1.60 mmol Cl'/g
Heavy metals	≤ 5 µg/g
Loss on drying	≤ 10.00 %
Microbiological properties	
Microbiological contamination	≤ 100 CFU/g

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