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CellR4 2017; 5 (2): e2298 – www.cellr4.org - ISSN: 2329-7042

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Supported by grants from the National Institute of Allergy and Infectious Diseases and the National Institute for Diabetes and Digestive and Kidney Diseases.
• At Emory University, U01AI089317.
• At Northwestern University, U01AI089316.
• At the University of Alberta, Edmonton: U01AI065191.
• At the University of California, San Francisco, U01DK085531.
• At the University of Illinois, Chicago, 5U01DK070431-10.
• At the University of Iowa, U01DK070431.
• At the University of Miami, U01DK070460.
• At the University of Minnesota, U01AI065193.
• At the University of Pennsylvania, U01DK070430.
• At Uppsala University, U01AI065192.
In addition, the study was supported by the following GCRC and CTSA awards:
• At Emory University: UL1TR000454.
• At Northwestern University: 5UL1RR025741 and 8UL1TR000150.
• At the University of California, San Francisco, UL1TR000004.
• At the University of Illinois, Chicago, UL1TR000050.
• At the University of Miami: 1UL1TR000460.
• At the University of Minnesota: 5M01-RR000400 and UL1TR000114.
• At the University of Pennsylvania: UL1TR000003.

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CellR4 2017; 5 (2): e2298 – www.cellr4.org - ISSN: 2329-7042

To cite this article

Purified Human Pancreatic Islets with Lisofylline, Certificate of Analysis (Product Code PHPI-L-01) – Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium

CellR4 2017; 5 (2): e2298

CellR4 2017; 5 (2): e2298 – www.cellr4.org - ISSN: 2329-7042

DAIT, NIAID, NIH				
	SOP ATTACHMENT			
Document No. SOP 3100, B04	**Revision No.** 02	**Effective Date** 21 July 2009	**Supersedes Date** 02 June 2008	**Page 1 of 2**

Document Title:

PURIFIED HUMAN PANCREATIC ISLETS WITH LISOFYLLINE, CERTIFICATE OF ANALYSIS

(PRODUCT CODE PHPI-L-01)

Manufacturing Facility: _____

Islets Lot Number: _____ **Recipient Study ID #:** _____

Recipient Medical Record Number: _____

Product Formulation:

Manufacture Date: _____
(Date 1st Infusion Bag filled)

Number of Bags in Lot: _____

Storage Condition: + 15°C to + 30°C

COMPONENT	CONCENTRATION
Islet Equivalents (IEQ)	≥ 4.0 X 10^3 IEQ/kg of Recipient Body Weight (Total IEQ/infusion)
Albumin Human USP	2.5%
Lisofylline	100 µM
CMRL 1066 Transplant Media, Contains HEPES and without Sodium Bicarbonate	q.s. to 200 mL per bag

TEST	REQUIREMENT	RESULTS
IDENTITY		
Recipient Identity	Recipient Study ID # and Recipient Medical Record Number on this CoA and on each infusion bag label are identical to that in the Production Batch Record, Section 12.3	Bag 1: _____ Bag 2: _____ Bag 3: _____
Islets Identity	Islets are present in each product bag	Bag 1: _____ Bag 2: _____ Bag 3: _____
VOLUMES IN BAGS		
Suspension Volume	200 mL per product bag ≤ 600 mL total in three product bags	Bag 1: _____ mL Bag 2: _____ mL Bag 3: _____ mL Total: _____ mL
Settled Tissue Volume	≤ 7.5 mL per product bag ≤ 15.0 mL total in three product bags	Bag 1: _____ mL Bag 2: _____ mL Bag 3: _____ mL Total: _____ mL
POTENCY		
High Purity Islets GSIR Index (Pre-culture Sample)	For Information Only	GSIR Index: _____
High Purity Islets GSIR Index (Post-culture Sample)	Glucose Stimulated Insulin Release Index > 1	GSIR Index: _____
Islets Quantity	First Infusion: ≥ 5.0 X 10^3 IEQ/kg of Recipient's Body Weight (Total IEQ/infusion) Subsequent Infusions: ≥ 4.0 X 10^3 IEQ/kg of Recipient's Body Weight (Total IEQ/infusion)	Bag 1: _____ IEQ/kg Bag 2: _____ IEQ/kg Bag 3: _____ IEQ/kg Total: _____ IEQ/kg

Document Title:

PURIFIED HUMAN PANCREATIC ISLETS WITH LISOFYLLINE, CERTIFICATE OF ANALYSIS

(PRODUCT CODE PHPI-L-01)

Islets Lot Number: _____ **Recipient Study ID #:** _____

Recipient Medical Record Number: _____

TEST	REQUIREMENT	RESULTS
POTENCY (CONTINUED)		
Viability	≥ 70% in each product bag	Bag 1: _____ % Bag 2: _____ % Bag 3: _____ %
PURITY		
Islets Concentration	≥ 20,000 Total IEQ/mL Total Settled Tissue Volume	Bag 1: _____ IEQ/mL Bag 2: _____ IEQ/mL Bag 3: _____ IEQ/mL Total: _____ IEQ/mL
SAFETY		
Appearance	Light yellow to amber liquid with visible aggregates in each product bag	Bag 1: _____ Bag 2: _____ Bag 3: _____
Endotoxin	≤ 5.0 EU/kg of Recipient's Body Weight (Total EU/infusion)	Bag 1: _____ EU/kg Bag 2: _____ EU/kg Bag 3: _____ EU/kg Total: _____ EU/kg
Islets Purity Levels Gram Stain (Pre-combination Samples)	No Organisms Seen	High Purity: _____ Middle Purity: _____ Low Purity: _____
Sterility (21CFR610.12 or validated alternate)	No Growth in each product bag	Bag 1: _____ Bag 2: _____ Bag 3: _____

All Test Results Meet Requirements: Yes No (Circle One)

_____ Date: _____

Recorded By

_____ Date: _____

Laboratory Director, Operations Manager, or Designee

_____ Date: _____

Quality Unit

CellR4 2017; 5 (2): e2298 – www.cellr4.org - ISSN: 2329-7042