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Document Title:

PURIFIED HUMAN PANCREATIC ISLETS WITH EXENATIDE, INTERIM CERTIFICATE OF ANALYSIS (PRODUCT CODE PHPI-E-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%
Exenatide	20 nM
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: _____
Islets Quantity	<u>First Infusion:</u> ≥ 5.0 X 10 ³ IEQ/kg of Recipient's Body Weight (Total IEQ/infusion) <u>Subsequent Infusions:</u> ≥ 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

