Purified Human Pancreatic Islets, Specification (Product Codes PHPI-A-01, PHPI-L-01, PHPI-E-01) – *Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium*

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Document Title:

PURIFIED HUMAN PANCREATIC ISLETS, SPECIFICATION
(PRODUCT CODES PHPI-A-01, PHPI-L-01, PHPI-E-01)

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Changes to this Specification Document must be proposed to the Chief, Regulatory Affairs, DAIT, NIAID, NIH, and approved by all the original signatories, or their successors, before implementation.

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2.0 Requirements:

TEST	METHOD	REQUIREMENT
IDENTITY		
Recipient Identity	Visual Inspection	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
Islets Identity	DTZ Stain & Microscopic Examination	Islets are present in each product bag
VOLUMES IN BAGS		
Suspension Volume	Direct Measurement	200 mL per product bag ≤ 600 mL total in three product bags
Settled Tissue Volume	Direct Measurement after 5-minute settling	≤ 7.5 mL per product bag ≤ 15.0 mL total in three product bags
POTENCY		
High Purity Islets GSIR Index (Pre-culture Sample)	Glucose Stimulated Insulin Release by ELISA	For Information Only
High Purity Islets GSIR Index (Post-culture Sample)	Glucose Stimulated Insulin Release by ELISA	Glucose Stimulated Insulin Release Index > 1
Islets Quantity	DTZ Stain & Microscopic Examination	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)
Viability	FDA/PI Stain & Microscopic Examination	≥ 70% in each product bag
PURITY		
Islets Concentration	DTZ Stain & Microscopic Examination	≥ 20,000 Total IEQ/mL Total Settled Tissue Volume
SAFETY		
Appearance	Visual Inspection	Light yellow to amber liquid with visible aggregates in each product bag
Endotoxins	LAL	≤ 5.0 EU/kg of Recipient's Body Weight (Total EU/infusion)
Gram Stain (Islets Purity Levels Pre-combination Samples)	Gram Stain	No Organisms Seen
Sterility	Sterility (21CFR610.12 or validated alternate)	No growth in each product bag

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