The NIH CIT Consortium Chemistry Manufacturing Controls Monitoring Committee:

The NIH CIT Consortium


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

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**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:

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>CONCENTRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Islet Equivalents (IEQ)</td>
<td>≥ 4.0 X 10^3 IEQ/kg of Recipient Body Weight (Total IEQ/infusion)</td>
</tr>
<tr>
<td>Albumin Human USP</td>
<td>2.5%</td>
</tr>
<tr>
<td>Exenatide</td>
<td>20 nM</td>
</tr>
<tr>
<td>CMRL 1066 Transplant Media, Contains HEPES and without Sodium Bicarbonate</td>
<td>q.s. to 200 mL per bag</td>
</tr>
</tbody>
</table>

**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

Islets Identity

Islets are present in each product bag

**VOLUMES IN BAGS**

Suspension Volume

200 mL per product bag

≤ 600 mL total in three product bags

Settled Tissue Volume

≤ 7.5 mL per product bag

≤ 15.0 mL total in three product bags

**POTENCY**

High Purity Islets GSIR Index (Pre-culture Sample)

For Information Only

GSIR Index: _____________

Islets Quantity

First Infusion: ≥ 5.0 X 10^4 IEQ/kg of Recipient’s Body Weight (Total IEQ/infusion)

Bag 1: _______ IEQ/kg

Bag 2: _______ IEQ/kg

Bag 3: _______ IEQ/kg

Subsequent Infusions: ≥ 4.0 X 10^4 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
# PURIFIED HUMAN PANCREATIC ISLETS WITH EXENATIDE, INTERIM CERTIFICATE OF ANALYSIS (PRODUCT CODE PHPI-E-01)

Islets Lot Number: ___________________  Recipient Study ID #: ___________________

Recipient Medical Record Number: ___________________

<table>
<thead>
<tr>
<th>TEST</th>
<th>REQUIREMENT</th>
<th>RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POTENCY (CONTINUED)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viability</td>
<td>≥ 70% in each product bag</td>
<td>Bag 1: ________ %</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bag 2: ________ %</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bag 3: ________ %</td>
</tr>
<tr>
<td><strong>PURITY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Islets Concentration</td>
<td>≥ 20,000 Total IEQ/mL. Total Settled Tissue Volume</td>
<td>Bag 1: ________ IEQ/mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bag 2: ________ IEQ/mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bag 3: ________ IEQ/mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total: ________ IEQ/mL</td>
</tr>
<tr>
<td><strong>SAFETY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appearance</td>
<td>Light yellow to amber liquid with visible aggregates in each product bag</td>
<td>Bag 1: ________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bag 2: ________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bag 3: ________</td>
</tr>
<tr>
<td>Endotoxins</td>
<td>≤ 5.0 EU/kg of Recipient’s Body Weight (Total EU/infusion)</td>
<td>Bag 1: ________ EU/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bag 2: ________ EU/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bag 3: ________ EU/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total: ________ EU/kg</td>
</tr>
<tr>
<td>Gram Stain (Islets Purity Levels Pre-combination Samples)</td>
<td>No Organisms Seen</td>
<td>High Purity: ________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Middle Purity: ________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low Purity: ________</td>
</tr>
</tbody>
</table>

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

Recorded By: ___________________  Date: _____________

Laboratory Director, Operations Manager, or Designee  Date: _____________