Purified Human Pancreatic Islets, CIT Culture Media – A Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium


The NIH CIT Consortium


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PURIFIED HUMAN PANCREATIC ISLETS,
CIT CULTURE MEDIA

Manufacturing Site: ____________________________ Date: ____________________________

1. Materials:

<table>
<thead>
<tr>
<th>Material</th>
<th>Source</th>
<th>Lot #</th>
<th>Expiration Date</th>
<th>Quantity Required</th>
<th>Quantity Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMRL 1066 Supplemented</td>
<td></td>
<td></td>
<td></td>
<td>500 mL Bottle</td>
<td>Bottle</td>
</tr>
<tr>
<td>Albumin Human USP, 25% Solution</td>
<td></td>
<td></td>
<td></td>
<td>10 mL</td>
<td>mL</td>
</tr>
<tr>
<td>Heparin Sodium Injection USP</td>
<td></td>
<td></td>
<td>5,000 units</td>
<td>5 mL</td>
<td>mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(   mL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrochloric Acid, 1 N</td>
<td></td>
<td></td>
<td>0.2 mL</td>
<td>mL</td>
<td></td>
</tr>
<tr>
<td>Sterile Water for Injection</td>
<td></td>
<td></td>
<td>20 mL</td>
<td>mL</td>
<td></td>
</tr>
<tr>
<td>IGF-1, 1 mg/vial</td>
<td>Cell Sciences</td>
<td></td>
<td></td>
<td>50 μL</td>
<td>μL</td>
</tr>
<tr>
<td></td>
<td>Cat. #CM001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Or other qualified vendor.

2. Procedure

2.1 In a BSC place a 500 mL bottle of CMRL 1066, Supplemented.
2.2 Add 10 mL of Albumin Human USP, 25% Solution to the bottle.
2.3 Add Heparin to the bottle to obtain a final concentration of 10 Units/mL (5,000 Units total).
2.4 Separately, add 0.2 mL of 1 N Hydrochloric Acid to 20 mL of Sterile Water for Injection to make 10 mM HCl solution. Reconstitute one 1 mg vial of IGF-1 with 1.0 mL of the 10 mM HCl solution. Add 50 μL of the IGF-1 solution to the bottle. Aliquot the remaining IGF-1 solution into 19 small sterile vials and store below -20°C. Cap the bottle and label it with:

- "CIT IGF-1 Solution, 50 μL, "
- Islet Lot Number (for traceability of preparation record)
- "Store below -20°C"
- Date Prepared
- Expiration Date (3 months after preparation)
- Initials of the person who prepared the solution

Islets Lot Number: ____________________________
PURIFIED HUMAN PANCREATIC ISLETS,
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2.5 Cap the bottle and mix by gentle inversion at least five times.
2.6 Label the bottle with:
   - "CIT Culture Media"
   - Islets Lot Number
   - "Store at 2°C to 8°C"
   - Date Prepared
   - Expiration Date (the end of the day after preparation)
   - Initials of the person who prepared the solution
2.7 Store the bottle of solution at 2°C to 8°C before use.

Total volume prepared: __________________ mL

Prepared by: ___________________________ Date: ____________

Reviewed by: ___________________________ Date: ____________

Islets Lot Number: ______________________