## Characteristics of Immunoglobulin Products Used to Treat Primary Immunodeficiency Diseases Licensed for Use in the United States

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>MANUFACTURER</th>
<th>METHOD OF PRODUCTION (Including Viral Inactivation)</th>
<th>SODIUM CONTENT</th>
<th>TIME TO INFUSE 35 gms</th>
<th>RECOMMENDATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bivigam</td>
<td>Biotest Pharmaceuticals Corporation</td>
<td>Cold alcohol fractionation, pre- and post-chromatography, &gt;30 mmol/L sodium</td>
<td>≤&lt; 20 mcg/mL</td>
<td>Time will vary depending on volume of administration and patient tolerability.</td>
<td>None</td>
</tr>
<tr>
<td>Cuvitru</td>
<td>Shire</td>
<td>Cold alcohol fractionation, pre- and post-chromatography, &gt;30 mmol/L sodium</td>
<td>≤&lt; 20 mcg/mL</td>
<td>Time will vary depending on volume of administration.</td>
<td>None</td>
</tr>
<tr>
<td>Pegivigam DIF</td>
<td>Shire</td>
<td>Cold alcohol fractionation, pre- and post-chromatography, &gt;30 mmol/L sodium</td>
<td>≤&lt; 20 mcg/mL</td>
<td>Time will vary depending on volume of administration.</td>
<td>None</td>
</tr>
<tr>
<td>Gammaxard Liquid</td>
<td>Shire</td>
<td>Cold alcohol fractionation, pre- and post-chromatography, &gt;30 mmol/L sodium</td>
<td>≤&lt; 20 mcg/mL</td>
<td>Time will vary depending on volume of administration.</td>
<td>None</td>
</tr>
<tr>
<td>Gammmagard S/D</td>
<td>Shire</td>
<td>Cold alcohol fractionation, pre- and post-chromatography, &gt;30 mmol/L sodium</td>
<td>≤&lt; 20 mcg/mL</td>
<td>Time will vary depending on volume of administration.</td>
<td>None</td>
</tr>
<tr>
<td>Gamnokem</td>
<td>Shire</td>
<td>Cold alcohol fractionation, pre- and post-chromatography, &gt;30 mmol/L sodium</td>
<td>≤&lt; 20 mcg/mL</td>
<td>Time will vary depending on volume of administration.</td>
<td>None</td>
</tr>
<tr>
<td>Gammagenex C</td>
<td>Bio Products Laboratory</td>
<td>Cold alcohol fractionation, pre- and post-chromatography, &gt;30 mmol/L sodium</td>
<td>≤&lt; 20 mcg/mL</td>
<td>Time will vary depending on volume of administration.</td>
<td>None</td>
</tr>
<tr>
<td>Hizentra</td>
<td>CSL Behring</td>
<td>Cold alcohol fractionation, pre- and post-chromatography, &gt;30 mmol/L sodium</td>
<td>≤&lt; 20 mcg/mL</td>
<td>Time will vary depending on volume of administration.</td>
<td>None</td>
</tr>
<tr>
<td>HYQVIA4</td>
<td>Octapharma</td>
<td>Cold alcohol fractionation, pre- and post-chromatography, &gt;30 mmol/L sodium</td>
<td>≤&lt; 20 mcg/mL</td>
<td>Time will vary depending on volume of administration.</td>
<td>None</td>
</tr>
<tr>
<td>Octagam</td>
<td>CSL Behring</td>
<td>Cold alcohol fractionation, pre- and post-chromatography, &gt;30 mmol/L sodium</td>
<td>≤&lt; 20 mcg/mL</td>
<td>Time will vary depending on volume of administration.</td>
<td>None</td>
</tr>
</tbody>
</table>

### TIME TO INFUSE 35 gms
- Time will vary based upon patient tolerance.
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### MAXIMUM RECOMMENDED INFUSION RATE
- 8 mL/kg/hour for CL 40 mL/kg/hour
- 8 mL/kg/hour for CL 40 mL/kg/hour
- 8 mL/kg/hour for CL 40 mL/kg/hour
- 8 mL/kg/hour for CL 40 mL/kg/hour
- 8 mL/kg/hour for CL 40 mL/kg/hour
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- 8 mL/kg/hour for CL 40 mL/kg/hour
- 8 mL/kg/hour for CL 40 mL/kg/hour
- 8 mL/kg/hour for CL 40 mL/kg/hour

### SUGAR CONTENT
- 2 g/kg glucose
- 2 g/kg glucose
- 2 g/kg glucose
- 2 g/kg glucose
- 2 g/kg glucose
- 2 g/kg glucose
- 2 g/kg glucose
- 2 g/kg glucose
- 2 g/kg glucose

### SODIUM CONTENT
- 8.5 mg/kg sodium chloride
- 8.5 mg/kg sodium chloride
- 8.5 mg/kg sodium chloride
- 8.5 mg/kg sodium chloride
- 8.5 mg/kg sodium chloride
- 8.5 mg/kg sodium chloride
- 8.5 mg/kg sodium chloride
- 8.5 mg/kg sodium chloride
- 8.5 mg/kg sodium chloride

### OSMOLARITY/OSMOLALITY
- ≥ 300 mOsm/kg
- ≥ 300 mOsm/kg
- ≥ 300 mOsm/kg
- ≥ 300 mOsm/kg
- ≥ 300 mOsm/kg
- ≥ 300 mOsm/kg
- ≥ 300 mOsm/kg
- ≥ 300 mOsm/kg
- ≥ 300 mOsm/kg

### PH
- 6.0 – 7.0
- 6.0 – 7.0
- 6.0 – 7.0
- 6.0 – 7.0
- 6.0 – 7.0
- 6.0 – 7.0
- 6.0 – 7.0
- 6.0 – 7.0
- 6.0 – 7.0

### IgG CONTENT
- ≤ 250 mg/mL
- ≤ 250 mg/mL
- ≤ 250 mg/mL
- ≤ 250 mg/mL
- ≤ 250 mg/mL
- ≤ 250 mg/mL
- ≤ 250 mg/mL
- ≤ 250 mg/mL
- ≤ 250 mg/mL

### APPROVED METHOD OF ADMINISTRATION
- Intravenous
- Subcutaneous
- Intravenous
- Subcutaneous
- Intravenous
- Subcutaneous
- Intravenous
- Subcutaneous
- Intravenous

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1. g/kg = grams per kg
2. mL = milliliters
3. mmol/L = millimoles per liter
4. Results are from the 2018 Annual Report of the Immune Deficiency Foundation Immunoglobulin Report.

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**Notes:**
- **TSE:** Transmissible Spongiform Encephalopathy
- **LV:** List A (List A, List A plaque morphology)
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**Table updated April 2018**