Celpure® Diatomite Filter Aid

The patented Celpure® manufacturing process is a major advance in filter aid technology. Manufactured in a stand-alone, FDA registered plant, the process produces a media that surpasses conventional diatomite filter aids in purity, performance, regulatory support, and finished product consistency and supplied with certificates of analysis to USP-NF or exceeding compendial standards.

Replacing conventional food grade diatomite filter aids with Celpure® diatomite filter aids significantly reduces extractable impurities.

<table>
<thead>
<tr>
<th>Extractables Expressed as mg/kg of Filter Aid</th>
<th>Celpure® 300 (High Purity grade)</th>
<th>Celpure® 841 (Food grade)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al</td>
<td>nd*</td>
<td>84.1</td>
</tr>
<tr>
<td>Ca</td>
<td>nd</td>
<td>52.5</td>
</tr>
<tr>
<td>Mg</td>
<td>50.5</td>
<td>6.2</td>
</tr>
<tr>
<td>Fe</td>
<td>20.0</td>
<td>2.8</td>
</tr>
<tr>
<td>Zn</td>
<td>10.5</td>
<td>nd*</td>
</tr>
<tr>
<td>Cu</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Sb</td>
<td>0.6</td>
<td>nd*</td>
</tr>
<tr>
<td>Mn</td>
<td>0.7</td>
<td>0.2</td>
</tr>
<tr>
<td>Cr</td>
<td>0.2</td>
<td>nd*</td>
</tr>
</tbody>
</table>

*(nd) Below detectable limit

**FILTER-AID MANUFACTURING DIAGRAM**

**FOOD GRADE**
- Celpure® Food Grade diatomite materials are produced in a legacy building with minimal control for material integrity.
- Food grade materials are manufactured in a dedicated FDA registered facility.
- Celpure® products are manufactured in a dedicated FDA registered facility.

<table>
<thead>
<tr>
<th>Production facilities</th>
<th>Food Grade</th>
<th>Acid Washed NF grade</th>
<th>Celpure®</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC</td>
<td>Release criteria based on filtration properties only</td>
<td>Specification based on NF criteria</td>
<td>Very tight specification, exceeding NF criteria</td>
</tr>
<tr>
<td>Purity</td>
<td>QC every 10,000kg</td>
<td>96% to 97% SiO₂</td>
<td>QC every 10,000kg</td>
</tr>
<tr>
<td>Extractables</td>
<td>Not controlled</td>
<td>Follow minimum NF standards</td>
<td>Consistently lower extractable substances, exceeding NF standards</td>
</tr>
<tr>
<td>Packaging</td>
<td>Paper bags labelled as &quot;Not intended for use in Pharmaceutical Manufacturing&quot;.</td>
<td>Packed in DuPont Tyvek bags offering protection against physical damage and moisture penetration.</td>
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</tr>
<tr>
<td>Regulatory Support</td>
<td>Nitrile use in pharmaceutical manufacturing.</td>
<td>Full regulatory support documentation and service</td>
<td>Full regulatory support documentation and service</td>
</tr>
<tr>
<td>Purification Stages</td>
<td>None, see addendum</td>
<td>Acid Wash of finished products to remove extractable component</td>
<td>Extensive, multiple purification procedures throughout production</td>
</tr>
</tbody>
</table>

Density: standard → lowest density

Celpure Media Exceeds Global Compendial Standards
Celpure media’s certificate of analysis exceeds the requirements of USP-NF certification. Testing is also performed for endotoxin and metals.

Celpure Media is Supported With a Drug Master File and a Regulatory Support Package
Celpure media’s regulatory support package supports biopharmaceutical as well as conventional high purity filtration.

Celpure Media is Packaged in Pharmaceutical Grade Packaging
Celpure media is available in either Tyvek® bags or plastic drums, both supported with a DMF. These packaging materials eliminate the bioburden and particulate issues associated with paper.

Celpure Media meets BSE / TSE guidelines
Celpure media production is in a controlled process (GMP) allowing full BSE / TSE risk management as per EMEA/401/01.

www.advancedminerals.com