CELPURE®

HIGH PURITY DIATOMITE FILTER MEDIA

The ideal filter aid if high purity standards are needed



Characteristics

Diatomaceous earth (DE) is used in many processes (e.g. cell removal, plasma fractionation) as a filter aid for alluvial filtration. DE is fossilized remains of diatoms. Diatoms are hard-shelled algae. Two different types are known: salt (marine) water and fresh water diatoms. Salt water DE is less homogeneous and consists of various types of algae skeletons which leads to different characteristics compared to fresh water DE which normally consists of only one type of algae skeletons. DE is also present in filter sheet. Depending on the retention rate are more or less DE added.

The patented Celpure® manufacturing process is a major advance in filter aid technology. This process produces media that surpasses conventional diatomite filter aids in purity, performance, regulatory support, and finished product consistency.

Celpure® is the ideal choice when developing new high purity processes with diatomite filter aid. Studies show that after replacing conventional diatomite filter aids with Celpure diatomite filter aids, extractable impurities are significantly reduced.

Benefits:

Celpure® has many benefits compared to standard DE grades for the pharmaceutical industry.

- FDA registered plant
- GMP process and change control systems in place
- Very good filtration properties
- Available from 30 g can to 15 kg Tyvek bags
- A broad range of filter aids for each application
- Full regulatory support

Available Celpure® grades

Physical properties of Celpure® grades used:

Celpure® grade	Permeability [mDarcy]	Solids removed* [µm]	Surface area [m^2/g]
25	25	280–360	7
65	40–80	690–865	6–7
100	70–140	0.3–0.45	5–6
300	150–300	0.45–0.6	3–4
1000	750–1250	> 1.0	1–2

* Data is provided for comparison purposes only. Depending on the compressibility of the solids, the values may vary by more than an order of magnitude.

Comparison of food grade and pharmaceutical grade filter aid

	Food grade	Celpure®
Production facilities	Food grade materials are produced under minimal control for material integrity	Celpure® products are manufactured in a dedicated FDA registered facility
Quality control (QC)	Release criteria based on filtration properties QC every 10'000 kg	Very tight specification QC every 100 kg
Purity / Typical SiO_2 content	86 %–93 %	96 %–98 %
Extractables (see figure 3)	Not controlled	Consistently lower extractable substances
Packaging	Paper bags, labeled as "Not intended for use in Pharma GMP manufacturing"	Packed in DuPont Tyvek bags offering protection against physical damage and moisture penetration
Regulatory support	No	Full regulatory support documentation and service
Purification steps	None, only one selection	Extensively, multiple purification procedures during manufacturing (see figure 3)
Density	Standard	Lowest density

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Extractables

Extractable analysis by ICP-MS except for Fe (colorimetric complex with 1,10-phenanthroline). Extractables expressed as mg/kg of filter aid extracted from 2-g samples incubated in 100-mL solutions.

Solution: 10 mg/mL albumin, 50 mM sodium acetate, pH 4.3. Incubation: 4 h, 160 rpm, 50 °C.

Extractable	Celite Standard Super-Cel® (Food grade)	Celpure® C300 (High purity grade)
Al_2O_3	84.1	nd*
Ca	52.5	nd*
MgO	50.5	6.2
Fe_2O_3	20.0	2.8
Zn	10.5	nd*
Cu	0.8	0.6
Sb	0.6	nd*
Mn	0.7	0.2
Cr	0.2	nd*

Figure 3, *not detectable

More detailed information is available in the Regulatory Support File (available on request).

Material (source advanced minerals)

Example Celpure C300:

Material	%	Material	%
SiO_2	98.65	CaO	0.08
Al_2O_3	0.60	TiO_2	0.03
Fe_2O_3	0.27	P_2O_5	0.03
Na_2O	0.14	MnO_2	nd*
K_2O	0.10	SO_3	nd*
MgO	0.08	Cl	nd*
		Total	99.98

*not detectable

Order information

Grade	Amount	Order number
S 25	1 kg	184209
S 25	15 kg	182908
C 65	0.03 kg	172653
C 65	0.3 kg	172655
C 65	1 kg	159529
C 65	15 kg	179862
C 100	0.03 kg	172652
C 100	0.3 kg	172654
C 100	1 kg	159528
C 100	15 kg	182187

Grade	Amount	Order number
C 300	0.03 kg	172651
C 300	0.3 kg	172656
C 300	1 kg	159527
C 300	15 kg	180259
C 1000	0.03 kg	172650
C 1000	0.3 kg	172657
C 1000	1 kg	158723
C 1000	15 kg	181282

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