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Carl Stuart Limited

ADVANCED APPLIED TECHNOLOGIES

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Comparative summary
Pharmaceutical Grade Filter Aid
(Celpure[®] and AW Celite[®] NF)
and
Food Grade Filter Aid materials.



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Comparative summary **Pharmaceutical Grade Filter Aid (Celpure® and AW Celite® NF)** and **Food Grade Filter Aid** materials.

	Food Grade	Acid Washed NF grade	Celpure®
Production facilities	Food grade materials are processed in a legacy building with minimal control for material integrity	AW Celite NF products are manufactured in a dedicated FDA registered facility	Celpure products are manufactured in a dedicated FDA registered facility
Q.C	Release criteria based on filtration properties only	Specification based on NF criteria	Very tight specification, exceeding NF criteria
Purity Typical SiO ₂ content (See table 2)	QC every 10,000kg 86% to 93% SiO ₂ .		QC every 100kg. 96% to 98% SiO ₂
Extractables.	Not controlled (See table 3b)	Follow minimum NF standards	consistently lower extractable substances exceeding NF standards (See table 3b & Fig. 1)
Packing	paper bags labelled as " <i>Not intended for use in Pharma GMP manufacturing</i> ".	packed in DuPont Tyvek bags offering protection against physical damage and moisture penetration	packed in DuPont Tyvek bags offering protection against physical damage and moisture penetration.
Regulatory Support	NOT for use in pharmaceutical manufacturing.	Full regulatory support documentation and service	Full regulatory support documentation and service
Purification Steps	None, ore selection	Acid Wash of finished products to remove extractable component	Extensive, multiple purification procedures throughout production
Density	standard	standard	Lowest density

References

The following is a quote from a credible source within the Pharma industry....

"Precedence is not accepted for component selection... Begin with a monograph search...and use it if it exists."

John Ianacone, Regulatory Administrator, Merck, Raw Materials & Contract Services, Newport Beach, CA July 16-18 2001.

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Parameters	AW Celite Hyflo Super-Cel® NF (High Purity grade)	Celite Hyflo Super-Cel® (Food Grade)
Centrifuged wet-density	≤ 0.37 g/cm ³	≤ 0.35 g/cm ³
Resistivity	≥ 50,000 ohms	*
150 Mesh Screen	≤ 9.5 %	≤ 12 %
USP-NF		
Loss on Drying	≤ 0.5 %	*
Loss on ignition	≤ 2.0 %	*
Leachable arsenic	≤ 10 mg As/kg	*
Leachable lead	≤ 10 mg Pb/kg	*
Water-soluble substances	≤ 0.2 %	*
Acid-soluble substances	≤ 2.0 %	*
Nonsiliceous substances	≤ 25 %	*
* No release specification		

Table 2. Comparison of release specifications for NF Grade and Food Grade Celite media.

	Celite Hyflo Super-Cel® (Food Grade)		AW Celite Hyflo Super-Cel® NF	
	Bulk Chemistry (%)	Extractables (mg/kg)	Bulk Chemistry (%)	Extractables (mg/kg)
SiO ₂	88.5		89.4	
Si		95.0		55.5
Al ₂ O ₃	3.5		3.4	
Al		18.4		1.4
Na ₂ O + K ₂ O				
Na	4.1		3.8	
K	0.7	49.5	0.6	17.5
Fe ₂ O ₃	1.5		1.3	
Fe		30.7		1.4
MgO	0.7		0.6	
Mg		59.0		3.4
CaO	0.6		0.5	
Ca				
Cr				
Cr		11.2		0.1
Cu				
Cu		1.35		0.5
TiO ₂	0.2		0.2	
Ti		6.4		Below Limit
P ₂ O ₅				
P		59.0		30.5
Totals	99.8%	330 mg/kg	99.8%	110 mg/kg

Table 3b.



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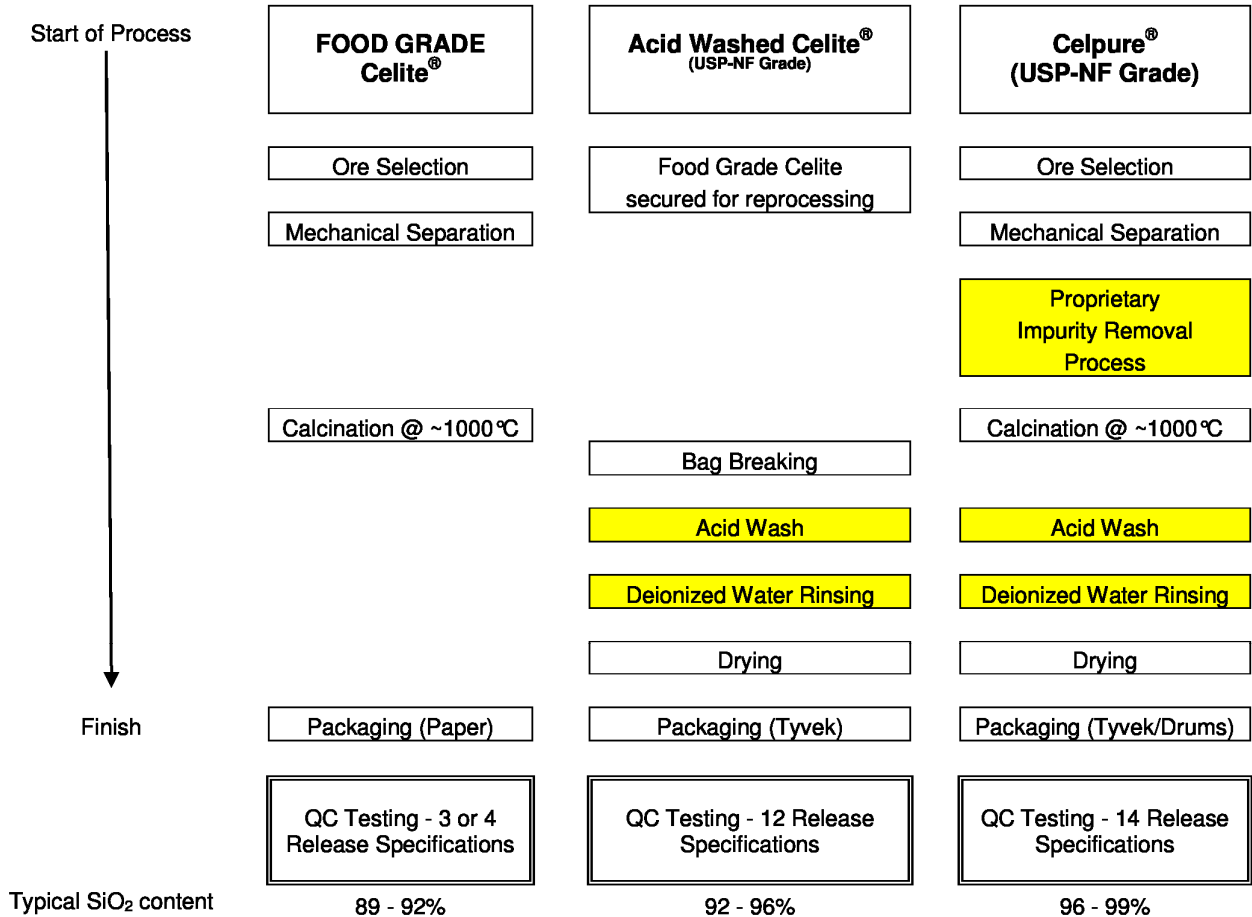
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FILTER-AID MANUFACTURING DIAGRAM



Definitions	
Ore Selection:	Securing the source material from the mine
Mechanical Separation:	Separating the diatomite ore from debris
Proprietary Impurity Removal Process:	A flotation treatment. By performing this process before the thermal processing step, the impurities are not fused into the silica during the thermal processing step.
Calcination:	Kiln heating below its melting point, to yield the degree of sintering and agglomeration of diatomite particles needed to result in a particular flow rate permeability. The typical temperature (~1000°C) is sufficient to oxidize all organics
Acid Wash:	Acid washing at approximately 100° C to remove extractable impurities
Deionized Water Rinsing:	Rinsing the diatomite of residual acid and acid-leached impurities
Drying:	Reducing moisture content after water rinse

Figure 1 – Filter-Aid manufacturing process