

SPECIFICATION / CELLETS®

Microcrystalline Cellulose Spheres (Cellulose Microcrystalline, pelletized)

Characters							Test method
Appearance	White or nearly white or beige, hard and almost spherical particles						Cellets Standard
Odor	Odorless						Ph.Eur.
Physical Parameters							
Particle size distribution	Cellets 100	Cellets 200	Cellets 350	Cellets 500	Cellets 700	Cellets 1000	Cellets Standard
	100 – 200 µm	200 – 355 µm	350 – 500 µm	500 – 710 µm	700 – 1000 µm	1000 – 1400 µm	
	≥ 85 %						
Loss on drying	≤ 7.0 %						Ph.Eur. / USP/NF
Bulk density	0.80 g/cm ³ ± 5 % (for information only)						Ph.Eur. / USP/NF
Sphericity degree (average)	≥ 0.9						Cellets Standard
Friability	0 %						Cellets Standard
Swelling index	≤ 2 ml/g						Cellets Standard
Chemical Parameters							
Identification							
Zinc chloride test	blue coloration						Ph.Eur. / USP/NF
Degree of Polymerization	≤ 350						
Dispersion test	no supernatant water after 3 hours						JPE
pH value	5.5 – 7.0						Ph.Eur. / USP/NF / JPE
Conductivity	≤ 75 µS/cm						Ph.Eur. / USP/NF
Ether soluble substances	≤ 0.05 %						Ph.Eur. / USP/NF
Water soluble substances	≤ 0.25 %						Ph.Eur. / USP/NF
Water soluble substances	≤ 0.16 %						JPE
Starch	negative						JPE
Heavy metals	≤ 10 ppm (Arsenic ≤ 2 ppm)						JP/JPE
Residue on ignition	< 0.1 % determined on 1.0 g substance < 0.05 % determined on 2.0 g substance						Ph.Eur. / USP/NF JPE
Microbiological Parameters							
TAMC	< 10 ³ CFU/g						Ph.Eur. / USP/NF
TYMC	< 10 ² CFU/g						Ph.Eur. / USP/NF
E. coli, Ps. aeruginosa, St. aureus	absence in 1 g sample						Ph.Eur. / USP/NF
Salmonella species	absence in 10 g sample						Ph.Eur. / USP/NF

Organic solvents in accordance to Ph.Eur., 5.4 and USP <467> (CPMP/ICH/283/95) are not used neither by manufacturing of CELLETS® nor by cleaning of equipment.

The starting material of CELLETS® is exclusively of vegetable origin. A contamination with animal material by manufacturing, storage or shipment in the original closed containers will not occur. Therefore, all types of CELLETS® are free from Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE). All types of CELLETS® comply with the requirements of EMA/410/01 rev.3

Note: Special fractions on demand.