SPECIFICATION / CELLETS®

Microcrystalline Cellulose Spheres

	Cellets 100	Cellets 200	Cellets 350	Cellets 500	Cellets 700	Cellets 1000	Test method
Characters							
Appearance	White or almost white or beige, hard and nearly spherical particles						Cellets Standard
Solubility	Insoluble in water, ethanol, acetone and toluene, diluted acids and sodium hydroxide solution (50 g/l)						Ph.Eur.
Odor	odorless						Ph.Eur. / USP/NF
Physical Parameters							
Particle size distribution	100 – 200 µm	200 – 355 µm	350 – 500 µm	500 – 710 µm	700 – 1000 µm	1000 – 1400 µm	Cellets Standard
	≥ 85 %	≥ 85 %	≥ 85 %	≥ 85 %	≥ 85 %	≥ 85 %	
Loss on drying	≤ 7.0 %	≤ 7.0 %	≤ 7.0 %	≤ 7.0 %	≤ 7.0 %	≤ 7.0 %	Ph.Eur. / USP/NF
Bulk density / g/cm³	0.80 ± 5 %	0.80 ± 5 %	0.80 ± 5 %	0.80 ± 5 %	0.80 ± 5 %	0.80 ± 5 %	Ph.Eur. / USP/NF
Sphericity degree (average)	0.90 ± 0.05	0.90 ± 0.05	0.93 ± 0.05	0.95 ± 0.05	0.95 ± 0.05	0.95 ± 0.05	Cellets Standard
Friability	0 %	0 %	0 %	0 %	0 %	0 %	Cellets Standard
Swelling index / ml/g	≤ 2	≤ 2	≤ 2	≤ 2	≤ 2	≤ 2	Cellets Standard
Chemical Parameters							
Identification Zinc chloride test	Passes						Ph.Eur. / USP/NF
Degree of Polymerization	≤ 350						
pH value	5.0 – 7.0						Ph.Eur. / USP/NF
Conductivity / µS/cm	≤ 75						Ph.Eur. / USP/NF
Ether soluble substances	≤ 0.05 %						Ph.Eur. / USP/NF
Water soluble substances	≤ 0.24 %						Ph.Eur. / USP/NF
Heavy metals	≤ 0.001 %						Ph.Eur. / USP/NF
Sulfated ash	≤ 0.05 %						Ph.Eur. / USP/NF
Microbiological Parameters							
Total aerobic microbial count	≤ 10^3 CFU/g						Ph.Eur. / USP/NF
Fungi / Moulds and yeasts	≤ 10^2 CFU/g						Ph.Eur. / USP/NF
E. coli, Pseudomonas 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 exclusive vegetable origin. A contamination with animal material by manufacturing, storage or shipment in the original closed containers is out of question. Because of that the requirements of Ph.Eur., 5.2.8 to “Minimising the risk of transmitting animal spongioform encephalopathy agents via human and veterinary medicinal products” are not applicable.

Date for Implementation : July 2005