



SPECIFICATION

CELLETS® MCC PELLETS (USP/NF / JPE / Ph. EUR)

Type	Celllets 100	Celllets 127	Celllets 175	Celllets 200	Celllets 263	Celllets 350	Celllets 500	Celllets 700	Celllets 780	Celllets 1000	Test Method
Appearance	White or nearly white or beige, hard and almost spherical particles										Celllets Standard
Odor	Odorless										Ph. EUR / JPE
Physical Parameters											
Particle Size	100 – 200 µm	100 – 160 µm	150 – 200 µm	200 – 355 µm	212 – 300 µm	350 – 500 µm	500 – 710 µm	700 – 1000 µm	710 – 850 µm	1000 – 1400 µm	Celllets Standard
	≥ 85 %										
Loss on drying	≤ 7.0 %										Ph. EUR / USP/NF / JP / JPE
Bulk Density	0.80 g/cm ³ ± 5 % (for information only)										Ph. EUR / USP/NF / JP
Sphericity degree (average)	≥ 0.9										Celllets Standard
Friability	0%										Celllets Standard
Swelling index	≤ 2ml/g										Celllets Standard
Chemical Parameters											
Identification	conform to reference standard (CRS microcrystalline cellulose)										Ph. EUR / USP/NF A / JP
IR spectroscopy											Ph. EUR / USP/NF B / JP / JPE
Zinc chloride test	blue coloration										Ph. EUR / USP/NF C / JP
Degree of Polymerization	≤ 350										JPE
Dispersion test	no supernatant water after 3 hours										
pH value	5.0 - 7.5										Ph. EUR / USP/NF / JP / JPE
Conductivity	≤ 75 µS/cm										Ph. EUR / USP/NF / JP / JPE
Ether soluble substances	≤ 0.05 %										Ph. EUR / USP/NF / JP / JPE
Water soluble substances	≤ 0.25 %										Ph. EUR / USP/NF / JP / JPE
Heavy Metals	≤ 10 ppm										JP / JPE
Residue on ignition	< 0.1 % determined on 1.0 g substance < 0.1 % determined on 2.0 g substance										Ph. EUR / USP/NF JP / JPE
Microbiological Parameters											
TAMC	< 1000 CFU/g										Ph. EUR / USP/NF / JP / JPE
TYMC	< 100 CFU/g										Ph. EUR / USP/NF / JP / JPE
E. coli, Ps. aeruginosa, St. Aureus	negative in 1 g sample										Ph. EUR / USP/NF / JP / JPE
Salmonella species	negative in 10 g sample										Ph. EUR / USP/NF / JP / JPE

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

Celllets is a proprietary registered mark belong to third parties and not to Pharmatrans

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