



## 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
<b>Physical Parameters</b>											
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
Bulk Density	0.80 g/cm <sup>3</sup> ± 5 % (for information only)										Ph. EUR / USP/NF
Sphericity degree (average)	≥ 0.9										Celllets Standard
Friability	0%										Celllets Standard
Swelling index	≤ 2ml/g										Celllets Standard
<b>Chemical Parameters</b>											
Identification	conform to reference standard (CRS microcrystalline cellulose)										Ph. EUR / USP/NF A
IR spectroscopy	blue coloration										Ph. EUR / USP/NF B
Zinc chloride test	≤ 350										Ph. EUR / USP/NF C
Degree of Polymerization	no supernatant water after 3 hours										JPE
Dispersion test											JPE
pH value	5.0 - 7.5										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 JPE
Heavy Metals	≤ 10 ppm										JPE
Residue on ignition	< 0.1 % determined on 1.0 g substance < 0.1 % determined on 2.0 g substance										Ph. EUR / USP/NF JPE
<b>Microbiological Parameters</b>											
TAMC	< 1000 CFU/g										Ph. EUR / USP/NF
TYMC	< 100 CFU/g										Ph. EUR / USP/NF
E. coli, Pseudomonas aeruginosa	negative in 10 g sample										Ph. EUR / USP/NF
St. Aureus, Salmonella species	negative 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

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

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