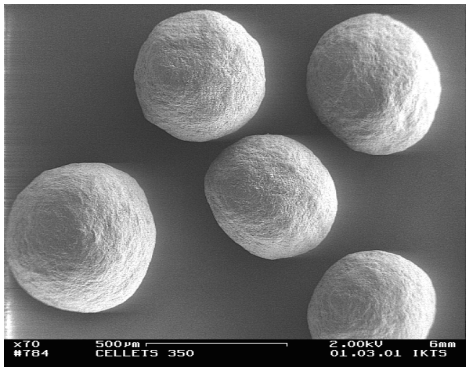
CELLETS®



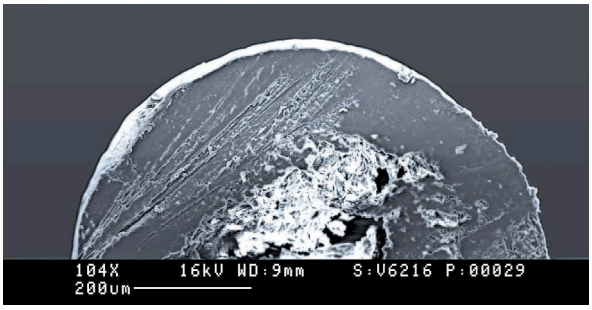
Pellets made of Microcristalline Cellulose for retard formulations and innovative drug delivery.

Homogenous distribution & controlled release

A homogenenous distribution of the active agent and the controlled release are two fundamental advantages of this dosage form.

Multiple dosage forms mean more reliable formulations thanks to the homogeneous concentration of highly active agents. CELLETS support this pioneering development We can supply this innovative pellet in almost any particle size starting from 100 µm micropellets.

	CELLETS 100	CELLETS 200	CELLETS 350	CELLETS 500	CELLETS 700	CELLETS 1000
Particle size /µm	100-200	200-355	355-500	500-710	710-1000	1000-1400
Distribution	≥ 85%	≥ 85%	≥ 85%	≥ 85%	≥ 85%	≥ 85%
Loss on Drying	≤ 7.0 %	≤ 7.0 %	≤ 7.0 %	≤ 7.0 %	≤ 7.0 %	≤ 7.0 %
Bulk density g/cm^3	0,80 ± 5%	0,80 ± 5%	0,80 ± 5%	0,80 ± 5%	0,80 ± 5%	0,80 ± 5%
Sphericity degree	0,90 ± 0,05%	0,90 ± 0,05%	0,93 ± 0,05%	0,95 ± 0,05%	0,95 ± 0,05%	0,95 ± 0,05%
Friability	0%	0%	0%	0%	0%	0%
Swelling index	≤ 2	≤ 2	≤ 2	≤ 2	≤ 2	≤ 2



CELLETS - Shot of the cross section

Advantages at a glance

- Micropellets (100 -200µm) for highly active low dosage API
- Perfect tool for combinatory and controlled release products
- Wide range of particle size fractions with uniform spherical shape and structure
- Narrow particle size distribution within each fraction
- CELLETS are made under GMP conditions using MCC from certified suppliers only
- Formulation of sensitive actives due to the inertness of MCC
- High abrasion resistance improves the coating process
- Excellent compactability due to the high plasticity of the CELLETS, for formulation of multidosage tablets
- Higher payload permits smaller capsule sizes

SPECIFICATION

Microcrystalline Cellulose Spheres

	Cellets 100	Cellets 200	Cellets 355	Cellets 500	Cellets 700	Cellets 1000	Test method
Description							
Appearance	White or nearly white or beige, hard and practically spherical particles						Cellets Standard
Odour	odourless						Cellets Standard
Solubility	Insoluble in water, absolute ethanol, acetone and toluene, diluted acids and sodium hydroxide solution (50 g/l)						Cellets Standard
Physical Parameters							
Particle size/µm	100-200	200-355	350-500	500-710	710-1000	1000-1400	
Distribution	≥ 85%	≥ 85%	≥ 85%	≥ 85%	≥ 85%	≥ 85%	Cellets Standard
Loss on drying	≤ 7%	≤ 7%	≤ 7%	≤ 7%	≤ 7%	≤ 7%	Ph. Eur. / USP
Bulk density /g/cm³	0,80 ± 5%	0,80 ± 5%	0,80 ± 5%	0,80 ± 5%	0,80 ± 5%	0,80 ± 5%	Ph. Eur.
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	≤ 2	≤ 2	≤ 2	≤ 2	≤ 2	≤ 2	Cellets Standard
Chemical Parameters							
Identification: degree of polymerisation	< 350						Ph. Eur./NF
Identification: zinc chloride test	passes						Ph. Eur./NF
pH value	5,0 - 7,0						Ph. Eur. / USP
Conductivity /µs/cm	≤ 75 µS/cm						Ph. Eur./NF
Ether soluble substances	≤ 0,05%						Ph. Eur./NF
Water soluble substances	≤ 0,24%						Ph. Eur. / USP
Heavy metals	≤ 10 ppm (0,001%)						Ph. Eur. / USP
Sulphated ash/ residue on ignition	≤ 0,05%						Ph. Eur. / USP

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.

Microbiological Parameters		
Total aerobic count	< 1000 CFU/g	Ph. Eur.
Fungi/Moulds and yeasts	< 100 CFU/g	Ph. Eur. / USP
E. coli, Pseudo-monas aeruginosa	negative in 10 g sample	Ph. Eur. / USP
St. Aureus, Salmonella species	negative in 10 g sample	Ph. Eur. / USP

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 requirements of Ph.Eur. 2002, 5.2.8. (EMEA/410/01 rev. 01) To Transmissible Spongioform Encephalopathies (TSE) are not applicable.

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