PHARMATRANS SANAQ AG

PHARMACEUTICALS

Cellets® Microcrystalline Cellulose Pellets: a safer and easier way to multiparticulate dosage forms

Pharmatrans Sanaq supplies Cellets® as a stand-alone brand for its highly optimized Microcristalline Cellulose MCC Pellets used as an alternative to sugar pellets for retard formulations and innovative drug delivery.

Cellets® have tangible advantages over sugar pellets in supporting dosage formulations optimized for homogeneous distribution and controlled release, as defined by the monographs of European and US pharmacopeias.

What is microcrystalline cellulose?

Microcrystalline cellulose (MCC) is a naturally occurring polymer composed of linear cellulose chains of glucose units connected by a 1-4 beta glycosidic bond. These are naturally bundled together as microfibrils spirals in plant cell walls, meaning that MCC can be derived from refined wood pulp.

Microcrystalline cellulose can also be synthesized from α-cellulose precursor, using processes such as reactive extrusion, enzyme mediated, mechanical grinding, ultrasonication, steam explosion and acid hydrolysis.

Pharmatrans manufactures Cellets® under GMP conditions using MCC from certified suppliers only and can supply these innovative micropellets in various particle sizes from 100 µm to 500 µm.

Cellets® applications

MCC is used as a texturizer, an anti-caking agent, a fat substitute, an emulsifier, an extender, and a bulking agent. In the pharma industry, its most common use is to modify dosage delivery in tablets. In this application, properties such as particle size, density, compressibility index, angle of repose, powder porosity, hydration swelling capacity, moisture sorption capacity, moisture content, crystallinity index, crystallite size, and hardness and tensile strength mechanical properties become relevant.

Approved within the European Union as a thickener, stabilizer or emulsifier, microcrystalline cellulose has E number E460(i), as compared with E460 basic cellulose. These forms have been defined by monographs for Microcrystalline Cellulose (Ph. Eur., USP-NF). DMF N° 18519 since July 15, 2005.

Cellets® advantages

Cellets® support the pioneering development of multiple dosage forms that deliver more reliable formulations thanks to the homogeneous concentration of highly active agents.

Two fundamental advantages of the microcellulose MCC-based multiple dosage form are homogeneous distribution of the active ingredient and its controlled release.

Compared with sugar pellets, MCC pellets have superior (smoother) surface and sphericity properties, making them a clear first choice for non-dissolving applications. Sugar pellets can be preferred where fast dissolution in water is desired.

Cellets® deliver a persuasive range of user benefits:

- 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.
- Formulation of sensitive actives due to the inertness of MCC.
- High abrasion resistance for superior coating process
- Excellent compactibility due to the high plasticity of the CELLETS® for formulation of multidosage tablets.
- Higher payload permitting smaller capsule sizes.

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SPECIFICATION

CELLETS®

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

Type	Cellets 100	Cellets 127	Cellets 175	Cellets 200	Cellets 263	Cellets 350	Cellets 500	Cellets 700	Cellets 780	Cellets 1000	Test Method
Appearance	White or nearly white or beige, hard and almost spherical particles										Cellets 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	Cellets Standard
	≥ 85 %										
Loss on drying	≤ 7.0 %										Ph. EUR / USP/NF / JP / JPE
Bulk Density	0.80 g/cm³ ± 5 % (for information only)										Ph. EUR / USP/NF / JP
Sphericity degree (average)	≥ 0.9										Cellets Standard
Friability	0%										Cellets Standard
Swelling index	≤ 2ml/g										Cellets Standard
Chemical Parameters											
Identification											
IR spectroscopy	conform to reference standard (CRS microcrystalline cellulose)										Ph. EUR / USP/NF A / JP
Zinc chloride test	blue coloration										Ph. EUR / USP/NF B / JP / JPE
Degree of Polymerization	≤ 350										Ph. EUR / USP/NF C / JP
Dispersion test	no supernatant water after 3 hours										JPE
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

Contact

Pharmatrans Sanaq AG
Gewerbestrasse 18
CH-4123 Allschwil - Basel
Switzerland
Tel.: +41 61 225 90 00
Email: info@pharmatrans-sanaq.com
Web: www.pharmatrans-sanaq.com

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