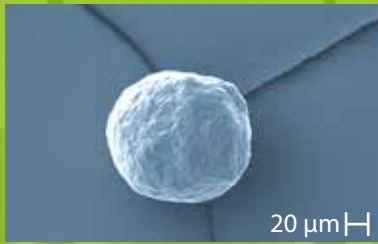




+ Pellets from microcrystalline cellulose

Successful formulation of new actives demand safe application and high quality excipients. Cellets are versatile starter cores for multiparticulate dosage forms.





Cellets 100
Magnification = 250 x
Date: 10 March 2008



Cellets 200
Magnification = 150 x
Date: 10 March 2008



Surface Cellets 200
Magnification = 500 x
Date: 10 March 2008

+ Cellets. The safe and easy way to multi-particular dosage forms

Multi-particular dosage forms have striking advantages compared to monolithic dosage forms, such as:

- + low variability of gastric emptying
- + low dependency on nutrition state
- + low risk of localized high drug concentrations in the GI
- + reduced risk of sudden dose dumping
- + lower intra- and inter-individual variability
- + high control on time and place of drug delivery

Altogether, this means higher safety and better compliance for your patients, and added-value for your products.

However, historically the way to successful formulation of multiparticular dosage forms was bumpy.

But: Cellets with their unique features NOW offer streamlined formulation and processing opportunities, making formulator's life easier, and your patient's lives more safe.

+ Processing advantages

The specific manufacturing process of Cellets provides mechanically extremely stable cores.

Low friability and solubility facilitates the layering process and improves the yield while the extreme hardness of the core makes Cellets a perfect carrier for later tableting.

Cellets 100 provide the same core quality in sphericity and stability as coarse fractions and therefore grant comparable content uniformity and constant release profiles.



Cellets 1000 coated
Stereomicroscopic shot



Cellets 1000
Stereomicroscopic shot

+ Content uniformity and controlled release

The homogeneous distribution of APIs in multiparticular dosage forms make high demands on core material characteristics:

- + narrow particle size distribution
- + even and dense surface
- + perfect sphericity
- + low friability
- + inertness

Altogether, this means higher safety and better compliance for your patients, and added-value for your products.

+ Neutral cores

As an inert odorless and tasteless excipient MCC is extremely versatile.

Cellets are made from certified MCC and pure water allowing you to multiply the benefits of neutral pellets with the unbeatable properties of MCC.



+ The advantages at a glance

- + Micropellets (100 µm - 200 µm) 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 with MCC from certified suppliers.
- + Quality analysed according to Ph. EU, USP/NF and JPE.
- + Formulation of sensitive actives due to the inertness of MCC.
- + Cellets® are water insoluble.
- + High abrasion resistance improves and simplifies the coating process.
- + Ideal for capsules.
- + Cellets® show excellent compactability due to the high plasticity of Cellets®.
- + Higher payload permits smaller capsule sizes.

+ Microcrystalline Cellulose Spheres

	Celllets 100	Celllets 200	Celllets 350	Celllets 500	Celllets 700	Celllets 1000	Test Method
Characters							
Appearance	White, nearly white or beige, hard and almost spherical particles						Celllets Standard
Solubility	Insoluble in water, ethanol, acetone and toluene, diluted acids Ph.Eur. 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	Celllets Standard
	≥ 85 %						
Loss on drying	≤ 7.0 %						Ph.Eur. / USP/ NF
Bulk density (g/m ³)	0.80 ± 5 % (for information only)						Ph.Eur. / USP/ NF
Sphericity degree (average)	≥ 0.9						Celllets Standard
Friability	0 %						Celllets Standard
Swelling index / ml/g	≤ 2 ml/g						Celllets Standard
Celllets 100 - Celllets 1000							Test Method
Chemical Parameters							
Identification							Ph.Eur. / USP/ NF
Zinc chloride test	Passes						
Degree of Polymerization	≤ 350						Ph.Eur. / USP/ NF
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 aerugin. 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 neither used when manufacturing CELLETS® nor when cleaning the equipment. The starting material of CELLETS® is an exclusive vegetable base. Contamination with animal material during manufacturing, storage or shipping in the original closed containers is out of question. Due to this the requirements of Ph.Eur., 5.2.8 to "Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" are not applicable.

Note: All values are presented only for the purpose of basic reference and not as specifications. Special fractions on demand.

