



ETHISPHERES®

MICROCRYSTALLINE CELLULOSE
SPHERES



NEUTRAL PELLETS FOR SUGAR FREE PRODUCTS

HIGH CONTROLLED-RELEASE PERFORMANCE

Product data sheet

Definition

- ✧ ETHISPHERES® is a spherical excipient, a neutral starter core for controlled release formulations by coating or layering processes. Usage in capsules, tablets and sachets.
- ✧ ETHISPHERES® have been developed using microcrystalline cellulose as exclusive compound.
- ✧ Microcrystalline cellulose (MCC) is a purified, partially depolymerised cellulose, prepared by controlled hydrolysis of α -cellulose.
- ✧ MCC complies with Ph. Eur., USP/NF and JPE and is also used in cosmetics and food products.
- ✧ ETHISPHERES® is produced in accordance with the cGMP.

Chemical specifications

- ✧ Degree of polymerisation < 350
- ✧ Heavy metals ≤ 10 ppm
- ✧ pH 5.0 to 7.5 for the supernatant liquid
- ✧ Starch negative
- ✧ Residue on ignition ≤ 0.1 %

* Organic solvents are not used neither by manufacturing of Ethispheres nor by cleaning of equipment.

* The starting material of Ethispheres is exclusive vegetable origin.

Physical specifications

- ✧ Loss on drying ≤ 7.0 %
- ✧ Bulk density ≈ 0.80 g/cm³ * vary with particle size
- ✧ Sphericity degree average > 0.90
- ✧ Friability 0 %

General properties

- ✧ Nearly white or almost white particles,
- ✧ Hard, uniform and spherical particles,
- ✧ High physicochemical inertness improves the stability of the finished product,
- ✧ High porosity increases the quantity of active substance absorbed,
- ✧ High mechanical strength reduce the product loss and assure an excellent processing properties,
- ✧ Insoluble in water, in anhydrous ethanol, in acetone and in toluene,
- ✧ Narrow particle size distribution, uniform shape and surface guarantee constant reproducible product quality.



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Particle size specifications

- ✧ Minimum of 90 % (w/w) of Ethispheres are between the lower and the upper limits of the size stated on the label.
- ✧ The ETHISPHERES® selection is obtained by the decreasing size sieving method.

ETHISPHERES®	<i>size (µm)</i>
ETHISPHERES® 90	63-125
ETHISPHERES® 150	100-200
ETHISPHERES® 250	200-355
ETHISPHERES® 450	355-500
ETHISPHERES® 600	500-710
ETHISPHERES® 850	710-1000
ETHISPHERES® 1200	1000-1400

Microbiological specifications

Total aerobic microbial count	< 1000/g
Salmonella	Absent/g
Escherichia coli	Absent/g
Staphylococcus aureus	Absent/g
Pseudomonas aeruginosa	Absent/g
Yeast and moulds	< 100/g

Application

- ✧ Used as cores to be coated in the manufacture of dry pharmaceutical and cosmetic forms.
- ✧ It enables greater accuracy and consistency in drug layering and coating.
- ✧ Suitable for non-cariogenic products.
- ✧ Adapted to controlled-release or sustained-release formulations: make it easy to produce spherical microgranules which has the most suitable size and dissolution profile to each specific purpose.

General information

- ✧ Packaging : 20 kg cardboard drums, tightly closed, with polyethylene liner.
- ✧ Storage conditions : in original sealed drums, protected from humidity, at a temperature between 15 and 30°C.
- ✧ Shelf life : 5 years.
- ✧ Samples kept for 5 years and records available for 6 years.
- ✧ Certificate of analysis and Material Safety Data Sheet attached to each delivery.

For further information, please contact

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