

pharm-a-spheres™

10 Reasons why

... you should decide to
use pharm-a-spheres™
sugars spheres



Reason ① ...

- **High mechanical stability**
- **No attrition**
- **Low friability**

Due to their special manufacturing process pharm-a-spheres™ sugar spheres have a high mechanical stability. Even when coated in fluidized-bed equipment and in contact with water or solvents the pharm-a-spheres™ sugar spheres do not disintegrate and form no attrition. The low friability is an important pro and may be quantified on request.



Texture Analyser™ used for testing the hardness of pellets

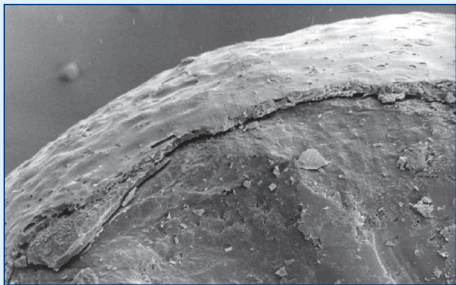


Friabimat™ used for testing the friability of pellets

Reason ② ...

- High degree of sphericity
- Non-porous surface
- Smooth surface

Also as a result of the production process the pharm-a-spheres™ sugar spheres show a high degree of sphericity. Even the small-sized microspheres have a non-porous, smooth, and spherical surface. This is important for a precise layering with API and reproducible release of the final pellet.



SEM photograph of the coated spheres.

Reason ③ ...

- **Outstanding microbiological quality**

The pharm-a-spheres™ sugar spheres excel by an outstanding microbiological quality. The reason is the use of high-quality excipients, thermal process steps, and the fact in long term production experience.



Petri dish Petri dish medium for the detection of bacteria.



Petri dish Petri dish medium for the detection of enterobacteria.

Reason ④ ...

- **All-natural ingredients**
- **Digestible**
- **Biodegradable**

The pharm-a-spheres™ sugar spheres consist of all-natural ingredients. Sucrose, corn starch, and liquid glucose are natural substances, also present in our daily food. They are digestible and biodegradable. By the way: The small amounts of these substances administered with the final drug are totally irrelevant as far as diabetes or dental caries is concerned.



Sucrose from beet root



Sarch from maize/corn

Reason 5 ...

- **Tailor-made, reproducible particle size distribution (PSD)**

The particle size is often a critical parameter in the customer's coating process. Our company is specialized to offer pharm-a-spheres™ sugar spheres with a tailor-made and reproducible particle size distribution. This is possible by long-term experience with the sizing, classification, and particle size analysis of this product.

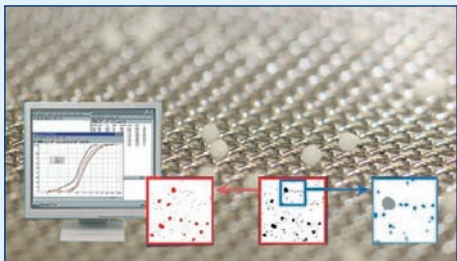


Image analysis system as an alternative to the traditional sieve tests

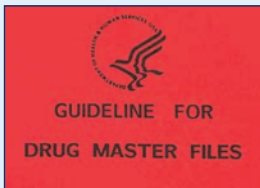
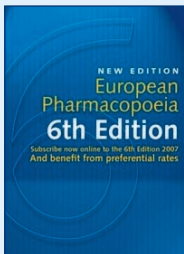
- particle size distribution
- sphericity
- calculation of medium diameter

It is possible to fit this method to the sieves of the customer's laboratory.

Reason 6 ...

- **Worldwide acceptance**
- **Easy registration for regulatory drug applications.**

Pharm-a-spheres™ sugar spheres conform to the pharmacopoeial monographs for sugar spheres in the USP/NF and the EP. Production and testing are according to the IPEC GMP Guideline. There is a DMF submitted to the FDA. These are the preconditions for the worldwide acceptance and easy registration for any regulatory drug applications.



EP	European Pharmacopoeia
USP	United States Pharmacopoeia
NF	National Formulary
DMF	Drug Master File
FDA	Food and Drug Administration
LoA	Letter of Authorization
NDA	New Drug Application

Reason 7 ...

- **Active ingredients are not involved in the forming process.**

The use of pharm-a-spheres™ sugar spheres as core for subsequent layering with API and sustained release excipients is a smart alternative to the manufacturing of API pellets. The active ingredient is not involved in the forming process which is connected with several advantages. You can minimize losses of precious API, save thermal and



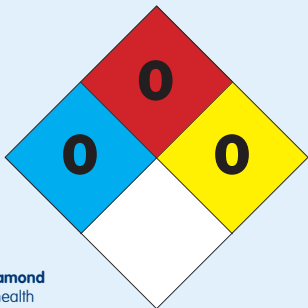
chemical deterioration of the active ingredient, and start with a defined surface area for reproducible coating.

fluidized-bed technology
top-spray / bottom-spray

Reason ⑧ ...

- **Chemically indifferent excipients**
- **No incompatibilities**

The excipients of the pharm-a-spheres™ sugar spheres are chemically indifferent and incompatibilities with the active ingredients are unlikely or may be solved by simple technological measures. There is really no need to use spheres of any other composition. Organic solvents are not used neither in the manufacturing process of the spheres nor in the production of its excipients.



hazard diamond

blue = health

red = flammability

yellow = reactivity / instability

white = special notice

0 = no risk

Reason 9 ...

- **Competitive prices**
- **Flexible service**
- **Delivery in time**

Considering the high quality of the pharm-a-spheres™ sugar spheres our prices are more than competitive. Accurate delivery in-time of the ordered quantities is a duty for us.



Reason 10 ...

- **More than 40 years of experience**

More than 40 years of experience with the manufacturing and testing of pharm-a-spheres™ sugar spheres for numerous customers guarantee the best solution for your application. A large in-house laboratory equipped with sophisticated instruments allows us a fast release process and provides reliable results of even special parameters. Technological experience from numerous applications is available for your assistance. Please challenge our capabilities.



GMP Philosophy

- IPEC-GMP-Guide for Bulk Pharmaceutical Excipients
- Only three non-active ingredients
- Only one product (different sizes)
- Small company with „lean“ structure

= „keep it simple, but effective!“



SUGAR SPHERES . . .

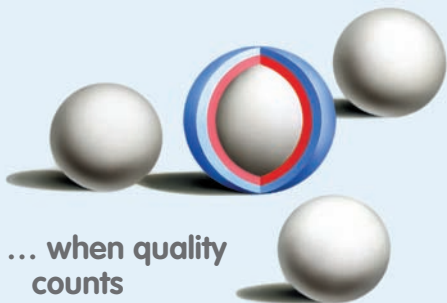
. . . carrier for your sustained-
release formulation



Please ask for a sample!

pharm-a-spheres™

sugars spheres



... when quality
counts

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