

pharm-a-spheres™

10 Reasons why

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



Please ask for this sample!

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 the pharm-a-spheres™ sugar spheres do not disintegrate and form no attrition.

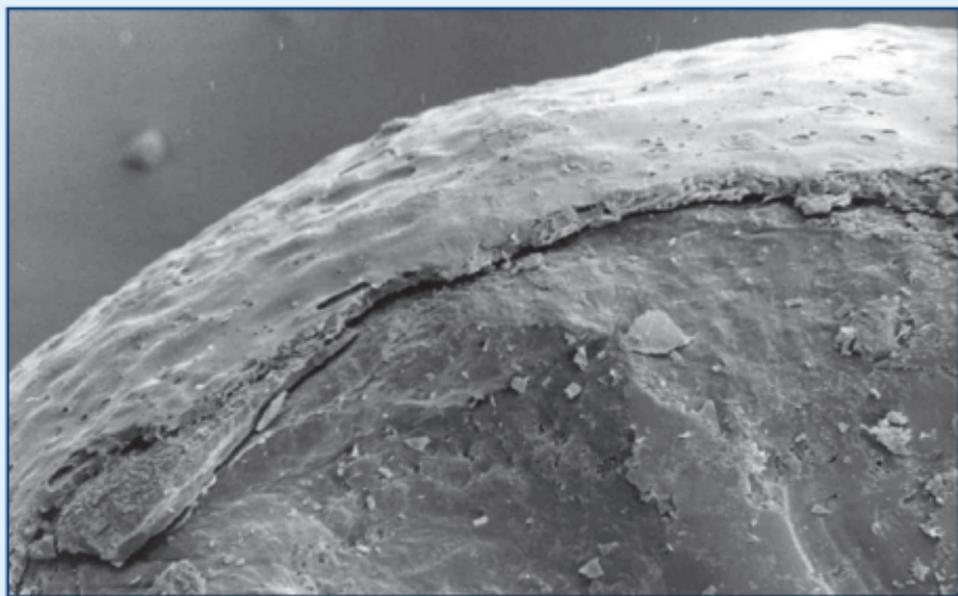


Friabimat™ used for testing the friability of pellets

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 ...

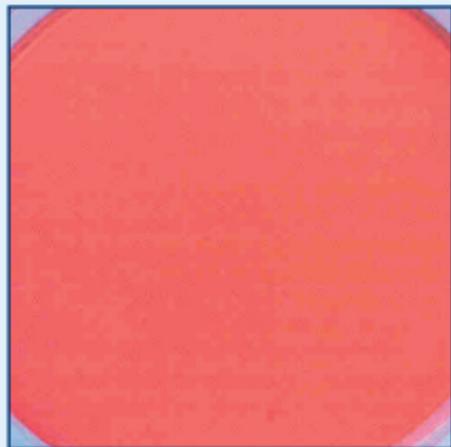
- **Outstanding microbiological quality**

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 long term production experience.



Petri dish Petri dish medium for the detection of bacteria.

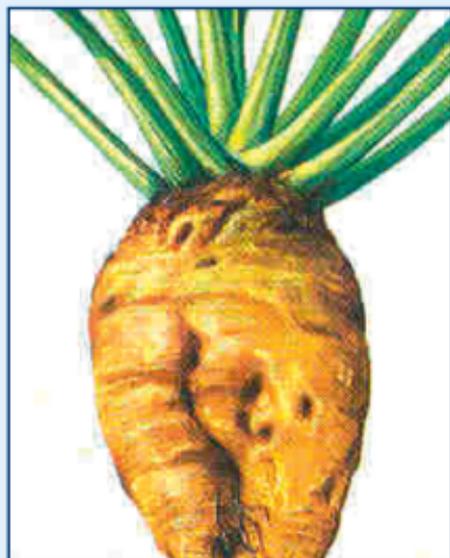


Petri dish Petri dish medium for the detection of enterobacteria.

Reason ④ ...

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

The pharm-a-spheres™ sugar spheres consist of all-natural ingredients. Sucrose and corn starch 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 irrelevant as far as diabetes or dental caries are concerned.



Sucrose from beet root



Starch from maize/corn

Reason 5 ...

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

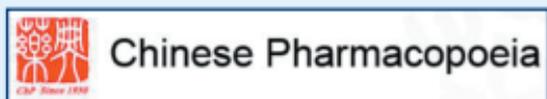
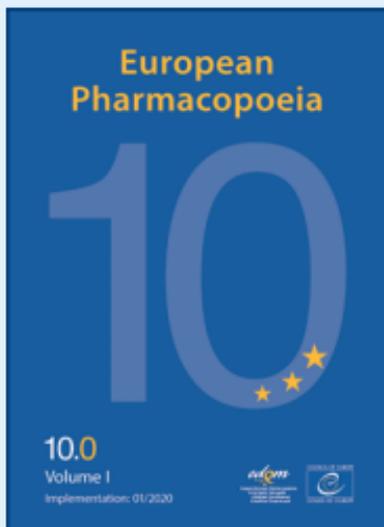
The particle size is often a critical parameter in the customer's coating process. Our company is specialized to offer pharm-a-spheres™ sugar spheres with a tailor-made and reproducible particle size distribution. This is possible by long-term experience with the sizing, classification, and particle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



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, EP, CP, JPE and others. Production and testing is according to the IPEC GMP guidelines. These are the preconditions for the worldwide acceptance and easy registration for any regulatory drug applications.

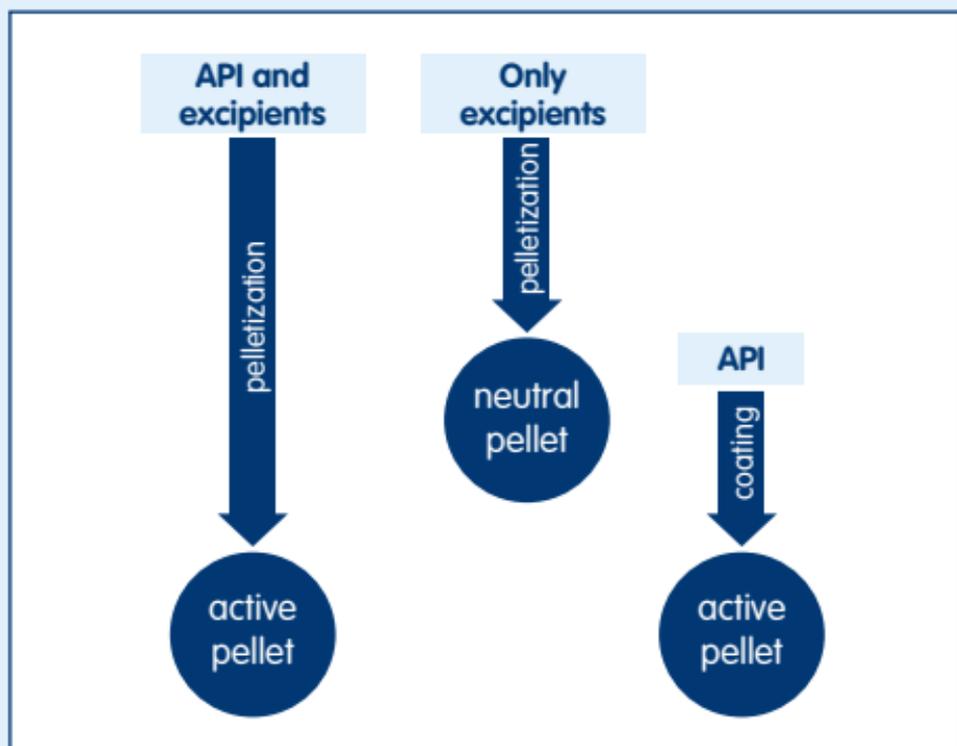


There is a registered DMF at the FDA.

Reason 7 ...

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

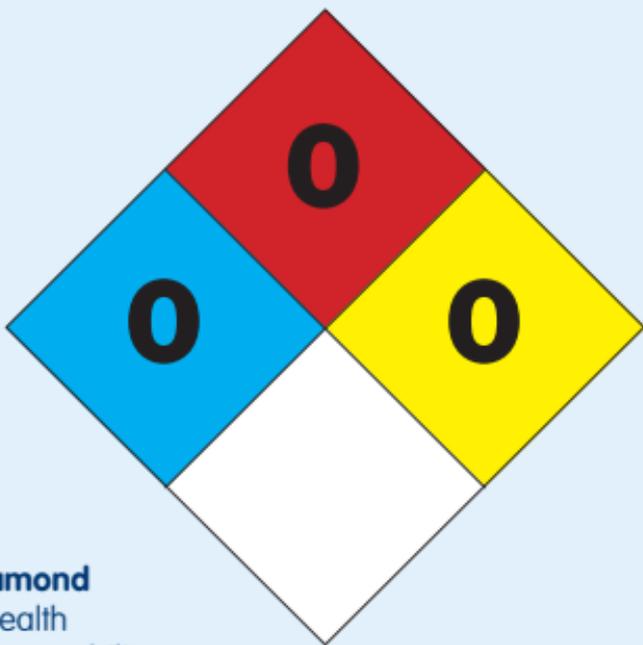
The use of pharm-a-spheres™ sugar spheres as core for subsequent layering with API and sustained release excipients is a smart alternative to the manufacturing of API pellets. The active ingredient is not involved in the manufacturing process which is connected with several advantages. You can minimize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



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

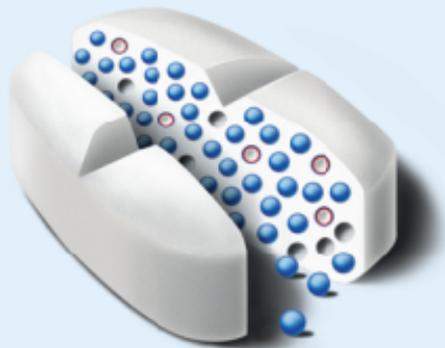
- IPEC-GMP-Guide for Bulk Pharmaceutical Excipients
- Only three non-active ingredients
- Only one product (different sizes)
- Small company with „lean“ structure

„keep it simple, but effective!“

Different applications:



Filled by our customers into capsules



compressed to tablets

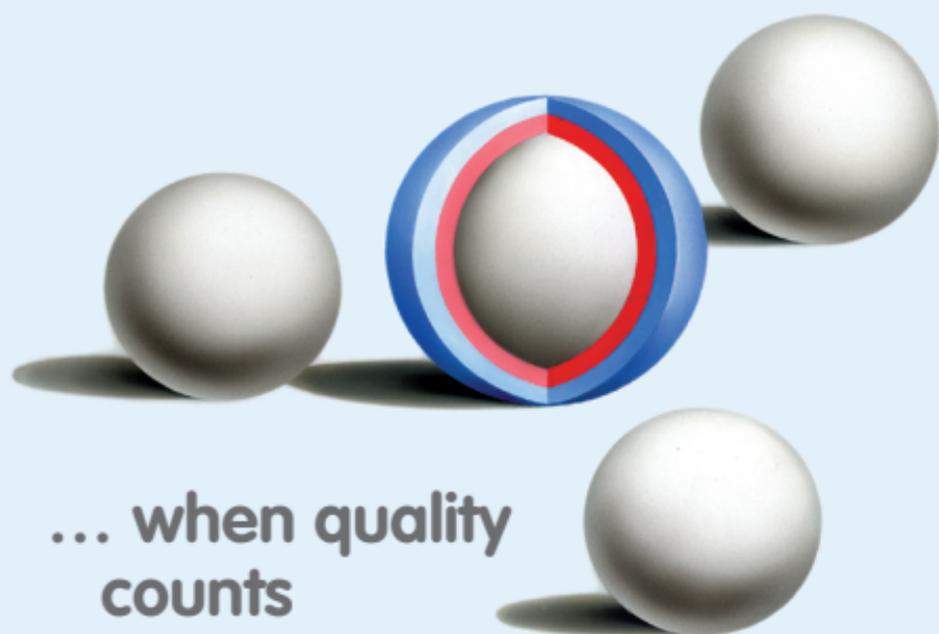
Neutral Pellets (sugar spheres)

The available standard sizes are:

item-no.	mesh ASTM	diameter in μm
08001	170 - 100	90 - 150
08013	100 - 80	150 - 180
08023	80 - 70	180 - 212
08025	80 - 60	180 - 250
08033	70 - 60	212 - 250
08035	70 - 50	212 - 300
08043	60 - 50	250 - 300
08050	50 - 45	300 - 355
08051	60 - 45	250 - 355
08052	50 - 40	300 - 425
08053	60 - 40	250 - 425
08062	45 - 35	355 - 500
08063	45 - 40	355 - 425
08065	50 - 35	300 - 500
08073	40 - 35	425 - 500
08130	35 - 30	500 - 600
08150	35 - 25	500 - 710
08230	30 - 25	600 - 710
08250	30 - 20	600 - 850
08330	25 - 20	710 - 850
08350	25 - 18	710 - 1,000
08430	20 - 18	850 - 1,000
08450	20 - 16	850 - 1,180
08530	18 - 16	1,000 - 1,180
08630	16 - 14	1,180 - 1,400
08643	16 - 12	1,180 - 1,700
08653	14 - 12	1,400 - 1,700
08663	12 - 10	1,700 - 2,000

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sugar spheres



... when quality
counts

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