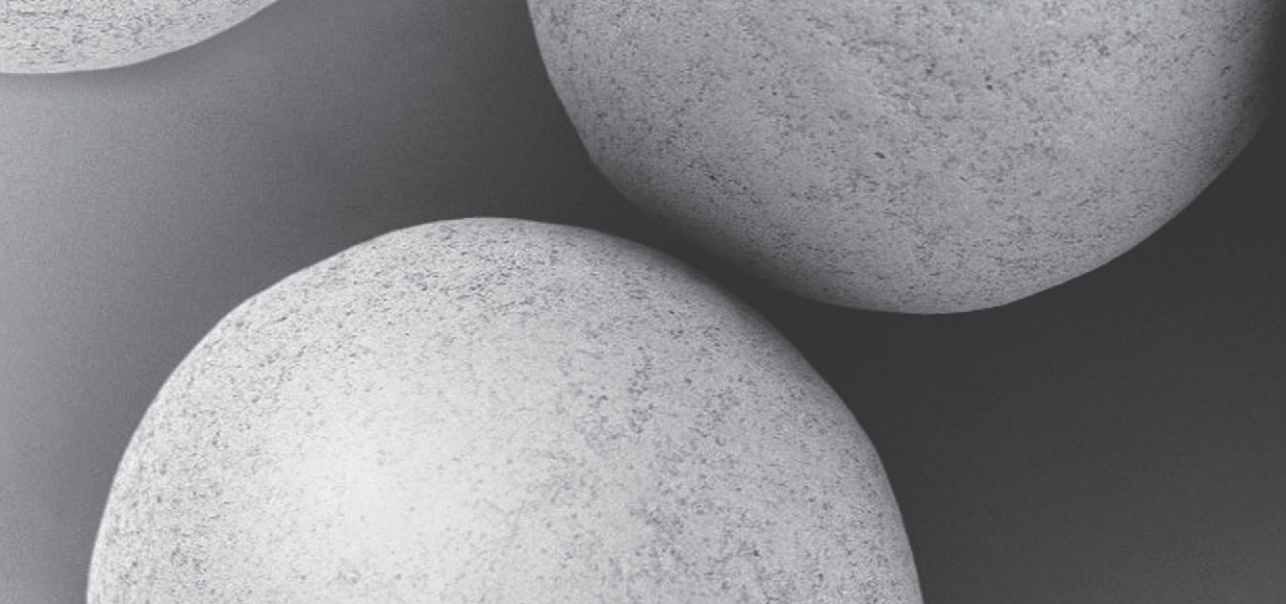


# VIVAPHARM<sup>®</sup> Sugar Spheres

Non-GMO; Ph. Eur., NF



Proven Carrier for  
Multiparticulate Dosage Forms

Sugar spheres – also known as neutral pellets, non-pareil seeds, microgranules or sugar beads – consist of 62.5 – 91.5 % sucrose and 8.5 – 37.5 % starch. JRS offers a wide selection of **VIVAPHARM® Sugar Spheres** for a variety of applications. JP compliant grades or special sizes are available on request.

[mesh]	Size	[µm]
40 - 60		250 - 425
40 - 50		300 - 425
35 - 45		355 - 500
35 - 40		425 - 500
30 - 35		500 - 600
25 - 30		600 - 710
20 - 25		710 - 850
18 - 20		850 - 1000
16 - 20		850 - 1180
16 - 18		1000 - 1180
14 - 18		1000 - 1400
12 - 14		1400 - 1700

Tab. 1 **VIVAPHARM® Sugar Spheres** are Available in 13 Different Sizes

### Advantages of **VIVAPHARM® Sugar Spheres**

- High degree of brightness
- GMO-free
- Outstanding sphericity
- Constant narrow particle size distribution
- Smooth surface
- Low friability for a trouble-free coating process



### Common Applications

Sugar spheres are well established, water-soluble carriers for multiparticulate dosage forms. Unlike monolithic forms, in which entire tablets or capsules are coated with functional layers, multiparticulate forms offer considerable advantages:

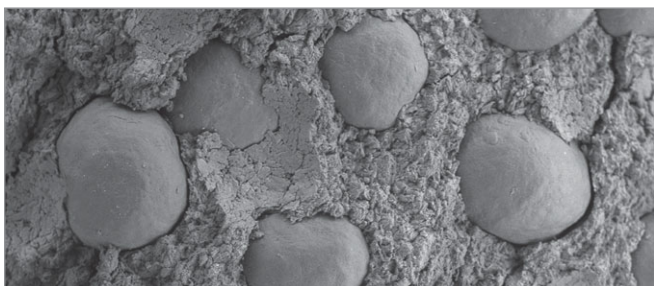
Regardless of fasting state, the small particle size of the sugar spheres enables predictable and reproducible gastroenteric transit. In addition, they reduce the risk of dose dumping by splitting the total drug content of a dosage form into smaller, individually coated sub-units.

**API protection:** Drugs layered onto spheres can be protected by non-functional seal coatings (e.g. **VIVACOAT®**) to enhance drug stability and to enable the combination of otherwise incompatible APIs in the same dosage form.

**Extended release:** Coating drug-layered spheres with semipermeable membranes leads to controlled release systems for extended, zero-order release. Sugar spheres are particularly well suited for this application, as they contribute to the osmotic pressure inside the pellet.

**Delayed release:** Multiparticulate systems find wide application in the field of gastro-resistant dosage forms. The spheres, which are individually protected by an enteric coating (e.g. **VIVACOAT® protect E**), pass through the acidic conditions in the stomach within a predictable time window and release the API in the small intestine.

The drug-layered and film-coated spheres can either be filled into hard gelatin capsules or compressed into tablets. In order to avoid damage to the spheres during compaction, high-performance tableting excipients should be used. **PROSOLV® SMCC** has been shown ideally suited for this application as it enables the production of hard tablets at low compaction forces.



Pic. 1 Cross Section of a Tablet Showing Undamaged Spheres Embedded in a Tablet Matrix of **PROSOLV® SMCC**

## Functionality-Related Characteristics (FRCs)

**VIVAPHARM® Sugar Spheres** have a well-defined, narrow particle size distribution with minimum batch-to-batch variation. This guarantees high consistency in particle surface area, which in turn yields consistent film thickness and thus reliable performance of the dosage form.

**VIVAPHARM® Sugar Spheres** are characterized by a high degree of sphericity and roundness, enabling defect-free API loading and coating.

All parameters critical for the quality of the final drug product are tightly monitored. Statistical evaluation can be provided to support QbD-based filings.

## Regulatory Information

- Ph. Eur., NF
- JP compliant grades are available on request
- US DMF No. 28032
- CDMF No. F20180001665
- Listed in the Inactive Ingredients Database (IID) on the FDA website
- Kosher
- Full regulatory documentation available
- European GMP production dedicated to pharma
- ISO 9001

## Packaging, Samples and Storage

### Storage

Store in original, well-closed containers protected from excessive heat and moisture.

### Packaging

All **VIVAPHARM® Sugar Spheres** are packaged in 25 kg carton boxes with polyethylene liner.

### Pallet

1 Europallet contains 16 carton boxes = 400 kg

1 container pallet contains 20 carton boxes = 500 kg

25 kg or 50 kg fiber drums are available on request.



### Sample Sizes

400 g Aluminum bag

1 kg Aluminum bag

Custom tariff 1704 90 99

## Additional Spheres in JRS PHARMA's Product Portfolio

For sugar-free formulations we recommend **VIVAPUR® MCC Spheres** which are water insoluble, inert, robust and show a high degree of sphericity.

Please contact your sales rep for more information or visit [www.jrspharma.com](http://www.jrspharma.com).

## The Global Excipient Maker

### Global Network

#### GMP Manufacturing and Service Sites

- Excipients
- Coatings
- Biopharma Services
- JRS Sales Companies (Additionally, dedicated representatives in almost every country.)
- Technical Competence Centers
- Application Labs



#### HIGH FUNCTIONALITY EXCIPIENTS

- PROSOLV® SMCC**  
Silicified Microcrystalline Cellulose
- PROSOLV® EASYtab SP**  
Microcrystalline Cellulose, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Sodium Stearyl Fumarate
- PROSOLV® EASYtab NUTRA**  
All-in-one Composite for Nutraceutical Applications
- PROSOLV® ODT G2**  
Microcrystalline Cellulose, Colloidal Silicon Dioxide, Mannitol, Fructose, Crospovidone

#### DISINTEGRANTS

- VIVASTAR®, EXPLATAB®**  
Sodium Starch Glycolate, Sodium Carboxymethyl Starch
- VIVASOL®**  
Croscarmellose Sodium
- EMCOSOY®**  
Soy Polysaccharides
- VIVAPHARM® Crospovidone**  
Polyvinylpyrrolidone, crosslinked

#### COATINGS

- VIVACOAT®**  
Ready-to-Use Coating System
- VIVACOAT® protect**  
Ready-to-Use High Functional Coating System
- VIVAPHARM® HPMC**  
Hypromellose
- VIVAPHARM® PVA**  
Polyvinyl Alcohol

#### BINDERS

- VIVAPUR®, EMCOCEL®**  
Microcrystalline Cellulose
- EMDEX®**  
Dextrates
- VIVAPHARM® Povidones**  
Povidone and Copovidone

#### LUBRICANTS

- PRUV®**  
Sodium Stearyl Fumarate
- LUBRITAB®**  
Hydrogenated Vegetable Oil, Hydrogenated Oil
- LUBRI-PREZ™**  
Magnesium Stearate

#### CARRIERS

- VIVAPUR® MCC SPHERES**  
Microcrystalline Cellulose Pellets
- VIVAPHARM® Sugar Spheres**  
Sugar Pellets, Non-GMO

#### FUNCTIONAL FILLERS

- ARBOCEL®**  
Powdered Cellulose
- EMCOMPRESS®**  
Calcium Phosphates
- COMPACTROL®**  
Calcium Sulfate Dihydrate

#### THICKENERS • STABILIZERS • GELLING AGENTS

- VIVAPUR® MCG**  
Microcrystalline Cellulose and Carboxymethylcellulose Sodium
- VIVAPHARM® Alginates**  
Calcium Alginate
- VIVAPHARM® Alginates**  
Sodium Alginate
- VIVAPHARM® Alginates**  
Alginate Acid
- VIVAPHARM® Pectins**

#### BIOPHARMA SERVICES

Members of the JRS PHARMA Family