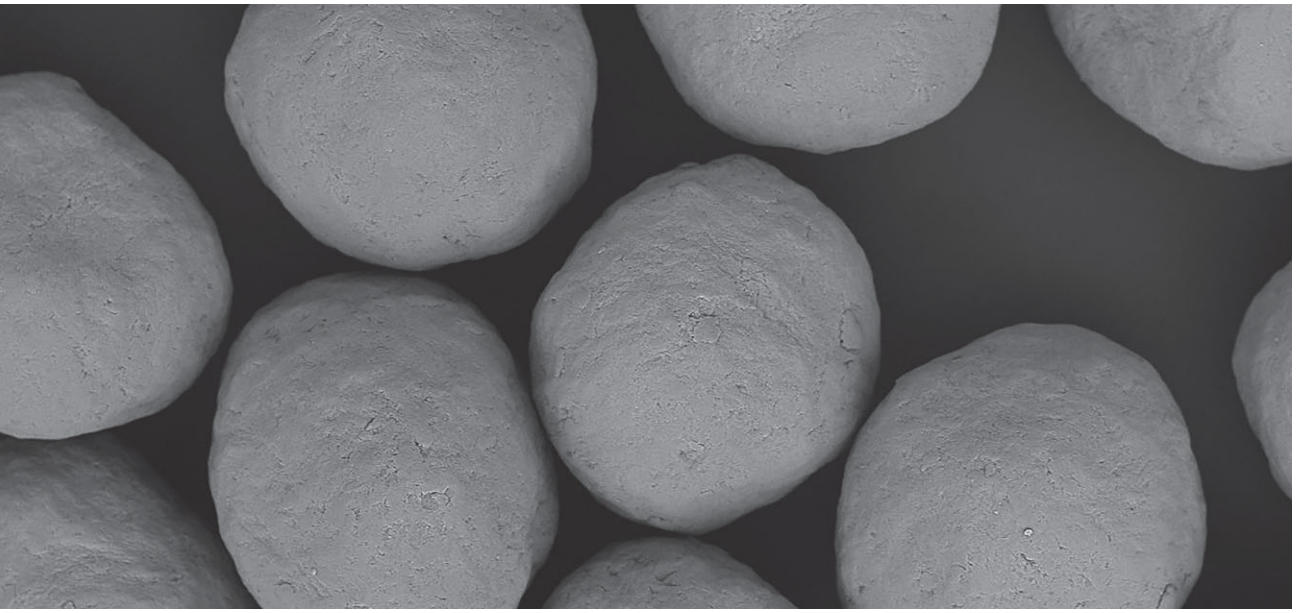
VIVAPUR® MCC SPHERES

Microcrystalline Cellulose Pellets, Ph. Eur., NF, JP



Plant Derived
Natural Carrier

Chemically Inert Carrier for
Multi-particulate Formulation Applications

Suitable for Aqueous and Solvent-Based Processing
Enables Dissolution Profile Design
Adaptable to High and Low Dose Loading

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Microcrystalline Cellulose Pellets

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General Information

Multiparticulate systems have become increasingly important in state-of-the-art formulation development. **VIVAPUR® MCC SPHERES** are particularly beneficial as a carrier for multiple-API dosage forms and controlled release formulations.

VIVAPUR® MCC SPHERES consist purely of Microcrystalline Cellulose (Ph. Eur., NF, JP), making them extremely robust and chemically inert. They are, therefore, excellently suited as a carrier system.

- Aqueous and solvent-based processing
- Dissolution profile design
- High and low dose loading

API-layered **VIVAPUR® MCC SPHERES** can be filled into capsules or compacted into tablets. **PROSOLV® SMCC** has proven particularly useful for the compaction of multiparticulate systems without damaging the spheres or their functional coating layers.

Product Portfolio

VIVAPUR® MCC SPHERES	µm	mesh
Grade 100	100 - 200	70 - 140
Grade 200	200 - 350	45 - 60
Grade 350	355 - 500	35 - 45
Grade 500	500 - 710	25 - 35
Grade 700	710 - 1000	18 - 25
Grade 1000	1000 - 1400	14 - 18

Tab. 1

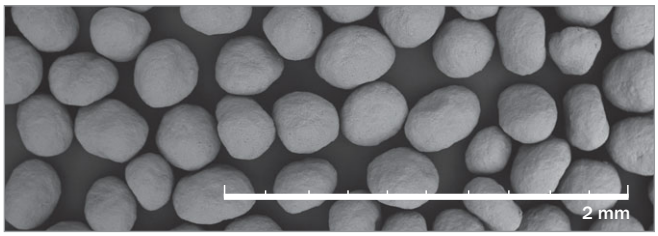
VIVAPUR® MCC SPHERES show a high degree of sphericity.

Characteristics

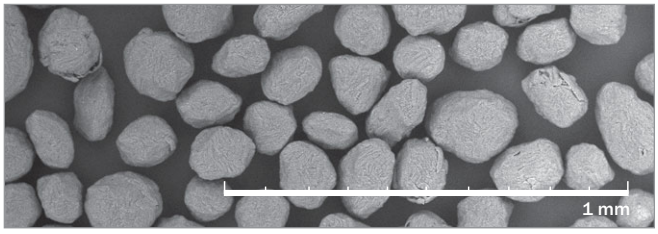
Appearance	nearly white round shaped spheres
Taste/Odor	tasteless, odorless
Solubility	insoluble in water and most organic solvents
Bulk Density	800 g/l
Sphericity	0.9 ± 0.05
Friability	< 0.1 %
Loss on Drying	≤ 7.0 %
Swelling Index	< 2

Tab. 2

A new technology allows the production of pellets in the range of 100-200 µm with high sphericity and smooth surface structure.



Pic 1 Scanning Electron Micrograph Picture **VIVAPUR® MCC SPHERES** Grade 200 Specific Surface Area: 0.11 m²/g



Pic 2 Scanning Electron Micrograph Picture from Competitor's MCC Pellets

Regulatory Information

- CAS- No. 9004-34-6
- Ph. Eur., NF, JP
- MCC is listed in the inactive ingredients database published by the FDA
- Food status: USA:GRAS / EU:E 460 (i)
- FSSC 22000
- Plant origin
- BSE/TSE free
- Allergen free, gluten free, sugar free
- Residual solvent free
- EXCiPACT™ certification, GMP, GDP
- ISO 9001
- ISO 50001
- CEP, US and Chinese Drug Master Files (DMFs)
- Halal
- Kosher

Why Use **VIVAPUR® MCC SPHERES** ?

Multiparticulate Technology Based on **VIVAPUR® MCC SPHERES** Bears Following Advantages:

Consistent and Controlled API Release Profiles

VIVAPUR® MCC SPHERES possess a tight particle size distribution allowing for better control and higher batch-to-batch consistency of API release profiles.

Excellent Content Uniformity

The sphere's particle size uniformity minimizes segregation risks during encapsulation or tableting, permitting greater API content uniformity.

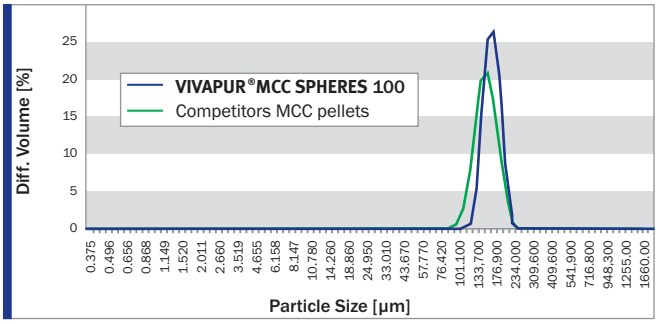


Fig. 1

Multiple Drugs can be Combined in One Unit Dose

It is possible to apply different APIs in various concentrations and combine the coated spheres in a single unit dose. By coating each API separately onto the **VIVAPUR® MCC SPHERES**, assay can be performed independently without other API interference.

High Drug Stability

In addition to the inert nature of **VIVAPUR® MCC SPHERES**, protective coatings can help to further enhance the stability of the API in the final dosage form.

Release Profile Design

In order to reach the therapeutic goal, it is often necessary, to deliver the API(s) contained in a unit dose at different release rate or at different absorption sites in the gastro-intestinal tract. While it is virtually impossible to achieve such complex release profile using a monolithic tablet, it is simply a matter of filling differently coated **VIVAPUR® MCC SPHERES** into a capsule in case of the multiparticulate formulation approach.

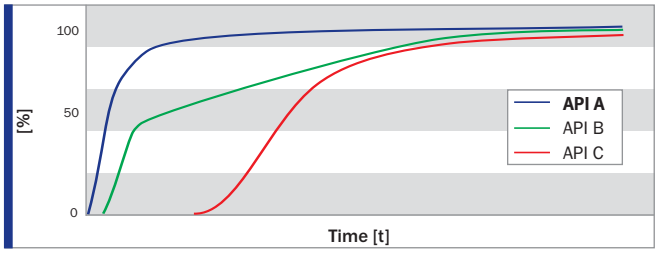


Fig. 2 The Example Given in Figure 2 Shows Immediate Release for API A, Initial Burst Followed by Zero-Order Release for API B and Delayed Release for API C.

Strong Drug Layer Adhesion

Irregular, rough spheres as shown in Picture 2 negatively affect the performance of functional coatings applied to the drug-layered spheres as surface roughness will lead to strong variation in the thickness of the functional coat.

A moderate surface rugosity as shown in Picture 1 for **VIVAPUR® MCC SPHERES**, on the other hand, promotes the adhesion of the drug-layer and therefore contributes to the efficiency of the layering process and the final drug's content uniformity.

VIVAPUR® MCC SPHERES Advantages

- Biologically inert
- Insoluble in water
- Moisture and heat resistant
- Adapted for coating and tableting
- Moderate surface rugosity
- Particle size < 200 µm available
- High storage stability

Packaging and Sample Size

Packaging

25 kg carton box with PE liner

Pallet

400 kg Euro pallets
500 kg Container pallets

Sample size

Aluminium bags 100 g, 400 g and 1 kg

JRS PHARMA

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®, EXPLOTAB®
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
Alginic Acid

VIVAPHARM® Pectins

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