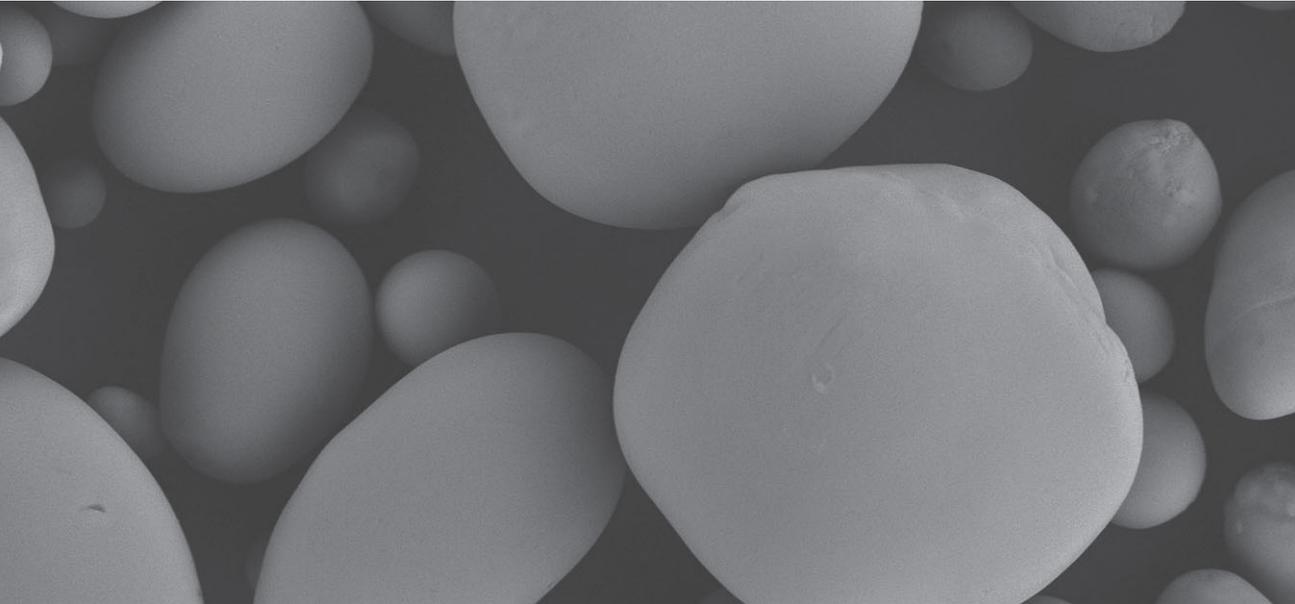


# EXPLOTAB®

Sodium Starch Glycolate

Ph. Eur., NF, JP



back-up security:  
**2 Production  
Plants**

## The Cost Effective Superdisintegrant

Secure Supply Chain  
Specialty Grades Available  
Technical Advantages



# EXPLOTAB®

Sodium Starch Glycolate

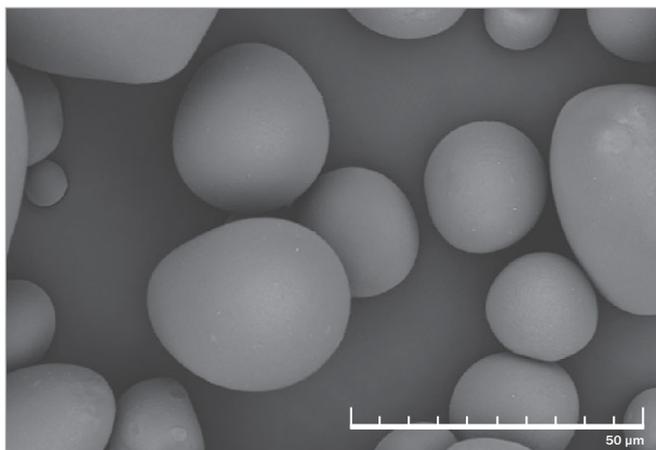
## What is EXPLOTAB® ?

### General Information

**EXPLOTAB®** Sodium Starch Glycolate is used as a superdisintegrant for tablets and other solid dosage forms. Its unique combination of performance and cost-effectiveness has established **EXPLOTAB®** as globally recognized product in the pharmaceutical industry.

### Manufacturing Process and Structure

**EXPLOTAB®** is produced from potato starch by crosslinking and carboxymethylation, leading to a three-dimensional cross-linked structure. The typical starch particle, with its spheroidal shape, remains unchanged. The resulting product demonstrates rapid and powerful swelling properties upon contact with water and other media.



Pic 1

Clean surface of **EXPLOTAB®**, derived from a renewable source.

## Your Benefits from EXPLOTAB® ?

### EXPLOTAB® Business Benefits

- Cost effective solution, because **EXPLOTAB®** is derived from starch
- High supply security guaranteed, through 2 independent production plants on 2 different continents
- One stop shopping of JRS PHARMA's proven excipients saves administration and logistic costs

### EXPLOTAB® Formulation and Manufacturing Benefits

- Enhanced disintegration through controlled starch modification
- High purity (low NaCl) of **EXPLOTAB®** and low settling volume accelerate disintegration
- Combination with **PRUV®** Sodium Stearyl Fumarate and/or **PROSOLV® SMCC** Silicified Microcrystalline Cellulose for improved disintegrant performance
- Good flowability and mixing properties allow its use in common manufacturing technologies
- High degree of brightness and reduced visible specks for quality finished dosage forms
- Specialty grades are available, including low pH and low solvent versions, for improved API stability
- Meets international monograph standards

**Importance of the Settling Volume**

**Better Crosslinking è Lower Settling Volume è Higher Disintegration Force**

Important for a better disintegration is the degree of crosslinking in the particle network of the Sodium Starch Glycolate (SSG).

A higher settling volume binds more disintegration energy. This leads to lower disintegration forces and longer disintegration times.

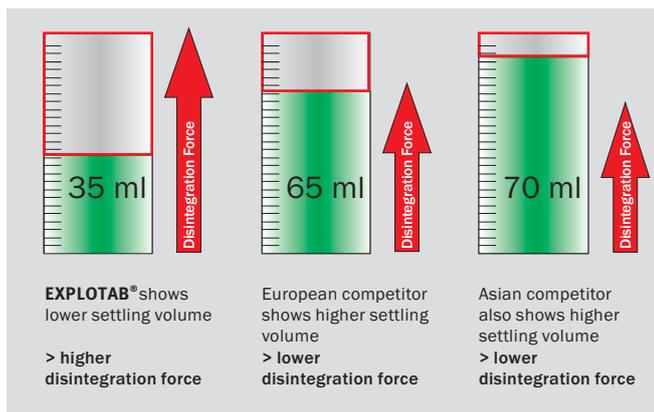


Fig. 1

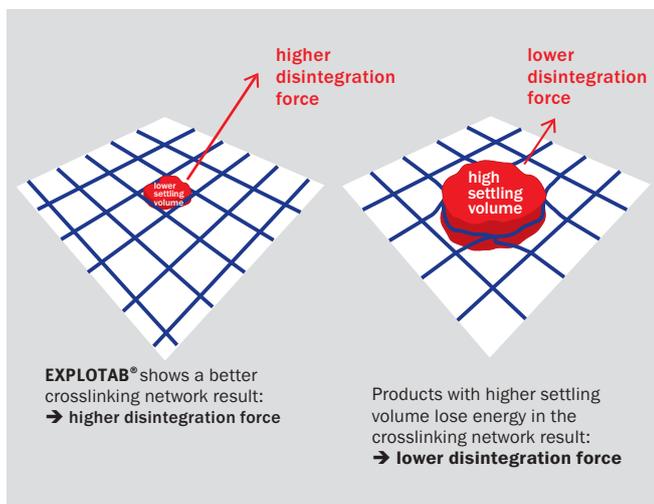


Fig. 2

**Test Method**

**Performance:**

Weigh 2.0 g Carboxymethyl Starch Sodium (mass relates to the dry weight) into a 150 ml beaker. Mix with 98 ml distilled water and stir with a glass rod. Transfer the suspension into a 100 ml graduated cylinder and keep it at room temperature.

**Assessment:**

After two hours, the setting volume of the settling (sediment) is read in ml.



# EXPLOTAB®

Sodium Starch Glycolate

## EXPLOTAB® – First in 1st Class

## Comparison

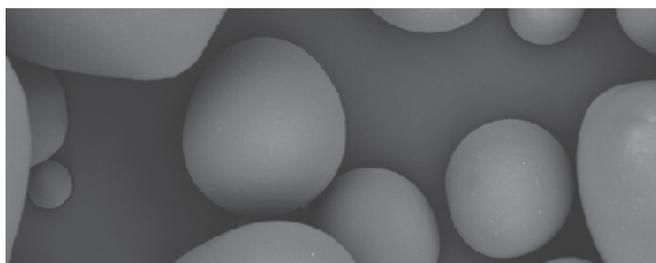
### EXPLOTAB® for High Chemical Purity

Low NaCl → High Purity → Good Disintegration

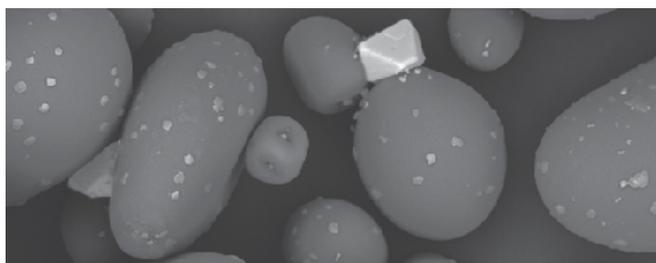
Sodium Chloride is a side product in the Sodium Starch Glycolate manufacturing process. A better washing process allows a higher purity to be handled, leading to improved disintegration power of the end product.

JRS PHARMA designed a special cleaning process for **EXPLOTAB®** to optimize NaCl reduction.

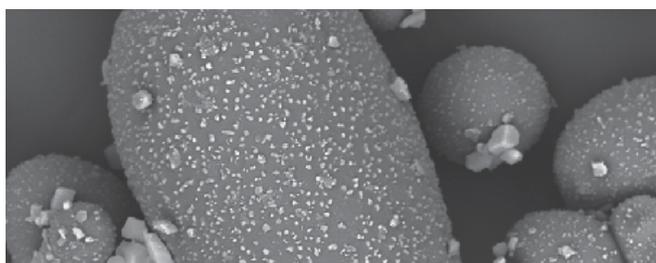
The result: better disintegration force in comparison to competitors' products.



Pic 2 REM **EXPLOTAB®** clean surface without NaCl impurities



Pic 3 REM European competitor smaller and big NaCl particles on the surface



Pic 4 REM Asian competitor smaller and bigger NaCl particles on the surface

Low Ethanol Content → Better API Stability  
→ Longer Shelf Life

### Ethanol Rest Content (Specification)

EXPLOTAB®	European Competitor
< 3%	4-6%

Tab. 1

JRS Pharma's special drying technology removes most of Ethanol used as process medium in the **EXPLOTAB®** production. The result is a better API stability which leads to longer shelf life.

### EXPLOTAB® for Good Tablet Appearance

Gentle Production → Higher Brightness  
→ Whiter Tablets

### Degree of Brightness

EXPLOTAB®	Asian Competitor	European Competitor
78%	68%	75%

Tab. 2

High Raw Material Standards → Limited Visible Specks  
→ Improved Tablet Appearance and Quality

### Dark Particles

EXPLOTAB®	Asian Competitor	European Competitor
6	12	6

Tab. 3

## Technical Data and Application

### Swelling

**EXPLOTAB®** swells upon contact with media. It absorbs water and expands significantly and rapidly, pushing against the other formulation ingredients and disrupting the tablet matrix. In capsules, the rapid and extreme swelling exhibited by **EXPLOTAB®** expels the capsule contents to promote API release.

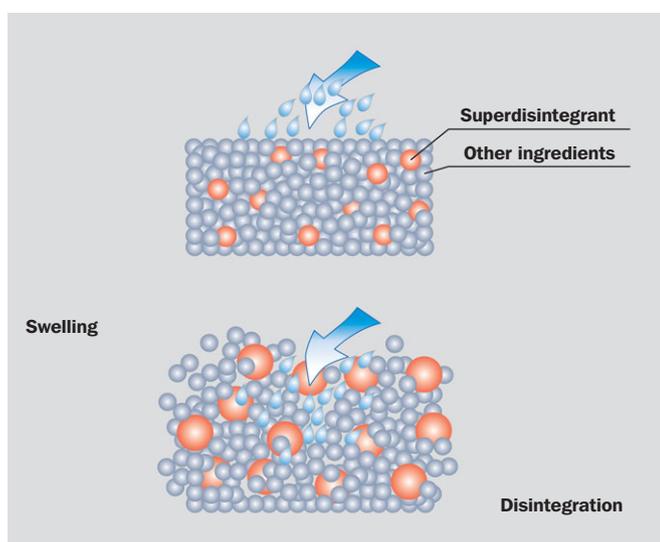


Fig. 4

### Formulation Advice

- **EXPLOTAB®** is normally used at a level of 2-4 % of the tableting mass. It is suitable for all tableting processes.
- With its high density and good flowability, **EXPLOTAB®** acts very well in direct compression. It is simply mixed and compressed with the other formulation ingredients.
- In wet granulation formulations **EXPLOTAB®** can be used intra-granularly, extra-granularly or both. When used intra-granularly, **EXPLOTAB®** absorbs some of the granulation fluid. The potential formation of lumps by the active or other ingredients is minimized.

### EXPLOTAB® Particle Size Distribution

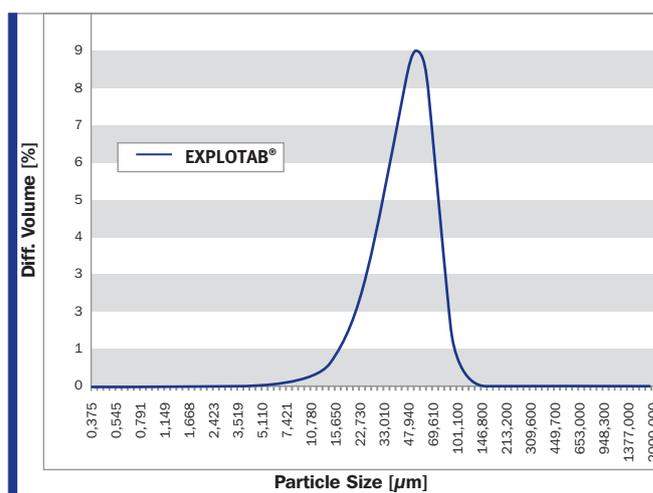


Fig. 5 Particle Size Distribution

Even better disintegration results could be achieved when combining **EXPLOTAB®** with **PRUV®** Sodium Stearyl Fumarate (lubricant) and/or **PROSOLV® SMCC** Silicified Microcrystalline Cellulose (high functionality binder).

In some formulation applications, **EXPLOTAB®** and **VIVASOL®** Croscarmellose Sodium are used in a synergistic combination to promote rapid tablet wicking and hydration, which compliments **EXPLOTAB®**'s rapid swelling.

In many cases, **EXPLOTAB®** Sodium Starch Glycolate can be used in wet granulation as a wet binder together with the active ingredient. For that, a concentration of disintegrant in the range of 5-8 % is optimal. The amount of water required depends of the properties of the active ingredient.

**More information could be obtained from the JRS brochure "Disintegration Mechanisms".**



# EXPLOTAB®

Sodium Starch Glycolate

## Fast Disintegration for More Patient Compliance

### Disintegration Mechanism of EXPLOTAB®

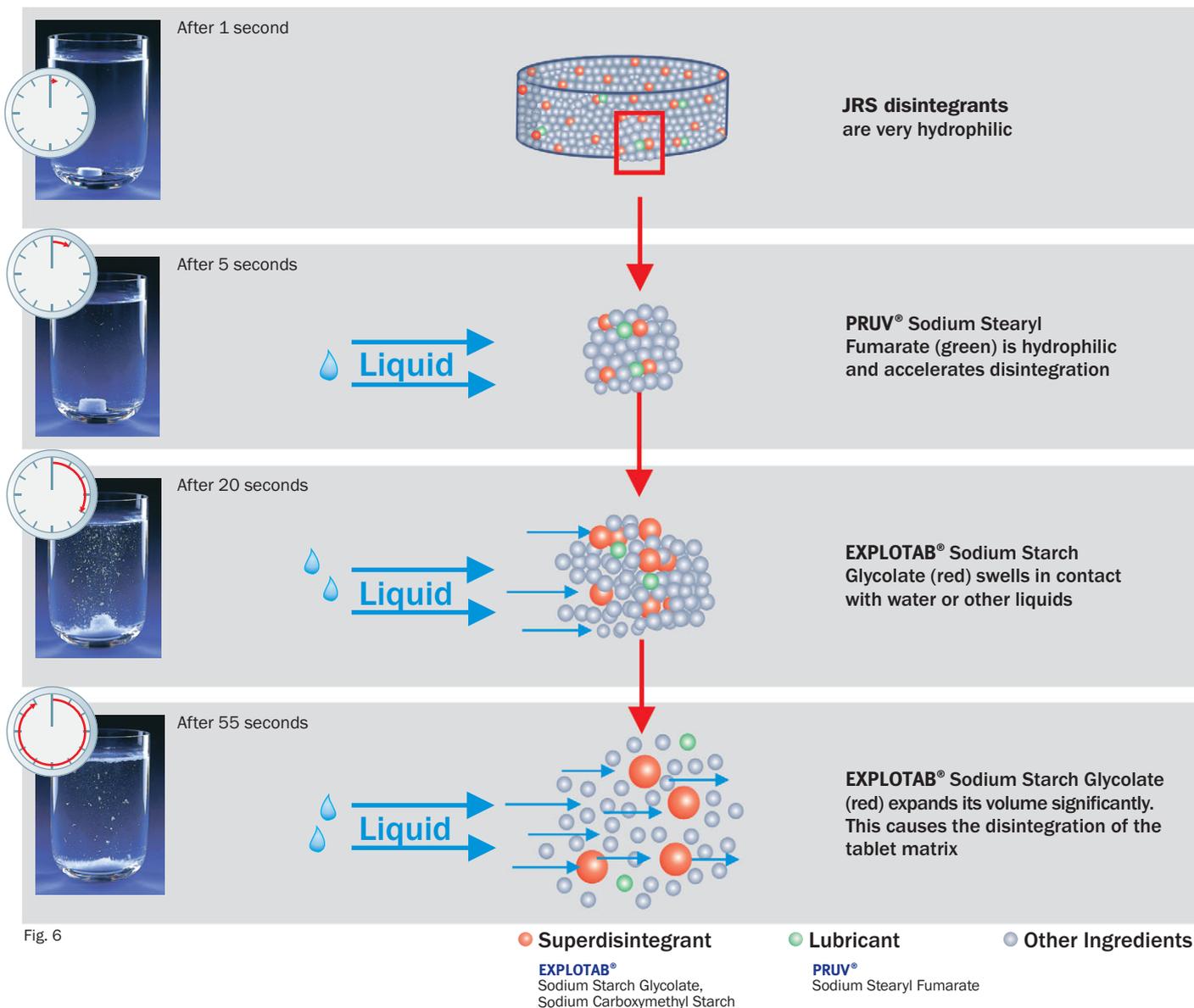


Fig. 6

### Specialities:

Brand Name	pH Value	Main Application
EXPLOTAB®	5.5 - 7.5	Superdisintegrant with a rapid and high degree of swelling for tablet and capsule formulations Especially for poor water soluble actives and tablet matrices with higher pH values.
EXPLOTAB® CLV	5.5 - 7.5	Special grade with increased number of crosslinkings. Especially suited for wet granulation applications.
EXPLOTAB® Low PH	3.0 - 5.0	Special grade with low pH value. Complies with Typ (B) Ph. Eur, NF.

Tab. 4

Tailor made low moisture grade available upon request. In addition to EXPLOTAB®, JRS PHARMA offers other superdisintegrants.

# EXPLOTAB® – More Supply Security

**EXPLOTAB®** – fulfills the following requirements:

CAS- No. 9063-38-1

- ✓ Ph. Eur., NF, JP
- ✓ Plant origin
- ✓ BSE/ TSE free
- ✓ GMO free
- ✓ Allergen free
- ✓ Gluten free
- ✓ Sodium Starch Glycolate is listed in the Inactive Ingredients List published by the FDA

Food Status:

USA and EU not allowed, Japan allowed

**Packaging:**

25 kg Boxes, and 50 kg Drums with PE Liner

**Sample Size:**

Aluminium Bags 100 g or 400 g

**Would you like to receive a sample?**

Please visit <http://orderforms.jrspharma.de>

**Disclaimer:** The information provided in this brochure is based on thorough research and is believed to be completely reliable. Application suggestions are given to assist our customers, but are for guidance only. Circumstances in which our material is used vary and are beyond our control. Therefore, we cannot assume any responsibility for risks or liabilities, which may result from the use of this technical advice.

## Manufacturing

High supply security through two independent production plants on two continents.

Plant I, CHP Pirna, Germany

ISO 9001

FDA DMF No. 3479

EIP available



Utilize the benefits offered by production in a lower cost country.



Plant II, GMW, India

ISO 9001

FDA DMF No. 24809

**EXPLOTAB®** is produced in accordance with the IPEC GMP guideline

## 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**  
Alginate Acid
- VIVAPHARM® Pectins**

#### BIOPHARMA SERVICES

Members of the JRS PHARMA Family