EXPLOTAB®
Sodium Starch Glycolate
Ph. Eur., NF, JP

The Cost Effective Superdisintegrant
Secure Supply Chain
Specialty Grades Available
Technical Advantages
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 a 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.

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 Cellose 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.

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® for High Chemical Purity

Low NaCl ➔ High Purity è Good Disintegration

Natrium 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.

Low Ethanol Content ➔ Better API Stability ➔ Longer Shelf Life

Ethanol Rest Content (Specification)

<table>
<thead>
<tr>
<th>EXPLOTAB®</th>
<th>European Competitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 3%</td>
<td>4-6%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>EXPLOTAB®</th>
<th>Asian Competitor</th>
<th>European Competitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>78%</td>
<td>68%</td>
<td>75%</td>
</tr>
</tbody>
</table>

Tab. 2

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

Dark Particles

<table>
<thead>
<tr>
<th>EXPLOTAB®</th>
<th>Asian Competitor</th>
<th>European Competitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>12</td>
<td>6</td>
</tr>
</tbody>
</table>

Tab. 3
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.

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”.

Formulation Advice

- EXPLOTAB® is normally used at a level of 2-4 % of the tablettng mass. It is suitable for all tablettng 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.
Fast Disintegration for More Patient Compliance

Disintegration Mechanism of **EXPLOTAB®**

After 1 second

- **JRS disintegrants** are very hydrophilic

After 5 seconds

- **PRUV® Sodium Stearyl Fumarate** (green) is hydrophilic and accelerates disintegration

After 20 seconds

- **EXPLOTAB® Sodium Starch Glycolate** (red) swells in contact with water or other liquids

After 55 seconds

- **EXPLOTAB® Sodium Starch Glycolate** (red) expands its volume significantly. This causes the disintegration of the tablet matrix

Specialities:

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>pH Value</th>
<th>Main Application</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EXPLOTAB®</strong></td>
<td>5.5 - 7.5</td>
<td>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.</td>
</tr>
<tr>
<td><strong>EXPLOTAB® CLV</strong></td>
<td>5.5 - 7.5</td>
<td>Special grade with increased number of crosslinkings. Especially suited for wet granulation applications.</td>
</tr>
<tr>
<td><strong>EXPLOTAB® Low PH</strong></td>
<td>3.0 - 5.0</td>
<td>Special grade with low pH value. Complies with Typ (B) Ph. Eur, NF.</td>
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</tbody>
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Tailor made low moisture grade available upon request. In addition to **EXPLOTAB®**, JRS PHARMA offers other superdisintegrants.

www.jrspharma.com
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

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

Would you like to receive a sample?
Please visit http://orderforms.jrspharma.de

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