EMCOMPRESS®

Calcium Hydrogen Phosphate, Ph.Eur., E 341(ii)
Dibasic Calcium Phosphate, USP/NF, FCC

A Proven Excipient for more than 60 Years

Functional Filler •
Flow Enhancer for High Speed Tableting •
Calcium and Phosphate Fortification •

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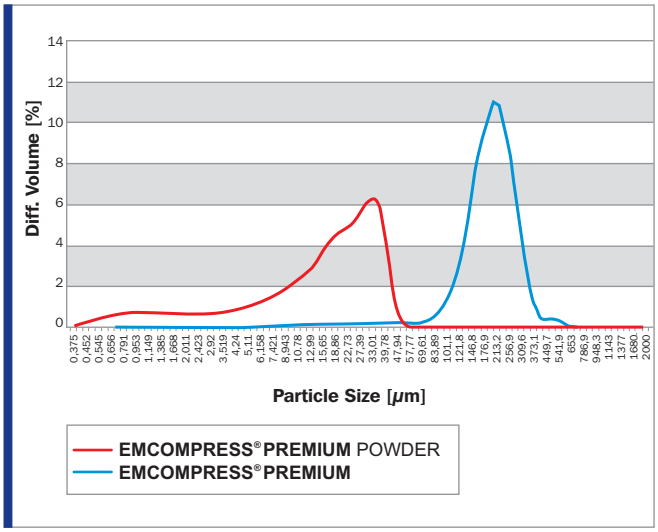
Introduction

EMCOMPRESS® Calcium Phosphates are water-insoluble functional fillers for wet granulation and direct compression applications. **EMCOMPRESS®** offers improved flow for all powder mixtures, including poorly flowing APIs and plant extracts. **EMCOMPRESS®** is available in three different grades:

- Anhydrous Calcium Hydrogen Phosphate (DCP anhydrous)
- Calcium Hydrogen Phosphate Dihydrate (DCP dihydrate)
- Calciumphosphate (TCP)



Graph 1: Particle Size Distribution of **EMCOMPRESS®** DC and Powder Grades

Physical Properties

- White, crystalline powder
- Water-insoluble
- High bulk density
- Spherical shape
- Neutral taste
- Good flowability
- Low elastic recovery
- Deforms by brittle fracture
- Available in different particle sizes ranging from large particles for direct compression to small powders for wet granulation

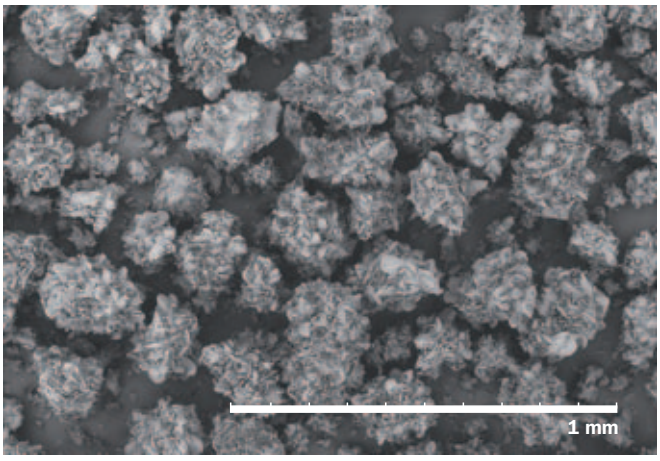


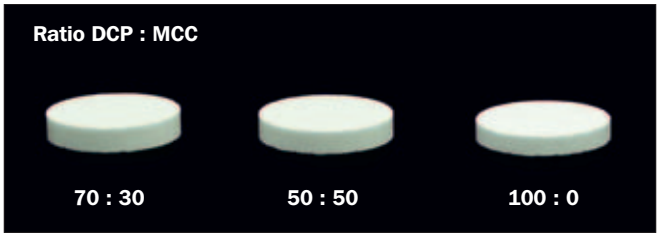
Fig. 1: Micrograph of **EMCOMPRESS®**

Benefits

- Direct compression grades act as flow enhancers in powder mixtures
- Enables the production of very dense and small tablets
- Boosts tablet robustness by synergistic effects with microcrystalline cellulose
- Less sensitive towards lubricants compared to plastically deforming materials
- Performs well in combination with a wide variety of APIs including sticky herbal extracts
- Perfectly suited for high-speed tableting due to low strain rate sensitivity
- Inorganic – no risk of BSE/TSE contamination and free of allergens
- High chemical stability, especially for anhydrous grades
- Premium grade is fully food compliant
- High supply security due to multiple production sites

Applications

- Direct compression (DC grades)
- Wet granulation (powder grades)
- Capsule filling
- Chewable tablets
- Herbal and sticky APIs
- Probiotics
- Premixes
- Flow improvement
- Modification of density
- Soft gel capsules



Pic. 1: Effect of amount of DCP on tablet height.

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Technical Data and Application

Tablet Binding Mechanisms

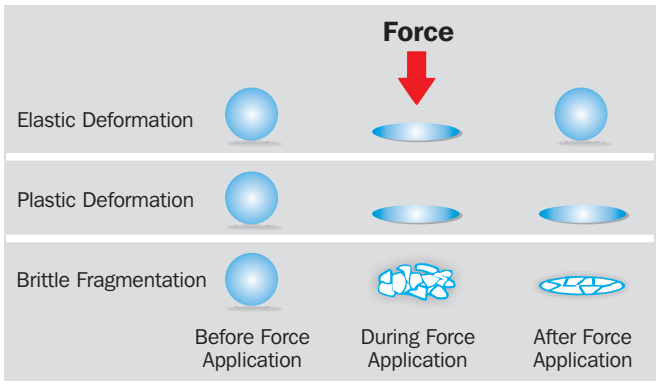
All excipients exhibit different behavior upon compaction. After the application of compression force, they can either deform elastically or plastically, or they can fragment into brittle pieces.

Elastic materials deform upon the application of pressure, but regain most of their original shape after removal of the force. This elastic recovery can, for example, be seen in many starches. It leads to less stable tablets, which tend to be difficult to handle.

In contrast, **plastic materials** are deformed upon the application of force, but when the force is removed, they stay in their deformed form and do not restore their former shape. A typical example of this type of material is microcrystalline cellulose.

Brittle materials form a category of their own. If they are exposed to force, they break into many small pieces at first – just as glass breaks into shards. These small pieces are compacted into one big particle upon further exposure to force. These secondary particles are very dense and stick together well. Typical members of this class of excipients are calcium phosphates such as **EMCOMPRESS®**.

Most excipients have a preferred mechanism of deformation, but they commonly display small shares of the other mechanisms as well.

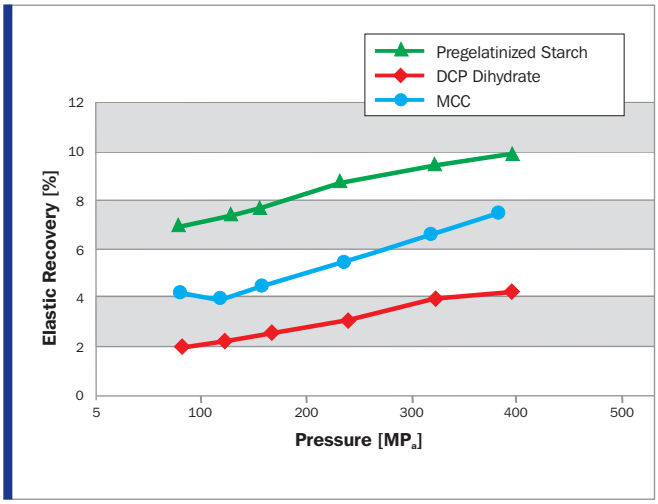


Pic. 2: Deformation Mechanism

Low Elastic Recovery

The share of elastic recovery is minimal for calcium hydrogen phosphate dihydrate, while the share of elastic recovery for pregelatinized starch is almost four times as high. The elastic recovery of microcrystalline cellulose is about twice the value of calcium hydrogen phosphate dihydrate.

This means that calcium hydrogen phosphate dihydrate is nearly free of elastic recovery and tablets made from calcium hydrogen phosphate will not regain size after compression. Thus, such tablets show a lower tendency towards capping and lamination.

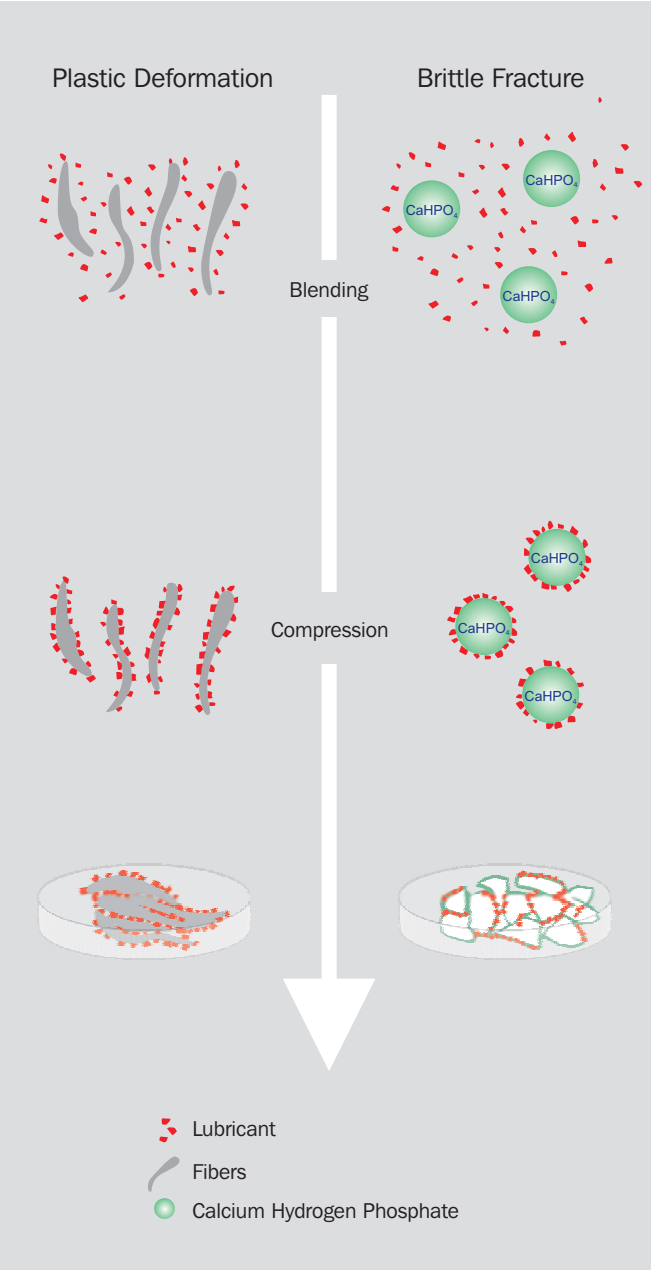


Graph 2 : Adopted from: Holger Schlack, PhD thesis, Freiburg, Germany

Low Lubricant Sensitivity

Lubricants are needed for the smooth ejection of tablets from the die. Within a tablet itself, lubricant is not needed; it even affects tablet hardness negatively. Wherever a lubricant is blended with other excipients, it forms a thin, slippery layer on the outside of the powder particles. If elastic or plastic particles are compressed, this layer impedes the cohesion between the individual particles, leading to low tablet hardness.

Brittle fragmenting materials, such as **EMCOMPRESS®** prove very beneficial if lubrication sensitivity is an issue. During lubrication, their particle surfaces are covered with lubricant particles. During compression, however, the excipient particles are broken into many smaller particles with a huge number of new surfaces which are not covered by any lubricant. These surfaces free of lubricant can stick together very well and guarantee good tablet hardness – even at high lubricant concentrations.



Pic. 3: Reduced lubricant sensitivity with **EMCOMPRESS®**. Brittle fraction creates unlubricated areas for efficient binding.

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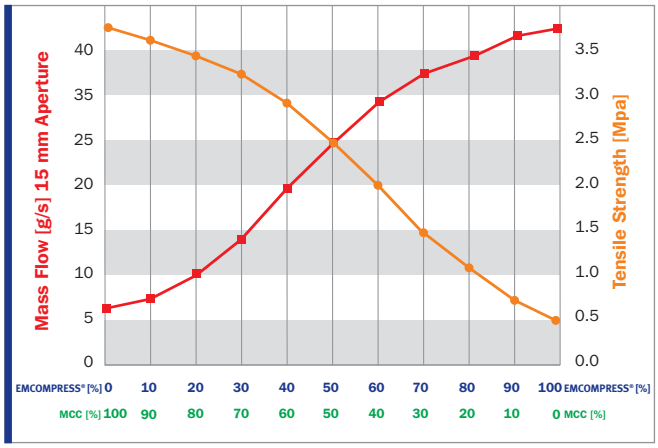
Low Strain Rate Sensitivity

Brittle fracturing materials break into small pieces immediately after the application of compression force and develop their binding abilities immediately.
In contrast, plastic deformation is dependent on the time of force application. Thus, increasing the tableting speed for a powder mixture containing mainly plastically deforming materials leads to a decrease in tablet hardness, while the mechanical strength of the tablet remains unchanged if mainly brittle materials are used. **EMCOMPRESS®** -based formulations are, therefore, highly suited for scale-up to high speed production.

Flow Improvement

EMCOMPRESS® DC grades improve powder due to their high bulk density, while microcrystalline cellulose exhibits outstanding compactibility. Using a combination of **EMCOMPRESS®** DC grades and microcrystalline cellulose, flowability and tablet hardness can be adjusted to formulation needs.



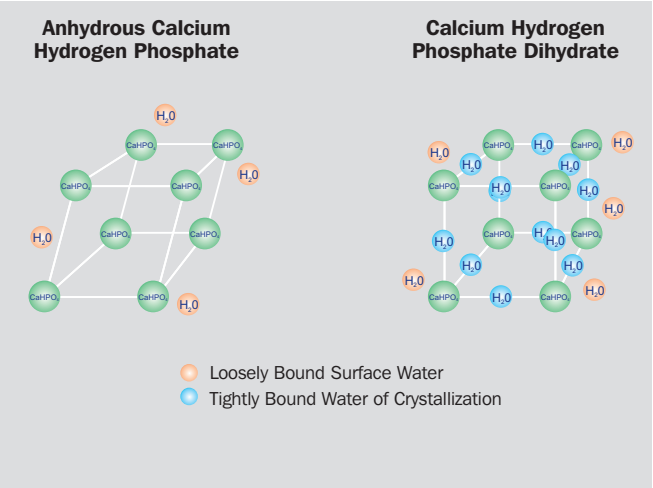
Graph 3: Influence of Different Ratios MCC / **EMCOMPRESS®** on the Mass Flow and the Tensile Strength of Placebo Tablets

Water of Crystallization and Stability

Both **EMCOMPRESS® ANHYDROUS** and **EMCOMPRESS®** bear loosely bound water on the particle surface which can be removed by simple heating (i.e. loss on drying; upper part of pic. 4). The difference between the two **EMCOMPRESS®** products lies in the amount of water of crystallization. **EMCOMPRESS®** (i.e. calcium hydrogen phosphate dihydrate) comprises water of crystallization, which is incorporated into the crystal structure.
In contrast, **EMCOMPRESS® ANHYDROU**S is free of any water of crystallization.

Water of crystallization is tightly bound in the DCP crystal lattice and cannot be removed easily. Nevertheless, elevated temperature and humidity may occasionally trigger the liberation of the water of crystallization. This unbound water is freely available for side reactions and can accelerate microbial growth and cause changes in powder flowability.

In order to always be on the safe side, it is advisable to use **EMCOMPRESS® ANHYDROUS** for new developments. Anhydrous DCP is free of crystal water and bears absolutely no stability risks, while maintaining the functional benefits of DCP dihydrate.



Pic. 4: Surface Water and Water of Crystallization

Regulatory Information

- Compliant with Ph.Eur., USP, JP
- GRAS listed
- Free of:
  - allergens
  - GMO contamination
  - BSE/TSE contamination
  - pesticides
  - irradiation
  - hormones and steroids
  - preservatives
  - organic solvents
  - gluten
- Fully complies with FCC monograph on Calcium Phosphates, E 341 (ii), and Commission Directive No. 231/2015/EC due to its low content of heavy metals and aluminum

Packaging, Samples and Storage

Standard Packaging:
25 kg paper bags available on Euro-pallets and container-pallets.
Special packaging available on request.

Case Studies
Case studies and formulation examples are available upon request. Please contact your sales rep for more information or visit *www.jrspharma.com.*

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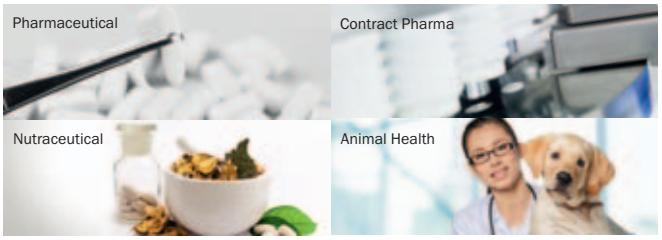

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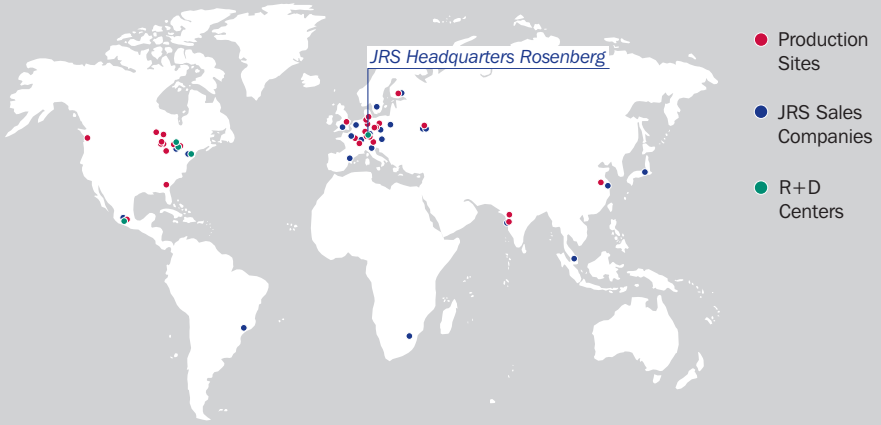
Manufacturing



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