

EXCIPIENTS

# STARCH 1500<sup>®</sup>

PARTIALLY PREGELATINIZED MAIZE STARCH

## Proven and Trusted Excipient for Performance and Versatility

- Effective and economical disintegrant
- Excellent stability for moisture sensitive drugs
- Manufactured exclusively for the global pharmaceutical industry

  
**Colorcon**

## Uniquely Colorcon

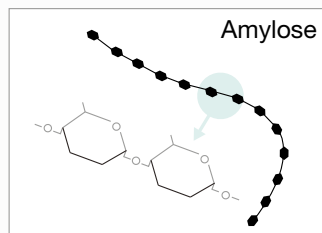
Starch 1500® is a partially pregelatinized maize starch manufactured exclusively for the pharmaceutical industry in dedicated cGMP facilities. The production procedure involves a physical modification of the starch resulting in the combined benefits of both the soluble and insoluble functionality.

For the modern formulator Starch 1500® will impart effective tablet disintegration properties and advantageous cold water binding and granulation properties. The physical structure of Starch 1500® also imparts good compactability, flow and lubrication properties.

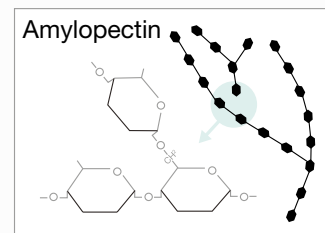
Maize starch is composed of two polymers, amylose and amylopectin which are tightly bound in a specific spherocrystalline structure.

Through a partial pregelatinization process which is unique to Colorcon, the bond between portions of the two polymers is broken, providing Starch 1500® with an effective functional balance and extraordinary properties.

Amylose has a straight-chain molecular structure, which exhibits a very strong intermolecular bonding capability. Amylose swells significantly when wetted, giving it excellent disintegrating characteristics.



Amylopectin has a branched-chain molecular structure, which makes it ready soluble in cold water. Amylopectin functions as a binder in wet granulation processes.



With over 50 years history, Starch 1500® has marketed product success in innovator, generic, OTC and nutritional market segments across more than 80 countries.

Starch 1500® continues to mitigate some of the most significant risks facing formulators and manufacturers:

- Content Uniformity
- Speed of Disintegration
- Moisture Management and Stability
- No Known API Incompatibilities

## Why Direct Compression

In solid oral dose development, API compatibility will drive the selection of the excipient. The choice of excipients will determine the necessary manufacturing process, which has the most significant impact upon long term production costs and resulting profitability.<sup>1</sup>

Direct compression continues to offer economic advantages:

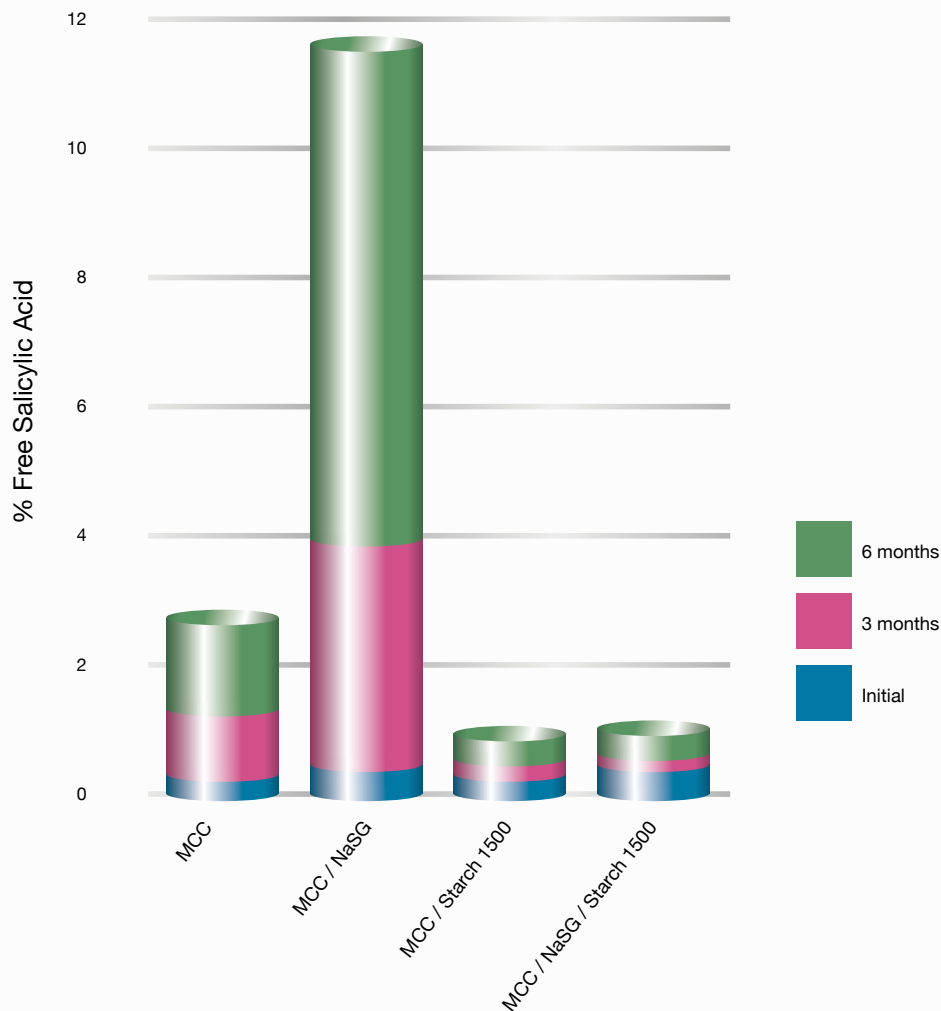
- Fewer Unit Operations
- Lower Production Time and Energy Consumption
- Less Equipment and Space
- More Cost Efficient Production of Tablets

# Excellent Stability for Moisture Sensitive Drugs

The properties of Starch 1500® makes it an excellent diluent to enhance stability of moisture sensitive drugs. Starch 1500® is inhibiting water activity within the formulation and retarding interaction with the moisture sensitive API [acetylsalicylic acid (ASA)].<sup>5</sup>

The use of Starch 1500® provides exceptional stability in this moisture sensitive application, it reduces or eliminates the detrimental effects of other excipients in the study.

Figure 2. Impact of Excipient Combinations on Free Salicylic Acid Stability with Moisture Sensitive API (ASA)<sup>6</sup>



## Tablet Weight Consistency

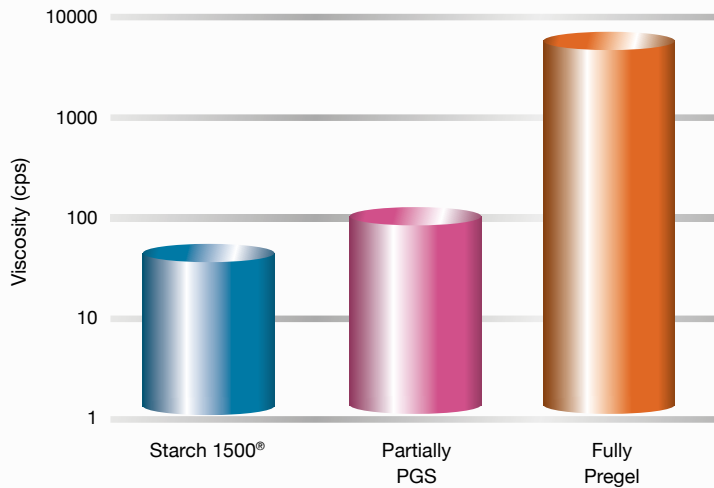
Starch 1500® improves formulation flow properties, resulting in good tablet weight uniformity demanded for high-speed tableting and capsule filling equipment; ensuring that manufacturers can produce tablets and capsules with consistent uniform weight and drug content.

## Process Flexibility for Granulation

In wet granulation applications, Starch 1500® exhibits dual functionality as both binder and disintegrant due to partial cold water solubility exhibited by the fully gelatinized portion.

Starch 1500® in cold water provides effective binding properties at high solids and lower viscosity compared to traditional starch pastes, which must be heated and prepared at lower concentrations.

*Figure 3. Viscosity Comparison of Pregelatinized Starch Dispersed in Water (24°C) at 10% Solids*



## High Quality Tablets for Film Coating

Starch 1500® when used as secondary excipient, alongside microcrystalline cellulose (MCC) delivers tablet hardness and low friability ideal for film coating and packaging.



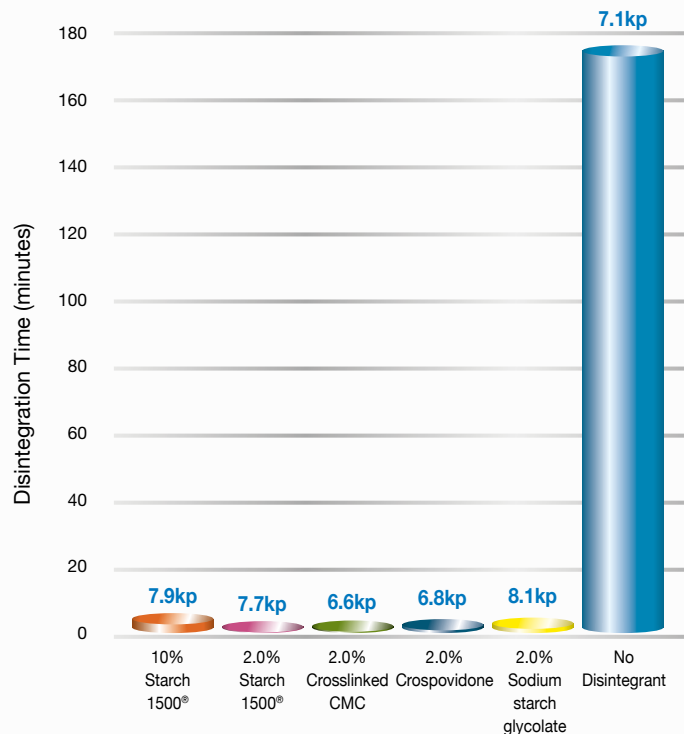
### References

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2. API incompatibilities – Handbook of Pharmaceutical Excipients
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5. Cunningham C. et al. Evaluation of a Partially Pregelatinized Starch in Comparison with Superdisintegrants in a Direct-Compression Hydrochlorothiazide Formulation. 1999 AAPS Poster
6. Cunningham C. et al. Effect of STARCH 1500® on the Stability of Aspirin Tablets Stored Under Accelerated Conditions. 2001 AAPS Poster

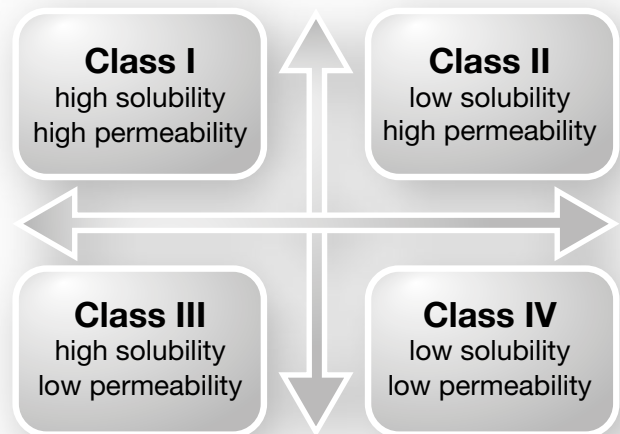
# An Effective and Economical Disintegrant in Direct Compression

Starch 1500® replaces problematic fillers and provides disintegrant action as effectively as super disintegrants, greatly reducing costs.<sup>3</sup>

Figure 1. Comparison of Starch 1500® with Superdisintegrants in a Direct Compression Hydrochlorothiazide Formulation<sup>4</sup>



## Effective Across all Classes of Drugs

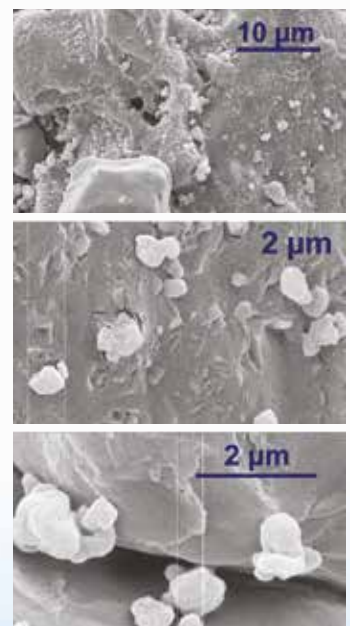


## Effective for Low Dose Drugs

The potency of both new and currently used drugs necessitates doses as low as 0.025 mg. During the development and manufacturing of a low dose tablet, content uniformity is the principal technical challenge.

In a dry blend, drug particles are attached and secured within the unique granular structure of Starch 1500® which ensures excellent content uniformity of low dose drugs in direct compression.

The SEM photos show micronized API (indomethacin) distributed within the crevices of Starch 1500®.<sup>4</sup> The morphology and beneficial moisture content inherent to Starch 1500® will facilitate uniform distribution and minimal API agglomeration. Both are critical in the development of a successful low dose product on commercial scale.



**STARCH 1500®**

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## Deliver High Performance Products – with Colorcon

Choose Colorcon, leader in pharmaceutical solid oral dose solutions, as a formulation partner of choice in every phase of your product development.

### Film Coatings:

- Optimized formulations specifically for your application and regulatory needs including customized colors and color matching
- Innovative products for mechanical integrity, gloss, pearlescence, and environmental protection
- Tablet design concepts, consulting and services to build a strong brand image and stand out from the competition.

### Formulation Technologies:

- Full range of functional excipients
- Technologies for development and production of delayed/enteric release and extended/controlled release tablets and multiparticulates
- HyperStart® service and extensive applications data to provide starting formulations to save you development time and money
- Extensive formulation know-how and technical support to achieve the exact drug release profile desired.

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