

Oral Solid Dose

# Primellose<sup>®</sup>



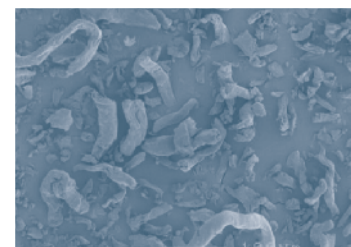
**Primellose<sup>®</sup>** is DFE Pharma's product brand name for Croscarmellose Sodium. It is made in a dedicated pharmaceutical plant in Foxhol, The Netherlands. Primellose<sup>®</sup> croscarmellose sodium is suitable for a variety of tablet and capsule formulations. Primellose<sup>®</sup> is effective in combination with both insoluble filler-binders and slightly soluble to soluble filler-binders at concentrations of 2%w/w - 6%w/w. It is also a choice for formulations which require non-starch products. Primellose<sup>®</sup> is effective when used intragranular and/or extragranular in granular formulations.

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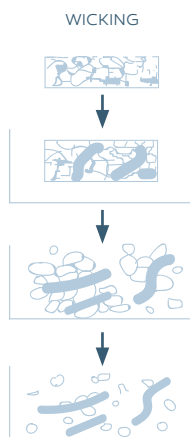
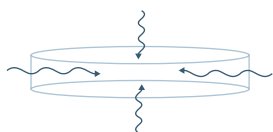
# Primellose®

## Benefits



### Superior performance

Primellose® can be used in wet granulation, dry granulation or direct compression in combination with nearly any type of API and excipient(s) (soluble or slightly soluble). Wicking is the most important factor in croscarmellose sodium performance, and it was found that the relatively large particle size distribution of Primellose® conferred superior performance compared to many other brands.



Water is pulled into pores by disintegrant and reduce the physical bonding forces between particles

### In wet granulation

We recommend that Primellose® is incorporated at least partly (50%w/w or more) during granulation. This is especially important when a high proportion of insoluble diluent is employed as shown in this example which uses Diclofenac Sodium as the API and dibasic calcium phosphate dihydrate as the main diluent.

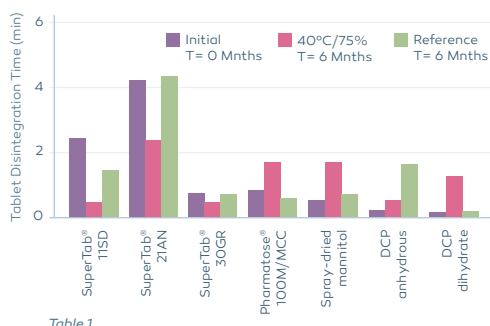
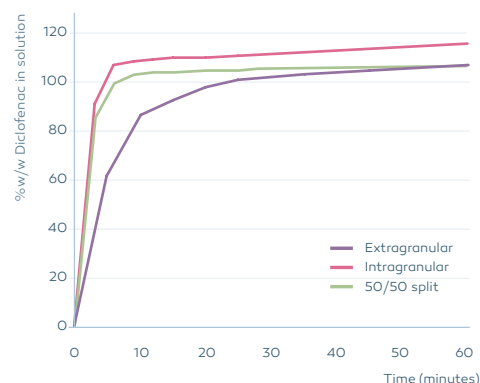


Table 1

### In direct compression

The recommended starting point is 2%w/w to 6%w/w of Primellose®. Table 1 shows how the disintegration time of various placebo tablets (250 mg / 9 mm tablets containing 4%w/w Primellose® and 0.5%w/w magnesium stearate) is maintained after storage for 6 months at 40 °C / 75% RH in open containers. The disintegration of reference tablets stored for 6 months under ambient laboratory conditions is also shown. This data confirms that Primellose® remains an effective super-disintegrant, even under the most stressful stability storage conditions.

## Facts

### Typical product data

Complies with Ph. Eur., USP-NF, JP  
Kosher certified

### Particle size distribution

Method: Alpine Airjet

Sieve %w/w <45 µm	65 - 85%
Sieve %w/w <75 µm	min. 90%
Sieve %w/w <125 µm	min. 98%

### High protective packaging

	Drum
Capacity	50 kg
Composition	HDPE + PE liner
Shelf life	5 years