

Oral Solid Dose

Primojel®



Primojel® Sodium starch glycolate is a superdisintegrant suitable for a variety of tablet and capsule formulations. In higher concentrations, Primojel® can act as a dissolution enhancing agent. Primojel® is highly effective when used intragranular and/or extragranular in granular formulations.

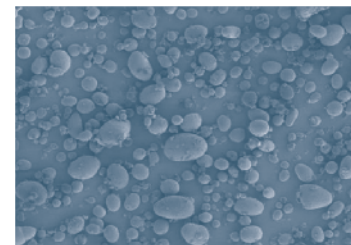
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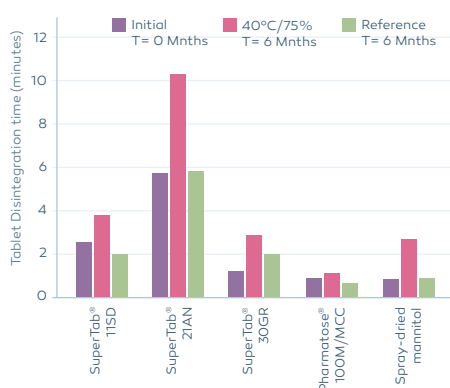
Primojel®

Benefits



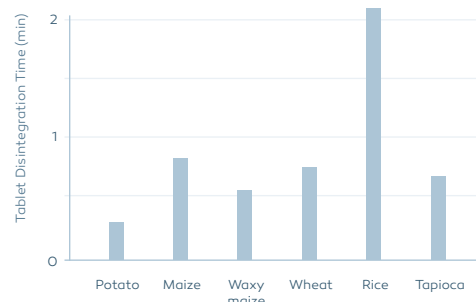
Disintegration performance

Primojel® takes up more than 20 times its own weight of water. Rapid water penetration into the tablets and powerful swelling results in rapid disintegration. The swelling actions makes Primojel® most effective in non-soluble matrices. Studies show that Primojel® takes up more water than comparative products on the market and develops a strong disintegrating force making it a highly effective product. The botanic source, degree of cross-linking and degree of substitution of Primojel® have been optimized in order to give rapid water uptake by the polymer without the formation of a viscous gel that may impede water penetration into the tablet.



In direct compression

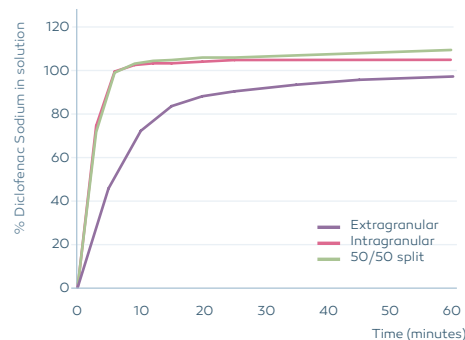
The recommended starting point is 2%w/w to 4%w/w of Primojel®. The figure shows how the disintegration time of various placebo tablets (250 mg / 9 mm tablets containing 4%w/w Primojel® and 0.5%w/w magnesium stearate) is maintained after storage for 6 months at 40 °C / 75% RH in open containers. The disintegration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



Disintegration time of alpha-lactose monohydrate tablets, containing 4% of different experimental sodium starch glycolates from different botanical sources as a disintegrant.

In wet granulation

We recommend that Primojel® is incorporated at least partly (50% or more) during the granulation. This is especially important when a high proportion of insoluble diluent is employed. The intragranular components were wet granulated (high shear), dried, sieved and blended with the extragranular portion of Primojel® and magnesium stearate. Tablets were compressed at 250 mg and dissolution tested in 900ml of water using USP apparatus 2. Dissolution of Diclofenac Sodium is slower when Primojel® is used only in the extragranular phase. If lactose is used instead of dibasic calcium phosphate, then the effect of Primojel® location is greatly reduced.



Facts

Typical product data

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

Particle size distribution

Method: Alpine Airjet

Sieve %w/w <63 µm	min. 95%
Sieve %w/w <125 µm	min. 100%

High protective packaging

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