The quality signature of DFE Pharma Superdisintegrants

The pursuit of excipient excellence
Superdisintegrants

Your Superdisintegrants by DFE Pharma

Your medicines are based on extremely precise formulations. They need to do what they are supposed to do. Always. Our market leading superdisintegrants ensure your formulation will disintegrate. Showing the quality signature of our superdisintegrants.

We continuously invest in advanced production technologies and to offer a reliable supply of high-end products from our production site in Foxhol, the Netherlands. Here we operate a state-of-the-art, purpose built factory, where a highly skilled, dedicated team delivers superior product quality. DFE Pharma is committed to delivering you the very best superdisintegrants available and assist you with the technical support you need.

DFE Pharma superdisintegrants are well suited for use in tablets and capsules.

DFE Pharma offers the following superdisintegrants:

- Primojel®: sodium starch glycolate
- Primellose®: croscarmellose sodium

We are the global leader in excipient solutions. We develop, produce and market excipients for oral solid dose and dry powder inhalation formulations. Our customers are pharmaceutical companies, operating globally, regionally and locally.

The pursuit of excipient excellence

Excipient excellence is a pursuit that will never be fully achieved. What is excellent today will be outdated tomorrow. That’s why to us the pursuit of excipient excellence is a way of life. A source of inspiration. Excipient excellence is what guides us on our way to developing and producing the best possible excipient solutions for our customers. Today, tomorrow, always.

Leading in expertise

We are here to help you create pharmaceutical products that set the new standard.

Leading in supply

We are here to ensure you can always produce your products. No matter what happens.

Leading in time to market

We are here to help you grow by minimizing the time to market.

We invite you to join us in our pursuit of excipient excellence.

Pursuit

‘the art of striving towards an ideal with strong determination.’
Primojel®
Sodium starch glycolate type A, USP-NF, Ph. Eur., JP.
Description
Primojel® is produced by cross-linking and carboxymethylation of potato starch. It is a white, free flowing powder.
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. 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 botanical source, degree of cross-linking and degree of substitution of Primojel® have been optimised 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. The botanical source for sodium starch glycolate is important and figure 2 (page 4) shows that potato starch, the source material for Primojel®, is the preferred type of starch for sodium starch glycolate.
Application
Primojel® is suitable for a variety of tablet and capsule formulations. In higher concentrations, Primojel® can act as a dissolution enhancing agent. Primojel® is effective when used as intra-granular or extra-granular superdisintegrant, or when divided between these locations.

Superdisintegrants
For tablets and capsules which need rapid disintegration, the inclusion of the right disintegrant is a prerequisite for optimal bioavailability. Superdisintegrants are used to improve the efficacy of solid dosage forms. This is achieved by decreasing the disintegration time which in turn enhances drug dissolution rate. Superdisintegrants are widely used in direct compression, wet granulation and capsule formulations. In order to closely match the functionality requirements, DFE Pharma produces two superdisintegrants: Primojel® (sodium starch glycolate) and Primellose® (croscarmellose sodium), which show outstanding disintegration characteristics for tablets prepared by direct compression, wet or dry granulation and for capsule formulations.

Primojel® & Primellose®
Why should you use Primojel® or Primellose®? Both products are hydrophilic and swell with the uptake of water. The combination of water uptake and swelling promotes disintegration of the dosage form. Superdisintegrants are effective in low concentrations of 2-6%, while traditional disintegrants such as starches often require concentrations of 10-20%. The relatively low concentration of the superdisintegrants helps to reduce overall tablet size or improves tablet compactability by inclusion of higher levels of compressible filler-binders (see the SuperTab® and Lactopress® range of DFE Pharma).

Formulation examples using Primojel®
Alprazolam tablets 2 mg by direct compression
Components
mg/tablet
Alprazolam 1.00
SuperTab® 14SD 76.0
Pharmacel® 102 39.9
Primojel® 2.40
Docusate sodium 0.12
Magnesium stearate 1.20
Total 120.6
Tablet properties
Mean weight 121 mg
Thickness 2.80 mm
Hardness 73 N
Friability 0%
Assay (% label) 98%
Content uniformity (RSD) 3.7%
Disintegration time (min:s) 00:19

Hydrochlorothiazide tablets 100 mg by wet granulation
Components
mg/tablet
Hydrochlorothiazide 100
Pharmatose® 200M 375
Primojel® 20.0
PVP 2.50
Magnesium stearate 2.50
Total 500
Tablet properties
Crushing strength 65 N
Disintegration time 32 s

Hydrochlorothiazide tablets 100 mg by wet granulation
Components
mg/tablet
Hydrochlorothiazide 100
Pharmatose® 200M 375
Primojel® 20.0
PVP 2.50
Magnesium stearate 2.50
Total 500
Tablet properties
Crushing strength 65 N
Disintegration time 32 s
Primellose®

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References

DMV-Fonterra Excipients GmbH & Co. KG - Warranty

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