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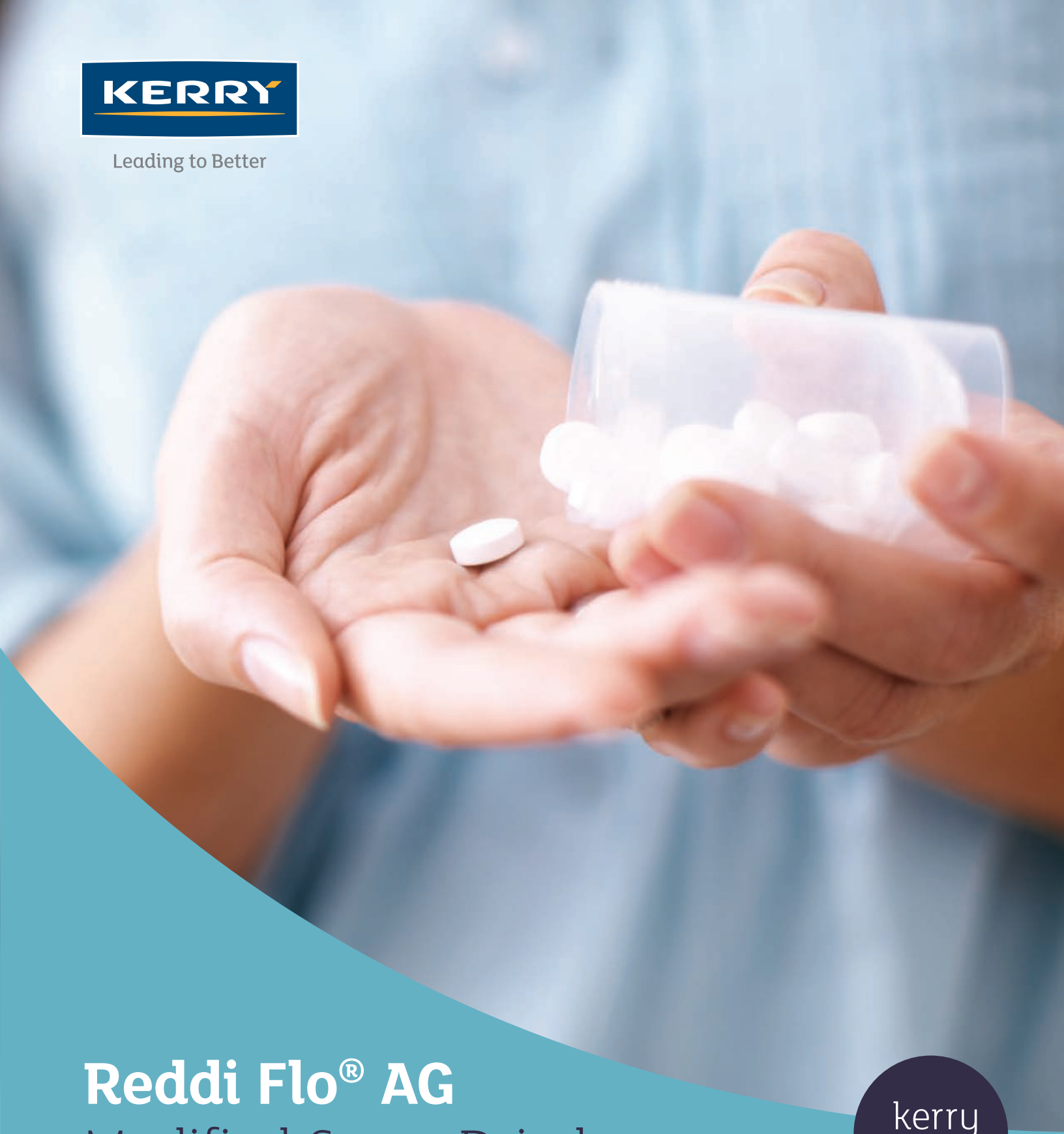
Leading to Better



Reddi Flo® AG

Modified Spray Dried Lactose, Agglomerated

kerry.com

Designed for optimal flow, compression, and stability

Reddi Flo® AG

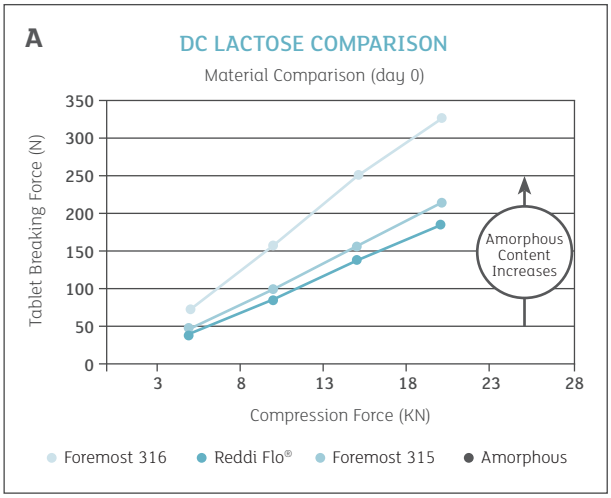
Reddi Flo® AG is a new, agglomerated crystalline lactose intended for use in direct tableting applications.

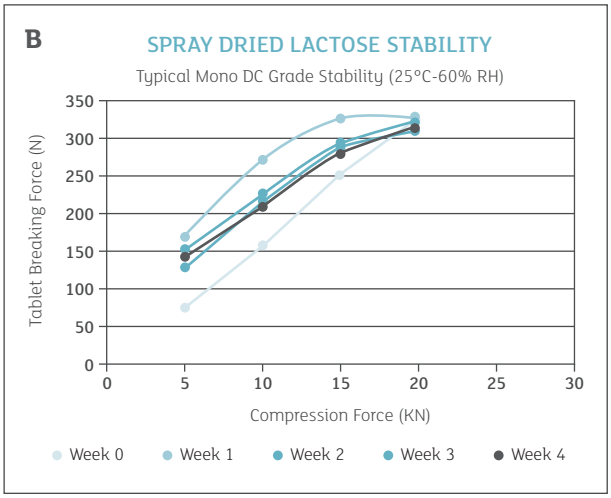
Why do we need an agglomerated monohydrate lactose? Standard crystalline monohydrate lactose is not very compressible, and typically has poor flow properties; which makes them a poor choice for direct tableting manufacturing techniques. For optimal tableting characteristics of monohydrate lactose, there needs to be balance struck to provide good powder flow properties, requiring fine particles of lactose (to increase surface area); and coarser lactose particles to provide good flow characteristics. Spray dried versions of monohydrate lactose have been used for many years, because it combines crystalline and amorphous lactose in a unique balance, to create excellent flow, and good compressibility. However, the presence of amorphous lactose, can also create some issues with tablet stability, depending on the API properties and drug loading in the finished dose.

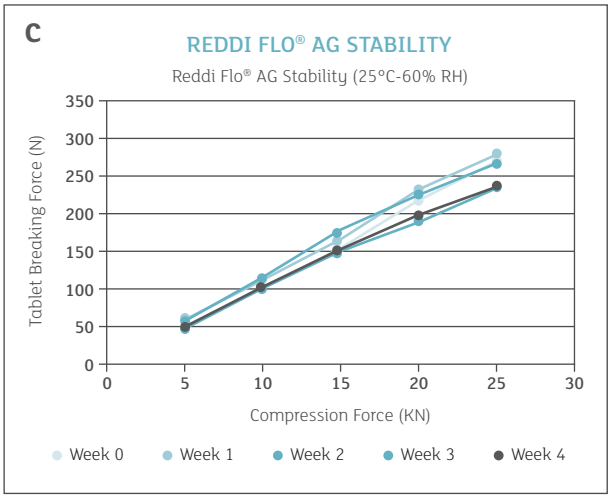
In addition to the size distribution of the lactose crystals, the morphology of the lactose plays a influential role regarding powder flow properties. As you can see on the next page, Reddi Flo® AG has a unique morphology where the smaller lactose particles are attached, or bonded, to the coarser ones, to create a free flowing lactose powder. This bonding between lactose particles of different sizes, is the result of the carefully controlled spray agglomeration process, that removes the water bridge, at a very precise rate of evaporation.

Reddi Flo® AG has excellent flow properties. Typically, this lactose will have a Carr's index of approximately 14, which is an indicator of good flowability. It is slightly coarser than other modified monohydrate crystalline grades of lactose. This is due to the agglomerated nature of the product, as well as its unique morphology.

Perhaps even more importantly, the manufacturing process for Reddi Flo® AG results in a negligible amount of amorphous lactose content being present in the lactose, compared to regular monohydrate lactose. This makes the product, less hygroscopic, more stable over time and less prone to tablet hardening over time (see comparative graphs B and C on the following page).

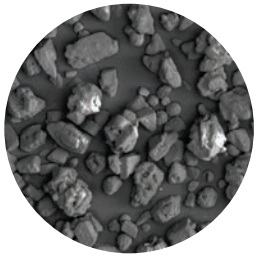






Some of the applications that would benefit from using Reddi Flo® AG, would be:

- Direct compression of moisture sensitive actives, with low dose / high potency API's
- Hard gelatin capsule filling
- Formulations that would otherwise require other excipients to attain desired compaction
- Whenever flowability is a concern or high volume throughput is needed



SEM x100

SEM x300

Reddi Flo® AG is manufactured under strict cGMP conditions, at our dedicated pharmaceutical lactose manufacturing site in Rothschild WI. This site has a long history of manufacturing crystalline and modified (spray dried) monohydrate, as well as Anhydrous and lactose combination products. Our history and know-how of manufacturing pharmaceutical lactose for more than 75 years, along with our strict QC protocol, ensure that Reddi Flo® AG will be consistent and meet our rigourous quality standards customers have come to expect.

From a regulatory perspective, Reddi Flo® AG will comply with harmonized USP-NF, Ph.Eur, and JP monographs for monohydrate lactose.

Packaging & Shelf Life

95 kg Fiber drum with inserted polyethylene liner.
Product code W400324

25 kg bag with inserted polyethylene liner.
Product code W401324

Shelf life is 36 months

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