In this edition of the column, Carrie Shipley discusses the basic carbohydrate chemistry of maltodextrin and its use in tablet and capsule formulations.

Maltodextrins have become popular excipients in the pharmaceutical industry because of their multifunctionality and cost-effectiveness. Manufacturers use them in a variety of applications, including as binders and as components in aqueous film coatings. They are also available in a range of particle sizes and dextrose equivalences (DEs).

What is a maltodextrin?

According to USP, maltodextrin is a “non-sweet, nutritive saccharide mixture of polymers with a dextrose equivalent of less than 20.” Maltodextrins are produced from the hydrolysis of starch, and the DE is a quantitative measurement of the degree of starch-polym er hydrolysis. The DE also can be defined as the measurement of the reducing power of the maltodextrin polymer when compared to a dextrose standard of 100. The higher the maltodextrin’s DE, the greater the extent of starch hydrolysis [1].

Basic starch hydrolysis starts with a starch slurry, which then is reacted with an amylase enzyme—such as glucoamylase, beta amylase, alpha amylase, or isoamylase—and/or an acid. Some manufacturers use both an acid and an enzyme reaction. The basic hydrolytic reaction cleaves the starch molecules into smaller chains of various lengths. The slurry is then (usually) refined and concentrated before the moisture is removed in a spray dryer. Sometimes the product will also undergo agglomeration.

Maltodextrins can be prepared from most grains and other sources of starch, including corn, potatoes, rice, tapioca, and wheat. The source of the maltodextrin can impart slightly different characteristics to it. The discussion below focuses on starch from corn, and in particular, yellow dent corn.

Corn starch consists of two major polymers, amylose and amylopectin. Amylose is a linear polymer with D-glucose alpha (1-4) bonds, while amylopectin is a highly branched polymer with alpha (1-6) linkages. Figure 1 shows the content and structures of the glucose, amylose, and amylopectin of corn starch. Waxy corn starch comprises almost all amylopectin, while yellow dent corn is about 76 percent amylopectin. This variation makes a difference in the final maltodextrin product, especially at a DE of less than 10. Maltodextrins made from waxy starch have a slightly
higher solubility and increased solution clarity in the lower DE range. That’s because they lack the linear molecules that can re-associate in waxy starch as compared to the starch of yellow dent corn [2].

**Direct-compression tabletting**

Direct compression is the fastest, simplest, and least expensive way to make tablets, and maltodextrins serve as binders in direct-compression tablets. Although all DE ranges of maltodextrins have some dry-binding capability, the higher the DE, the better the dry binding. When determining the correct DE to use in a direct-compression tablet, also consider its tackiness since as the maltodextrin’s DE increases, so does its hygroscopicity. Too high a DE (17 to 19.9) in the maltodextrin can cause tablet stickiness and die-wall friction. Therefore, it is important during product development to consider how much maltodextrin your formulation requires and what the DE of the maltodextrin should be to achieve good binding.

Maltodextrins can also add bulk to a tablet. Since they are easily compressible, are inexpensive, and can contribute to overall binding, maltodextrins are attractive to manufacturers, who may choose a low-DE maltodextrin instead of more expensive fillers.

Much like microcrystalline cellulose (MCC), maltodextrin used in direct-compression tablets increases tablet hardness, reduces friability, and alleviates capping. MCC also helps decrease disintegration, while maltodextrin neither increases nor decreases disintegration time. Many manufacturers use a 50-50 blend of MCC and maltodextrin. This combination helps cut costs but still produces a strong tablet that disintegrates quickly.

Maltodextrins come in a range of particle sizes and bulk densities, including spray-dried powders and agglomerated forms. Specialty products with fine particle sizes or very low bulk densities are also available, and those products can be used as diluents or carriers in direct-compression formulas. Agglomerated products are porous and have a large surface area, which promotes flow. The agglomerated forms also generate less dust than spray-dried powders.

Chewable tablets or orally disintegrating tablets (ODTs) are another area where maltodextrins are used. They have bland flavors, and the higher-DE products are only very mildly sweet. Thus, they can hide bitter flavors and improve mouth-feel by smoothing out grittiness.

**Wet, dry granulations**

Maltodextrins also serve as binders in wet granulations, and any DE can be used for binding wet granulations because they all have wet binding abilities. The lower the DE, however, the greater the wet-binding strength that the maltodextrin provides. Maltodextrins are soluble in cold water; they need no heat. In addition, the solubility is high, eliminating the need to keep the solution agitated while pumping it. See Figure 2. A normal binding solution contains 10 to 20 percent maltodextrin in water. Figure 3 shows the viscosity of a maltodextrin solution derived from dent corn. The DE ranges of 5 to 19 percent are represented. Within the range of 10 to 20 percent, the graph shows that vis-
cosity is less than 100 centipoise, which means that the solution will be extremely thin, even on the higher end of the recommended amount of binder usage. This quality allows it to be pumped easily into a fluid-bed or conventional high-shear granulator.

Some manufacturers prefer to granulate with water only, foregoing a binding solution. In that case, they add maltodextrins with the dry powders, and the wetting process activates binding. Binding strength is lower in this type of granulation compared to granulations that include a maltodextrin solution, but the method is quick and can achieve sufficient binding.

Maltodextrins can also be used as binders in roller compaction. Their compressibility is advantageous in this type of granulation but, as mentioned above, maltodextrins do not increase or decrease disintegration time.

**Capsules**

Most two-piece capsules are filled using modern high-speed capsule filling equipment, and reliable flow is very important to keep the process moving smoothly. As discussed above, most maltodextrin manufacturers produce not only spray-dried powders but agglomerated forms as well. Capsule manufacturing uses agglomerated maltodextrins as fillers or in forming slugs due to their fast and even flow, as well as their dry-binding abilities. Maltodextrins are also used as adhesive agents in the shell layer of soft non-gelatin capsules [1].

**Aqueous film coatings**

As with many starches, maltodextrins are good film-formers, allowing them to be used as coatings for tablets and granules. Manufacturers can use maltodextrins as the main film-forming polymer, but maltodextrin films alone are not as strong as many of the other film-forming polymers that are available. They can also be quite tacky, so most manufacturers use them either as a secondary polymer or add them to increase the solids of a coating solution.

Many of the strong film-forming polymers used in tablet coating formulations are expensive. To keep coating costs down, formulators add maltodextrin as a secondary film-former. Maltodextrins not only extend the film-forming properties of the main polymer, but add gloss and enhance the color while simultaneously increasing the solids content of the formula. Increasing the solids in a formula enables manufacturers to obtain the desired weight gain more quickly, thereby reducing production time and cost. They can achieve all these benefits with little if any variation in the solution’s viscosity.

**Other uses**

Maltodextrins have a large presence in medical nutrition because they are a readily digestible carbohydrate source that can provide energy and rehydration at body osmolality.

Their ability to inhibit crystal growth as well as regulate sweetness and viscosity allows manufacturers to use maltodextrins for liquid pharmaceuticals as well as for lozenges. Agglomerated and lower-bulk density maltodextrins find a place in reconstituted dry blends. They act as bulking agents as well as carriers that dissolve quickly in water.

**Conclusion**

The pharmaceutical industry uses maltodextrins in many ways. Their varied particle sizes, bulk densities, and DEs make them a cost-effective choice for many pharmaceutical manufacturers.

**References**


Carrie Shipley is an applications scientist at Grain Processing Corp., 1600 Oregon Street, Muscatine, IA 52761. Tel. 563 264 4265. E-mail: carrie_shipley@grainprocessing.com.