Pharmaceutical MANUFACTURING



# Co-Processed Excipients Help Formulate Better OSDs

Coatings, simple excipients and traditional manufacturing processes will continue to play a role

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Co-processed excipients are expected to play a key role in the production of new chemical entities (NCEs), according to BCC Research. As developing new excipients can be time-consuming and expensive from a safety perspective, manufacturers see co-processing of already approved excipients as an attractive alternative. These excipients are engineered to achieve the properties of the key components of the tableting blend in a single, highly flowable and compressible granular material.1 As a result, where there were less than a handful of co-processed excipients on the market 15 or 20 years ago, there now are more than 20 that are commercially available to formulators, and it is very likely that this number will continue to grow.

“While manufacturing methods of oral solid dosage has largely remained unchanged, with the usual bias toward direct compression wherever possible, the advent of co-processed materials to achieve even more efficient performance in tableting operations has come to the forefront of development efforts at almost all excipient manufacturers,” says Nigel Sloane, vice president, excipients, Kerry (formerly Sheffield Bio-Science). “Developing an excipient with synergistic benefits to the OSD formulator, while avoiding a new chemical entity (which would face a much more difficult regulatory pathway for drug manufacturers), is the desirable outcome for any co-processed excipient.”

Kerry has been active in the development of co-processed excipients. For example, Sloane explains that the

company has synergistically combined lactose with Microcrystalline Cellulose in a unique spray drying process to create Disintequik MCC25. “This co-processing of these two widely accepted excipients has created a product that compresses better, and disintegrates quicker, than could be achieved by simply blending these two excipients together.”

He adds that Kerry has also introduced a line of LubriTose self-lubricating excipients, a co-processing of Glyceryl Monostearate together with Lactose, Microcrystalline Cellulose or Mannitol. This provides formulators with a new excipient that does not require any external lubricant (magnesium stearate) to manufacture an OSD with good compaction and ejection properties. “It is it well known that incorporating an external lubricant such as magnesium stearate can lead to compression problems if the final blending step is not precisely timed, resulting in over blending,” he says. “This potential problem is avoided completely with LubriTose, as studies have shown that even prolonged blending does not have a detrimental impact on compression properties.”

Despite the advantages to producers, most co-processed excipients are not found in official monographs, which is holding back their use in the market. Additionally, Sloane says it is important that the co-processed excipient can demonstrate effectiveness in manufacturing process efficiencies, as invariably the cost of a co-processed excipient will be higher on a per/kg basis than a simple blend of the same excipients.

**COATINGS BECOME MORE SOPHISTICATED**

The film coatings market has also seen a dramatic shift in the last 10 years. While companies used to have to rely mainly on one film coating manufacturer, today there are several manufacturers of pharmaceutical film coatings from which a formulator can choose.

According to the 2017 Nice Insight Pharmaceutical Excipients Survey, 38 percent of respondents procure excipients to use as coatings.2 And FDA guidelines, published in March 2013, made the interchangeability of film coatings clearer and simpler for drug manufacturers, giving them more leverage when it comes to negotiating the price of film coatings. Film coatings can bring many important attributes to the tablet. For example, a film coating may protect the tablet from chipping or dusting, adding gloss, shine or whiteness to a tablet, and provide a unique color to the drug, which enables easier patient recognition and dose discrimination.

“Tablet coatings are becoming more sophisticated in terms of enabling better patient compliance or otherwise improving the consumer experience,” says Sloane. “This is especially true in the competitive OTC market where consumer appeal and preference are key differentiators.” For example, he says that Kerry has developed film coatings with attributes that appeal directly to the consumer, such as ease of swallow. Another coating developed by Kerry is Sheffcoat Enhance, which incorporates pleasant tasting flavors and aromas to the film coating.

In addition to enhancing the consumer experience, coatings can enhance the manufacturing process. “Colorcon developed Opadry QX, a quick and flexible film coating system that enables manufacturers to coat tablets in a continuous coating process with improved coating uniformity and a perfect finish in a much reduced time compared to other coatings,” says Pankaj Rege, Ph.D, MBA, general manager - manufactured excipients, Colorcon. “Opadry QX also overcomes process challenges and can be used across a range of coating equipment without compromising on the tablet finish,” he says. “The added flexibility of operating at low bed temperature settings also makes Opadry QX a film coating suited for temperature-sensitive APIs. The increased solids level, up to 35 percent, means that films are applied faster, color uniformity is reached earlier, and all coated tablets have a defect-free finished appearance.”

**EXCIPIENTS ADDRESS POOR FLOW AND STABILITY**

The last five years have seen a surge in the focus that pharma companies place on their excipients. This is being driven by factors such as increased demands from regulatory authorities, global supply chain scrutiny, high-potency APIs (which in turn increase the demand for highly functional excipients), Quality by Design (QbD), consolidation within the generics industry, manufacturing rationalization and budget cuts within the traditional pharmaceutical R&D companies. “The drug and excipients industries have a symbiotic

relationship," says Sloane. "Each is reliant on the other to successfully bring their products to market."

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