



## Granular Formulations - Oral Powder Delivery Systems

### Expertise in Taste-Masking

A major component of successful oral powders is that the product needs to have no taste or a good taste. The single most significant issue with oral powders is the bitterness of the drug that is experienced during oral ingestion. Skillful taste-masking is needed to hide this bitterness, and combining this with the right flavor/sweetness levels will result in a superior product. Over the years, consumers have become more knowledgeable and discerning about drug products due to many reasons, including direct-to-consumer advertising, medical websites, and the growth in over-the-counter. Consequently, consumers now have a wider range of options than ever before, and as with any other orally consumed product, taste is a deciding factor.

CIMA LABS has unparalleled knowledge of the complex relationship between the physicochemical properties of a drug molecule and effective taste-masking. CIMA LABS has been able to taste-mask drug molecules in the dose range of 0.1 mg to 750 mg for tablets, independent of solubility. It is expected that oral powders will accommodate even larger dose strengths. We have also tackled technical challenges such as needle-shaped or micronized active pharmaceutical ingredients (APIs), reactive or hydrate-forming APIs, and extended release formulations.

CIMA LABS has experience with a variety of taste-masking and particle-coating processes. Some of these processes include solution layering, wet granulation, suspension layering, hydro-alcoholic solution layering, and direct coating. Fluid-bed particle coating (Wurster) is used for the majority of these processes. Selection of the right coating excipients is paramount, as the taste-masking of a drug must be balanced with the dissolution and organoleptic properties of the finished product. CIMA LABS has utilized polymers such as celluloses (EC, HPMC, etc.) which slow down dissolution independent

of pH and methacrylates (EUDRAGIT®), which exhibit pH dependent dissolution.

### Oral Powder Drug Delivery Technology

Oral powder technology is comprised of taste-masked drug granules with or without flavor, packaged in a sachet. The granules can be administered with or without food. The oral powder technology can accommodate significantly higher doses compared to other solid dosage forms (>1 gram). The packaging sachet for the oral powder technology is unit dose, moisture impermeable, and has the flexibility to meet many child resistant packaging requirements.

If you are interested in learning more about our oral powder technology, please contact Richard J. Welter, Ph.D., V.P. of Business Development at 763-488-4790 or John C. Nagel, MBA, Senior Director of Business Development at 763-488-4975.

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