



Expertise in Taste-Masking

A major component of successful orally disintegrating tablets (ODT) is good taste. Even when an ODT dissolves in seconds, a poorly taste-masked product will leave an unpleasant aftertaste. One of the most significant issues with an ODT is that the bitterness of the drug that may be exposed as the tablet disintegrates in the mouth. Skillful taste-masking is needed to hide this bitterness, and combining this with the right flavors and sweeteners will result in a superior product.

CIMA LABS has unparalleled knowledge of the complex relationship between the physicochemical properties of a drug molecule and its taste. CIMA LABS has been able to taste-mask drug molecules in the dose range of 0.1 mg to 750 mg, independent of solubility. CIMA LABS has also successfully tackled technical challenges such as needle-shaped or micronized compounds ("APIs"), reactive or hydrate-forming APIs, and extended/controlled and delayed-release formulations.

CIMA LABS has experience with a variety of taste-masking and particle coating processes. Some of these processes include solution layering, wet and/or dry granulation, suspension layering, alcoholic or 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 utilizes polymers such as celluloses (EC, HPMC, etc.) which moderate dissolution, independent of pH and methacrylates (EUDRAGIT®) which exhibit pH dependent dissolution.

Our taste-masking expertise has been successfully applied to OraSolv®, DuraSolv®, Lyoc™, and oral powder technologies (this is especially significant for the Lyoc technology whose formulation is a suspension or an emulsion prior to the lyophilization manufacturing process). A coating must be applied to the drug that is stable during manufacturing and

during disintegration in the mouth but provides the appropriate dissolution profile in the gastrointestinal tract.

If you are interested in learning more about the CIMA LABS taste-masking expertise, please contact Richard J. Welter, Ph.D. Vice President 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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