



Lyoc™ Orally Disintegrating Tablet Technology

CIMA LABS has the capability to develop and globally commercialize multiple orally disintegrating tablet (ODT) technologies. This versatility provides a breadth of drug delivery solutions to meet partners' drug product needs. CIMA LABS family of ODT technologies includes OraSolv[®], DuraSolv[®], and Lyoc. All of these technologies meet the CDER definition of an ODT, "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue". ODTs are growing in popularity because they offer many advantages to patients and physicians, such as:

- Convenience - Can be taken with or without water.
- Great taste – Bitter drugs can be taste-masked and many flavor options are available.
- Ease of administration - Disintegration of the dosage form in the mouth makes swallowing the dosage form an easy task.
- Discreet - Taken whenever and wherever patients want – quick disintegration of tablet, convenient packaging.
- Safety – Blisters can be made to meet many child resistant packaging requirements.

In contrast to the compressed tablet technologies of OraSolv and DuraSolv, the Lyoc technology is a lyophilized dosage form. The lyophilization manufacturing process produces tablets with greater porosity, allowing for shorter disintegration times than orally disintegrating compressed tablets. The Lyoc technology thereby produces tablets with fast disintegration speeds in the range of 2 to 20 seconds.

The lyophilization manufacturing process encompasses freeze-drying of an aqueous solution, suspension, or emulsion of the drug compound and

excipients. After this liquid homogeneous formulation is optimized, it is distributed into preformed blisters. Very low temperature freezing (below -40°C) is then employed. Specific pressure conditions are then applied to the product that results in sublimation (direct ice to water vapor transformation), which removes water from the formulation. The finished product is a porous, stable solid tablet. The overall process is environmentally friendly and cost effective since it operates in the absence of organic solvents.

In addition to the drug, formulations using Lyoc technology may include fillers, binders, flavors, sweeteners, surfactants, absorption enhancers, and suspending agents. Generally, drug product strengths in the range of 500 mcg to 500 mg can be developed. Drug products based on Lyoc technology have been developed for drug molecules of varying physicochemical properties. Due to the conditions experienced by the drug formulation during the manufacturing process, the use of additives and preservatives in the formulation is not necessary.

To date, Lyoc technology products have largely been developed to be bioequivalent to the commercialized orally administered tablet or capsule formulation. The drug release can however, be tailored to meet virtually any immediate or controlled release requirement.

Seven products utilizing the Lyoc technology have been commercialized in Europe and Africa.

In today's highly competitive pharmaceutical market, Lyoc technology offers solutions to a myriad of business needs such as product differentiation, patent extension, as well as the marketing advantage of a more convenient, patient-friendly dosage form.

If you are interested in learning about our Lyoc technology for your molecule, please contact Richard 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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