

## Excipient solutions A palette of innovation





#### Together, we are innovators

Chr. Hansen believes that a working partnership with the customer is the best way to inspire and create true innovations. That is why we take each project individually and work closely with you to develop a total solution that matches your specific needs. You can achieve success, not only with our excipients and coating systems, but also with our specialized technologies, industry experience, and superior quality.

#### Science and experience lead to unique solutions

In the 1870s, our company was founded on a biotechnical advancement that revolutionized the manufacturing of dairy products. Since then, Chr. Hansen has continued to bring effective, well-researched ingredients and technologies to the pharmaceutical, nutritional, and food industries. Our corporate vision is to improve the quality of food and health for people all over the world, and we are focused on delivering the innovations our customers require.



## Clearly, a black and white distinction

Chr. Hansen's unsurpassed expertise provides customers with customization, ongoing cost savings in manufacturing, and development of innovative products. We can address formulation issues, regulatory concerns, and guality standards.

#### Your project is our project

At our applications center, we are competently positioned to take on new challenges and formulate innovative solutions for customers. We formulate inactive ingredients and provide excipients and coating systems to your specifications. We work directly with your equipment and raw materials to develop prototypes and help solve your manufacturing issues.

Chr. Hansen's pilot plant and laboratories are centered around the customer. Equipped with pilot-scale models of all major film coating equipment, larger conventional pans, and perforated pans, we ensure customers of proper quality control standards, manufacturing methods, and reproducibility.

#### Partnership means success for the customer

A working partnership with Chr. Hansen means that together, we can achieve your goals. For one client, we successfully converted an organic solvent coating system to a new aqueous system. For others, we have enhanced color compatibility from core substrate, optimized logo definition, and developed the process to improve product stability and appearance.

By building a close alliance with you, we can deliver total solutions that match all your excipient requirements, either from our existing range or by developing an entirely novel, tailored solution.







# Real results from a passionate commitment to excellence

Chr. Hansen is an IPEC member company, and our dedicated pharmaceutical grade facility complies with strict quality and regulatory standards. This speaks clearly of our dedication to the industry, level of quality and regulatory procedures, and participation in the creation of global standards.

#### Superior quality products build trust

Chr. Hansen's excipients are manufactured in our state-of-the-art facility in Stoughton, Wisconsin. The facility is compliant with Good Manufacturing Practices (GMP) for Bulk Pharmaceutical Excipients per United States Pharmacopoeia (USP) <1078>, and to National Formulary and International Pharmaceutical Excipients Council (IPEC) standards. It is also registered with the United States Food and Drug Administration's (FDA) Type IV Drug Master File (for Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation), which requires ongoing FDA inspection. In addition, Chr. Hansen's facility successfully passed supplier audits, as well as an audit by a European Union (EU) regulatory authority, confirming that this facility meets current EU quality standards.

Product traceability, previously required only for active pharmaceutical ingredients, is increasingly being demanded of excipients and other non-active ingredients. Chr. Hansen's advanced production systems improve lot segregation and traceability of raw components.

Chr. Hansen holds major patents, as well as proprietary developments, on colored dispersion, film forming processes. We also have pending patents in film coating technology and controlled release systems.

### Strong compliance fulfills your highest expectations

Pharmaceutical and nutritional companies look for suppliers to assist them in extending current patents, formulation work, and saving costs. With the regulatory environment continuing to tighten, and the demand for additional high-level requirements, Chr. Hansen is well positioned as a reliable global supplier to help you be effective in the marketplace.

Our products are certified Kosher Pareve, and comply with all FDA, EU, and international regulations to meet the growing demand for non-GMO compliance and BSE risk mitigation requirements. All ingredients conform to current USP/NF requirements, and are approved by the FDA or are Generally Recognized As Safe (GRAS).

