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MEDIA RELEASE

Clariant introduces new high-performing excipients at the CPHI India 2024 trade show

- **Clariant Health Care is presenting eight new products in its portfolio of high-performing pharmaceutical ingredients to support the evolution of safe and effective medicines**
- **The expanded range includes excipients for different applications such as for sensitive active pharmaceutical ingredients, parenteral formulations or applications where the final formulation needs to be colorless**
- **Our experts will be available at Booth Number O 05 Hall 6 at the India Expo Centre, Greater Noida, Delhi NCR, India**

MUMBAI, NOVEMBER 25, 2024

Clariant is excited to present the company's latest portfolio of products for the healthcare industry at the upcoming CPHI India tradeshow in Delhi NCR on November 26 through 28, 2024. This year's event will showcase Clariant Health Care's Made in India products, local Bonthapally operations, and expertise in biologics, generics, and excipient production. This includes a range of reliable, high-quality, cost-effective, and tailored solutions for the growing Indian healthcare market.

"We are leveraging India's manufacturing capabilities to provide high-purity excipients to the global pharmaceutical market and our Made in India products are integral to the pharmaceutical sector's commitment to improving drug formulation, delivery, and patient outcomes. We're also simultaneously focused on ensuring compliance with the highest industry standards," comments Vaios Barlas, Global Head of Health Care at Clariant.

Excipients are essential to the stability, bioavailability, and efficacy of active pharmaceutical ingredients (APIs) and the global excipients market is expected to grow at a compound annual growth rate (CAGR) of 6 to 7%. This increase has been driven by rising demand for specialty drugs and biologics, stricter regulatory standards, and the increasing needs of aging populations worldwide.

To ensure the uninterrupted supply of ultra-pure excipients, Clariant has combined the global expertise of Clariant International Ltd (Switzerland) with local manufacturing capabilities in India to offer customized solutions for the evolving needs of the pharmaceutical industry. India is now a global leader in pharmaceutical manufacturing, supplying over 50% of global vaccines and 40% of generic drugs.

“Our customers want high quality products that support local economies and Clariant’s manufacturing operations in India cater to the specialized needs of the Indian and regional markets while also ensuring that we meet the global standards required by the FDA, EMA, and other regulatory bodies. This makes us a preferred partner in the development of biologics, injectables, and complex drug formulations,” says Bhushan Thekedar, Head of Global Business Development, Health Care.

Parenteral excipients manufactured in Bonthapally facility are equipped with advanced clean room environments, adhering to the highest international standards of sterility and purity to ensure the efficacy and safety of the excipients. Through the local production of key excipients like VitiPure™ Superior and Meglumine, Clariant’s Bonthapally facility plays a central role in supporting the global healthcare supply chain.

Clariant is pleased to be launching a variety of innovative products for the pharmaceutical sector, with applications ranging from sensitive API to parenteral formulations to oral and topical agents, as described below.

Clariant introduces VitiPure LEX 3350 S, VitiPure LEX 4000 S, and Polyglykol 1450 S to solve API delivery and bioavailability challenges

The VitiPure LEX which is low in endotoxin, is a product line which has been designed for customers who require stringent control of the microbial load in their formulations. These co-solvents have been optimized for sensitive applications, as well as for the safe use with a variety of APIs, including those with low water solubility.

VitiPure LEX 3350 S and VitiPure LEX 4000 S not only surpass the general pharmacopoeia monograph requirements, but they have also been risk-assessed in their production for their use as excipients in parenteral applications. In addition to the general monograph requirements, specific microbiological aspects have also been certified.

Polyglykol 1450 S is an alternative polyethylene glycol co-solvent specified according to the current USP-NF monograph, which is additionally meeting the monoethylene and diethylene glycol limits recommended by the corresponding FDA guideline on this topic. Polyglykol 1450 S is produced under IPEC GMP conditions in the form of flakes, which allows easier handling during production. This product surpasses current international pharmacopeia requirements.

New launch of VitiPure CO 35 Superior (Polyoxyl 35 Castor Oil), VitiPure O 80 Superior (Polysorbate 80), and VitiPure L 20 Superior (Polysorbate 20) for colorless and parenteral applications with the highest purity excipients.

The VitiPure Superior line offers nearly colorless excipients and hence adds no color to the final formulation due to its ultra-low residual impurities. Additionally, this line is suitable for APIs that are sensitive to residual impurities and for formulations that require low microbial loads with low endotoxins. VitiPure Superior products are highly-purified excipients, suitable for parenteral formulations. VitiPure CO 35 Superior is addressing the parenteral application where the highest purity of the excipient is required. VitiPure O 80 Superior and VitiPure L 20 Superior are additionally appropriate for the stabilization of human and veterinary vaccines and biologics.

Compared to the standard excipient grade, all three Superior products improve the stability of the finished API formulations. In addition, the steel packaging with nitrogen purging assures low levels of peroxide formation during product storage.

New VitiPure Meglumine LEX for sensitive formulations
Clariant has developed Meglumine for sensitive formulations where both a low bioburden and low endotoxin grade are required. This solubilizer can be used as a counter-ion in contrast media, a buffering agent, and a bioavailability and solubility enhancer of mildly acidic APIs. Due to its low microbial load, Meglumine LEX is suitable for parenteral applications.

VitiPure HCO is a new hydrogenated castor oil (HCO) in micronized form for solid oral and topical use
Clariant has developed VitiPure HCO for tablet formulations as a lubricant or sustained-release agent. Additionally, VitiPure HCO is suitable as a consistency factor for topical formulations. The consistent particle size distribution is well-suited as a tablet lubricant for applications where a hydrophobic lubricant is needed or as a replacement of magnesium stearate. Therefore, this product is suitable for processing through direct compression or dry granulation.

Clariant is committed to providing strong quality assurance and robust regulatory support for its customers. For more information on Clariant's one-stop shop solutions for excipients, visit the team at CPHI India Booth Number O 05 Hall 6 at the India Expo Centre, Greater Noida, Delhi NCR, India, on November 26 through 28, 2024.

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Clariant is a focused specialty chemical company led by the overarching purpose of “Greater chemistry – between people and planet.” By connecting customer focus, innovation, and people the company creates solutions to foster sustainability in different industries. On 31 December 2023, Clariant totaled a staff number of 10 481 and recorded sales of CHF 4.377 billion in the fiscal year for its continuing businesses. Since January 2023, the Group conducts its business through the three Business Units Care Chemicals, Catalysts, and Adsorbents & Additives. Clariant is based in Switzerland.

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