Press release



Evonik launches GMP-quality plant-based squalene

- PhytoSquene[®] now available for clinical and commercial use
- Adjuvant component for parenteral drug delivery applications
- Provides batch-to-batch consistency, quality and purity and reduces reliance on animal-derived materials

Essen, Germany. Evonik's non-animal-derived squalene PhytoSquene[®] is now available produced under GMP. Launched last year, PhytoSquene[®], is the first GMP amaranth oil-derived squalene on the market for use in adjuvants in parenteral dosage forms. By offering plant-based squalene, Evonik is meeting the demand for a secure commercial supply of squalene for pharmaceutical applications, which is currently refined from shark liver oil.

Evonik's life sciences division, Nutrition & Care, is committed to reducing the need for animal-derived products and preserving biodiversity and ecosystems. The company aims to transform more than 70 percent of its portfolio to Next Generation Solutions by 2032. These solutions are based on a thorough portfolio assessment and represent a superior sustainability benefit.

"With PhytoSquene[®], our customers can create a drug product that promotes a healthy life and reduces dependence on animalderived materials. Our GMP material now helps move these sustainable pharmaceuticals into the clinical and commercial phase," said Paul Spencer, head of Drug Delivery & Products at Evonik's Health Care business.

PhytoSquene[®] is made from the oil of amaranth (*Amaranthus caudatus*) which is an herbaceous plant cultivated in many parts of the world. Being plant derived, PhytoSquene[®] provides batch-to-batch consistency, quality and purity. It is compliant with European Pharmacopoeia (Ph. Eur.) specifications. PhytoSquene[®] is also a solution for patients who cannot use animal-derived products for cultural or religious reasons.

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PhytoSquene[®] manufactured under GMP is the latest of Evonik's innovations to provide the market with sustainable, non-animal-derived solutions. In 2021, Evonik increased the global supply of the pharma-grade, plant-derived cholesterol PhytoChol[®].

Squalene is a natural organic compound that is used as a component in some adjuvant systems. Adjuvants are additives that boost the body's immune response to the active ingredient in a vaccine. They reduce the amount of active ingredient needed, thus making it faster and easier to scale vaccine production and reducing the risk of side effects in patients.

As a partner to the pharmaceutical industry, Evonik Health Care has been a leader in advanced drug delivery for decades. It supports pharmaceutical companies worldwide with comprehensive services for developing and manufacturing complex parenteral and oral drug products. This includes pharmaceutical excipients such as polymers and lipids, formulation development and the manufacture of clinical samples, as well as commercial drug products.

More information

https://healthcare.evonik.com/en/drugdelivery/parenteral-drugdelivery/parenteral-excipients/plant-based-squalene

Company information

Evonik is one of the world leaders in specialty chemicals. The company is active in more than 100 countries around the world and generated sales of \in 18.5 billion and an operating profit (adjusted EBITDA) of \in 2.49 billion in 2022. Evonik goes far beyond chemistry to create innovative, profitable, and sustainable solutions for customers. About 34,000 employees work together for a common purpose: We want to improve life today and tomorrow.

About Nutrition & Care

The focus of the business of the Nutrition & Care division is on health and quality of life. It develops differentiated solutions for active pharmaceutical ingredients, medical devices, nutrition for humans and animals, personal care, cosmetics, and household cleaning. In these resilient end markets, the division generated sales of \notin 4.24 billion in 2022 with about 5,700 employees.

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