Evolvemer™ materials are biocompatible composite materials composed of beta-tri-calcium phosphate additive and bioresorbable base polymer. Evolvemer™ materials are next generation compositions utilizing improved manufacturing technologies with improved micro-particle dispersion.

ABM COMPOSITE
Arctic Biomaterials

Evolvemer™ TCP30PLGA

Technical data sheet

Description

Composite pellet composed of 85L/15G PLGA and beta-TCP

Property, Test Condition	Specification		Test method
Specification			
Appearance, colour	White		Visual
Appearance, shape	Pellets		Visual
Inherent viscosity of polymer	≥ 3.0	dl/g	Microviscometry
Residual lactide monomer content	≤ 0.5	wt-%	Gas Chromatography (GC)
Residual glycolide monomer content	≤ 0.5	wt-%	Gas Chromatography (GC)
Beta-TCP content	30 ± 5	wt-%	Ignition loss
Elemental impurities	Conforms to ICH Q3D requirements		ICP-MS
Packaging			
Pellets are packaged in to a double polymer pouch. Outer pouch contains aluminum barrier layer. Maximum amount in a package is 1 kg.			
Storage and Handling			
Pellets to be stored below or at -15 °C temperature.			

Stability Studies

Evolvemer™ Composite materials have received a shelf life/re-test statement for up to 5 years storage either in -60 ºC or in -20 ºC based on a real time shelf life study.

The product/packaging system met all pre-specified acceptance criteria for inherent viscosity (IV) and residual monomer content. Packaging was visually intact, containing no holes, tears, etc., and seals were intact. The package label remained legible and affixed after the storage conditions.

Residual Solvents

According to the ICH Q3C guideline on residual solvents, residual solvents are defined as organic volatile chemicals, that are used or produced in the manufacture of drug substances or excipients, or in preparation of drug products and that are not completely removed by practical manufacturing techniques. In reference to this guideline, we hereby confirm that Evolvemer™ Composite materials are manufactured without addition of any solvent. The residual solvents of the used polymers are controlled by the supplier's certificate of analysis according to ASTM F1925 Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants.

Elemental Impurities

According to the ICH guideline Q3D on elemental impurities, elemental impurities tested from the Evolvemer™ Composite have been chosen after a Risk Assessment in accordance with the guideline: As, Cd, Hg, Pb, Co, V, Ni, Li, Sb, Sn and Cu. None of the elements listed, are used or added intentionally during the manufacturing process. Based on the Risk Assessment performed, these elements are tested periodically and not for each batch.

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Residual Water

Evolvemer™ Composite materials are vacuum dried before the packages are sealed to minimize residual water.

Evolvemer™ Composite materials must still be always dried before processing with dehumidifying dryer, due to fact that insufficient drying will cause decrease of molecular weight in melt processing. Evolvemer™ Composite materials can be e.g. vacuum dried at 80 °C for >8 hours. The targeted moisture content of dried Evolvemer™ Composite materials is below 100 ppm.

Please note that a combination of a very long drying time and high temperature may cause degradation of the polymer and agglomeration of pellets and may cause yellowing. Please note also that the control of moisture content during the melt processing is of uttermost importance to produce products with uniform quality. Therefore, it is recommended to transport the dried Evolvemer™ Composite pellets immediately after drying to a closed feeder device. It is also recommended that the relative humidity (in temperatures less than 25°C) inside the feeder device and hopper of melt processing device is below 10%.

Materials and Manufacturing

All raw materials have been selected as a quality suitable to allow use of such material in the manufacture of an implantable composite material. Such quality includes adequate control of particles and other potential contaminants.
The beta-TCP material is selected to fulfill the requirements set in standard ASTM F1088 (Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation).
The polymer material is selected to fulfill the requirements set in standard ASTM F1925 Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants.
Evolvemer™ Composite manufacturing is undertaken under conditions suitable to allow use of composite in the manufacture of an implantable medical product.

Biocompatibility

Biocompatibility of the Evolvemer™ Composite has been evaluated according to ISO 10993-1:2009 (“Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”). Based on the evaluation, Evolvemer™ Composite presents no risk of systemic toxicological effects. Cytotoxicity and Plastic Class V tests have been conducted for Evolvemer™ Composite to support the biocompatibility statement of the composite. However, it is the sole responsibility of the manufacturer of the final end-use product to determine the biocompatibility of the final product.

Certificate of analysis

Certificate of analysis is provided for each batch, showing the analytical results.