

TheraPEA™ Biodegradable Polyester Amide Platform

Enabling the development
of novel sustained drug
delivery treatments

Enabling reliable sustained and controlled drug release formulations

DSM is a global leader in biomedical materials science – experience that we are now embracing to create advanced drug delivery technologies. TheraPEA™ is a biodegradable polymeric platform for use in long-acting sustained drug delivery applications. A robust synthetic polymer platform based on naturally occurring amino acids,¹ TheraPEA™ was designed to address limitations associated with the use of traditional polymeric materials.

At DSM Biomedical, we enable product innovation in sustained drug delivery with our partners through the development of customized solutions that leverage our proprietary material technologies with tunable properties to suit the Active Pharmaceutical Ingredient (API), the physiology of the delivery site, and the desired target profile of the end-product.

Working together in this way, therapeutic solutions are developed for new dosage forms, incorporating both new and established APIs to extend product life cycles and to provide a competitive advantage. We have the experience and expertise to help our partners overcome existing formulation challenges and to design patient centric therapies.

Why choose TheraPEA™ as your biodegradable polymeric platform?

More than 15 years of development and clinical studies² support the value of our polyester amide (PEA) biodegradable polymers. One of the differentiating characteristics of PEAs in enabling the development of novel sustained release products is their unique degradation. The TheraPEA™ platform exhibits zero order degradation kinetics assuring long lasting, controlled and sustained delivery of APIs.¹ PEAs degrade via non-acidic mechanism, thus preventing a low pH (acidic) microenvironment, often associated with biodegradation of competing platforms. This lack of acidification allows formulation of pH sensitive APIs (small molecules and biologics) and eliminates potential adverse events associated with drop of pH from material degradation.

The TheraPEA™ platform displays a very mild foreign body response and excellent biocompatibility,¹ proven in multiple areas including ophthalmic, intravascular, and intraarticular applications. The TheraPEA™ platform enables formulations of a wide range of active ingredients in a variety of treatment forms.

Fibers and Rods

- Microfiber diameter: 100µm – mm.
- API loading from <10 – 50% by weight.



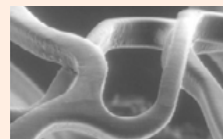
Injectable Microparticles

- Typical diameter range from 10 – 100µm.
- API loading from <5 – 30% by weight.



Drug Eluting Coatings and Films

- Good compatibility with various substrates, with excellent adhesion to metals.
- Excellent melt processability.
- Unique solubility properties including low molecular weight hydrocarbon alcohols.



Copyright © Svelte Medical

Differentiated Technology to Enable Innovative Therapies for the Patient

DSM Biomedical's TheraPEA™ biodegradable platform facilitates the formulation of therapeutic solutions where they are needed most, including the treatment of coronary artery disease, pain management, diabetes management or in vision preservation. Offering proven compatibility with a wide range of active pharmaceutical ingredients and across different routes of administration, TheraPEA™ enables the development of safe and effective therapies for the patient.

TheraPEA™ provides proven differentiators over traditional biodegradable polymers including:¹

- The ability to enable formulations with near linear release rates from weeks to greater than six months.
- Controlled degradation kinetics (weeks to multiple months) without acidification of the micro- environment.
- Unique solubility properties, including low hydrocarbon alcohols, for ease of processing with active pharmaceutical ingredients including low temperature melt processing into multiple treatment forms.
- Broad IP (Intellectual Property) protection, which provides opportunities for drug life cycle extension.
- Excellent material shelf-life- up to five years- at recommended storage conditions.

A partner you can depend on

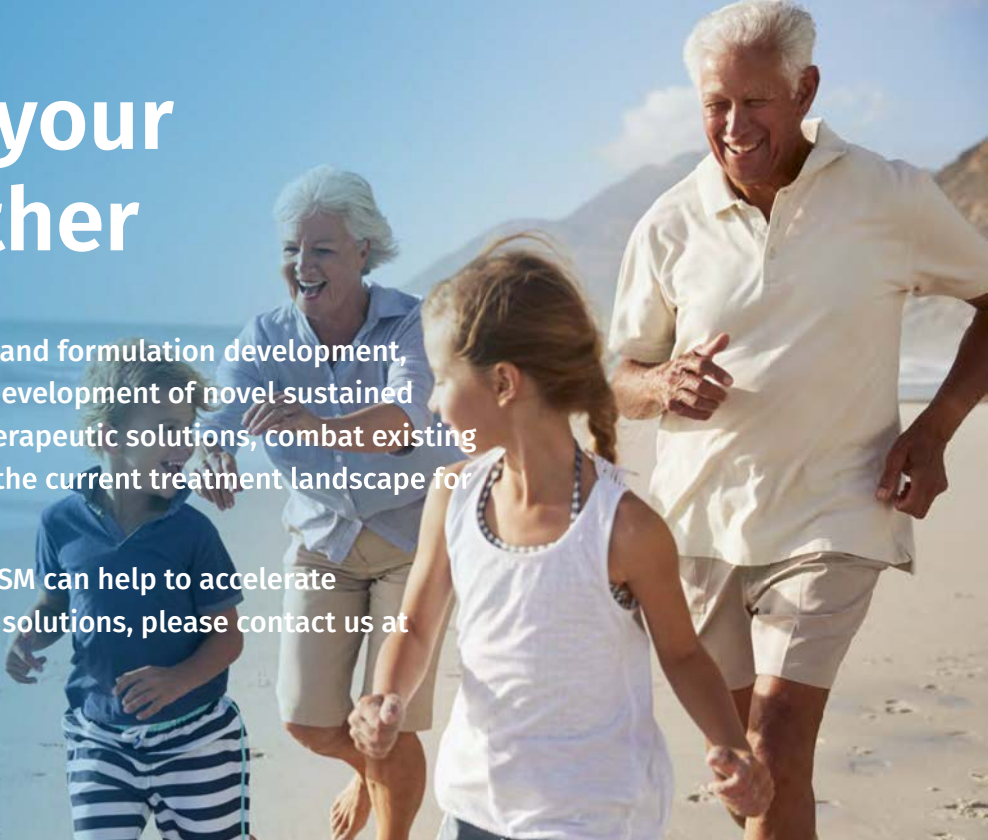
Across the globe, our partners rely on DSM Biomedical's support to realize their envisioned product profile from development to final treatment form. DSM offers extensive in-house expertise, including analytical competencies and melt and solution-based processing techniques. Partners can also rely on our team as an extension of their R&D, to accelerate formulation development efforts in our dedicated high potency laboratory.

TheraPEA™ biodegradable polymers are produced in a Pharma GMP certified facility and are backed by Material Master Files, to support our partners during their clinical and commercial development activities.

Let DSM take your therapies further

With our experience in materials science and formulation development, DSM's TheraPEA™ platform enables the development of novel sustained delivery solutions to design improved therapeutic solutions, combat existing compliance issues, and sustainably shift the current treatment landscape for the patient.

To learn more about our team and how DSM can help to accelerate development for your sustained delivery solutions, please contact us at DrugDelivery.Biomedical@dsm.com.



About DSM Biomedical

DSM Biomedical is a part of Royal DSM and the world's unrivaled biomaterials expert and committed partner in driving sustainable innovation in healthcare. The company has been at the forefront of biomaterial science and process innovation, and the leading resource for global medical device and pharmaceutical companies for more than 30 years. As a strategic partner with an approach driven not only by market dynamics but by the unique needs of every customer, DSM Biomedical brings an unparalleled breadth of product portfolios, proprietary manufacturing and processing capabilities, world-class IP, and extensive regulatory experience and expertise. Furthermore, DSM Biomedical's products and services are recognized for their unmatched quality, consistency, and performance in multiple markets across the globe, supporting their company-wide vision of solving the world's healthcare needs through sustainable science. To learn more, visit www.dsmbiomedical.com

PRODUCT DISCLAIMER

The description by DSM Biomedical of the characteristics and properties of its products and services as contained in this brochure is for general information purposes only, and may not be relied upon in individual situations. All materials offered by DSM Biomedical are supplied under a contract containing detailed product specifications, and the user shall be exclusively responsible for, and shall bear full responsibility for the consequences of, (i) whether or not the product is suitable for use in the devices (or for any other (authorized) use that customer may wish to make of the product), and (ii) whether the product specifications are sufficient and sufficiently well defined in order for the product to be fit and suitable for use by user. User undertakes to keep itself actively informed as to developments in the relevant fields of its applications.

(1) Data on file at DSM, (2) Data based on clinical development by Svelte Medical and Aerie Pharmaceuticals.

NORTH AMERICA

DSM Biomedical
735 Pennsylvania Drive
Exton, PA 19341 USA
Phone: +1 484 713 2100
Fax: +1 484 713 2900

EUROPE/ASIA

DSM Biomedical B.V.
Urmonderbaan 22
Geleen The Netherlands
Trade Register Limburg:
14096470

www.dsm.com/medical

