



Biologicals & Pharmaceuticals

Nordmark - Expert in Development and Manufacturing of Biological Products

Manufacturing

- > Biological Active Pharmaceutical Ingredients (APIs)
 - animal-sourced (e.g. pancreas, liver)
 - biotechnology-derived from recombinant and non-recombinant cell expression systems
- > Finished Medicinal Products
 - solid, semisolid (sterile) and liquid dosage forms
- > Clinical Trial Medication
- > Biochemicals
- > Agency-inspected (e.g. BfArM, FDA, ANVISA)

Development

- > New Biological APIs
- > Medicinal Products based on new Biological APIs
- > Clinical Development of Nordmark Compounds
 - Ancrod (Anticoagulation)
 - Bacterial Lipase (Exocrine Pancreatic Insufficiency)

Therapeutic Areas

- > Gastroenterology (Replacement of Digestive Enzymes)
- > Surgery and Dermatology (Wound Healing)
- > Vascular Disorders (Anticoagulation)
- > Tissue Engineering (Cell disintegration)

Services

- > Analytical Development and Testing
- > Regulatory Affairs
- > Stability Testing



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Nordmark Arzneimittel GmbH & Co.KG

Pinnauallee 4 | 25436 UETERSEN | www.nordmark-pharma.de



Digestive Enzymes

Pancreatin

Manufacturer & Global Supplier

- > One of the world-leading manufacturers of Pancreatin/Pancrelipase API
- > Manufacturer of various Pancreatin/Pancrelipase containing medicinal products (approved by FDA in the USA)
- > State-of-the-art, approved monitoring of Biological Safety (e.g. FDA, BfArM)

Medicinal Products

- > Customized Multi Unit Dosage forms based on
 - enteric coated pellets
 - enteric coated microtablets
- > Strengths from 5.000 to 40.000 Ph. Eur. Units per capsule
- > Variety of packaging systems (e.g. glass bottles, alu/alu blisters)

Bacterial Lipase

New Generation PERT

- > Pure, well-defined and highly active single lipase
- > Non-animal source
- > Stable in acidic conditions
- > Liquid formulation
- > Orphan Designation (EU)
- > Clinical Development Phase II



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