

Your Partner for

BIOLOGICAL ASSAYS



Enzyme Activities:

Pancreatin / Pancrelipase

- > Lipase
- > Amylase
- > Proteases
- > Trypsin
- > Chymotrypsin

Pepsin Collagenase

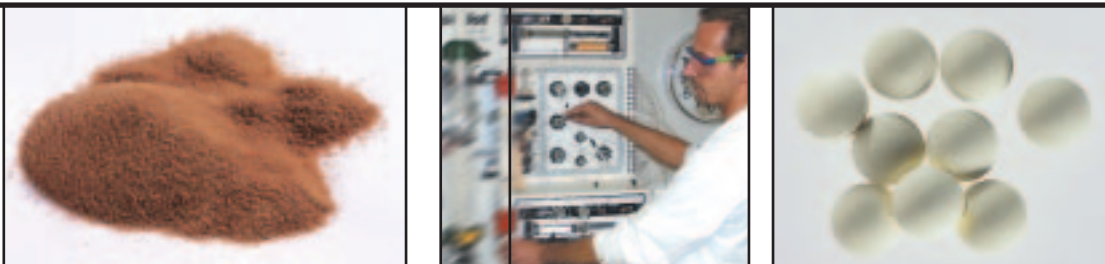
Potency of Heparin:

Heparins and Low Molecular Weight Heparins

Assay Development:

Enzyme Assays Protein Assays ELISA

VALIDATION · ANALYTICS · STABILITY



Nordmark produces biological active ingredients and medicinal finished products. We sell our products world wide. Aside from production our pharmaceutical and process development departments elaborate innovative solutions and products for our customers and permanently improve production processes for active pharmaceutical ingredients.

Nordmark achieved during decades a high professionalism in extracting APIs from materials of animal source as well as biotechnological know-how for production and purification of active ingredients in fermentation plants.

We are one of the world leading manufacturers e. g. of Pancreatin and Collagenase.

This practical experience consequentially comprises biological assays, indispensable for warranting ultimate product and operation quality.

Thus biological assays are essential daily routine for us, whereof our customers also shall benefit.

Our peculiarities – the customer’s advantage and confidence:

- 16.000 analyses per year (incl. 3000 enzyme analytics)
- statistical quality control of analytic results
- system suitability tests
- internal control substances to check out the analytic results
- participation in international collaborative studies (FIP; WHO)
- **cost effectiveness**
- **short-term availability**

““ *One of the crucial points of Pancreatin is the determination of the enzymatic activities (lipases, proteases, amylases). This analysis is performed on the active ingredient and on the Pancreatin containing formulations in our laboratory, which specialises in the analysis of natural substances.* ““



Biological



Assays

_ Assay Development

- according to customer requests
- development of new methods
- establishing of existing methods

_ Validation of Methods

- validation according to ICH guidelines or customer requests
- applicability of methods (e.g. Ph.Eur.) to finished medicinal products
- influence of ingredients on validation process
- repeatability and accuracy of analytic results

_ Biological Analytics

- active pharmaceutical ingredients (Ph.Eur., USP)
- finished medicinal product

_ Stability Testing

Including

- organisation
- storage
- documentation

carried out in climatic chambers in accordance with international ICH guidelines.

- basic-stability including long - term testing at climatic zones II (25°C/60% RH) and IV (30°C/65% RH) and testing under accelerated (40°C/75% RH) and intermediate conditions (30°C/65%RH) (e.g. for registration purposes)
- in-use-stability (e.g. for registration purposes)
- follow up stability (current production)
- validity of stability testing results is warranted by quality of analysis

If required, we offer tests under other special conditions.