

# A COMPREHENSIVE DIGESTIVE ENZYME COMPLEX FOR THERAPEUTIC AND NUTRITIONAL APPLICATIONS



Enzymes are fundamental biocatalysts that sustain human physiological processes, including digestion, metabolism, detoxification, immune defense, and tissue repair. Among therapeutic enzyme systems, Pancreatin represents a well established, broad-spectrum digestive enzyme complex used extensively in pharmaceutical and nutraceutical applications. EB-PancraZyme™ is a high quality Pancreatin preparation manufactured under stringent GMP conditions and compliant with IP, BP, USP, and EP pharmacopoeial standards. This document outlines the biochemical rationale, mechanism of action, clinical relevance, applications, and technical specifications of EB-PancraZyme™, positioning it as a reliable and globally accepted enzyme solution for digestive health and enzyme replacement therapy.

# INTRODUCTION

Enzymes act as biological catalysts essential for sustaining life by accelerating biochemical reactions without being consumed in the process. Every major physiological function depends on enzymatic activity to convert dietary substrates into absorbable nutrients and bioavailable energy forms.

In therapeutic and nutritional contexts, enzyme supplementation supports the body's intrinsic biological processes rather than replacing them. By enhancing reaction efficiency, enzymes reduce metabolic stress, improve nutrient bioavailability, and promote recovery from physiological strain. These attributes make enzyme-based interventions particularly valuable in aging populations, inflammatory conditions, digestive disorders, and metabolic insufficiencies.

Advances in enzyme science have enabled the development of targeted, pharmacopoeia-compliant enzyme systems that align with the body's natural regulatory mechanisms, supporting long-term health, balance, and resilience.



# PANCREATIN: COMPOSITION AND FUNCTIONAL OVERVIEW

Pancreatin is a naturally derived multi-enzyme complex obtained from porcine pancreatic tissue. It comprises a balanced combination of:



- **Protease**  
For protein hydrolysis



- **Amylase**  
For carbohydrate digestion



- **Lipase**  
For fat digestion

This enzymatic composition closely mimics endogenous pancreatic secretions, enabling comprehensive digestion of macronutrients. Due to its broad-spectrum activity and long-standing clinical acceptance, Pancreatin remains a cornerstone ingredient in pharmaceutical digestive therapies and clinical nutrition formulations.

EB-PancraZyme® is Enzyme Bioscience's proprietary Pancreatin offering, manufactured and standardized to meet IP, BP, USP, and EP requirements, ensuring global regulatory acceptance, batch-to-batch consistency, and reliable enzymatic performance.

# 1

BROAD-SPECTRUM DIGESTIVE  
ACTIVITY

Unlike single-enzyme preparations, Pancreatin delivers complete digestive support through its synergistic multi-enzyme profile, enabling efficient breakdown of proteins, carbohydrates, and lipids. This comprehensive action supports digestion of complex meals and maximizes nutrient utilization.

# 2

SUPPORT IN PANCREATIC  
INSUFFICIENCY AND  
DIGESTIVE DISORDERS

**Pancreatin is extensively used in pancreatic enzyme replacement therapy (PERT) for conditions including:**

- Pancreatic enzyme insufficiency
- Chronic pancreatitis
- Post-pancreatectomy digestive support
- Malabsorption syndromes

**By supplementing endogenous enzyme levels, Pancreatin restores digestive efficiency, alleviates gastrointestinal symptoms, and improves nutritional status and quality of life.**

# 3

ENHANCED NUTRIENT  
ABSORPTION AND METABOLIC  
EFFICIENCY

Efficient enzymatic digestion is essential for optimal nutrient absorption. Pancreatin facilitates complete macronutrient breakdown, reducing undigested residues and minimizing gastrointestinal discomfort. Improved nutrient assimilation supports better energy utilization and overall metabolic efficiency.

# 4

CLINICAL VALIDATION AND  
REGULATORY ACCEPTANCE

**Pancreatin has decades of documented clinical use and is officially recognized in major pharmacopoeias (IP, BP, USP, EP). This ensures:**

- Standardized activity assays
- Defined quality parameters
- Regulatory compatibility across global markets

**Such acceptance establishes Pancreatin as a trusted ingredient for regulated pharmaceutical and nutraceutical applications.**

# 5

FORMULATION  
VERSATILITY

**Pancreatin can be incorporated into diverse dosage forms, including:**

- Tablets and capsules
- Enteric-coated formulations
- Powders and granules

**This versatility allows formulation scientists to optimize enzyme stability, targeted release, and therapeutic efficacy.**

Rationale for  
Pancreatin Use

# MECHANISM OF ACTION

Pancreatin provides exogenous digestive enzymes that function synergistically within the gastrointestinal tract:



**Protease hydrolyzes proteins into peptides and amino acids**

**Amylase converts starch into simpler sugars**

**Lipase breaks down triglycerides into fatty acids and glycerol**

Collectively, these enzymes replicate physiological pancreatic activity, ensuring efficient digestion and nutrient absorption under normal gastrointestinal conditions.





# APPLICATIONS



## PHARMACEUTICAL APPLICATIONS

- > Pancreatic enzyme replacement therapy (PERT)
- > Digestive aid formulations
- > Clinical nutrition products



## NUTRACEUTICAL AND HEALTH SUPPLEMENTS

- > Digestive health supplements
- > High-protein and high-fat diet support
- > Nutritional enhancement formulations



## CLINICAL AND HOSPITAL NUTRITION

- > Support in malnutrition and absorption disorders
- > Post-surgical nutritional management

# TECHNICAL SPECIFICATIONS

**PRODUCT NAME :** PANCREATIN IP

**Exp. Date :** 3.5 Years from manufacturing

| TEST                                   | LIMITS                                                                           |
|----------------------------------------|----------------------------------------------------------------------------------|
| Description                            | White or Buff Colored free flowing Powder; Odor, Meaty but Not Unpleasant.       |
| Identification A & B                   | As per I.P1996 (Page-553)                                                        |
| Loss On Drying                         | Not more than 5% drying at 60 °C at a Pressure 0.7 kPa for 4 hours.              |
| Fat                                    | Not more than 5% dried 105°C for 2 hours.                                        |
| Assay – Proteolytic                    | The difference between the two titration is not less than 4.5 ml of 0.1 M NaOH.  |
| Assay – Amylase                        | Not less than 100 units per gm.                                                  |
| Assay – Lipase                         | The difference between the two titration is not less than 1.0 ml of 0.05 M NaOH. |
| Microbial Limit – E.coli<br>Salmonella | Should be Absent/g<br>Should be Absent/10 g                                      |

**PRODUCT NAME :** PANCREATIN USP

**Exp. Date :** 3.5 Years from manufacturing

| TEST                                      | LIMITS                                                                                                             |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| Description                               | White or Buff Colored Amorphous Powder;<br>Odor, Meaty But Not Unpleasant.                                         |
| Solubility                                | Soluble in water forming a slightly turbid solution; practically insoluble in ethanol (95 %) and in solvent ether. |
| Loss On Drying                            | Not more than 5% drying at 60 °C at a Pressure 0.7 kPa for 4 hours.                                                |
| Fat                                       | Not more than 5%                                                                                                   |
| Assay –<br>Protease<br>Amylase<br>Lipase  | NLT 250 USP U/mg<br>NLT 250 USP U/mg<br>NLT 60 USP U/mg                                                            |
| Microbial Limit –<br>E.coli<br>Salmonella | Should be Absent/g<br>Should be Absent/10 g                                                                        |

**PRODUCT NAME :** PANCREATIN EP

**Exp. Date :** 3.5 Years from manufacturing

| Parameter         | EP Specification                                                 | Test / Reference         |
|-------------------|------------------------------------------------------------------|--------------------------|
| Description       | Beige to light brown powder with characteristic odour            | EP Monograph             |
| Solubility        | Partly soluble in water, practically insoluble in alcohol        | EP General Test          |
| Identification    | Demonstrates enzymatic activity of lipase, amylase, and protease | EP Identification Tests  |
| Lipase Activity   | Not less than 15 Ph. Eur. Units/mg                               | EP Enzymatic Assay       |
| Amylase Activity  | Not less than 100 Ph. Eur. Units/mg                              | EP Enzymatic Assay       |
| Protease Activity | Not less than 12 Ph. Eur. Units/mg                               | EP Enzymatic Assay       |
| Loss on Drying    | NMT 5.0 %                                                        | EP Method                |
| Microbial Quality | Complies with EP limits for non-sterile products                 | EP General Chapter 5.1.4 |
| Pathogens         | Escherichia coli – Absent<br>Salmonella- Absent                  | EP Microbiological Test  |
| Storage           | Store in tightly closed container protected from moisture        | EP Storage Conditions    |

**PRODUCT NAME :** PANCREATIN BP

**Exp. Date :** 3.5 Years from manufacturing

| Parameter                                 | BP Specification                                                | Test / Reference                                         |
|-------------------------------------------|-----------------------------------------------------------------|----------------------------------------------------------|
| Description                               | Cream to light brown coloured powder with characteristic odour  | BP Monograph                                             |
| Solubility                                | Partially soluble in water;<br>practically insoluble in alcohol | BP General Tests                                         |
| Identification                            | Shows enzymatic activity of<br>protease, amylase and lipase     | BP Identification Tests                                  |
| Protease Activity                         | Not less than 6000 BP Units per g                               | BP Enzymatic Assay                                       |
| Amylase Activity                          | Not less than 25000 BP Units per g                              | BP Enzymatic Assay                                       |
| Lipase Activity                           | Not less than 2000 BP Units per g                               | BP Enzymatic Assay                                       |
| Loss on Drying                            | NMT 5.0 %                                                       | BP Method (Drying at 105°C)                              |
| Microbial Limits                          | Complies with pharmacopoeial microbial limits                   | EP General Chapter 5.1.4                                 |
| Pathogens                                 | Escherichia coli – Absent<br>Salmonella- Absent                 | BP Microbiological<br>Quality of Non-Sterile<br>Products |
| Heavy Metals /<br>Elemental<br>Impurities | Complies with BP limits                                         | BP Elemental Impurities<br>Chapter                       |
| Storage                                   | Store in well-closed container,<br>protected from moisture      | BP Storage Conditions                                    |

# QUALITY, SAFETY, AND COMPLIANCE

EB-PancraZyme™ is manufactured under GMP controlled conditions with comprehensive quality monitoring at every production stage. Each batch undergoes rigorous testing for enzymatic activity, microbial safety, and compliance with applicable pharmacopoeial standards.

# HANDLING, STORAGE, AND PACKAGING

- Store in a cool, dry environment away from heat, light, and moisture.
- Avoid excessive humidity to preserve enzymatic activity.

## WHY CHOOSE ENZYME BIOSCIENCE



Enzyme Bioscience integrates advanced R&D expertise, pharmacopoeial knowledge, and robust quality systems to deliver high-performance enzyme solutions. EB-PancraZyme exemplifies the company's commitment to consistency, compliance, and application-driven enzyme innovation.



### Standard Packaging

25 kg drum Custom Packaging: Available upon request.

#### Regulatory Disclaimer

EB-PancraZyme™ is intended for B2B use only. Final application suitability, formulation claims, and regulatory compliance remain the responsibility of the customer as per applicable local regulations.