

# A TECHNICAL AND SCIENTIFIC REVIEW

Enzymes represent nature's most efficient biocatalysts, exhibiting unparalleled specificity, repeatability, and biological intelligence. EB-PepZyme™ is a high quality Pepsin enzyme preparation manufactured in compliance with Indian Pharmacopoeia (IP) and United States Pharmacopeia (USP) standards.

This document presents a comprehensive scientific overview of EB-PepZyme™, detailing its molecular mechanism, digestive relevance, pharmacopoeial compliance, applications, and quality specifications. The paper aims to provide formulation scientists, pharmaceutical developers, and nutraceutical manufacturers with a clear technical understanding of Pepsin's role in gastric protein digestion and its suitability for regulated digestive health applications.

# INTRODUCTION: ENZYMES AND MOLECULAR PRECISION



Enzymes are biological catalysts that govern virtually every biochemical process in living systems. Their effectiveness arises from precise three-dimensional molecular structures that enable selective substrate recognition and controlled catalysis

Unlike synthetic chemical catalysts, enzymes operate efficiently under physiological conditions, ensuring reaction accuracy without disrupting surrounding biological systems.

A defining characteristic of enzymes is their catalytic repeatability: after completing a reaction, an enzyme remains structurally intact and immediately available for subsequent reactions.

This combination of specificity, efficiency, and reusability positions enzymes as indispensable tools in pharmaceutical and biotechnological applications where reliability, safety, and reproducibility are critical.

# PEPSIN: A GASTRIC PROTEOLYTIC ENZYME

Pepsin is a potent proteolytic enzyme of porcine gastric origin and serves as the primary enzyme responsible for initiating protein digestion in the stomach. Operating optimally under acidic conditions, Pepsin hydrolyzes complex dietary proteins into smaller peptides, facilitating efficient downstream digestion and absorption in the intestine.



With decades of therapeutic and pharmaceutical use, Pepsin has achieved well-established recognition in global pharmacopoeias. Its consistent efficacy and safety profile have made it a cornerstone ingredient in digestive aid formulations and clinical nutrition products.

At Enzyme Bioscience, Pepsin is commercialized as EB-PepZyme®, manufactured and controlled to meet both IP and USP requirements, ensuring standardized activity, safety, and international regulatory acceptance.

# RATIONALE FOR PEPSIN IN DIGESTIVE FORMULATIONS

## INITIATION OF GASTRIC PROTEIN DIGESTION

Pepsin catalyzes the first and most critical stage of protein digestion by cleaving complex protein structures into smaller peptide fragments. This early-stage hydrolysis enhances digestive efficiency and significantly improves amino acid bioavailability.

## ACTIVITY IN ACIDIC PH CONDITIONS

Pepsin exhibits optimal enzymatic activity within the gastric pH range, distinguishing it from many other proteases that are inactive in acidic environments. This property makes it uniquely effective in the stomach, particularly in individuals with compromised digestive efficiency.

## SUPPORT FOR DIGESTIVE COMFORT AND NUTRIENT UTILIZATION

Incomplete protein digestion can result in bloating, gastrointestinal discomfort, and reduced nutrient absorption. By minimizing undigested protein residues, Pepsin contributes to improved digestive comfort and metabolic efficiency, especially in high-protein diets.

## ESTABLISHED CLINICAL AND PHARMACOPOEIAL ACCEPTANCE

Pepsin's inclusion in IP and USP monographs ensures:

- Defined activity measurement
- Consistent quality and potency
- High regulatory confidence for global markets.

These attributes make Pepsin a trusted component in regulated pharmaceutical and nutraceutical formulations.

## COMPATIBILITY WITH MULTI-ENZYME SYSTEMS

Pepsin is commonly incorporated into multi-enzyme formulations alongside pancreatin and fungal proteases. Its gastric-phase activity complements intestinal enzymes, enabling complete protein digestion throughout the gastrointestinal tract.

# MECHANISM OF ACTION

Pepsin is an endopeptidase (EC 3.4.23.1) that catalyzes the cleavage of peptide bonds, particularly those involving aromatic amino acids. It is synthesized as an inactive precursor, pepsinogen, which is activated under acidic gastric conditions.

## Key functional characteristics include:

**01**

Efficient hydrolysis of proteins in low-pH environments.

**02**

Generation of peptide substrates suitable for intestinal digestion.

**03**

Selective proteolysis without damaging gastric mucosa when properly formulated.

**These properties underscore Pepsin's essential role in physiological protein digestion.**

# APPLICATIONS AND BENEFITS



## PHARMACEUTICAL APPLICATIONS

- Digestive aid formulations
- Management of protein maldigestion
- Gastric digestive support products



## NUTRACEUTICAL AND HEALTH SUPPLEMENT APPLICATIONS

- Protein digestion support supplements
- High-protein dietary formulations
- General digestive health products



## CLINICAL AND SPECIALIZED NUTRITION

- Support for individuals with low gastric enzyme secretion
- Nutritional management of digestive insufficiency



# TECHNICAL SPECIFICATIONS

## SPECIFICATION OF PEPSIN (1:3000)IP

**Product Name:** PEPSIN (IP)

**Expiry Date:** 3 Years from manufacturing date

| TEST                                                             | LIMITS                                                                                        |
|------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| <b>Description</b>                                               | White or light Buff colored amorphous powder, or translucent scale odor, meaty but not rancid |
| <b>Solubility</b>                                                | Soluble in water solution; practically insoluble in ethanol (95 %) and in solvent ether.      |
| <b>Loss on Drying</b>                                            | NMT 5%                                                                                        |
| <b>Identification</b>                                            | As per IP                                                                                     |
| <b>Sulfate Ash</b>                                               | NMT 3 %                                                                                       |
| <b>Assay – Proteolytic</b>                                       | Volume of undigested egg albumin not more than 2.0 ml                                         |
| <b>Microbial Limit –<br/>E. coli<br/>Salmonella<br/>Shigella</b> | Should be Absent/g<br>Should be Absent/10 g<br>Should be Absent/10 g                          |

# SPECIFICATION OF PEPSIN (USP)

**Product Name:** PEPSIN (USP)  
**Expiry Date:** 3 Years from manufacturing date  
**Standards Referenced:** USP (United States Pharmacopeia),  
NF (National Formulary)

## I. PRODUCT IDENTIFICATION

| Parameter             | Specification                                                                  |
|-----------------------|--------------------------------------------------------------------------------|
| Product Name          | Pepsin (USP Grade)                                                             |
| CAS Number            | 9001-75-6                                                                      |
| Molecular Formula     | C <sub>82</sub> H <sub>131</sub> N <sub>23</sub> O <sub>26</sub> (Approximate) |
| Enzyme Classification | Serine Protease (EC 3.4.23.1)                                                  |
| Physical Form         | White to light yellow amorphous                                                |
| Odor                  | Meaty but not rancid                                                           |
| Expiry Date           | 3 Years from manufacturing                                                     |

## II. QUALITY SPECIFICATIONS AND TEST LIMITS

| Test Parameter       | Specification Limit                        | Test Method              |
|----------------------|--------------------------------------------|--------------------------|
| Description          | White to light yellow amorphous powder;    | Visual Inspection        |
| Identification       | As per USP Monograph                       | USP <191>                |
| Solubility           | Soluble in water; practically insoluble in | USP <721>                |
| Loss on Drying       | NMT 5%                                     | USP <731>                |
| Sulfate Ash          | NMT 3%                                     | USP <561>                |
| Proteolytic Activity | NLT 10,000 USP Units/mg (or 1:10,000 NF)   | USP <2000> Enzyme Assays |
| Assay - Proteolytic  | Volume of undigested hemoglobin NMT 2.0 mL | Hemoglobin Method (USP)  |

### III. MICROBIAL CONTAMINATION LIMITS

| Microorganism               | Limit           | Method     |
|-----------------------------|-----------------|------------|
| E. coli                     | Absent/g        | USP <2022> |
| Salmonella                  | Absent/10 g     | USP <2022> |
| Shigella                    | Absent/10 g     | USP <2022> |
| Total Plate Count (Aerobic) | NMT 1,000 CFU/g | USP <2023> |
| Yeast and Mold              | NMT 100 CFU/g   | USP <2023> |

### IV. STORAGE AND HANDLING CONDITIONS

| Parameter           | Specification                                      |
|---------------------|----------------------------------------------------|
| Storage Temperature | 2–8°C (Refrigerated)                               |
| Humidity Control    | Relative humidity: NMT 60%                         |
| Container Material  | Amber/Dark colored glass bottle with tight closure |

# STORAGE, HANDLING, AND PACKAGING

**EB-PEPZYME®  
SHOULD BE STORED  
IN A COOL, DRY  
ENVIRONMENT,  
PROTECTED FROM  
HEAT, LIGHT, AND  
MOISTURE.**

Milestone passed in less  
than one year

Relative Humidity: NMT 60%

Packaging: 25 kg drum

Custom Packaging:  
Available upon request



## QUALITY, SAFETY, AND COMPLIANCE

**EB-PepZyme™** is manufactured under stringent GMP-controlled conditions. Each batch undergoes comprehensive testing for enzymatic activity, purity, microbial safety, and pharmacopoeial compliance in accordance with IP and USP standards.





## CONCLUSION

EB-PepZyme® represents a scientifically validated, pharmacopoeial-grade Pepsin enzyme designed for reliable gastric protein digestion. Its molecular precision, clinical legacy, and regulatory compliance make it an essential ingredient for pharmaceutical, nutraceutical, and clinical nutrition applications.

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## REGULATORY DISCLAIMER

EB-PepZyme™ is intended for B2B use only. Final formulation, claims, and regulatory compliance are the responsibility of the customer in accordance with applicable local regulations.