

A SYSTEMIC PROTEOLYTIC ENZYME

for Anti-Inflammatory and
Therapeutic Applications

Enzymes play a critical role in biological efficiency by catalyzing highly specific biochemical reactions essential for physiological balance.



Serratiopeptidase, a proteolytic metalloprotease derived from *Serratia marcescens* through controlled fermentation, has gained significant recognition for its anti-inflammatory, anti-edematous, and fibrinolytic properties. This document outlines the biochemical characteristics, mechanism of action, therapeutic applications, technical specifications, and quality parameters of EB-SerraZyme™, a pharmaceutical-grade Serratiopeptidase preparation intended for systemic use in pharmaceutical and nutraceutical formulations.

INTRODUCTION

Biological systems rely on enzymes to regulate complex biochemical reactions with precision and efficiency. Enzymes exhibit high substrate specificity, ensuring targeted catalysis while maintaining physiological homeostasis. In clinical and industrial contexts, enzymes facilitate the transformation of complex biomolecules into bioavailable and functional forms.

Serratiopeptidase represents a specialized systemic enzyme designed for therapeutic modulation of inflammation and tissue recovery processes.

BIOCHEMICAL PROFILE OF SERRATIOPEPTIDASE

Serratiopeptidase is a highly active proteolytic enzyme classified as a metalloprotease. Originally isolated from *Serratia marcescens*, it is now produced through controlled microbial fermentation under GMP-compliant conditions.

This selective proteolytic action supports reduction in inflammatory burden without affecting viable healthy tissues.

Biochemically, Serratiopeptidase selectively hydrolyzes non-viable proteins including:

1**INFLAMMATORY MEDIATORS****2****FIBRIN DEPOSITS****3****NECROTIC TISSUE DEBRIS**

WHY SERRATIOPEPTIDASE?

A Clinically Proven Enzyme with Multifunctional Benefits

Serratiopeptidase stands apart from conventional proteolytic enzymes due to its systemic mode of action and strong clinical acceptance across pharmaceutical applications.



1.POTENT ANTI-INFLAMMATORY & ANTI-EDEMATOUS ACTIVITY

Serratiopeptidase helps reduce inflammation by breaking down inflammatory proteins and mediators, thereby:

- Reducing pain and swelling
- Improving tissue drainage
- Supporting faster recovery in acute and chronic inflammation

It is widely used in formulations for musculoskeletal disorders, trauma, and post-operative care.

2.FIBRINOLYTIC ACTION & IMPROVED MICROCIRCULATION

The enzyme exhibits fibrinolytic activity by breaking down fibrin deposits, which helps:

- Improve blood circulation
- Reduce localized edema
- Enhance tissue oxygenation

This makes Serratiopeptidase suitable for vascular, respiratory, and systemic inflammation support products.

3.RESPIRATORY HEALTH & MUCOLYTIC SUPPORT

Serratiopeptidase reduces viscosity of mucus and helps clear airway secretions, making it beneficial in:

- Sinusitis
- Bronchitis
- Upper and lower respiratory tract inflammation

It supports easier breathing and improved respiratory comfort.

4.ENHANCED DRUG PENETRATION & SYNERGISTIC ACTION

By reducing inflammatory barriers and protein debris, Serratiopeptidase improves tissue permeability, helping enhance the effectiveness of antibiotics and other co-administered therapies.

5.SAFE, WELL-TOLERATED & CLINICALLY TRUSTED

Produced via fermentation and purified under controlled conditions, Serratiopeptidase is:

- Non-toxic and non-habit forming
- Well tolerated when properly formulated
- Widely accepted in regulated pharmaceutical markets

Its safety profile supports long-term and combination therapy use.

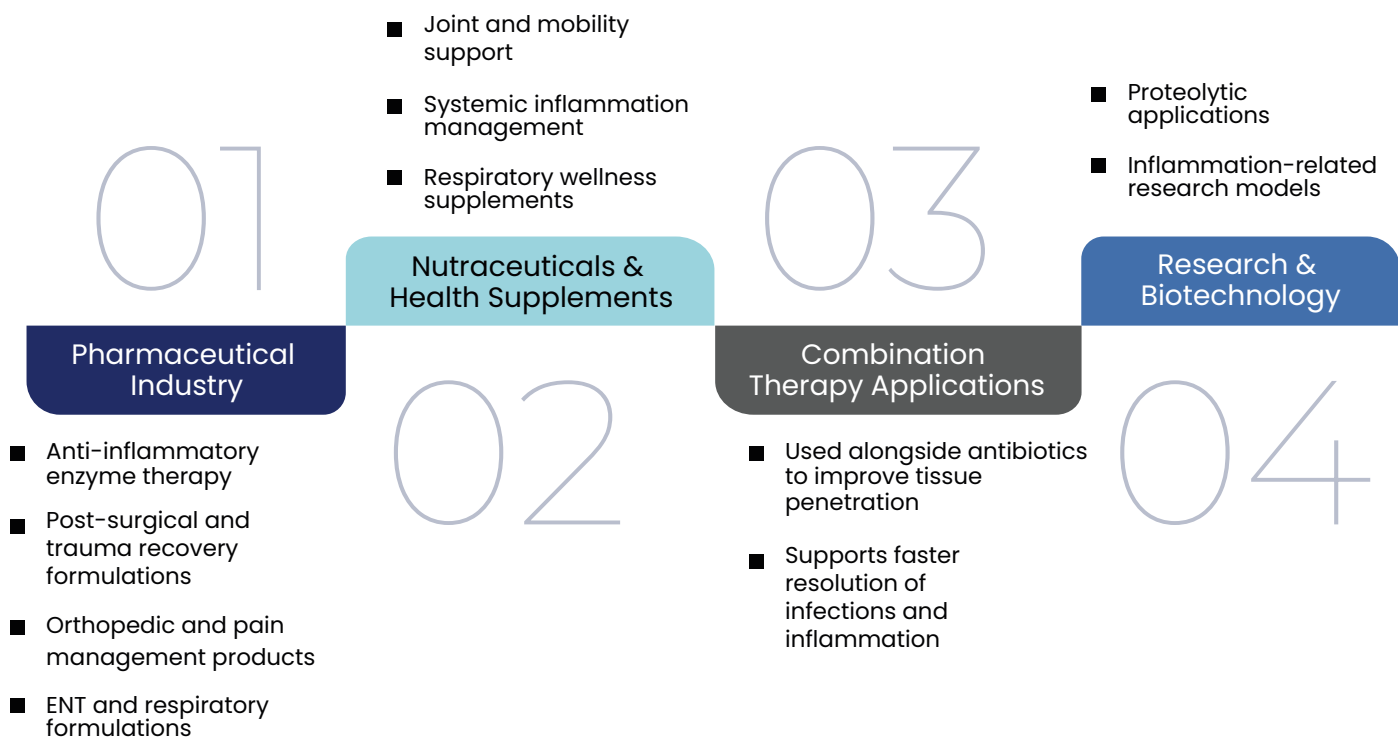
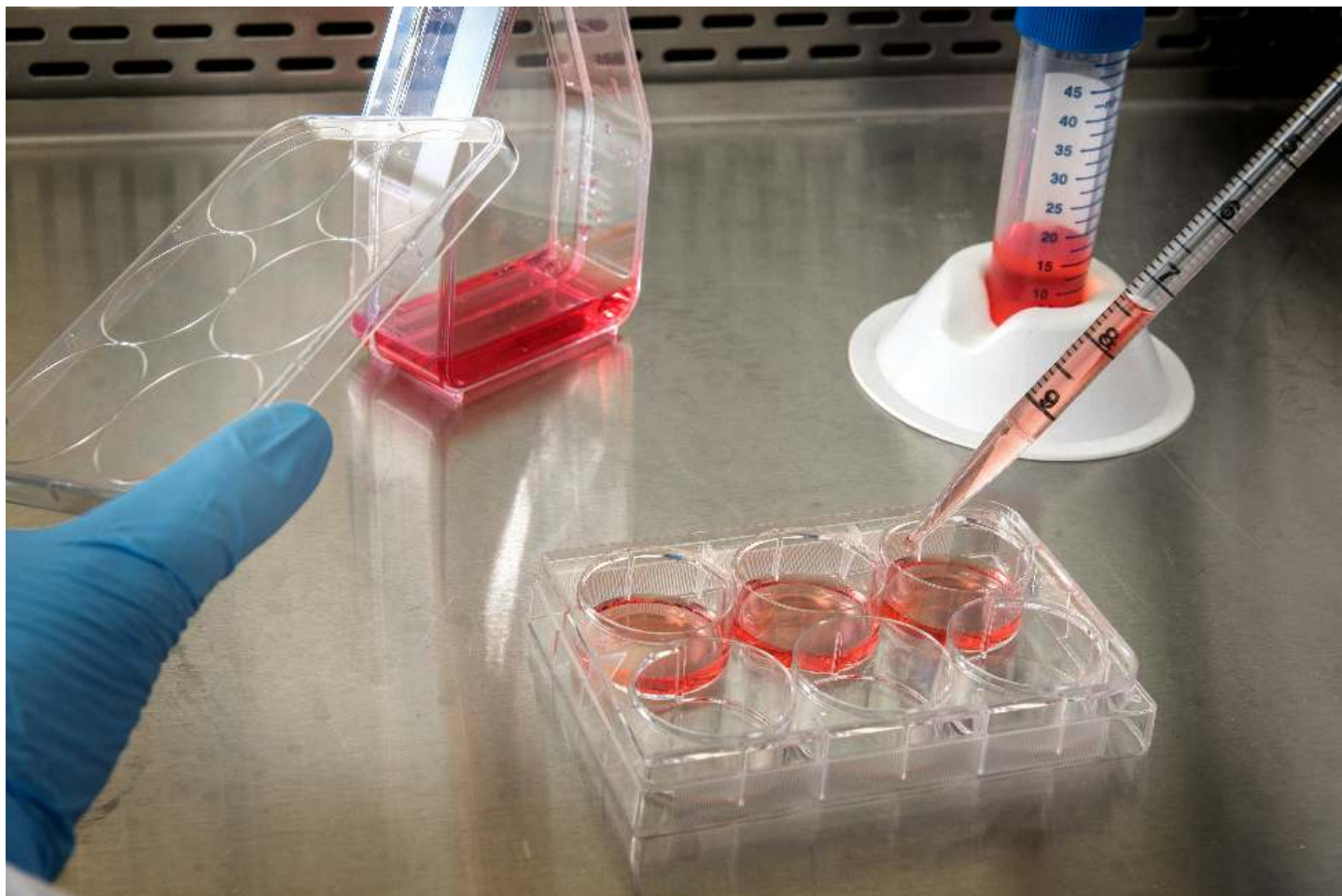
MECHANISM OF ACTION

Serratiopeptidase catalyzes the hydrolysis of peptide bonds in inflammatory proteins and fibrin complexes. When formulated appropriately (e.g., enteric-coated delivery systems), it is absorbed systemically and exerts activity at inflammatory sites.

Primary Functional Actions



Collectively, these mechanisms contribute to reduced pain, swelling, and accelerated tissue recovery.



SPECIFICATION OF SERRATIOPEPTIDASE IP

PRODUCT NAME	SHELF LIFE
Serratiopeptidase IP	4 years from date of manufacturing

PARAMETER	SPECIFICATION
Appearance	Grayish White to Cream Powder With Characteristics Odor
Loss on Drying	NMT 7.0% w/w
Identification	The activities of solution A and B are almost same and the activity of C is not more than 5% of activity of A.
Heavy Metals	NMT 20 ppm
Sulphate Ash	NMT 5.0% w/w
Assay	NLT 2000 IU/mg
Microbial Limits	TVC: NMT 1000 cfu/g; Yeast & Mold: NMT 100 cfu/g; E. coli: Absent/g; Salmonella: Absent/10g; Shigella: Absent/10g

Note: Technical parameters may vary depending on grade.

SPECIFICATION OF SERRATIOPEPTIDASE IP EC

PRODUCT NAME	SHELF LIFE
Serratiopeptidase IP EC	4 years from date of manufacturing
PARAMETER	SPECIFICATION
Description	Pale Brown Granules, with Characteristics Oder
Loss on Drying	NMT 7.0% w/w
Identification	The activities of solution A and B are almost same and the activity of C is not more than 5 % of activity of A.
Heavy Metals	NMT 20 ppm
Arsenic	NMT 5 ppm
Sulphate Ash	NMT 7.0 % w/w
Enteric coated test	In 0.1 M HCL: EC granules should be intact up to 2 hours In Phosphate buffer pH 6.8, EC granules should be completely get dispersed within 60 minutes.
Assay	NLT 2000 U/mg
Microbial Limit – Total Viable Count Yeast & Mold Count E. coli Salmonella Shigella	NMT 10000 cfu/g NMT 100 cfu/g Should be Absent/g Should be Absent/10 g Should be Absent/10 g

QUALITY ASSURANCE AND COMPLIANCE

EB-SerraZyme™ is manufactured under stringent GMP-controlled conditions. Each batch undergoes comprehensive testing including:

Enzyme activity validation

Microbial limit testing

Heavy metal analysis

Stability assessment

This ensures batch-to-batch consistency, regulatory compliance, and product reliability.

HANDLING, STORAGE, AND PACKAGING

Store in a cool, dry environment away from moisture, heat, and direct light.

Avoid inhalation of enzyme dust during handling.

Use appropriate protective equipment.

Standard Packaging: 25 kg drum

Custom packaging: Available upon request

MANUFACTURER OVERVIEW

Enzyme Bioscience integrates advanced fermentation capabilities, research expertise, and rigorous quality systems to deliver pharmaceutical-grade enzyme solutions. Emphasis is placed on documentation, regulatory alignment, and formulation support for industry partners.

REGULATORY DISCLAIMER

EB-SerraZyme™ is intended strictly for B2B applications. Final formulation claims, labeling, and regulatory compliance remain the responsibility of the customer in accordance with applicable local regulations.

