



Technical Data Sheet

EB-AmylZyme(Alpha amylase IP)

1. Product Information

- Product Type: Enzyme Preparation
- Enzyme Class: Hydrolase (Amylase)
- EC Number: 3.2.1.1
- Pharmacopoeia Compliance: Indian Pharmacopoeia (IP)
- Source: Microbial fermentation (Aspergillus oryzae / Bacillus spp.)
- Form: Off-white to light cream powder
- Grade: Pharmaceutical Grade
- Intended Use: Digestive enzyme formulations

2. Product Description

Alpha Amylase IP is a starch-hydrolyzing enzyme that catalyzes the breakdown of complex carbohydrates into dextrins and sugars. It is produced through controlled microbial fermentation and standardized to deliver consistent enzymatic activity. The product complies with IP specifications and is suitable for pharmaceutical applications, particularly in digestive formulations.

3. Source of Organism

- Microorganism: Aspergillus niger
- Production Process: Fermentation → Filtration → Purification → Concentration → Drying → Standardization
- Animal Origin: Free from animal-derived materials
- GMO Status: Non-GMO (if applicable)

4. Enzyme Characteristics

Parameter: Specification

Enzyme Type: Alpha Amylase

Substrate Specificity: Starch, glycogen

Mode of Action: Endo-acting hydrolysis of α -1,4 glycosidic bonds

Optimum pH: 5.0 – 6.5

Effective pH Range: 4.5 – 7.0

Optimum Temperature: 50°C – 60°C

Temperature Stability: Up to 65°C

Solubility: Freely soluble in water

5. Technical Specifications

Parameter: Specification

Appearance: Off-white to Light yellow powder

Odor: Characteristic

Activity: 2000 IP Units/g

Loss on Drying: $\leq 7\%$

pH (1% solution): 4.5 – 6.5

Ash Content: $\leq 5\%$

Particle Size: 90% pass through 40–60 mesh

6. Microbiological Specifications

Parameter: Limit

Total Plate Count: $\leq 1,000$ CFU/g

Yeast & Mold: ≤ 100 CFU/g

Escherichia coli: Absent

Salmonella: Absent

7. Heavy Metals Limits

Parameter: Limit

Lead (Pb): ≤ 3 ppm

Arsenic (As): ≤ 3 ppm

Cadmium (Cd): ≤ 1 ppm

Mercury (Hg): ≤ 0.1 ppm

8. Applications:

1 Pharmaceutical Applications

- Digestive enzyme formulations
- Carbohydrate digestion support
- Enzyme replacement therapy

2 Therapeutic Uses

- Indigestion and bloating
- Starch malabsorption conditions
- Adjunct in multi-enzyme formulations

3 Formulation Applications

- Tablets and capsules
- Syrups and oral liquids
- Combination enzyme products (Amylase + Protease + Lipase)

9. Safety and Handling:

- Avoid inhalation of enzyme dust
- Use PPE (mask, gloves, goggles)
- May cause allergic sensitization
- Avoid contact with eyes and skin

10. Storage Condition:

- Store below 25°C in a dry place
- Protect from moisture and heat
- Keep container tightly closed

11. Packaging:

- 1 kg / 5 kg aluminum containers
- 10 kg / 25 kg HDPE drums with inner liner
- Customized packaging available

12. Shelf Life:

- **36** months under recommended storage conditions

13. Regulatory and Compliance:

- Complies with Indian Pharmacopoeia (IP)
- Manufactured under GMP conditions
- Suitable for pharmaceutical applications
- Non-GMO and free from animal-origin materials
- Halal/Kosher certification available upon request

14. Disclaimer

The information provided herein is based on current technical knowledge and IP standards. It is intended as a guideline and does not constitute a guarantee of performance. Users must validate suitability for their specific pharmaceutical formulations and regulatory requirements.



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