

# **Good Manufacturing Practice in microbial food enzyme production**

## **General**

Good Manufacturing Practice in the microbial food enzyme industry ensures that enzyme preparations are produced, packed and handled in a hygienic way.

All operations are designed to avoid contamination, formation of undesirable by-products, deterioration and handling errors.

The principles of GMP include systems of quality control and quality assurance, employee qualifications, maintenance standards for equipment, control of raw materials and product stability.

The key issues in GMP are the microbiological control of the microorganism selected for enzyme production, the control and monitoring systems ensuring pure culture and optimum enzyme productivity conditions during fermentation and control of the hygienic conditions throughout recovery and finishing of the enzyme preparations.

## **Identity control and laboratory management of the production strain.**

When a microorganism has been selected for enzyme production, its taxonomic identity is checked. The master culture is kept as spores, on slants or as a dried preparation and stored at temperatures sufficiently low to avoid degeneration and secure genetic stability. All vials or slants for seed cultures are clearly labelled and in revival of the culture, strict aseptic techniques are applied. The seed culture is also checked for identity by morphological characterization and comparison with the taxonomic characteristics originally identified. Its purity is checked before transfer to the fermentation equipment by serial dilutions, plating and macroscopic and microscopic inspection for any foreign microorganisms.

## **Control of pure culture and operational parameters during fermentation.**

Prior to fermentation the growth medium, consisting of a mixture of food or feed grade quality substances is sterilized and, in the case of submerged fermentations it is checked for sterility. Contamination during fermentation is prevented by the use of large inoculum, carefully controlled optimum growth conditions for the production strain, overpressure in fermentation vessel, appropriate foam control in submerged fermentation and the use of sterile air.

The culture liquid from submerged fermentation is sampled at regular intervals throughout processing and inspected by microscopy. To ensure sterility, incubated plates are checked for the presence of foreign microorganisms.

In semi-solid surface fermentation, sterility control is restricted to visual inspection.

If a significant contamination develops, the batch is rejected from further food grade processing.

Enzyme activity and operational parameters like temperature, pH and oxygen content are monitored during fermentation and kept within predetermined ranges based on experience. Deviations from these ranges may indicate a contamination before it can be detected in microbial assays.

### **Hygienic control during enzyme recovery**

GIVIP will ensure that contamination of the product during recovery is minimized. Hygienic conditions are assured by careful cleaning of equipment. Samples from down-stream processing are analyzed for the level of contamination and the finished enzyme preparation is analyzed for total viable counts, as well as for pathogenic micro-organisms.

The final product has to meet the criteria formulated by the WHO/FAO Joint Experts Committee on Food Additives (JECFA) and the Food Chemicals Codex (FCC).