



National Enzyme Company

Quality Assurance

Raw Material

Raw material monographs for all raw materials are developed in-house defining all appropriate release testing, including identity, activity, strength and microbiological test limits.

All raw materials and components are quarantined and sampled by QC.

Testing is performed in our in-house lab prior to release for use.

**Lab managed and staffed only by degreed chemists and microbiologists.

All raw materials are stored in environmentally controlled warehouses managed by NEC.

Production

All Master Production records are verified and controlled by QC

All Batch Formulation records are verified for accuracy by Q.C.

All Encapsulation batch records are verified for accuracy by Q.C.

All Packaging batch records verified by Q.C.

All manufacturing paperwork available for customer review and/or auditing.

Microbiological screening is run on all products prior to leaving NEC facility.

Additional production verification is done at appropriate intervals; including blend uniformity, capability analysis of encapsulated products, and net count verification of packaged goods.

Retain samples of packaged goods are taken and held in environmentally controlled storage area.

All operators maintain authority to stop processes at any time.

QC is staffed to do any additional testing requested by our customers.

Product C of As are issued from the lab for all outgoing products.

GMP Training and Support

All new hires are given extensive GMP introduction

Additional GMP training is held company-wide.

Complete set of Operational SOPs are written and followed.

Biannual review of all SOPs ensures they are up to date with procedural modifications.

Outside Audits

NSF certified for GMP Contract Manufacturing

TGA (Therapeutic Goods Administration in Australia) certified for GMP Contract Manufacturing