



Robust Analytical Support for Late-Stage Biocatalytic Process Development

Robust Analytical Support for Late-Stage Biocatalytic Process Development

Effective assessment of enzyme performance and stability is essential as manufacturing progresses toward commercialisation. Almac Sciences offers a comprehensive suite of analytical services to support this transition, working closely with our in-house biocatalysis team.



Analytical Method Development

A typical enzyme batch release specification includes appearance, activity, total protein content (Bradford or BCA assay), endotoxin levels, microbial absence, host cell protein (ELISA or Western blot), host cell DNA (qPCR or RT-PCR), elemental impurities (ICP-MS), and PEI content (HPLC).

For oligonucleotide-focused enzyme applications, additional analyses such as residual nuclease detection (fluorescence-based) and ATPase/phosphatase activity may be included.

Almac employs a range of platform methods suitable for multiple enzyme classes and routinely uses validated commercial kits. While full GMP testing is not required for these materials, all analyses are performed on GMP-calibrated and maintained equipment to ensure data reliability.

Troubleshooting and Method Optimisation

Our extensive experience across small molecules, large molecules, enzymes, and antibodies enables rapid troubleshooting when analytical challenges arise. Platform methods serve as a strong foundation, and the team readily conducts investigative work when needed.

The biocatalysis group can also engineer enzymes to improve stability, activity and selectivity in order to deliver economic advantages during commercialisation.

Stability Study Capabilities

As products advance toward commercial manufacturing, enzyme stability becomes increasingly critical. Almac currently manages more than 2,000 ongoing ICH stability studies and designs customised protocols tailored to a diverse range of enzyme products.



Contact us:

almacanalytical@almacgroup.com