ALMAC

Partnering to Advance Human Health

Almac Voice

Spotlight on Reference Standards

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Reference standard management is becoming an increasingly critical component of pharmaceutical development and quality control. While often considered a supporting activity, reference standards are fundamental to the successful development, validation, and execution of analytical methods used throughout a product's lifecycle.

Reference standards play a vital role in method familiarisation, method development, validation, active pharmaceutical ingredient (API) release testing, drug product release, and for ongoing stability studies. Effective management of these materials requires a detailed understanding of analytical methodologies, regulatory expectations, and the impact that standard quality can have on analytical results.

Comprehensive Reference Standard Capabilities

Almac provides a broad range of analytical capabilities to support the manufacture, qualification, storage, testing, and recertification of reference standards.

This includes: primary reference standards, secondary reference standards, system suitability standards, cleaning validation standards and retention time markers

These reference standards are used to support sample release testing, stability studies, method development and validation activities, and specific customer requirements.

Reference standards can be initially certified at Almac and subsequently recertified at defined intervals to maintain their suitability for use. Where possible, recertification testing can be streamlined by scheduling the work alongside related customer samples using the same analytical methods. This integrated approach maximises laboratory efficiency, helps ensure testing is completed within required timelines, and supports the extension of standard retest periods while maintaining the integrity and reliability of the material.

Reference Standard Management at Almac Sciences

Almac Sciences operates a centralised reference standard management system supported by a dedicated team. The team is responsible for the qualification, storage, subdivision, shipment and retesting of reference standards required across the department and for customer storage programmes.



This service supports every stage of the drug substance lifecycle, from early development and non-GMP studies through to GMP validation, commercial testing, API release, stability studies, and ongoing customer requirements.

Centralised Storage and Inventory Control

All reference standards are managed through a Laboratory Information Management System (LIMS), where each material is assigned a unique identifier and maintained as part of a fully traceable inventory. The LIMS database captures detailed information including batch number, supplier details, storage conditions, packaging requirements, available quantities (including reconciliation), retest dates and exact storage locations. All standards are housed within a centralised storage facility with controlled access restricted to authorised members of the dedicated reference standard team. This approach ensures the security, integrity, and traceability of all materials.

Storage Capacity and Environmental Control

Almac Sciences maintains storage facilities operating at a range of ICH-compliant temperature conditions, including:

Storage Condition	Temperature Range
Refrigerated	2°C to 8°C
Controlled Ambient	20°C to 25°C
Frozen	-15°C to -20°C
Ultra-Low Temperature	-70°C

Standard Usage and Traceability

To protect material integrity, bulk reference standards are retained by the Reference Standard Team and subdivided only when required for routine analytical testing or shipment activities.

Material requests are submitted electronically, approved by the team, and tracked within LIMS to maintain visibility of the standard's location throughout use and return. All transactions are recorded in LIMS, including quantities issued, remaining and used, together with references to the associated analytical activity. This robust process provides complete traceability, maintains accurate inventory records, and ensures accountability throughout the lifecycle of each reference standard.

Conclusion

With dedicated expertise, secure storage, and proactive lifecycle management, Almac Sciences ensures your reference standards remain compliant, traceable, and available when needed, helping you minimise risk and maintain confidence in your analytical results.

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