



Product Quality Designations at Cambridge Isotope Laboratories SP and MG Products

Cambridge Isotope Laboratories produces stable isotope labeled products at several levels of control beyond the standard research product grade (xLM-*nnn*-0). These grades are designated as xLM-*nnn*-SP and xLM-*nnn*-MG, where “x” refers to the type of labeling (C, N, D, CN, etc.) and “*nnn*” is the catalogue number (please inquire about materials suitable for Phase I clinical trials). As an aid to customers in selecting the appropriate product grade for applications, the Table below shows the levels of control applied to manufacturing, quality control and quality assurance and the level of testing applied to each grade of product.

		-SP Products	-MG Products
Manufacturing	Synthetic Methods	Catalogue products may be prepared under SOP or following laboratory notebook procedures	Catalogue products prepared under SOP
	Packaging	Performed in Packaging Dept.	
	SOPs	SOPs controlled by departmental management	
	Change Control	Departmental management approval	
	Raw Material Traceability	May be available upon request	Vendor Certificate of Analysis for critical raw materials
	Glassware	Standard laboratory cleaning, glassware - multiple use	
	Cross Contamination Control	Standard laboratory practice	
	Deviations	Dept. management approval	
Quality Control	Test methods	SOP/good scientific practice	
	SOPs	SOPs controlled by departmental management	
	Change Control	Departmental management approval	
	Out of Specification	Managed by Department	
	Deviation	Dept. management approval	
Product Quality	Certificate of Analysis	Provided by QC	
	Material Specifications	Determined by CIL	
	USP Specifications	Does not apply	Tested to meet USP specifications, but not necessarily using USP test methods
	Microbiological Testing	Bulk material tested at release for bacterial endotoxin and USP microbial enumeration test	
	BSE/TSE	Certificate may be available upon request	Certificate provided
Quality Assurance	Data Review	Reviewed by QC	



Product Quality Designations at Cambridge Isotope Laboratories SP and MG Products

NOTES:

1. Please note that “S&P tested” and “MG” products are not guaranteed to be sterile and pyrogen-free when received by the customer, and microbial enumeration and endotoxin testing does not imply suitability for any intended use. If the product must be sterile and pyrogen-free for an intended application, CIL recommends that the product be packaged or formulated into its ultimate dose form by the customer or appropriate local facility. The product should always be tested by a qualified pharmacy/facility prior to actual use.
2. Systems controlled by departmental management or subject to departmental management approval are the responsibility of the operating department and are controlled by the departmental manager
3. BSE/TSE statements are developed on a risk estimate basis that meets or exceeds the guidelines laid out in section 5.2.8 European Pharmacopeia Fifth Edition. CIL does not use mammalian sourced materials whenever possible and rarely uses materials of bovine origin.
4. Technical data packages for –SP and –MG products may be available upon receipt of an executed CDA.