Product Quality Designations

Cambridge Isotope Laboratories, Inc (CIL) and Euriso-Top(ET). produce stable isotope labeled products at several levels of control beyond the standard research product grade. These grades are designated as **CTM** and **MPT** in the catalog number. A brief description of the two grades of products are:

- **CTM** – Clinical Trial Materials are manufactured in accordance with Section 19 of the ICH Guidance Q7, "**GMP** Guidance for Active Pharmaceutical Ingredients (APIs)" to mutually agreed upon specifications and regulatory controls.
- **MPT** – Microbiological and Pyrogen Tested products are research grade products that are tested in the bulk form for *S. aureus, P. aeruginosa, E. coli, Salmonella sp.,* aerobic bacteria, yeast, and mold and for bacterial endotoxins.

The table below demonstrates the level of controls applied to manufacturing, quality control, quality assurance, and the testing applied to each grade of product.

		CTM Products	MPT Products
Manufacturing	Synthetic Methods	Products prepared according to an approved, documented batch record	Catalog products may be prepared under Standard Operating Procedure (SOP) or following laboratory notebook procedures
	Packaging	Performed in dedicated GMP Facility with Quality Assurance (QA) release. Validated and monitored environmental controls. Labels are reviewed and approved by QA with label reconciliation.	Performed in dedicated Packaging Dept with environmental controls. Labels are produced and reviewed by the Packaging Department. Records are maintained by the Operations and Logistics Department.
	Standard Operating Procedures (SOPs)	Batch record and SOPs reviewed, approved and retained by Quality Assurance (QA)	SOPs controlled by departmental management
	Raw Material Traceability	QC testing and QA release of raw materials	May be available upon request
	Contact Glassware	Dedicated / New glassware and/or glassware cleaned per cleaning verification protocol	Standard laboratory cleaning, glassware used for multiple products
	Facility Management	FDA audited, environmentally controlled GMP ISO Class 8 facility with room clearance procedure and/or Product Changeover Procedure	Environmentally Controlled. Certified Hoods.
	In-Process Testing	Performed by QC using scientifically sound, documented methods or USP / EP methods*	Performed by Production or Quality Control personnel

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		CTM Products	MPT Products
Quality Control	Test methods	Performed by QC using scientifically sound, documented methods or USP/EP methods*	Standard practice or written test methods
	Standard Operating Procedures	QA Reviewed and approved	SOPs controlled by departmental management
	Out of Specification	Documented QA/QC controlled procedure and QA approval.	Operations and Logistics Department review
	Microbiological Testing	Bulk material tested at release by USP <61> Microbial Enumeration[2]	Bulk material tested at release for *S. aureus, P. aeruginosa, E. coli, Salmonella sp.,* aerobic bacteria, yeast and mold and for bacterial endotoxins.[2]
Regulatory / Quality Assurance	Final Data Review	Reviewed by QC and QA	Reviewed by Operations Quality review group
	Certificate of Analysis	Prepared/approved by QA	Provided by Operations and Logistics
	Material Specifications	Mutually agreed upon specifications between CIL/ET and customer. Approved by QA.	Determined by CIL/ET
	BSE/TSE	Certificate provided	Certificate may be available upon request
	Document Control	Documented QA controlled procedure	Follow departmental procedures
	Change Control	Documented QA controlled procedure	Departmental management approval
	Deviation	Documented QA controlled procedure and investigation	Departmental management approval
	Retain Samples	Retain samples are kept in accordance with CIL's SOPs for a minimum period of three years after the distribution of the batch.	Not required
	for a Record Retention	In accordance to CIL/ET's SOPs, records are retained minimum of five years.	Departmental records are retained for a minimum of five years
	Product Stability	May be available at an additional fee	Not routinely tested
	Drug Master Files	May be available at an additional fee	Not applicable

* USP/EP analytical methods may be modified to reduce the amount of material required for testing.

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NOTES:

1. CIL/ET's CTM products are labeled “For Investigational Use Only. The performance characteristics of this product have not been established”. CIL's MPT products are labeled “For Research Use Only. Not for use in diagnostic procedures”.

2. Please note that CTM and MPT products are not guaranteed to be sterile and pyrogen-free when received by the customer and microbiological and pyrogen testing does not imply suitability for any desired use. If the product must be sterile and pyrogen-free for a desired 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.

3. Systems or procedures controlled by departmental management or subject to departmental management approval are the responsibility of the operating department.

4. 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/ET does not use mammalian sourced materials whenever possible and rarely uses materials of bovine origin.

5. CILa,d ET offer an Enhanced Data Package (EDP) for most CTM and MPT products. It includes annotated data for the CTM or MPT product, plus additional information pertaining to the synthesis, purity, and stability of the product. This is available for an additional charge. EDPs may be require an executed CDA. Please inquire for further details.