Cambridge Isotope Laboratories, Inc.



50 Frontage Road, Andover, MA 01810-5413 USA PH: 800.322.1174 (N. America) PH: 978-749-8000

Fax: 978-749-2768 URL: www.isotope.com

CIL Enhanced Technical Data Package (EDP)

To better serve our customers' needs, CIL is proud to announce the option of an Enhanced Technical Data Package. This data package is available for most –MPT products. It includes all of the data currently included with the -MPT products, as well as the additional information listed below.

Our customers have the option of purchasing this package at the time of order or at a later date. *Please* note that if you choose to purchase at a later date, some of the information listed below may not be available. Also, the EDP may not be available for all lots; availability to be confirmed prior to order.

Enhanced Technical Data Package Contents:

- 1. Additional testing data; products with an EDP have been tested to the specifications detailed in USP or EP, but not using compendia methods.
- 2. Product description: structural formula, stereochemical description, molecular formula.
- 3. Product physical properties: melting point, pH, optical rotation (mix of literature or measured values).
- 4. Outline of the synthesis route, including details of solvents used.
- 5. Data used to confirm structure and chemical purity.
- 6. Impurity profile: available data on impurities detected and identified together with the method of detection and the cutoff applied.
- 7. Residual solvents: measured residual solvents from the final synthetic step and purification.
- 8. Certificates of Analysis raw materials as appropriate.
- 9. Stability data: estimated and measured.
 - a. This will be either actual shelf life data, if it can be obtained from CIL history or by analysis of in-stock batches or,
 - b. If no data is available, CIL will commit to assaying the batch provided after 6 months and 1 year. Data will be provided after 1 year, unless the batch fails assay after 6 months. This option will not be available if the Enhanced Data Package is ordered at a later date.