

ISOTEC® STABLE ISOTOPE CUSTOM SYNTHESIS AND CGMP CAPABILITIES



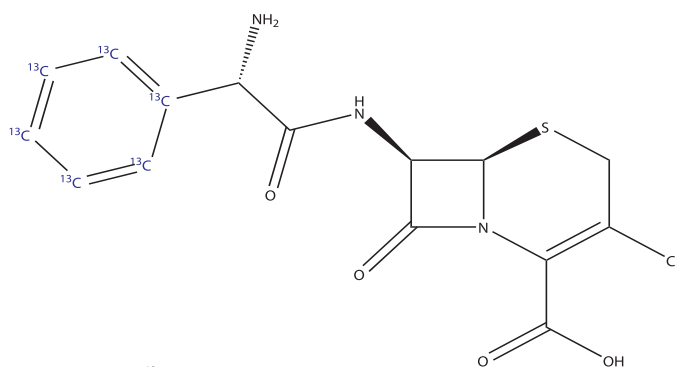
ISOTEC® Specializes in the Custom Synthesis of Complex Stable Isotope Labeled Products

Stable isotope containing compounds are utilized in a wide range of applications, including tracers in clinical studies, labeled amino acids for use in protein quantification and standards for metabolic research. As science and applications evolve, new labeled substrates are needed.

Isotec Stable Isotopes specializes in the custom synthesis of labeled compounds. Isotec employs a highly trained group of stable isotope scientists led by industry expert, Dr. C.T. Tan. This group has a wide range of chemistry expertise ensuring the synthesis of a vast array of compounds. The stable isotope R&D group routinely engages in complex, multi-step syntheses of a wide range of complex compounds with a variety of labeling patterns, including:

- Amino acids
- Biomarkers
- Building blocks
- Carbohydrates
- Drugs
- Fatty acids
- Metabolites
- Synthetic reagents

Our facilities give us the capability to perform syntheses ranging from milligram to kilogram quantities, provide custom packaging services and guarantee client confidentiality. In addition, we offer a variety of product grades including S&P tested to full GMP utilizing the most rigorous standards in the industry to verify that the products meet customer specifications.



Cefaclor-phenyl-¹³C₆ (678198)

ISOTEC Synthetic Expertise Includes:

- Alkylations
- Asymmetric synthesis
- Biosynthesis
- Bromination and iodination
- Carbohydrate chemistry
- Carbonylation
- Catalytic reductions (high and low pressure)
- Diazotizations
- Diels-Alder reactions
- Enzymatic reactions
- Esterifications

ISOTEC® Routinely Produces cGMP Grade Material to Meet Any Need

ISOTEC Stable Isotopes also has the scientific and regulatory expertise to meet any cGMP product need. From the beginning, each project is supported by a team of chemists experienced in the manufacturing, testing and control of cGMP materials. This includes a project leader who serves as a single point of contact. Good Manufacturing Practices are followed for the production, testing, packaging and release of regulated products. Also, ISOTEC is ISO certified and its facilities are FDA inspected. Though manufactured in compliance with current regulatory requirements, all ISOTEC products require further manufacturing, processing or repacking in compliance with applicable laws before being used in FDA-approved applications.

Production

The cGMP production team is experienced in all phases of bulk pharmaceutical manufacturing, from process development through scale-up. They are capable of optimizing the synthetic route for new compounds and process validation for later-phase projects, and also routinely manufacture established bulk APIs. ISOTEC also has the advantage of having a reliable and consistent supply of raw materials from Sigma-Aldrich, including an extensive inventory of stable isotope labeled compounds.

For more information on these services or to request a custom quote, contact:

Stable Isotopes Customer Service

Phone : (937) 859-1808
US and Canada : (800) 448-9760
Fax : (937) 859-4878
Email : isosales@sial.com
Website : aldrich.com/isotec

Analytical

ISOTEC's analytical group of chemists and scientists constantly develop new methods to determine the chemical and isotopic purity of its products by using a variety of instrumentation and compendial methods. This experience provides a strong foundation for developing and validating the analytical methods needed to ensure the quality of its cGMP products. ISOTEC has developed stability indicating assays, isotopic analyses and impurity profiles to fulfill its customers' requirements. Stability studies are performed following ICH guidelines.

Quality Assurance

ISOTEC's QA team has the knowledge and expertise to fulfill its customers' cGMP regulatory needs. They are responsible for the review and approval of specifications, procedures, batch records and validation activities. They also control product release, conduct audits and provide training. ISOTEC maintains DMFs in over 15 countries and regularly provides documentation to support its customers' regulatory filings.

*Enabling Science to
Improve the Quality of Life*

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