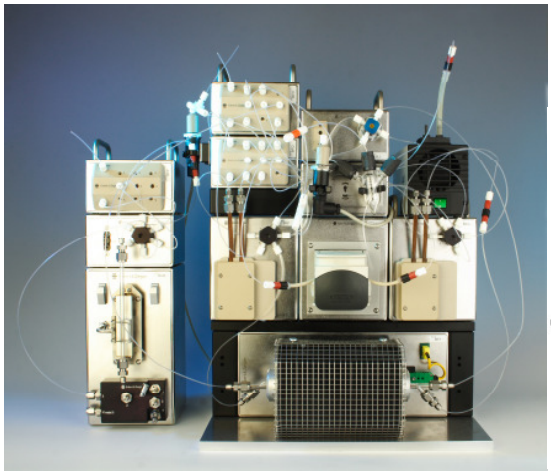
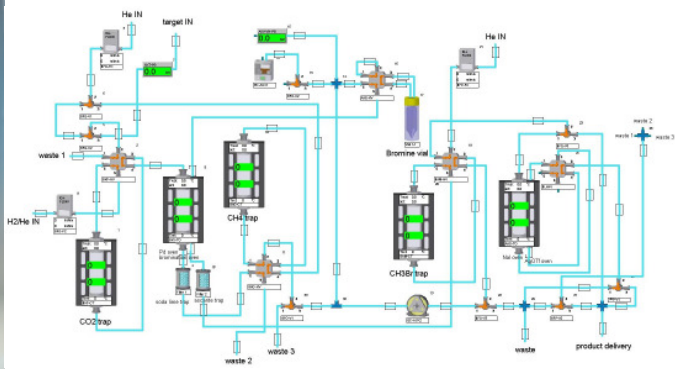
Modular-Lab

For gas-phase [^{11}C]Methyl Iodide production





The Modular-Lab technology opens new production possibilities of Carbon-11 based tracers for clinical use – gas-phase [^{11}C] methyl iodide production.

Application

Carbon-11 - characterized by its relatively short half life - has the advantage to be applicable for repeated PET studies while still allowing multi-step radiosynthesis sequences. [^{11}C]methyl iodide is the most important and frequently used secondary ^{11}C-labelling precursor. Its versatility allows the synthesis of a wide variety of PET tracers.

Technology

[^{11}C]methyl iodide can be easily produced with the automated synthesis device Modular-Lab* resulting in high radiochemical yields and high specific radioactivity. The Modular-Lab technology now offers an alternative to the already existing liquid-phase method - the gas-phase based production of [^{11}C]methyl iodide ([^{11}C]CH_3I) and [^{11}C]methyl triflate ([^{11}C]CH_3OTf) respectively.

Instead of using liquid nitrogen for [^{11}C]CO_2 trapping, the cyclotron produced [^{11}C]CO_2 is reversibly adsorbed to molecular sieves (CTM technology) or Carbosphere™ material (CCTM technology). After controlled release by heating the adsorbing material, [^{11}C]CO_2 is converted into [^{11}C]CH_4 (Methane) by hydrogenation of [^{11}C]CO_2 in a Palladium oven (TOM). The generated [^{11}C]CH_4 is then adsorbed and processed to ^{11}C methyl bromide, which can be converted to [^{11}C]CH_3I - using a sodium iodide oven - or [^{11}C]CH_3OTf - using a silver triflate oven. The produced [^{11}C]CH_3I or [^{11}C]CH_3OTf is then available for tracer synthesis. If desired more modules can be easily included into the system. The products can be purified by SPE or, if necessary, an HPLC can be easily integrated into the system.

Standard Regulatory Compliance

The Modular-Lab Software combines easy programming via a self-explanatory graphical user interface complying with GMP, GAMP 4/5 and 21 CFR part 11 regulations.

Advantages

- Higher yields and higher specific activity compared to the liquid-phase method
- Multiple batches without needs for apparatus replacement or setup

*patent pending

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Key Features

- Fully automated synthesis process, no user intervention necessary
- Fully automated cleaning routine after each process to ensure a minimum of chemical or bacterial contamination of the system
- Plug & play system setup through integrated bus-system
- Traceability of the complete process, including documentation of all process parameters and functions
- Upgradeable for further applications
- Short synthesis and pre-preparation time
- Turnaround time between successive batches of [^{11}C]methyl iodide: 20 to 30 minutes

Modular-Lab Components

Tube Oven Module (TOM) (double tube oven, horizontal setup)	Dimensions: 130 x 130 x 314 mm The Tube Oven Module (TOM) is a used for continuous flow reactions of gases on hot surfaces. The oven has an inner diameter of 15 mm and a heated zone of the length of 100 mm. The reaction takes place in a quartz glass tubes within the TOM. The TOM can be fitted with two quartz glass tubes (OD = 6.35 mm / ¼") which are kept in place by two holders. The quartz glass tubes are connected with a Teflon ferrule - using Swagelok™ connectors - to a standard 1/16" tube and fixed by two holders. They can be filled with different catalysts or other filling material. The TOM can be operated up to 900°C. Active cooling is not possible.
Cooled Carbon Trapping Module (CCTM)	Dimensions: 130 x 130 x 156 mm The Cooled Carbon Trapping Module (CCTM) is used for reversible adsorption of radioactive gases. It is directly connected to target and gas supply. [^{11}C]CO_2 from a cyclotron is trapped inside a copper U-tube filled with carbosphere™ for adsorbing gases. The U-tube is equipped with Swagelok™ connectors that can be easily connected to Teflon, FEP or PEEK tubing material. The trapped [^{11}C]CO_2 can be separated from the target gas by a flow of inert gas through the U-tube. By heating the U-tube [^{11}C]CO_2 is released from the carbosphere™ and can be swept out of the U-tube with gas suitable for further processing. Heating and cooling is achieved with integrated Peltier elements.
Carbon Trapping Unit (CTM)	Dimensions: 130 x 130 x 234 mm Trapping of [^{11}C]CO_2 is achieved by a molecular sieve at room temperature. The column for heating is supplied by VICI with following attributes: 1/4"x5cm and 1/16" tube fitting. Compressed air influx through 4mm tubing and 2/2 way valve. Gas distribution is performed by a valve manifold with two types of connectors: 1/16" tube fitting to waste, reactor and column; 1/8" tube fitting for [^{11}C]CO_2 and Helium gas. The gases are distributed by 3/2 way valves. The Helium flow is especially controlled by an integrated Helium flow controller ranging from 0 to 150 ml/min (max. pressure: 3 bar).
Flow Controller Module (FCM)	Dimensions: 130 x 130 x 78 mm A flow controller module (FCM) is used to control a flow of a certain gas in a limited range. This module contains a mass flow controller and three 3/2 way valves.

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