Modular-Lab PharmTracer

For production of ^{64}Cu

A powerful solution from a creative triad

Introduction

The positron-emitting radionuclide ^{64}Copper is a relevant radionuclide for applications in Nuclear Medicine such as antibody labeling (diagnosis) or immunoPET with fully intact mAbs (therapy).

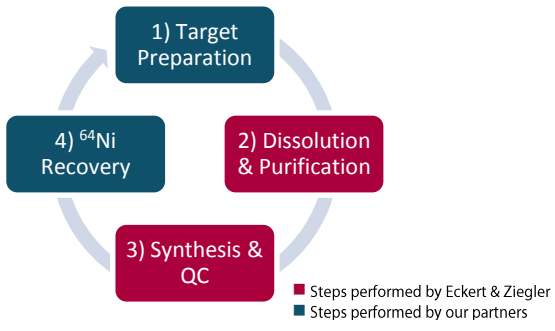
Production of ^{64}Copper

The production of ^{64}Copper has been a complicated process so far, especially when referring to the dissolution and purification of ^{64}Copper from ^{64}Ni and Cobalt.

Active together - the partners

To face such a challenge it takes competent and experienced partners. In cooperation with the Scientific Research Department of the Sant'Orsola Hospital Bologna, Italy and the hot cell and radioprotection equipment manufacturer TEMA Sinergie, Italy we created a turn-key solution for the easy and validated production and automated purification of ^{64}Copper, the recovery of ^{64}Ni and synthesis of ^{64}Copper based radiopharmaceuticals.

The automated solution



Step 1: Target Preparation

The target is prepared through electro galvanic deposition of enriched ^{64}Ni on a pure gold disc by the Electro Deposit Unit. The coin will be manually loaded into the irradiation unit. Irradiation, cooling and coin release phases take place at cyclotron and are at target manufacturer charge.

The Solid Target Transport System (STTS) transports the irradiated coin from the irradiation unit to the destination hot cell in the chemistry lab, for the pre-synthesis and synthesis operations. Up to 6 coins can be transferred with the STTS. To avoid cross contamination metals and halogens are moved through two separate transfer lines.

Step 2: Dissolution and Purification

The Modular-Lab synthesis technology allows the fully automated and reproducible production of ^{64}Cu based radiopharmaceuticals, including the separation from ^{64}Ni target material, purification and labeling of the final product. The tubing-based Modular-Lab Standard part of the ^{64}Copper system enables the dissolution of the solid target (Ni/Cu on gold medal) and the automated purification of 64Cu on resin.

Step 3: Synthesis & Quality Control (QC)

The tracer labeling will be carried out with the cassette-based Modular-Lab PharmTracer. The sterile and disposable synthesis cassettes guarantee a sterile fluid path without the need of cleaning validation for full compliance to GMP standards.

Step 4: ^{64}Ni Recovery

After the dissolution of the target ^{64}Nickel is separated from ^{64}Copper. A step for ^{64}Ni recovery and recycling to prepare future targets is established (electrochemical depostition). By this it can be used again for the target preparation.

Application Results	
Heating Temp. to dissolve the target	95° C
Heating Time to dissolve the target	45 minutes
Radionuclide Purity	> 99.99 %
Recovery Fraction	2 - 3 ml
Recovery of ^{64}Cu	~ 80%
Reaction Time	150 min
Overall Recovery of ^{64}Ni	> 98%

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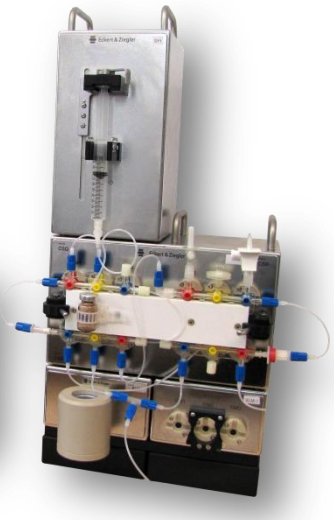
Key Features

- Fully automated process, no user intervention necessary
- Sterile, disposable cassettes with a complete closed fluid path for full compliance to GMP standards
- Pre-validated process for a standardized and reproducible synthesis of ^{64}Cu-ATSM
- Same configuration can be used for different application of ^{64}Cu labeling (e.g. ^{89}Zr produced from ^{89}Y)
- 80% of activity available for use

Technical Features

Dimension of the system:	Synthesizer	262 x 220 x 560 mm (W x D x H)
	Purification Unit	262 x 200 x 480 mm (W x D x H)
Power Supply:	Electrical Cabinet (EC) / Power Interface Module (PIM) 115 V ~ 60Hz or 230V ~ 50 Hz	
Software:	Modular-Lab / Modular-Lab SoftPLC	
Interfaces:	Ethernet / USB	

Modular-Lab Standard Purification Unit



Modular-Lab PharmTracer Synthesis Unit

This project is a cooperation of

Eckert & Ziegler Eurotope

Tema Sinergie

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