

## Setting up radiolabeling of <sup>68</sup>Ga-NODAGA-Exendin-4

Authors: Victor EL-JAMMAL1; Fouzi KHAYI1; David KRYZA1,2,3

1: Service de médecine nucléaire LUMEN, Radiopharmacie, Hospices Civils de Lyon et Centre Léon Bérard, Lyon, France; 2: Hospices Civils de Lyon, France; 3: Université de Lyon; Université Claude Bernard Lvon 1. France

Purification cartridge: (5)

Elution: WFI/Ethanol 60:40



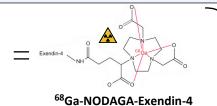
#### Introduction

Gallium 68, positron emitter

→ PET/CT scan

**Exendin-4** agonist of the GLP1 receptors → highly expression in insulinomas:

pancreatic neuroendocrine tumors



Investigational

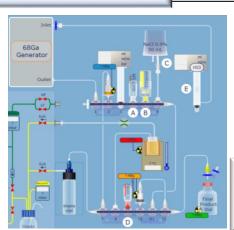
## **Objective**

Setting up radiolabelling of 68Ga-NODAGA-Exendin-4

Preparation of the Investigational Medicinal Product Dossier (IMPD)

Request for compassionate use (French Agency for the Safety of Health Products)

#### Materials and methods





Laminar Flow Isolator





radiopharmaceutical used in **PET imaging** of insulinomas

EDTA/Tween

15min (3)

50 μg peptide + WFI + Acid Asc. +

**HEPES** 

Summary of the radiolabelling sequence

#### Results

### The 3 validation batches comply with all the criteria tested at t0 and t+2h:

- Organoleptic properties
- Activity (MBg/mL)
- На

ransfer by

filtration

- Half-life
- Radiochemical purity
- Radionuclide purity
- Residual solvents: HEPES, ethanol
- Sterility test
- **Endotoxin test**
- Media Fill Test
- Bioburden Test
- ✓ Filter Integrity Test

User interface (sequence control and programming module)

# Programming and testing the radioactivity-free automated sequence Execution of 3 validation batches 3 Process and final product controls

Setting up radiosynthesis

At the same time

**Analytical** method validation

Equipment qualification Raw materials qualification

Elution: NaCl 5M (2)

Elution 68 Ga

in HCl 0,1M

Manufacturing process description

### Conclusion

The analytical methods were validated in accordance with the European Pharmacopoeia and the three synthesis batches complied with the specifications defined. Following data integration into the IMPD, the National Agency for the Safety of Medicines and Health Products has authorized us to synthesize and use 68Ga-NODAGA-Exendin-4 in clinical applications.

Contacts

victor.eljammal@hotmail.fr fouzi.khayi@lyon.unicancer.fr david.krvza@lvon.unicancer.fr