

Implementation of DOTATOC-Gallium 68 (⁶⁸Ga) radiolabelling

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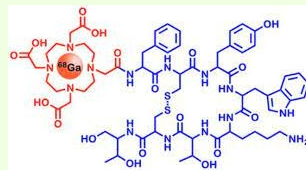
Introduction :

⁶⁸Ga-DOTATOC : radiopharmaceutical drug indicated in the diagnosis of neuroendocrine tumors. Radiolabelling = a complexation reaction between ⁶⁸Ga and a somatostatin analogue (DOTATOC).

It requires :

- radiation protection constraints
- special conditions of hygiene
- strict parameters : temperature and pH

→ **Objective = to implement ⁶⁸Ga-DOTATOC labelling in our department**



Results/Discussion :

9 compliant syntheses : RCP 99,26 % (± 0,31)

Microbiological controls :

- **Preparations** → 100% compliant (10/10)
- **Gloves** → 3/14 non-compliant with 1CFU
- **Shielded workstation** → 100% compliant (2/2)

N=1

Manual

(vacuum by air intake)

7 min à 95°C

120 minutes

N=10

Automatic

(vacuum with tubing 15cm)

2 min à 120°C + 7 min à 95°C

45 minutes

N=4

Automatic

0,57mL buffer → adaptation to the the 3-way valves dead volume

2 min at 120°C (to let the oven reaches 95°C) + 7 min at 95°C

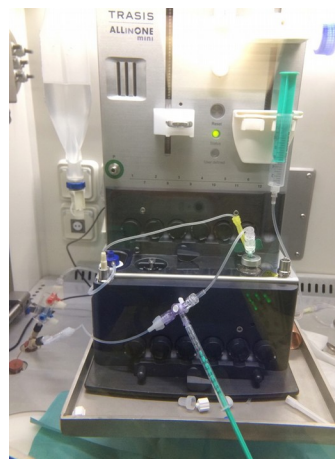
pH 2,5 and **RCP 6,96%** : Tubing 30cm≠15cm (theory)



→ too long to vacuum

→ buffer not fully injected


75 minutes



Synthesis module installation (MiniAiO®)

Material and methods :

- 10 manual or automatic syntheses → Mini AllinOne® synthesis module
- Preparation parameters compared to those described in Summary of Product Characteristics : **buffer volume** (0.5mL), **temperature and heating time** (95°C ≤ 10 minutes)
- Quality and microbiological controls :

Quality controls (QC)		Microbiological controls
Organoleptic characteristics		Preparations
Clear		BacTALERT® bottle
pH	3,2 – 3,8	 Results : positive or negative
TLC	RCP ≥ 97%	
Stationary phase	ITLC-SG paper	Gloves
Mobile phase	ITLC 1 : Ammonium acetate 1M / methanol (1:1 V/V)	Blood agar
	ITLC 2 : Sodium citrate 0,1M pH5	Shielded workstation
⁶⁸ Ga uncomplexed = 0 – 0,1 ⁶⁸ Ga-Dotatoc = 0,8 – 1		Contact agar
⁶⁸ Ga-Dotatoc = 0,1 – 0,2 ⁶⁸ Ga free = 0,9 – 1		standard <5 CFU

- Total duration = material preparation + synthesis + QC

Conclusion : This radiolabelling is sensitive to technical characteristics and also to the knowledge/availability of medical devices. Its optimization and the satisfactory hygiene results have allowed the implementation of this technique in routine.

→ Other molecules could be radiolabelled with ⁶⁸Ga.

