

Impact of hospital production vs commercial kits purchase of ^{68}Ga -DOTA peptides.

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Introduction:

^{68}Ga -DOTA peptides, somatostatin analogs, are used for neuroendocrine tumors diagnosis. Commercial kits of ^{68}Ga -DOTATATE are available for this indication with an expansive supplying.

Purpose:

Evaluation of the impact of a switch from commercial kits to an hospital production of ^{68}Ga -DOTATOC.

Material and methods:

Quality dossier for SWISSMEDIC.

Description of synthesis process:

- 3 validation batches.
- Modular synthesis : Mini AiO[®] (TRASIS, Belgium).

Description of quality control (QC) process:

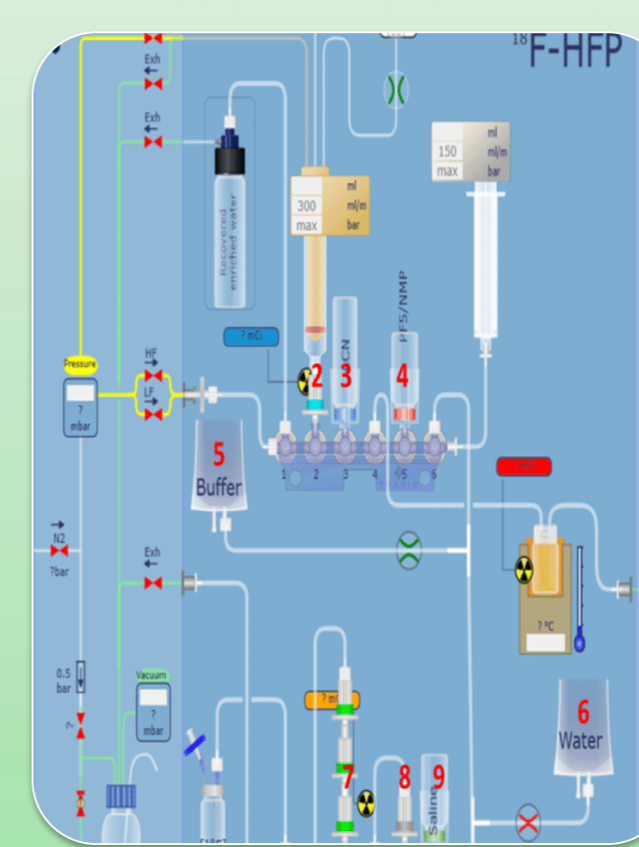
- All required QC in European Pharmacopeia (8th edition).
- Filter integrity test (Mini AiO[®]).
- Microbiological analysis : sterility + endotoxin.



Mini AiO[®] devices: modular + software.

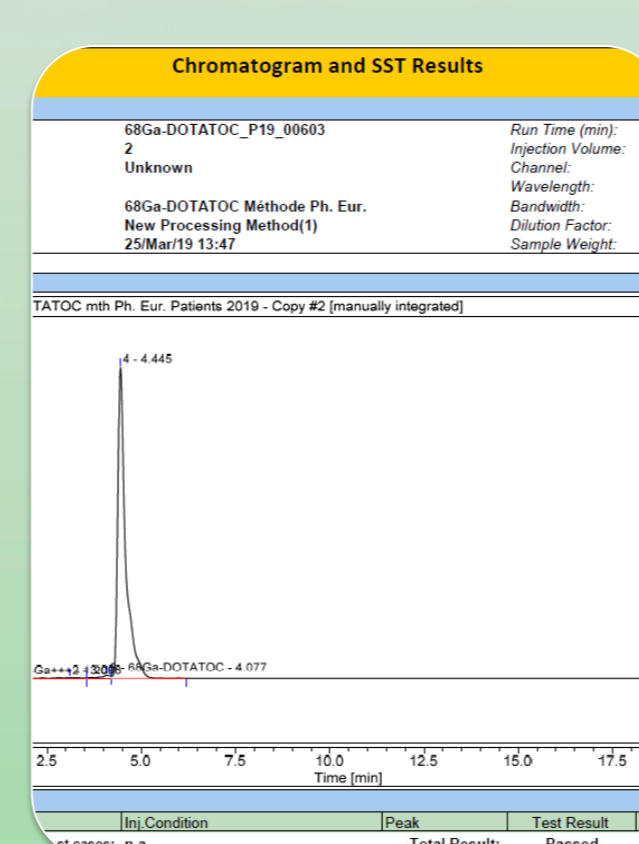
Synthesis of ^{68}Ga -DOTATOC was compared to ^{68}Ga -DOTATATE kits in regards to costs and time of production.

Results and discussion:



^{68}Ga -DOTATOC synthesis:

- Activity yield: $84.4\% \pm 6.31\%$
- Radioprotection benefits.



QC parameters:

- Radiochemical purity: $99.36\% \pm 0.15\%$
- Residual ethanol: $7.77\% \pm 0.83\%$
- Sterility conditions in the entire process (microbiological analyses).
- Filter integrity test successful for all validation batches.



Comparison with ^{68}Ga -DOTATATE kits:

- Synthesis + QC process longer (60 min + 130 min vs 30 min + 15 min).
- More QC needed with ^{68}Ga -DOTATOC synthesis (HPLC, TLC, GC).
- Additional human resources needed.
- Cheaper than ^{68}Ga -DOTATATE kits.

Microbiological analyses:

- Only on validation batches and every 6 months (class A GMP).
- Filter integrity test before pharmaceutical release.

130 synthesis per year scheduled by nuclear medicine department

→ Important saving for the institution allowed by ^{68}Ga -DOTATOC production.

Conclusion:

Compared to commercial kits available in Switzerland, ^{68}Ga -DOTATOC is conveniently prepared in sterile conditions by using Mini AiO[®] with:

- High radiochemical purity (> 99.3%).
- Enough final activity for 2-3 patients in a single batch.
- Advantageous costs saving.

These results prompt to extend this work to other ^{68}Ga radiotracers.

Radioprotection benefits of automatized synthesis vs manual preparation of commercial kits could be assessed in a future study.