



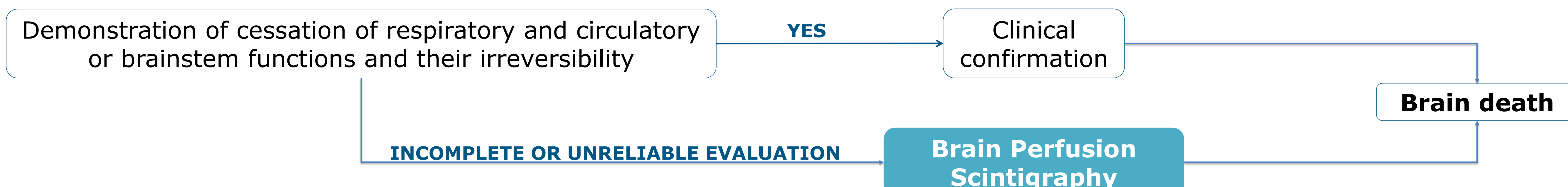
## Brain Death: radiochemical purity of the Radiopharmaceutical $^{99m}\text{Tc}$ -HMPAO stabilized with cobalt

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### Why was it done?



### Brain Perfusion Scintigraphy

- ✓ Performed after injection of the radiopharmaceutical technetium-99m hexamethylpropyleneamine oxime ( $^{99m}\text{Tc}$ -HMPAO);
- ✓ It evaluates, through the images obtained, the **absence of cerebral perfusion**;
- ✓ A **high radiochemical purity** of  $^{99m}\text{Tc}$ -HMPAO is required in quality control (QC) → prevent false positives.

### What was done?

- ✓ Selection of a method to evaluate the radiochemical purity of  $^{99m}\text{Tc}$ -HMPAO.

### How was it done?

- ✓ A **literature review** was conducted to select the most suitable method for the conditions existing in the institution.
- ✓ The research focused on the Summary of Product Characteristics (SmPC), the European Pharmacopoeia (Ph. Eur. 11.0), the United States Pharmacopoeia (USP 42) and several published articles.

### What has been achieved?

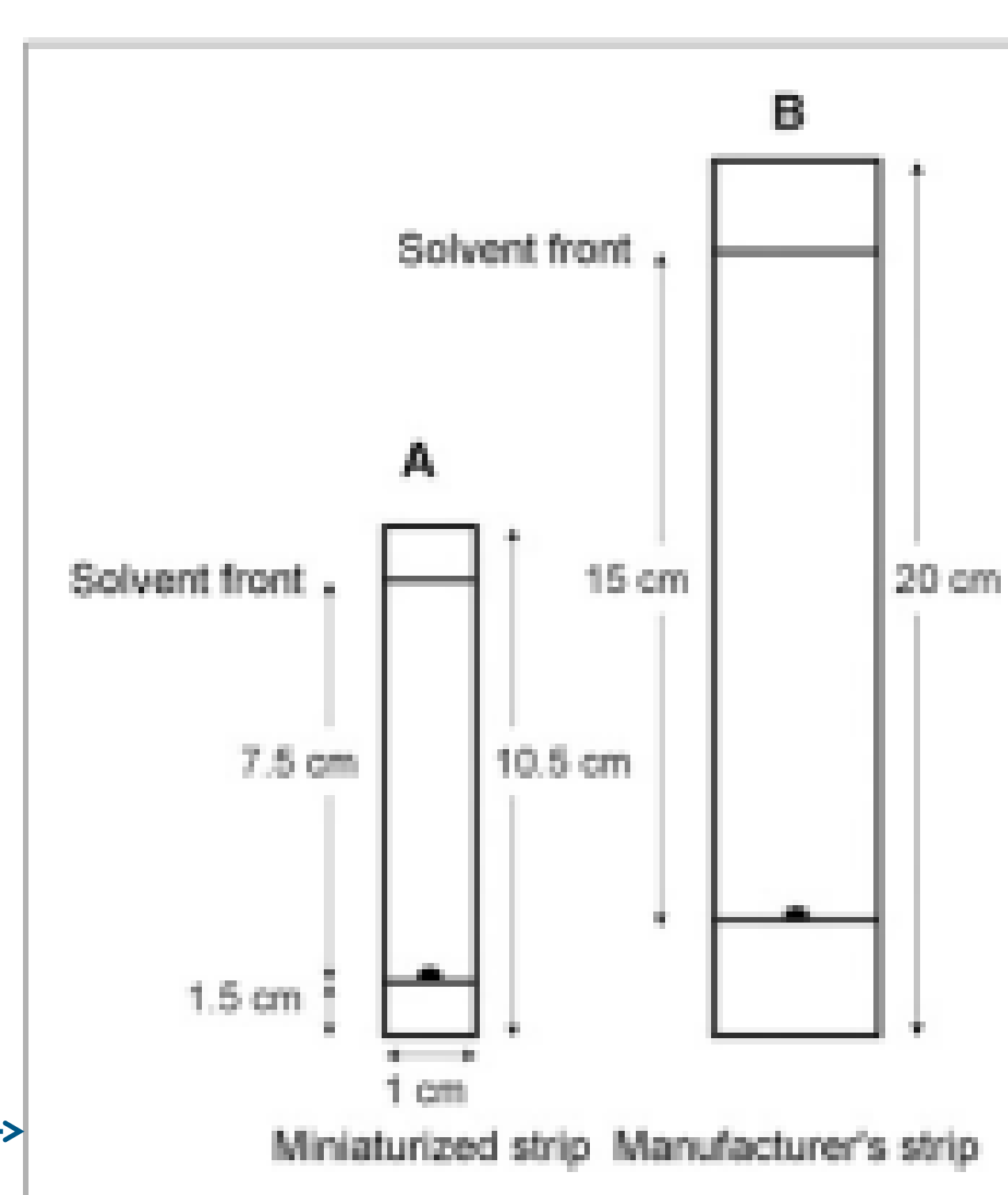
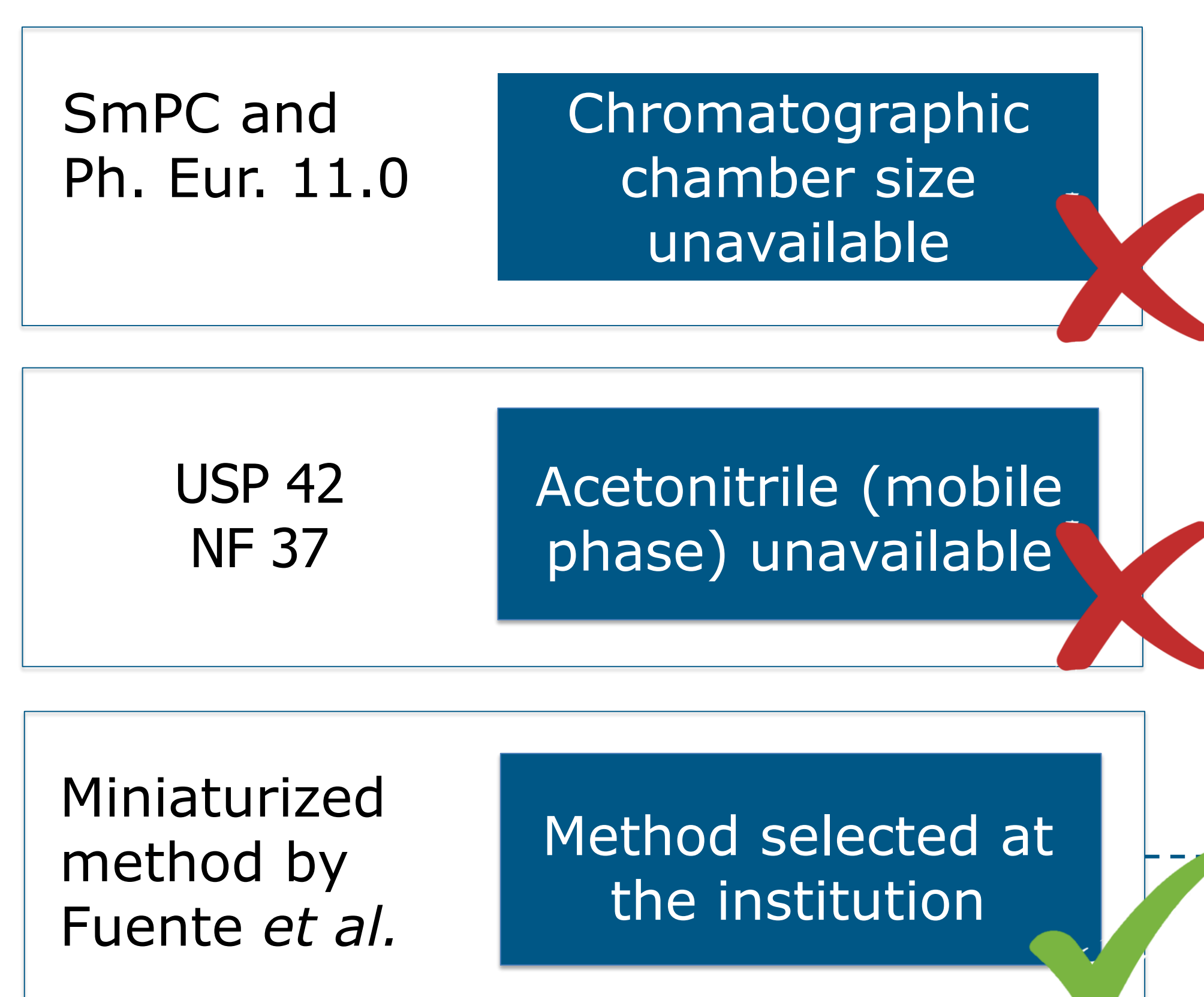


Figure 1 –  $^{99m}\text{Tc}$ -HMPAO QC method adopted at the institution (adapted from [5]).

### General Specifications:

- pH: 5 to 8
- clear and yellowish aqueous solution
- Quality control
  - % System 1 (ITLC<sub>SG</sub>/MEK)  
 $^{99m}\text{Tc}$ -RH +  $^{99m}\text{Tc}$ -HMPAO 2°  
Rf=0
  - % System 2 (ITLC<sub>SG</sub>/NaCl 0,9%)  
Free  $^{99m}\text{Tc}$   
Rf=1
- %radiochemical purity>80%

Figure 2 –General QC Specifications of  $^{99m}\text{Tc}$ -HMPAO [2]

Data	Referência Radiofármaco	Operador	pH	Características Físicas	Impurezas % Sistema 1 (ITLC-SG/MEK) Rf=0	Impurezas % Sistema 2 (ITLC-SG/NaCl) Rf=1	%pureza radioquímica (pentetato de tecnécio)	Conformidade	Libertação pelo Farmacêutico (iniciais e nº mec)	Coluna1
22-07-2022	230322E1CERETEC	SM	7	Conforme	3,98%	0,30%	95,72%	Conforme	SM 12874	Ensaio 1
05-08-2022	230405E1ceretec	LA	7	Conforme	3,66%	0,4%	95,93%	Conforme	LA 11409	Ensaio 2
10-08-2023	20230804e2hmpaomak	LA	6	Conforme	4,5%	0,7%	94,75%	Conforme	LA 11409	Ensaio 3
11-04-2023	20230411E1ceretec	SM	6	Conforme	4,0%	0,5%	95,45%	Conforme	LA 11409	Morte cerebral
14-06-2023	20230614E1certec	SM	6	Conforme	2,6%	1,1%	96,31%	Conforme	SM 12874	Morte cerebral
30-08-2023	20280830E1HMPAO	SM	6	Conforme	2,8%	0,5%	96,69%	Conforme	SM 12874	
26-09-2023	20230926E2HMPAO	LA	6	Conforme	8,4%	3,5%	88,12%	Conforme	LA 11409	Morte cerebral

- ✓ Method validation:
  - ✓ Three assays were conducted, **yielding values exceeding 80%** (the reference value).
- ✓ The selected method represents a **rapid, reproducible** and **reliable** alternative for evaluating the radiochemical purity of  $^{99m}\text{Tc}$ -HMPAO.
- ✓ It was implemented in the institution in October 2022.

### What next?

- ✓ In the future, we aim to develop quality control methods for all radiopharmaceuticals in use at the institution, in order to guaranty the quality of all the exams performed.

### References

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2. Summary of Product Characteristics - CERETEC.: INFARMED, 2014.
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5. FUENTE, Ana de la [et al.] - Miniaturized Radiochemical Purity Testing for  $^{99m}\text{Tc}$ -HMPAO,  $^{99m}\text{Tc}$ -HMDP, and  $^{99m}\text{Tc}$ -Tetrofosmin. **Journal of Nuclear Medicine Technology**. 45:3 (Jul. 2017) 236-240.