



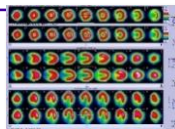
Development of a « flash » method based on thin-layer-chromatography for radiochemical purity assessment of ^{99m}Tc-tetrofosmin

Leyenberger Lisa, Grosjean Christine, Andanson Macchi Magali, Brentot Cédric
Centre hospitalier Montluçon – Nérès les Bains, 18 Avenue du 8 Mai 1945, 03100 Montluçon, France



Background/objectives

- Radiopharmaceutical : ^{99m}Tc-tetrofosmin, tracer of myocardial perfusion
- Determination of radiochemical purity (RCP) by thin-layer-chromatography (TLC) described in the summary of product characteristics (SPC) **very time-consuming**
- **Development and validation, according to the guidelines of the European Agency for Nuclear Medicine (EANM)¹, of a new faster TLC technique**



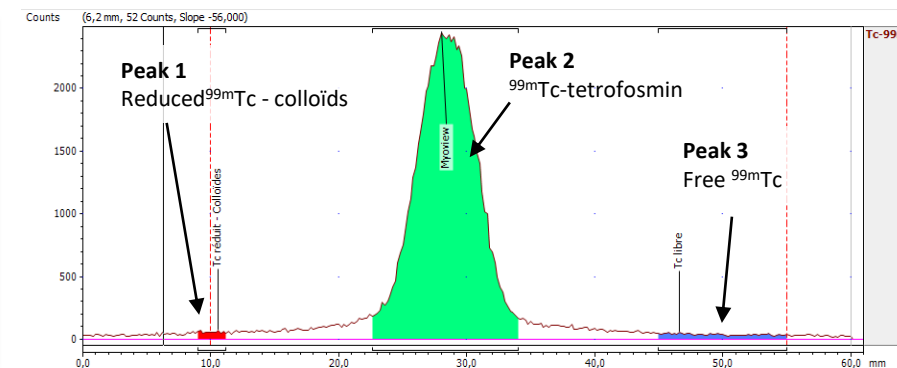
Materials and methods

	SPC Method	« Flash » Method
Mobile phase	Acetone/dichloromethane 65/35	Ethyl acetate/acetonitrile 65/35
Stationary phase	GMCP-SA 20cm x 2cm strip, 150mm migration distance	GMCP-SA 6cm x 0,7cm strip, 45mm migration distance
Student α = 5%	Comparaison of RCP, migration time	

Results

Parameter	Threshold	Obtained value
Specificity:		
Resolution $R_s = \frac{1,18 \times (RF_2 - RF_1)}{W_{h1} + W_{h2}}$	$R_s > 1$	$R_s(\text{peak 1} - \text{peak 2}) = 2,85 \pm 0,35$ (n=12) $R_s(\text{peak 2} - \text{peak 3}) = 2,35 \pm 0,37$ (n=12)
Accuracy:		
Recovery rate $\%R = \frac{RCP_{flash}}{RCP_{SPC}} \times 100$		$\%R = 99,8\%$ (n=6)
Comparaison of RCP	$p \leq 0,05$	$p=0,28$ ($n_{SPC}=6$, $n_{flash}=12$)
Precision/repeatability:		
Coefficient of variation (CV)	$CV \leq 15\%$	$CV = 0,35\%$ (n=12)
Duration:		
Migration time (MT)		$MT_{flash} = 2 \text{ min } 58 \text{ sec} \pm 22 \text{ sec}$ ($n_{flash}=12$)
Comparaison of MT	$p \leq 0,05$	$MT_{SPC} = 27 \text{ min } 29 \text{ sec} \pm 17 \text{ sec}$ ($n_{SPC}=6$)
Radiochromatograph analysis time (AT)		$p < 0,000001$ $AT_{flash} = 1 \text{ min } 3 \text{ sec}$ $AT_{SPC} = 2 \text{ min } 44 \text{ sec}$

Radiochromatogram obtained using the « flash » method



Discussion – conclusion

- Validation** of the method ✓
- A lot faster** → improved patient care
→ improved responsiveness in the case of non-compliance ☺
- « Miniaturization » (paper, solvent) → **more cost-effective** €
- Reducing employee exposure to dichloromethane, a category 2 carcinogen
→ **improve employee safety** ☺