# OPTIMIZATION OF QUALITY CONTROL FOR 68GA-EDOTREOTIDE (SOMAKIT®): TIME IS OF THE ESSENCE...

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## BACKGROUND AND IMPORTANCE

**Edotreotide (SomaKit®),** radiolabeled with $^{68}$Ga, is used in Positron Emission Tomography imaging to study somatostatin receptor overexpression. Quality control (QC), as outlined in the product summary (SmPC), includes determining radiochemical purity (RCP) via a two-system radiochromatographic method. The eluent migration step **is the most time-consuming in this process**.

→ **Aim and objectives :** This study aimed to **optimize** the radiochromatographic method by reducing the migration distance (Dm) while maintaining acceptable analytical performance.

## MATERIAL AND METHODS

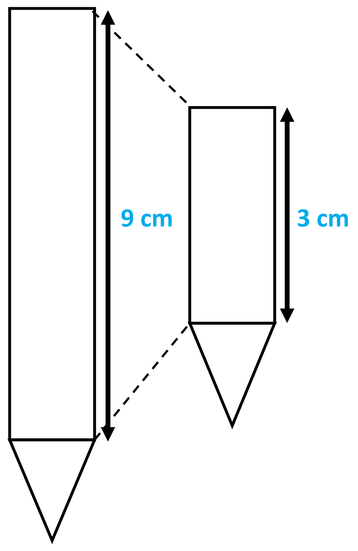
**10 trials**, each with 2 radiochromatographic systems :

| | System 1 | System 2 |
|---|---|---|
| **Stationary phase** | ITLC-SG | ITLC-SG |
| **Mobile phase** | 77g/L ammonium acetate in a 50:50 water/methanol | 0,1 mol/L sodium citrate in water |

Each trial used 4 chromatography strip :

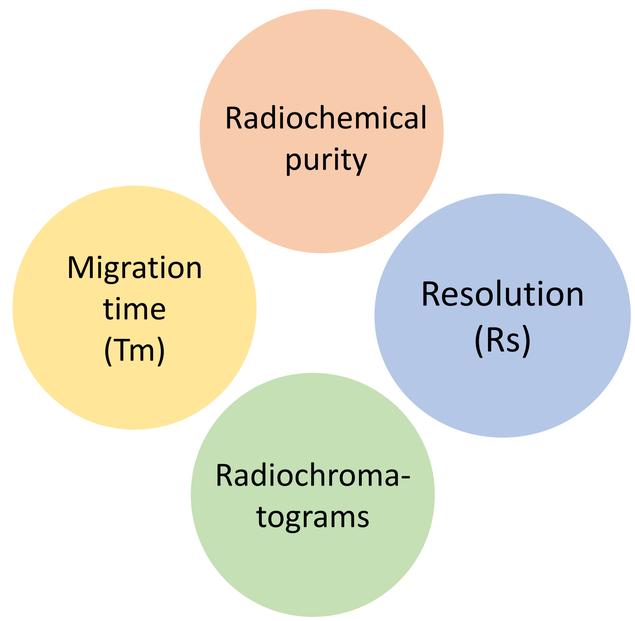
- 2 following the **SmPC** (12 cm strips with 9 cm of Distance migration Dm)
- 2 with a **alternative method** (4 cm strips with 3 cm of Dm)

**Reduction of Tm**




**Data analysis**

With Gina® software

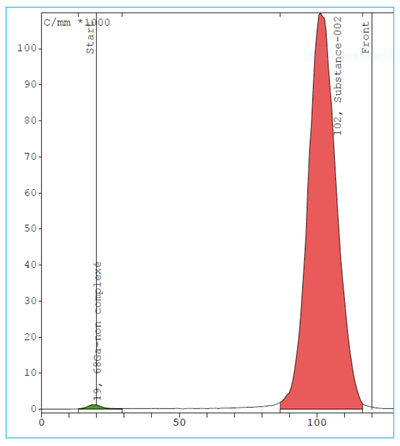


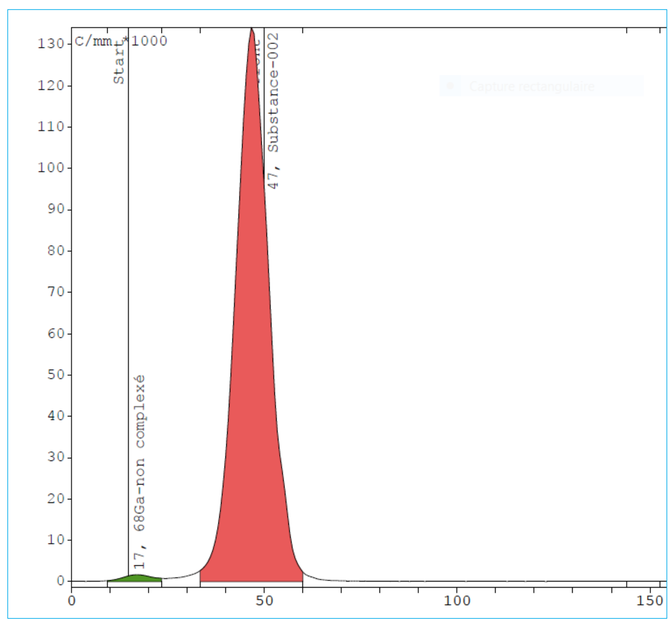

→ Results were expressed as mean ± standard deviation, and a significance level of α = 0.05 was used to compare RCP means.

All chromatograms required Rs > 1.5 (EANM standard).

## RESULTS

| | System 1 | System 2 | System 1 | System 2 |
|---|---|---|---|---|
| **Strip length (cm) distance de migration** | **9** | | **3** | |
| **RCP (%)** | **98.39 ± 1.16 %** | | **97.98 ± 1.65 %** | |
| **Rs** | **> 1.5** | **> 1.5** | **> 1.5** | **> 1.5** |
| **Migration time (min)** | **22.67 ± 1.53** | **7.08 ± 0.80** | **2.67 ± 0.29** | **1.50 ± 0.50** |
| **Time saving (min)** | | | **20** | **5.58** |




## CONCLUSION AND RELEVANCE

Reducing the migration distance **significantly reduced QC time** while maintaining **satisfactory analytical characteristics** (Rs > 1.5) and **comparable RCP** to the reference method (p ≥ 0.05).

This time saving, taking into account the radioactive half-life of $^{68}$Ga (67.8 minutes), allowed us to **increase** the average number of doses dispensed per preparation.

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