Ga-68 Radiochemical Purity Analysis Using Molpure ITLC-SG Strips

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Abstract

Rapid and reliable assessment of radiochemical purity (RCP) is essential for Ga-68 radiopharmaceuticals prior to clinical use. This study presents practical application guidance for the use of Molpure instant thin-layer chromatography with silica gel (ITLC-SG) for routine quality control. Representative chromatographic data demonstrate effective separation of radiolabeled Ga-68 compounds, including **PSMA and DOTATATE**, from free and colloidal impurities using complementary solvent systems.

Introduction

Gallium-68 (Ga-68) labeled radiopharmaceuticals, including **PSMA and DOTATATE**, require robust quality control to ensure safety and efficacy. Instant thin-layer chromatography (ITLC) is widely adopted in nuclear medicine due to its speed, simplicity, and reproducibility. ITLC-SG (silica gel on glass fiber) enables rapid separation of different chemical forms of Ga-68 based on their interaction with stationary and mobile phases.

Materials and Methods

Materials

- ITLC-SG strips (silica gel on glass fiber)
- Mobile phases:
    - Ammonium acetate : methanol (1:1)
    - Sodium citrate buffer
- Radio-TLC scanner

Procedure

Samples were applied at the origin (~1 cm from base) of ITLC-SG strips. Strips were developed in the selected mobile phase until the solvent front reached approximately 8–10 cm. After drying, radioactivity distribution was analyzed using a radio-TLC scanner.

Chromatographic Systems

Ammonium Acetate / Methanol System

This system is designed to detect colloidal Ga-68 impurities.

- Radiolabeled Ga-68 (PSMA, DOTATATE): Rf ~0.7–0.8
- Colloidal Ga-68: Rf ~0.0–0.3

Citrate System

This system is used to identify free (unbound) Ga-68.

- Radiolabeled Ga-68: (PSMA): Rf ~0.7–0.8
- Free Ga-68: Rf ~0.0

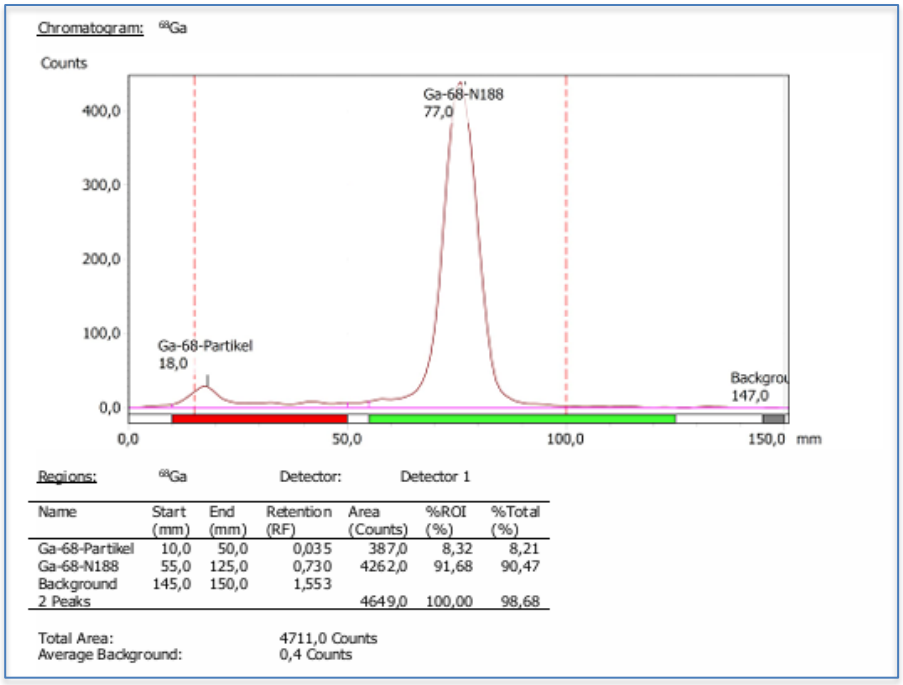
Results

Representative chromatograms demonstrate clear separation between radiolabeled Ga-68 and impurity species for both **PSMA and DOTATATE**. In the ammonium acetate system, a dominant peak at Rf ~0.7–0.8 (~90% of total activity) is observed, with a minor peak at the origin corresponding to colloidal impurities. In the citrate system, a single dominant peak confirms minimal free Ga-68.

Additional evaluation using Ga-68 DOTATATE demonstrates a highly pure radiolabeled peak (Rf ~0.85, ~99.9% of total activity) with negligible baseline-associated activity.

Figures

Figure 1. Radio-TLC chromatogram of Ga-68 PSMA-11 using Molpure ITLC-SG with ammonium acetate/methanol (1:1) mobile phase. The chromatogram demonstrates separation of radiolabeled Ga-68 (Rf ~0.7–0.8) from colloidal Ga-68 impurities (Rf ~0.0–0.3). The major peak corresponds to the radiolabeled compound (~90% of total activity), while the minor peak at the origin represents colloidal species (~8%).

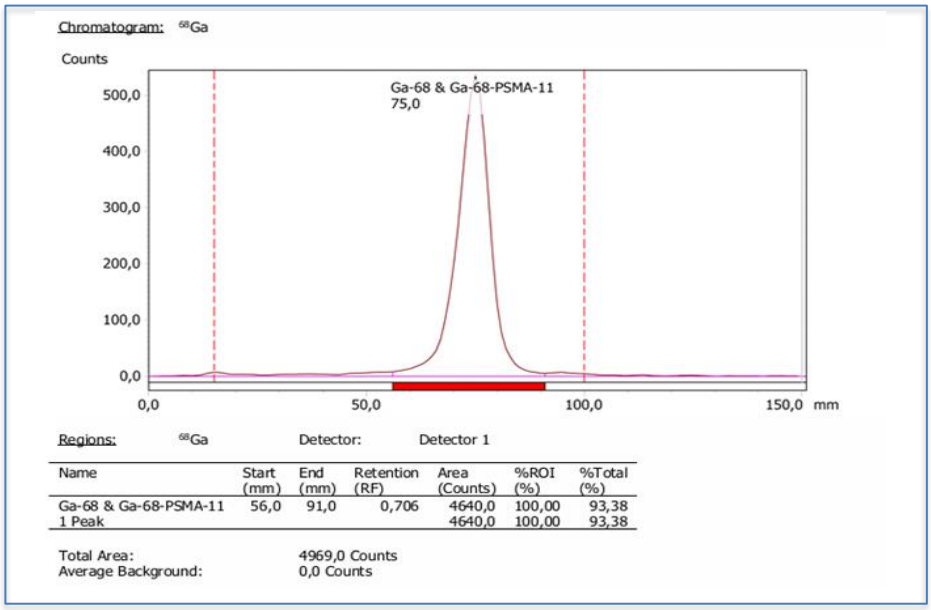


Regions: ⁶⁸Ga Detector: Detector 1

Name	Start (mm)	End (mm)	Retention (RF)	Area (Counts)	%ROI (%)	%Total (%)
Ga-68-Partikel	10,0	50,0	0,035	387,0	8,32	8,21
Ga-68-N188	55,0	125,0	0,730	4262,0	91,68	90,47
Background	145,0	150,0	1,553			
2 Peaks				4649,0	100,00	98,68

Total Area: 4711,0 Counts
Average Background: 0,4 Counts

Figure 2. Radio-TLC chromatogram of Ga-68 PSMA-11 using Molpure ITLC-SG with citrate mobile phase. The chromatogram shows a dominant peak corresponding to radiolabeled Ga-68 (Rf ~0.7–0.8), with minimal or no detectable free Ga-68 remaining at the origin (Rf ~0.0), confirming high radiochemical purity.

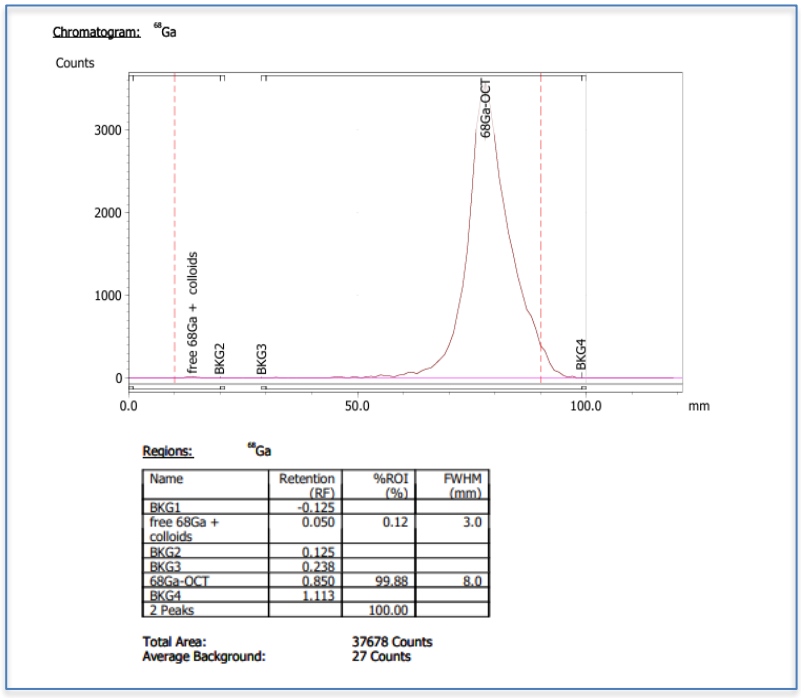


Regions: 68Ga Detector: Detector 1

Name	Start (mm)	End (mm)	Retention (RF)	Area (Counts)	%ROI (%)	%Total (%)
Ga-68 & Ga-68-PSMA-11	56,0	91,0	0,706	4640,0	100,00	93,38
1 Peak				4640,0	100,00	93,38

Total Area: 4969,0 Counts
Average Background: 0,0 Counts

Figure 3. Radio-TLC chromatogram of Ga-68 DOTATATE using Molpure ITLC-SG. The chromatogram demonstrates a dominant peak corresponding to radiolabeled Ga-68 DOTATATE at Rf ~0.85 (~99.9% of total activity), with negligible activity observed near the origin (Rf ~0.0–0.1). Minimal baseline signal (~0.12%) indicates the absence of significant free or colloidal Ga-68 species.



Regions: 68Ga

Name	Retention (RF)	%ROI (%)	FWHM (mm)
BKG1	-0.125		
free 68Ga + colloids	0.050	0.12	3.0
BKG2	0.125		
BKG3	0.238		
68Ga-OCT	0.850	99.88	8.0
BKG4	1.113		
2 Peaks		100.00	

Total Area: 37678 Counts
Average Background: 27 Counts

Discussion

The use of complementary mobile phase systems enables comprehensive impurity profiling. The ammonium acetate system effectively isolates colloidal species, while the citrate system confirms the absence of free Ga-68. Together, these methods provide a robust and efficient approach for routine RCP assessment in clinical radiopharmacy settings.

Observation

In routine quality control using conventional ITLC strips, low levels of free or colloidal Ga-68 are often observed at or near the origin (Rf ~0.0), even in otherwise acceptable preparations. However, based on internal and customer-generated data using Molpure ITLC-SG strips, such baseline-associated activity is consistently minimized or not observed.

As demonstrated in Figure 3, the Ga-68 DOTATATE sample shows a highly clean chromatographic profile, with nearly all activity associated with the radiolabeled compound and negligible signal at the origin. This observation suggests improved separation performance and reduced nonspecific retention compared to conventional ITLC media.

Conclusion

Molpure ITLC-SG provides a fast, reliable, and practical method for evaluating Ga-68 radiochemical purity. The approach enables clear differentiation between bound, free, and colloidal species across multiple radiopharmaceuticals, including PSMA and DOTATATE, supporting routine quality control workflows.

Note

This document is intended as application guidance based on internal and customer-generated data. Performance may vary depending on experimental conditions.

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