

Validation of the use of Sodium Chloride Injection from Braun Mini-Plasco Connect ampoules in the preparation of $^{99m}\text{Tc-MAG}_3$ Injection

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Purpose

The renal imaging radiopharmaceutical Technetium-99m Mercaptoacetyltriglycine Injection ($^{99m}\text{Tc-MAG}_3$) is prepared daily in our radiopharmacy. Reports have suggested that sodium chloride injection from plastic ampoules can produce low radiochemical purity of this product.¹⁻³ Routine analytical work in our radiopharmacy has shown that sodium chloride injection from the Braun Mini-Plasco ampoule (Braun, Melsungen, Germany) is compatible with $^{99m}\text{Tc-MAG}_3$ but these ampoules have been discontinued. The aim of this work was to determine if sodium chloride injection from its replacement, the new Braun Mini-Plasco Connect ampoule, is also suitable for use in the preparation of $^{99m}\text{Tc-MAG}_3$ Injection.

Methods

^{99m}Tc generator eluate was diluted to a radioactive concentration of 500 MBq/10 ml with Sodium Chloride Injection Ph Eur from a Braun Connect ampoule and used to reconstitute a MAG_3 kit (DRN4334, Mallinckrodt, Petten, The Netherlands) according to the manufacturer's instructions. The radiochemical purity was determined at 1 and 6 hours after preparation using standard liquid chromatography as follows⁴:

- HyperClone ODS column, 5 μm , 250 x 4.6mm (Phenomenex, Torrance, USA)
- Mobile phase: ethanol and 10 mM sodium phosphate buffer pH 6 (5:95) for 7 min then methanol and water (90:10) for 8 min at room temperature
- Flow-rate 1 ml min⁻¹
- 20 μl sample via a loop valve injector
- On-line sodium iodide crystal scintillation detector
- Chromatogram recorded and analysed using LauraLite software (LabLogic, Sheffield, UK)
- Radiochemical purity calculated by expressing the counts in the $^{99m}\text{Tc-MAG}_3$ peak as a percentage of the total counts in the chromatogram

The procedure was repeated using sodium chloride injection from a glass vial (Drytec, GE Healthcare, Amersham, UK) as a control. Each experiment was performed five times. Radiochemical purity >94% was considered satisfactory as specified in the European Pharmacopoeia.

References

1. Beattie LA, O'Brien LM, Waight CC, Homer NZ, Andrew R, Millar AM. Preparation of $^{99m}\text{Tc-MAG}_3$: The effect on radiochemical purity of using sodium chloride injection from plastic ampoules that have been exposed to light. *Nucl Med Commun* 2008 (in press).
2. Stringer RE, Maltby PJ. A 1 year study of factors affecting $^{99m}\text{Tc-MAG}_3$ kit failure. *Nucl Med Commun* 1996; 17: 993.
3. Mallinckrodt Medical. Use of saline in "plastic bottles" for dilution of technetium kits. Letter to customers, 1996.
4. Millar AM, Wilkinson AG, McAteer E, Best JJK. $^{99m}\text{Tc-MAG}_3$: *In vitro* stability and *in vivo* behaviour at different times after preparation. *Nucl Med Commun* 1990; 11: 405-412.

Results

A typical liquid chromatogram for $^{99m}\text{Tc-MAG}_3$ with a radiochemical purity of >94% is shown in figure 1. The results of the radiochemical purity measurements are shown in table 1. Each sample had a radiochemical purity of >94%. No significant differences were observed between the radiochemical purities of the $^{99m}\text{Tc-MAG}_3$ samples prepared using the two sources of sodium chloride injection ($P > 0.05$, unpaired t-test).

Figure 1. Liquid chromatogram for $^{99m}\text{Tc-MAG}_3$ Injection of satisfactory radiochemical purity

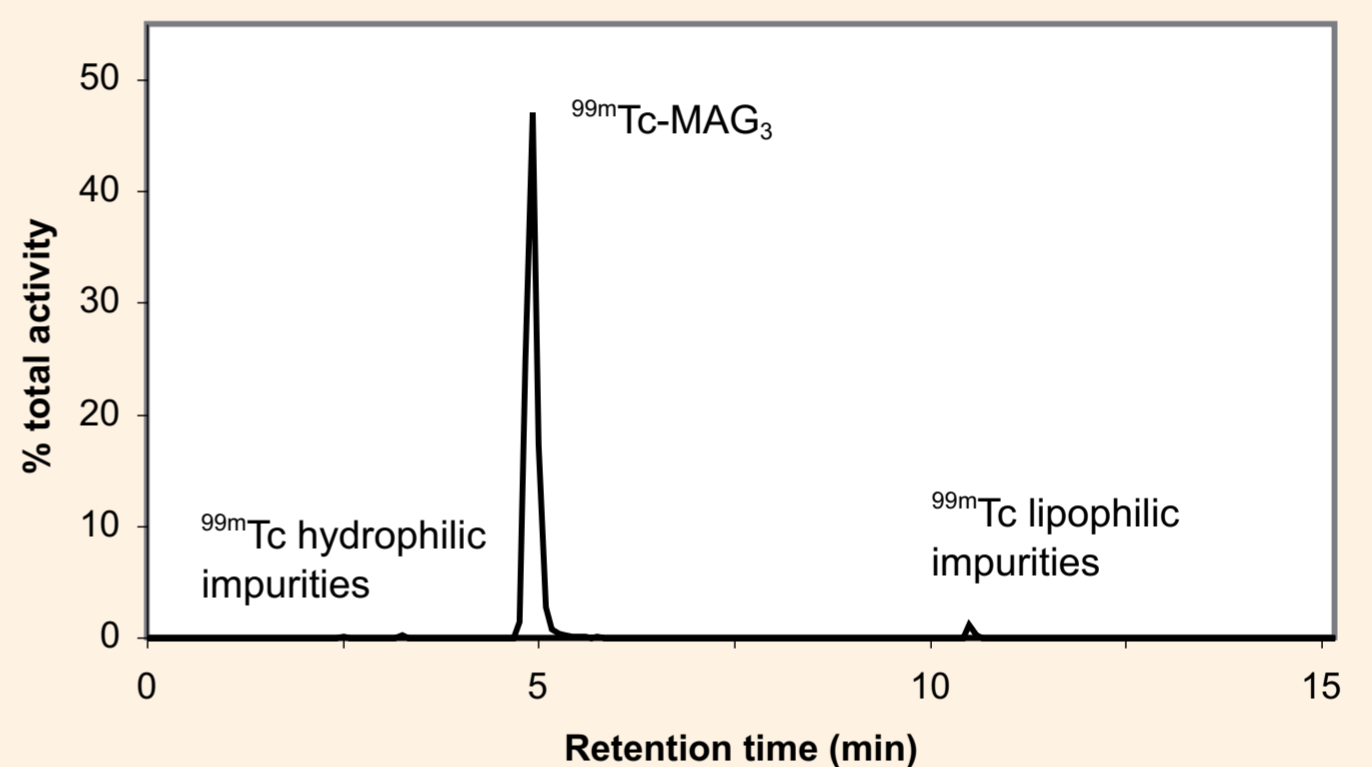


Table 1. Comparison of radiochemical purities of $^{99m}\text{Tc-MAG}_3$ injections at 1 and 6 hours after reconstitution with sodium chloride injection from Connect ampoules and Drytec vials

	Radiochemical purity (%)	
	1 h	6 h
Sodium chloride injection		
Connect plastic ampoule	97.3 \pm 0.6	96.9 \pm 0.8
Drytec glass vial	97.5 \pm 0.3	97.7 \pm 0.5

Each value is the mean \pm standard deviation of 5 results

Conclusion

Sodium chloride injection from Braun's new Mini-Plasco Connect ampoules is suitable for use in the preparation of $^{99m}\text{Tc-MAG}_3$ Injection.