## VARIABLE RADIOCHEMICAL PURITY RESULTS USING THREE MINIATURIZED CHROMATOGRAPHY SYSTEMS ON A COMMERCIAL TECHNETIUM-99m SULFUR COLLOID PREPARATION

To the Editor: At our institution, we have used Tesuloid® (Squibb Diagnostics, Princeton, NJ) as the kit for the preparation of technetium-99m (99mTc) sulfur colloid. Using this preparation, number of unacceptable radiochemical purity (RCP) data were obtained using the acteone/Whatman 31ET system (1). As this occurred more frequently, we investigated the use of other chromatography systems. We set up a comparison study using three different miniaturized chromatography systems to determine the optimal quality control system for Squibb's sulfur colloid preparation. The three systems were: acetone/Whatman 31ET; 0.9% NaCl/instant thin-layer chromatography-silicon gel (ITLC-SG); and 85% methanol/Whatman 31ET. For all of our 99mTc sulfur colloid preparations, the 99mTc sodium pertechnetate used was eluted from Mallinckrodt's 99mTc generator (Ultra-Technekow® FM, Mallinckrodt Medical, St. Louis, MO). The data was collected over a 20-wk period. U.S. Pharmacopeia XXII recommends the use of 85% methanol for RCP measurement of 99mTc sulfur colloid and the minimal acceptance level of RCP is 92% (2).

Table 1 displays the chromatography data for each of the systems for each day of the week. The numbers refer to the percent of kit preparations that failed the RCP test using a particular chromatography system. While no

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preparations failed using the 0.9% NaCl/ITLC-SG and 85% methanol/ Whatman 31ET systems, the acetone/ Whatman 31ET system showed a trend toward increasing RCP failure as the week progressed. We should also note that this trend was not observed previously when we used sulfur colloid kits supplied by Medi-Physics.

A possible explanation for the trend we observed is that Squibb's sulfur colloid kit contains an ingredient that is not present in the Medi-Physics kit (3, 4); this ingredient could cause migration to occur in the acetone/Whatman 31ET system. It is not clear why this would cause a greater problem later in the week. Another possible explanation is that a substance in the generator eluate is interfering in the acetone/ Whatman 31 ET system and producing unacceptable results. A greater volume of eluate is needed for the sulfur colloid preparation later in the week, which may help explain the increasing frequency of the problem as the week progresses.

Although we did not pursue the issue to find the explanation for our observations, we did want to share our observations with the nuclear medicine community. We would also like to note that our laboratory now uses the 85% methanol/Whatman 31ET system for the determination of RCP for 99mTc-sulfur colloid preparations.

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TABLE 1. Determination of Technetium-99m Sulfur Colloid RCP: Comparison Among Three Chromatography Systems

Chromatography Systems	Percentage of Kits that Failed RCP Test				
	Monday	Tuesday	Wednesday	Thursday	Friday
Acetone/Whatman 31ET	8.3	33.3	46.7	66.7	69.2
0.9% NaCI/ITLC-SG	0	0	0	0	0
85% methanol/Whatman 31ET	0	0	0	0	0
	n = 12	n = 15	n = 15	n = 15	n = 13

## REFERENCES

- Zimmer AM, Pavel DG. Rapid miniaturized chromatographic quality-control procedures for Tc-99m radiopharmaceuticals. J Nucl Med 1977; 18:1230–1233.
- Techentium Tc-99m sulfur colloid injection. *United States Pharmacopeia XXII*. Rockville, MD: United States Pharmacopeial Convention; 1990:1320.
- Technetium Tc-99m TSC package insert. Paramus, NJ: Medi-Physics; 1988.
- Tesuloid<sup>®</sup> package insert. Princeton, NJ: Squibb Diagnostics; September 1988.

## SPECTamine®: CORRECT EXPIRATION TIME AND DISTRIBUTION METHOD

To the Editor: Some corrections are required for Dr. Bushnell's article Comparison of IMP and HMPAO for SPECT Brain Imaging, published in the June issue of the Journal of Nuclear Medicine Technology. First, since January of 1989, the expiration time for commercially available **IMP** (SPECTamine®) has been 12 hours rather than the 6 hours stated in the article. This is a significant difference because the change in expiration time was made concurrently with the manufacturing process change, incorporating the highest purity iodine-123 for the SPECTamine® 123I label. This change very substantially diminished radiological impurities and improved image quality. Second, the commercial product has never been distributed in multidose vials.

Ann S. Lamb
Director, Regulatory Affairs
IMP Incorporated
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Reply: We appreciate the comments from Ms Lamb of IMP Inc. regarding our article entitled Comparison of IMP and HMPAO for SPECT Brain Imaging. As she correctly points out, the current expiration time for IMP is 12 hours postcalibration (as opposed to the 6 hours stated in the article). She also correctly points out that multidose vials of IMP are not available. We thank Ms Lamb for identifying these discrepencies in our article.

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