Simplified Reconstitution Recommendations for DRAXIMAGE® MAA

5 MILLION PARTICLES per VIAL - USA

Recommendations

The following table shows the amount of 99m Tc-Sodium Pertechnetate that should be added to a vial of MacroAggregated Albumin of 5 million (5 x 10^6) particles to produce a standardized dose of 350,000 particles and 2.5 mCi (93 MBq) of 99m Tc for a 70 kg adult. Since MAA requires not only a specific amount of 99m Tc but also a specific number of particles, the reconstitution of the kit requires more care. The table assumes that all doses will be used at the same time period. To produce paediatric doses or doses for mixed time periods please refer to the **Dosage and Administration** section of the package insert.

To produce doses of 350,000 particles but other than 2.5 mCi (93 MBq) simply adjust the amount of pertechnetate added accordingly. For example, to produce a dose of 350,000 particles and 2.0 mCi (74 MBq) at 1 hour post reconstitution add 32 mCi (1.19 GBq) in 8.0 mL, each dose is 0.56 mL.

Delay in Hours	Reconstitution Recommendation
Before Use	
0	Add 36 mCi (1.32 GBq) in 8 mL. Each dose is 0.56 mL
1	Add 40 mCi (1.48 GBq) in 8 mL. Each Dose is 0.56 mL
2	Add 45 mCi (1.66 GBq) in 8 mL. Each Dose is 0.56 mL
3	Add 50 mCi (1.87 GBq) in 8 mL. Each Dose is 0.56 mL
4	Add 57 mCi (2.09 GBq) in 8 mL. Each Dose is 0.56 mL
5	Add 63 mCi (2.35 GBq) in 8 mL. Each Dose is 0.56 mL
6	Add 71 mCi (2.63 GBq) in 8 mL. Each Dose is 0.56 mL
7	Add 80 mCi (2.95 GBq) in 8 mL. Each Dose is 0.56 mL
8	Add 90 mCi (3.31 GBq) in 8 mL. Each Dose is 0.56 mL

Note:

- 1) It is <u>not</u> recommended that the vial be reconstituted with saline and that aliquots then be mixed with ^{99m}Tc-sodium pertechnetate in another container.
- 2) It is <u>not</u> recommended that the vial be reconstituted with saline and then frozen. Once reconstituted, the maximum shelf-life is 6 hours.
- 3) This table is intended only as a simplification of the Dosage and Administration section in the package insert. There has been no change in the product or in its method of use.

Please note: this chart is specific for vials of 5 million particles and should not be used to prepare doses for any other number of particles. Please consult the Simplified Reconstitution Recommendations for each specific number of particles.

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