

Simplified Reconstitution Recommendations for DRAXIMAGE® MAA

3 MILLION PARTICLES per VIAL – AUSTRALIA 3000001020

Lot No: 0M383A Expiry Date: 11/2022 Particles/vial: 3 x 10⁶ / vial

Recommendations

The following table is an example showing the amount of ^{99m}Tc-Sodium Pertechnetate that should be added to a vial of MacroAggregated Albumin of **3 million (3 x 10⁶) particles** to produce a 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 equations in the **Dosage and Administration** section of the package insert.

Delay in Hours Before Use	Reconstitution Recommendation
0	Add 21 mCi (0.78 GBq) in 8 mL. Each dose is 0.93 mL
1	Add 24 mCi (0.88 GBq) in 8 mL. Each dose is 0.93 mL
2	Add 27 mCi (1.00 GBq) in 8 mL. Each dose is 0.93 mL
3	Add 30 mCi (1.11 GBq) in 8 mL. Each dose is 0.93 mL
4	Add 34 mCi (1.26 GBq) in 8 mL. Each dose is 0.93 mL
5	Add 38 mCi (1.41 GBq) in 8 mL. Each dose is 0.93 mL
6	Add 43 mCi (1.59 GBq) in 8 mL. Each dose is 0.93 mL
7	Add 48 mCi (1.78 GBq) in 8 mL. Each dose is 0.93 mL
8	Add 54 mCi (2.00 GBq) in 8 mL. Each dose is 0.93 mL
9	Add 61 mCi (2.26 GBq) in 8 mL. Each dose is 0.93 mL
10	Add 68 mCi (2.52 GBq) in 8 mL. Each dose is 0.93 mL
11	Add 76 mCi (2.81 GBq) in 8 mL. Each dose is 0.93 mL
12	Add 86 mCi (3.18 GBq) in 8 mL. Each dose is 0.93 mL

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 **19 mCi (0.70 GBq)** in 8.0 mL, each dose is 0.93 mL.

Note:

- 1) It is **not** 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 **not** recommended that the vial be reconstituted with saline and then frozen. Once reconstituted the maximum shelf life is **12.0 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 Lot No: 0M383A and should not be used to prepare doses for any other batch.

Prepared by: HANANE SALEM	Approved by: MUSTAPHA TOLLABI
Date: 20 21 JA 26	Date: 20 21 JA 26.