at selected intervals of time are shown in Tables 3 and 4. Mo-99 and technetium Tc-99m, the fractions that remain 23 hours. To correct for physical decay of molybdenum such that only 88.6% of the decaying molybdenum Mo-99 attenuate the radiation emitted by a factor of about 1000.

Since the eluate does not contain an antimicrobial agent, it should not be used after 12 hours from the time of generation.

The Ultra-TechneKow™ DTE Generator is prepared with fission-produced molybdenum Mo-99 adsorbed onto alumina columns immersed in a reduction bath containing sodium bisulfide. This generator provides a closed system for the production of technetium Tc-99m, which is the most widely used radionuclide in the clinical practice of nuclear medicine.
To obtain radiation absorbed dose in rads (30 mCi dose) from the above table, divide individual organ values by a factor.

In pediatric patients, an average 30 minute exposure to 37 mCi of Sodium Pertechnetate Tc 99m results in the organ absorbed fractional dose rates shown in Table 8. When using the generator, always wear a lead apron and shield the patient and personnel. The absorbed dose rates listed in Table 8 are used with the absorbed dose rate to air, assuming a 90% occupancy.

To determine the Tc-99m concentration and molybdenum Mo-99 content for dispensing purposes, the generator eluate may be assayed using an appropriate detector system. The manufacturer’s instructions for operation of the reprocessing/recovery system should be followed for measurement of Tc-99m and Molybdenum Mo-99 activity. NOTE: Molybdenum Mo-99 Breakthrough Limit – The acceptable limit is 0.15 kilobecquerel per megabecquerel Tc-99m. See section 7.13.3, Molybdenum Mo-99 Breakthrough Limit. Do not use generator eluate if its appearance is discolored.

Storage
Store generator and Sodium Pertechnetate Tc 99m solution at controlled room temperature (20° to 25°C [68° to 77°F]) (see USP Controlled Room Temperature).

Expiration Date
The expiration time of the Sodium Pertechnetate Tc 99m is not more than 12 hours after time of elution if the eluate is not used to reevacuate the vial. The eluate should not be used after 12 hours from the time of expiration stated on the label for the reprocessed vial used in the labeling for the prepared drug, whichever is earlier.

Tissue

<table>
<thead>
<tr>
<th>Tissue</th>
<th>10 minute</th>
<th>15 minute</th>
<th>30 minute</th>
<th>60 minute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone Soft Tissue</td>
<td>2.8</td>
<td>2.9</td>
<td>3.3</td>
<td>4.7</td>
</tr>
<tr>
<td>Bone Hard Tissue</td>
<td>7.4</td>
<td>7.7</td>
<td>9.4</td>
<td>13.1</td>
</tr>
<tr>
<td>Brain</td>
<td>2.6</td>
<td>2.9</td>
<td>3.3</td>
<td>4.6</td>
</tr>
<tr>
<td>Blood</td>
<td>13.9</td>
<td>14.3</td>
<td>18.3</td>
<td>21.4</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>22.3</td>
<td>20.3</td>
<td>22.6</td>
<td>23.9</td>
</tr>
<tr>
<td>Liver</td>
<td>31.3</td>
<td>32.0</td>
<td>34.2</td>
<td>34.6</td>
</tr>
<tr>
<td>Lung</td>
<td>17.5</td>
<td>18.5</td>
<td>21.1</td>
<td>22.4</td>
</tr>
<tr>
<td>Muscle</td>
<td>2.9</td>
<td>3.0</td>
<td>3.1</td>
<td>3.3</td>
</tr>
</tbody>
</table>

The estimated absorbed radiation dose to an adult patient from the radiopharmaceutical and a 30 mCi dose is shown above. The absorbed dose rate to air and the radiopharmaceutical concentration at 0.022 mg/mL and 0.088 mg/mL are available on request in 10 and 20 milliliter sizes.

NOTE: Molybdenum Mo-99 Breakthrough Limit – The acceptable limit is 0.15 kilobecquerel per megabecquerel Tc-99m. See section 7.13.3, Molybdenum Mo-99 Breakthrough Limit. Do not use generator eluate if its appearance is discolored.

Dear Health Care Professional,

The FDA has issued an advisory to the Healthcare Profession warning about the potential for Molybdenum Mo-99 Breakthrough into Sodium Pertechnetate Tc-99m generator eluates. Note: Molybdenum Mo-99 Breakthrough Limit – The acceptable limit is 0.15 kilobecquerel per megabecquerel Tc-99m.

Storage
Store Sodium Pertechnetate Tc 99m solution at controlled room temperature (20° to 25°C [68° to 77°F]) (see USP Controlled Room Temperature).

Expiration Date
The expiration time of Sodium Pertechnetate Tc 99m is not more than 12 hours after time of elution if the eluate is not used to reevacuate the vial. The eluate should not be used after 12 hours from the time of expiration stated on the label for the reprocessed vial used in the labeling for the prepared drug, whichever is earlier.

Directions for Use of the Technetium Tc 99m Generator

NOTE: If drainage turnover is 100%/year, the generator should be placed within a minimum of 2 inches shielding in a room not less than 200 cubic feet to minimize radiation exposure to operating personnel.

NOTE: Wear waterproof gloves during the elution procedures and during subsequent reprocessing of kits with the eluate.

NOTE: Use a shielded syringe to withdraw generator dose or to transfer Sodium Pertechnetate Tc 99m into mixing vials during kit reprocessing.

NOTE: The needles on the generator are sterile beneath their covers, and the generator has been cleaned underneath the top cover. Additional dissection of these areas with agents containing alcohol will result in the presence of alcohol in the eluate.

Elution:
Eluting the generator every 24 hours will provide optimal amounts of Sodium Pertechnetate Tc 99m. However, the generator may be used otherwise and will yield less activity and shorter half-life. Sodium Pertechnetate Tc 99m activity will have accumulated within the column.

For Example

<table>
<thead>
<tr>
<th>Type</th>
<th>First Elution (%)</th>
<th>Appropriate Yield % of First Elution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>12.3 (1.23)</td>
</tr>
<tr>
<td>2</td>
<td>0.5</td>
<td>5.6 (0.56)</td>
</tr>
<tr>
<td>3</td>
<td>0.1</td>
<td>0.5 (0.05)</td>
</tr>
</tbody>
</table>

Preparation

NOTE: The following instructions are applicable for operation of the Ultra-TechnoKow™ DTE Generator with or without the utilization of the alignment adaptor.

1. Rotate the top cover 30° counterclockwise and stop.
2. Appropriate, remove and store the alignment Adapter for use with replacement generator.
3. Cover the elution and eluant needles with the sterile needle covers.
4. Close the generator system with its top cover by rotating with downward pressure.
5. The intact generator assembly should be either returned to Mallinckrodt Inc. or disposed of in accordance with applicable regulations.

This generator is approved for use by persons licensed by the U.S. Nuclear Regulatory Commission to use byproduct material identified in Section 12.280 or under any similar licenten agreements of Licensee.

Expiry Generator Disposal
1. Following the life of the generator, remove and dispose of the used TechnoKow™ vial and the eluant vial.
2. Cover the elution and eluant needles with the sterile needle covers.
3. Close the generator system with its top cover by rotating with downward pressure.
4. Remove the alignment adaptor from the elution station.
5. The intact generator assembly should be either returned to Mallinckrodt Inc. or disposed of in accordance with applicable regulations.

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NOTE:

Do not use the generator’s system at any time after the expiration time stated on the label.

If the vacuum in the collecting vial is lost, do not attempt to re-evacuate the vial, but discard and use a new collection vial.

Expiration Date

Storage
Store Sodium Pertechnetate Tc 99m solution at controlled room temperature (20° to 25°C [68° to 77°F]) (see USP Controlled Room Temperature).

Expiration Date
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