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Measurement of Radionuclidic purity and Chemical purity in Free Tc^{99m} Pertechnetate

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Abstract:
The safety of Tc^{99m} and Tc^{99m} radiopharmaceuticals compound depends mainly on radionuclidic and chemical purity of Tc^{99m} pertechnetate. The radionuclidic impurities increase the patient's overall radiation dose and impact the image quality while the chemical impurities may cause toxic or undesirable interactions.
The main objectives of this study were to determine the radionuclidic purity (Mo^{99} impurity) and chemical purity (Al^{+3} impurities) of Tc^{99m} pertechnetate before reconstitution with pharmaceuticals kits.
The radionuclidic Mo^{99} impurity was determined by the use of dose calibrator and 6-mm thick lead cylinder.
The chemical Al^{+3} impurities were determined by comparing the intensity of Tc^{99m} pertechnetate spot to intensity of standard aluminum spot on aluminum indicator paper.
51 Samples of Tc^{99m} elutions were taken from three different radiopharmacy units (Khartoum Oncology Centre, Alneelain Medical Diagnostic Centre and Royal Care Hospital) and form different type of generators (POLATOM, MON.TEK MONOROL and Mallinckrodt pharmaceuticals). Samples were tested for Mo^{99} impurity and all the samples were in the acceptable limit. The mean radionuclidic purity resulted was 0.0026% with STD 0.0018 for all samples.
41 Spot samples of Tc^{99m} elutions were taken from three different radiopharmacy units (Khartoum Oncology Centre, Alneelain Medical Diagnostic Centre and Royal Care Hospital) and form different type of generators (POLATOM, MON.TEK MONOROL and Mallinckrodt pharmaceuticals). Samples were tested for Al^{+3} impurity and all the samples were in the acceptable limit.
It is recommended to assay each Tc^{99m} pertechnetate elution for Mo^{99} impurity and Al^{+3} impurities prior to the administration of Tc^{99m} and Tc^{99m} radiopharmaceuticals patients.
Key words: Radionuclidic purity, chemical purity, Tc^{99m} pertechnetate.

المستخلص

سلامه وفاعليه وثبات مركبات التكنشيوم99م المشع والمواد الصيدلانية المشعة المعلمة بالتكنشيوم99م المشع تعتمد على النقاء النووي–الإشعاعي (وجود شوائب الملوبدنيوم99 في التكنشيوم99م المشع) وعلى النقاء الكيميائي (وجود شوائب المونيوم في التكنشيوم99م المشع).

اهميه النقاء النووي– الإشعاعي تكمن في ان تأثير شوائب الملوبدنيوم99 تؤثر على زياده الجرعة الإشعاعية التى تحقن للمرضى وتؤثر ايضا على جوده ووضوح صوره الطب النووي وبالتالي تؤدى لتشخيص خاطئ. اما النقاء الكيميائي وشوائب

الألمونيوم لها تأثير سمى ولها تفاعلات حيوية غير مرغوبه وبالتالي تؤثر على التوزيع الحيوي داخل جسم المريض وايضا تؤثر على استقرار وسلامه المركبات الصيدلانية المشعة.

اهداف الدراسة هي قياس النقاء النووي–الإشعاعي والنقاء الكيميائي للتكنشيوم 99م المشع قبل تركيبه وتعليمه مع المواد الصيدلانية لإنتاج المواد الصيدلانية–المشعة في وحدات الصيدلة الإشعاعية في الخرطوم.

تم قياس51 عينه من ثلاث مستشفيات فى الخرطوم ومن ثلاث مولدات اشعاعيه مختلفه لقياس مستوى النقاء النووي–الإشعاعي (لمعرفه شوائب المولبدنوم99) لعينات من التكنشيوم99م المشع قبل تركيبه مع المواد الصيدلانية عن طريق جهاز معاير الجرعة وأسطوانة الرصاص بسمك 6 ملميتر ومتوسط المولبدنوم لكل العينات وجد 0.0026% وانحراف معياري 0.0018.

تم اخذ 41 عينه من ثلاث مستشفيات فى الخرطوم ومن ثلاث مولدات اشعاعيه مختلفه لقياس النقاء الكيميائي (لمعرفه شوائب الالمونيوم) للتكنشيوم99م المشع قبل تركيبه مع المواد الصيدلانية عن طريق مقارنه نقطه من عينه التكنشيوم ونقطه من الالمونيوم القياسي (10 ملى جرام\مل و5 ملى جرام\مل)على ورقه مؤشر الالمونيوم وكل العينات وجدت في نطاق الحد المسموح به.

نوصى باتباع بروتوكول ضمان جوده يتضمن قياس النقاء النووي–الإشعاعي و النقاء الكيميائي للتكنشيوم 99م المشع قبل تركيبه وتعليمه مع المواد الصيدلانية لإنتاج المواد الصيدلانية–المشعة التي تحقن للمرضى.

Introduction

Radiopharmacy also called nuclear pharmacy is a clinical service that procures, prepares or compounds, dispenses radiopharmaceuticals, and assures quality for diagnostic or therapeutic use in patients referred to the nuclear medicine service of a hospital.[4]

A radiopharmaceutical is a radioactive drug used for the diagnosis and therapeutic treatment of human diseases. A radiopharmaceutical has two components: a radionuclide and a pharmaceutical. The usefulness of a radiopharmaceutical is dictated by the characteristics of these two components.[8]

The nuclear pharmacy prepares the radiopharmaceutical product using the components of the kit and by adding radioactive material eluted from a radionuclide generator for eventual administration to a patient.[9]

More than 80% of radiopharmaceuticals used in nuclear medicine are Technetium 99m labeled compounds. The reason for such a preeminent position of Tc^{99m} in clinical use is its favorable physical and radiation characteristics.[8]

Tc^{99m} radiopharmaceuticals formulations must have high radiation safety standards as well as high pharmaceutical standards because radiation is harmful for both patients and staff.[8]

Free Tc^{99m} eluate is primarily used for preparation of Tc^{99m} radiopharmaceuticals, but it is used as such for thyroid imaging and Meckel's diverticulum detection.[9]

The molybdenum/technetium generator consists of an alumina-filled column on to which is absorbed ^{99}Mo. The ^{99}Mo is present as $^{99}MoO_4^{2-}$, which decays to its daughter radionuclide ^{99m}Tc as pertechnetate $^{99m}TcO4^-$. ^{99m}Tc is removed from the columns as $^{99m}TcO4^-$ by drawing over a solution of sodium chloride (NaCl) 0.9% w/v across the column. This process is known as 'eluting the generator' and the resultant eluate is used to compound the radiopharmaceuticals.[1]

Free Tc^{99m} pertechnetate is eluted from Moly generators as pertechnetate $^{99m}TcO_4$ with 6 hours half life, and a high yield of 140 keV Gamma γ rays, which is ideal for the current generation of imaging devices in nuclear medicine.[6]

Technetium 99m has the ability to readily bind to a wide variety of compounds under physiological conditions without causing physiological changes in the patient.[1]

In all ^{99m} Tc radiopharmaceuticals preparations, regular checks should be made for radiochemical purity (compounding efficiency), chemical Purity (aluminum breakthrough), Radionuclidic purity (molybdenum impurity), pH, sterility, and apyrogenicity of all labeled products.[8]

The main objectives of this study were to determine the radionuclidic purity (Mo^{99} impurity) and chemical purity (Al^{+3} impurity) of Tc^{99m} pertechnetate before reconstitution with pharmaceuticals kits.

The radionuclidic purity is the ratio of the stated radionuclide activity to the total radioactivity. Radionuclidic impurities can contribute significant effects on the patient's overall radiation dose as well as impact the image quality.

A radionuclidic impurity of particular concern to nuclear pharmacies is molybdenum ^{99}Mo contamination in a ^{99m}Tc elution. This occurs when ^{99}Mo is eluted along with ^{99m}Tc pertechnetate during a generator elution. The NRC and USP limit for Acceptance limit of radionuclidic purity in Tc^{99m} pertechnetate is < 0.15 μ Ci ^{99}Mo per mCi of ^{99m}Tc at the time of patient administration. The assay for ^{99}Mo breakthrough can be performed using a dose calibrator and a lead or tungsten shield of sufficient thickness to attenuate the 140 keV gamma emission of ^{99m}Tc while allowing the penetration of a portion of the higher energy gammas of ^{99}Mo. Since only a portion of the higher energy gammas (740 – 780 keV) of ^{99}Mo will be attenuated.[10]

The A_{Mo}/A_{Tc} ratio increases with time because ^{99}Mo ($t_{1/2}$ = 66 h) decays more slowly than ^{99m}Tc ($t_{1/2}$ =6 h). Thus $^{99m}TcO_4$ obtained from the Moly generator has an expiration period of 12 h for clinical use.[8]

For ^{99m}Tc generators this is to be performed at a minimum on the first eluate from each new generator or if there is a concern that the column could have been disturbed for example the generator has been moved.

The EP limit is 0.1% (1 kBq ^{99}Mo per MBq ^{99m}Tc).[7]

Acceptance limits 5.55 KBq (0.15μCi) ^{99}Mo per 37 MBq (1 mCi) ^{99m} Tc.[2]

Chemical purity is the proportion of the total mass present in the stated chemical form. With respect to radiopharmaceuticals, this refers to the amount of undesirable chemical species present. In the compounding of short-lived radiopharmaceuticals, chemical impurities are considered all nonradioactive substances that can either affect radiolabling or directly produce adverse biological effects.[10]

In ^{99}Mo /^{99m}Tc generators, alumina oxide (Al_2O_3) is used as the column media to which the ^{99}Mo radioactivity in the form of molybdate ion (MoO_4) is bound. Alumina breakthrough resulting in significant quantities of aluminum ions present in ^{99m}Tc eluates have been reported to cause the agglomeration of ^{99m}Tc sulfur colloid to yield undesirably large particles, This, in turn, may cause lung uptake on a liver/spleen study. [10]

The assay for aluminum ion is a colorimetric spot test of the generator eluate. It involves applying one drop of generator eluate and the same size drop of a standard solution to test paper impregnated with the aluminum ion specific indicator (ammonium salt of aurin tricarboxylic acid) and comparing the two spots.

Acceptance limit of Al^{+3} concentrations is less than10 µg/mL in USA pharmacopeia and less than 5 µg/mL in British/ European pharmacopeia.[10]

Aluminium testing should be performed if using the following products:

a. Products where the manufacturer specifies a limit for eluate aluminium content e.g. Myoview (myocardial perfusion kid) for which the eluate should contain no more than 5 µg Al^{3+}/mL ^{99m}Tc eluate, the European Pharmacopoeia limit.

b. Products where drug interactions have been reported e.g. colloidal preparations. Consideration should also be given to products to be used in children, where high aluminium levels could in theory cause harm.

In common practice test the first elution of each new generator, rather than test every eluate.[7]

If ^{99m}Tc eluate spot is denser than the standard aluminum spot, then the amount of aluminum is considered excessive and the ^{99m}Tc-eluate should be discarded. Excessive amounts of aluminum in the eluate indicate lack of stability of the column.[8]

2. Materials and Methods

2.1 Materials

- Dose calibrator as counting instruments, CAPENTEC Inc. CRC 25R, USA and Veenstra, VDC- 404, Netherlands.
- Tc ^{99m} pertechnetate elution from different generators companies (POLATOM, MON.TEK MONOROL and Mallinckrodt pharmaceuticals).
- 6-mm thick lead cylinder to stop all 140-keV photons from Tc ^{99m} and to count only 740-keV and 780-keV photons from Mo^{99}.
- Standard solution of aluminum 10 µg/mL and 5 µg/mL from Biodex Medical, Inc. New York, USA.
- Commercial strips of aluminum indicator paper containing acolor complexing from Biodex Medical, Inc. New York, USA.
- 19-26G needle and syringe.
- 0.01cc spots per sample from free Tc^{99m} pertechnetate.

2.2 Study samples:

Total 51 Samples of Tc^{99m} pertechnetate elutions were taken for radionuclidic purity before reconstitution and 41 Samples of 0.01cc spots per sample from Tc^{99m} pertechnetate elutions were taken for radiochemical purity before reconstitution.

The samples were collected randomly from three hospital radiopharmacy units and the laboratory units in nuclear medicine department in Khartoum (Khartoum Oncology Centre, Alneelain Medical Diagnostic Centre and Royal Care Hospital).

2.3 Methods

2.3.1 Measurments of radionuclidic purity in Tc^{99m} pertechnetate

The eluate was measured in a dose calibrator and the eluate vial was placed in a lead shield (6-mm thick) to stop all 140-keV photons from Tc ^{99m} and to count only 740-keV and 780-keV photons from Mo^{99}.

From these measures the purity of the solution was determined, by determining the amount of MBT (molybdenum break through), as in this equation.

MBT = (Mo^{99} activity - B) / (Tc ^{99m} activity - B) *100%.

MBT: molybdenum breaks through.

Mo^{99} activity: Mo^{99} activity measured with shielding.

B: Background.

Tc ^{99m} activity: Tc ^{99m} activity measured without shielding.

The NRC and USP limit for Acceptance limit of radionuclidic purity in Tc^{99m} pertechnetate is < 0.15 µ Ci ^{99}Mo per mCi of ^{99m}Tc at the time of patient administration.

Acceptance limits 5.55 KBq (0.15µCi) ^{99}Mo per 37 MBq (1 mCi) ^{99m} Tc.

2.3.2 Measurements of chemical purity in free Tc^{99m} pertechnetate

1. 0.01cc spots per sample from Tc^{99m} pertechnetate was placed on the indicator paper.
2. Same size of a drop from standard aluminum solvent was placed on the indicator paper.
3. The intensity color of Tc^{99m} pertechnetate sample was compared to the intensity of standard one.

If Tc^{99m} eluate spot is denser than the standard aluminum spot, then the amount of aluminum is considered excessive and the ^{99m}Tc-eluate should be discarded.

If the color of the eluate spot is not as intense as that of the aluminum standard solution spot, the test is interpreted as negative.

Acceptance limit of Al^{+3} concentrations is less than10 µg/mL in USA pharmacopeia and less than 5 µg/mL in British/ European pharmacopeia.

3. Results

Table1 Examples for measurements of radionuclidic Mo^{99} impurity in Tc^{99m} eluate

Tc^{99m} elution samples	Mo^{99m} reading in mCi-background	Tc^{99m} reading in mCi-background	Contamination% (specifications < 0.010%)
1	0.011	492	0.002
2	0.009	343	0.001
3	0.029	1467	0.002
4	0.005	350	0.001
5	0.027	1477	0.002
6	0.020	1079	0.001
7	0.21	1079	0.002
8	0.012	496	0.002
9	0.017	1314	0.001
10	0.024	1200	0.002
11	0.017	768	0.002
12	0.028	1363	0.002
13	0.015	709	0.002
14	0.005	355	0.001
15	0.0012	580	0.002
16	0.031	1349.8	0.002
17	0.005	380	0.001
18	0.004	296	0.002
19	0.012	777.2	0.001
20	0.011	1049.5	0.001
21	0.014	943	0.001
22	0.014	1105	0.001
23	0.023	612	0.004
24	0.010	245	0.004
25	0.002	115	0.002
26	0.016	690	0.002
27	0.005	85	0.004
28	0.034	807	0.002

29	0.054	905	0.004
30	0.005	365	0.001
31	0.017	1314	0.001
32	0.011	497	0.002

Table2 Examples for measurements of radionuclidic Mo^{99} impurity in Tc^{99m} eluate

Tc^{99m} elution samples	Mo^{99m} reading in mCi-background	Tc^{99m} reading in mCi-background	Contamination% (specifications < 0.010%)
33	0.052	701	0.007
34	0.025	533	0.004
35	0.012	681	0.001
36	0.027	404	0.006
37	0.010	734	0.001
38	0.045	713	0.006
39	0.250	732	0.003
40	0.016	724	0.002
41	0.040	743	0.005
42	0.040	742	0.005
43	0.013	711	0.001
44	0.047	524	0.008
45	0.032	704	0.004
46	0.029	459	0.006
47	0.021	324	0.006
48	0.045	1075	0.004
49	0.048	983	0.004
50	0.050	1119	0.004
51	0.060	1038	0.005

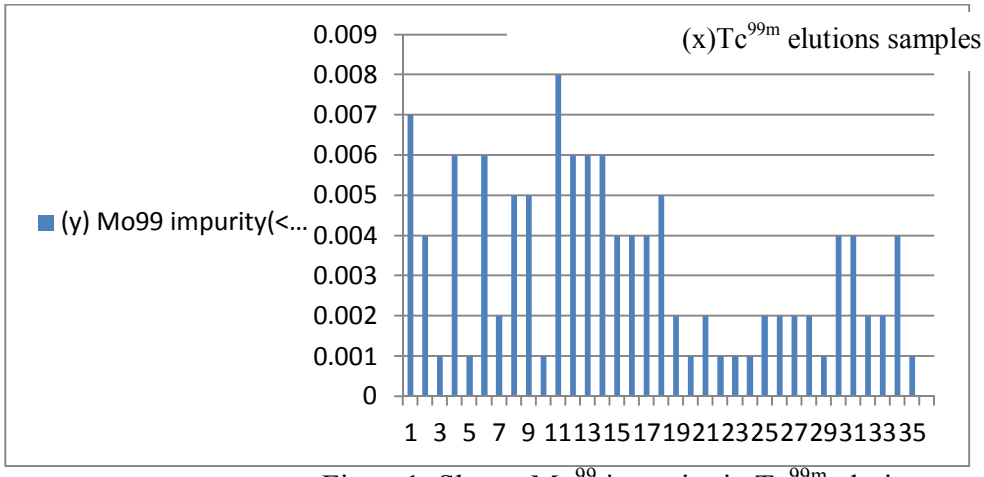

Figure1. Shows Mo^{99} impurity in Tc^{99m} elutions

Total 51 samples from Tc^{99m} eluate were taken for radionuclidic purity measurements before reconstitution .The samples were taken from three different radiopharmacy units (Khartoum Oncology Centre, Alneelain Medical Diagnostic Centre and Royal Care Hospital) and form different type of generators (POLATOM, MON.TEK MONOROL and Mallinckrodt pharmaceuticals).

All reading was in range of specification. The mean radionuclidic purity resulted was 0.0026% with STD 0.0018 for all samples.

Table 3 Measurements of chemical Al^{+3} impurities in Tc^{99m} eluate

Sample	Total No. of samples	Al^{+3} reading (eluate colour)	Comments (specification)
Drop from free Tc^{99m} perechnetate	12	All the samples were less intense	Less than < 10 µg/mL

Table 4 Measurements of chemical Al^{+3} impurities in Tc^{99m} eluate

Sample	Total No. of samples	Al^{+3} reading (eluate colour)	Comments (specification)
Drop from Free Tc^{99m} perechnetate	29	All the samples were less intense	Less than < 5 µg/mL

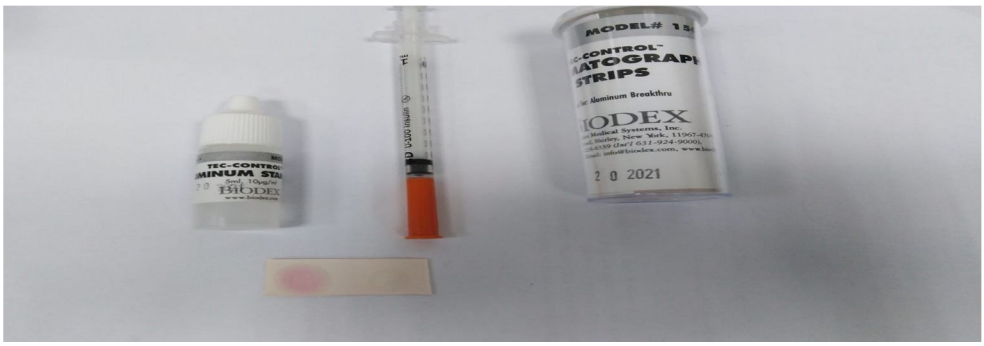

Figure 2 shows less intense eluate sample compared to standard Al+3 sample

Total 41 samples from Tc^{99m} eluate were taken for chemical purity measurements before reconstitution (Al+3 concentrations in the Tc-99m eluate). The samples were taken from three different radiopharmacy units and form three different types of generators.

29 samples were examined by standard Aluminum 5 µg/mL and all the reading fall in the normal range and in the range of specification.

12 samples were examined by standard Aluminum 10 µg/mL and the all results were in the range of specification.

Discussion

51 Samples of Tc^{99m} pertechnetate elutions were collected randomly from different radiopharmcy units in Khartoum (Khartoum Oncology Centre, Alneelain Medical Diagnostic Centre and Royal Care Hospital). The samples were taken from different generators companies (POLATOM, MON.TEK MONOROL and Mallinckrodt pharmaceuticals), the samples were tested for Mo^{99} impurity and all the samples were in the acceptable limit. The mean radionuclidic purity resulted was 0.0026% with STD 0.0018 for all samples.

The NRC and USP limit for ^{99}Mo is < 0.15 µ Ci ^{99}Mo per mCi of ^{99m}Tc at the time of patient administration (specifications < 0.010%).

41 Spot samples of Tc^{99m} pertechnetate were collected randomly from different radiopharmcy units in Khartoum (Khartoum Oncology Centre, Alneelain Medical Diagnostic Centre and Royal Care Hospital). The samples were taken from different generators companies (POLATOM, MON.TEK MONOROL and Mallinckrodt pharmaceuticals), the samples were tested for Al+3 impurity and all the samples were in the acceptable limit.

29 samples were examined by standard Aluminum 5 µg/mL and all the reading fall in the normal range and in the range of specification.

12 samples were examined by standard Aluminum 10 µg/mL and the all results were in the range of specification.

The acceptance limit of Al+3 concentrations in the Tc-99m eluate should be lower than10 µg/mL (USP)

The acceptance limit of Al+3 concentrations in the Tc-99m eluate should be lower than 5 µg/mL (Ph. Eur.)

The Tc^{99m} elution should be discarded in case excessive amount of Mo^{99} and Al+3 concentrations.

The United State Nuclear Regulatory Commission NRC requires measurement of the ^{99}Mo concentration of the first eluate following receipt of the generator.

The NRC issued an information notice (2009) about elevated molybdenum ^{99}Mo breakthrough in generator elution. This IN discusses reports of ^{99}Mo breakthrough exceeding the limits at the first elution whereas others reported^{99}Mo concentration within limits on the first elution but exceeded limits on subsequent elutions. In the IN, the NRC strongly recommends that all licensees using ^{99}Mo /^{99m}Tc generators assay each eluate for ^{99}Mo breakthrough prior to the administration of ^{99m}Tc to humans.[10]

All reading for Mo^{99} impurity was in range of specification. The mean radionuclidic purity resulted was 0.0026% with STD 0.0018. There was similar study carried out in Iran 2010 by M. Momennezhad, S.R. Zakavi, R. Sadeghi and the result showed that all samples from Tc^{99m} pertechnetate elutions which were tested for radionuclidic Mo^{99} breakthrough were in normal limit.

All reading for Mo^{99} impurity was in range of specification. The mean radionuclidic purity resulted was 0.0026% with STD 0.0018, and all samples which were tested for Al+3 impurity were in the acceptable limit. There was similar study carried out in Brazil 2009 by Wellington G. Andrade, Fabiana F. Lima and the result showed 2.0% of samples gave levels of Mo^{99} above the reference value and two samples were outside of the recommended Al3+ concentration.

3. Conclusion

The safety, stability and efficacy of ^{99m} Tc and ^{99m} Tc radiopharmaceuticals compound depends mainly on radiochemical purity, radionuclidic purity, and chemical purity.

When Tc^{99m} eluate radionuclidic purity and chemical purity are high. A high Tc^{99m} radiopharmaceuticals compounding obtained and hence a safe product obtained.

One important aspect of this study is to improve the quality and safety parameters of Tc^{99m} and Tc^{99m} radiopharmaceutical in Khartoum and to improve the use of Tc^{99m} radiopharmaceuticals in diagnosis of diseases.

Although all samples from Tc^{99m} pertechnetate elution which were tested for radionuclidic Mo^{99} breakthrough and chemical Al^{+3} impurity were in normal limit, it recommended to implement daily quality control test for each Tc^{99m} pertechnetate before reconstitution to the pharmaceuticals kit as part of routine quality assurance protocol in radiopharmacy units.

4. Recommendations

The impurities tests should be done before Tc^{99m} administered to patients because the radionuclidic impurities can contribute significant effects on the patient's overall radiation dose as well as impact the image quality and the chemical impurities in preparations of radiopharmaceuticals may cause toxic or undesirable interactions e.g. (aluminum can induce flocculation of ^{99m}Tc- sulphur colloid).

It is recommended to assay each Tc^{99m} pertechnetate elution for Mo^{99} impurity and Al^{+3} impurities prior to the administration of Tc^{99m} to humans.

Before Tc^{99m} pertechnetate is being reconstituted to pharmaceutical kits the level of Mo^{99} reading and Al^{+3} reading should be according to the accepted level stated in International Atomic Energy Agency IAEA, European Pharmacopoeia EP and the United States Pharmacopeia USP.

The expiration time for Tc^{99m} pertechnetate elution must be determined because the Mo^{99} impurity changes with time.

It is also recommended to implement quality assurance program for Tc^{99m} and Tc^{99m} radiopharmaceuticals and the records should be kept.

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