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GB 13172-2009

Replacing GB 13172-1991

Molybdenum 99-Technetium 99m chromatographic generator (fission)

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Issued by: General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China;

Standardization Administration of the People's Republic of China.

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Foreword

All the technical contents of this standard are mandatory.

This standard replaces GB 13172-1991 “Molybdenum 99-Technetium 99m chromatographic generator (fission)”. As compared with GB 13172-1991, the main changes of this standard are as follows:

a) MODIFY the standard name;

b) ADD 5 normative references;

c) CHANGE the test and determination in the original standard into inspection;

d) DELETE clause 3.3 of the original standard; ADD such items as the elution, eluate, calibration time, and aluminum concentration, etc.;

e) CHANGE the sodium chloride injection of the original standard into elution;

f) DELETE the Chapter 4 from the original standard;

g) ADD the new product specifications;

h) DELETE the clause 6.1.1 and 6.1.4 from the original standard;

i) ADD the technical requirements for radioactive contamination of the generator surface;

j) ADJUST the clause 6.2.9 of the original standard into the technical requirements of the generator;

k) DELETE the clause 7.2 from the original standard;

l) ADD the chapter of inspection rules;

m) SPLIT the original chapter 8 into two chapters: Marking, sign and instruction manual, AND packaging, transportation, and storage.

This standard was proposed by China National Nuclear Corporation.

This standard shall be under the jurisdiction of the National Nuclear Energy Standardization Technical Committee.

The drafting organization of this standard: China Atomic Energy Research Institute.

The drafters of this standard: Niu Xuxiang, Chen Daming, Liu Guangyu.

Molybdenum 99-Technetium 99m chromatographic generator (fission)

1 Scope

This standard specifies the technical requirements, inspection methods, inspection rules, marking, inspection certificate and instruction manual, packaging, transportation and storage of molybdenum 99-Technetium 99m chromatographic generator (fission).

This standard applies to the medical molybdenum 99-Technetium 99m chromatographic generator which uses the Al_2O_3 as the adsorbent; AND it is not applicable to the technetium 99m generator of other types.

2 Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. For the dated references, the subsequent amendments (excluding corrections) or revisions do not apply to this Standard; however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB 11806 Regulations for the safe transport of radioactive material

GB/T 15239 Sampling procedures and tables for isolated lot inspection by attributes

EJ/T 843-1994 Radioactive nuclide activity measurement - Well-type ionization chamber method

EJ/T 845-1994 Radioactive drug solution – pH determination method

State Food and Drug Administration Note [2006] No.264 “Detailed rules for the radioactive drug instruction specification”

People's Republic of China Pharmacopoeia II (2005 version)

3 Terms and definitions

The following terms and definitions apply to this standard.

3.1

Molybdenum 99-technetium 99m chromatographic generator (fission)

^{89}Sr: 6×10^{-5}%

^{90}Sr: 6×10^{-6}%

α impurity nuclide: 1×10^{-7}%

Other total β, γ nuclide: 1×10^{-2}%

5.2.5 Radiochemical purity

$Na^{99m}TcO_4$ content shall not be less than 98%.

5.2.6 Activity

The activity of the ^{99m}Tc eluted from the generator shall be 90.0% ~ 110.0% of the indicated amount if calculated in accordance with the calibration time.

5.2.7 Bacterial endotoxin

It shall comply with the provisions of the People's Republic of China Pharmacopoeia II (2005 version).

5.2.8 Sterile

It shall comply with the provisions of the People's Republic of China Pharmacopoeia II (2005 version).

6 Test methods

6.1 Generator test

6.1.1 Eluting efficiency

In accordance with the calibration time and product specifications, CALCULATE the activity A_1 of the ^{99m}Tc in the generator at the time of eluting; USE 10 mL of elution to elute the generator; DETERMINE the activity A_2 of the ^{99m}Tc in the generator; USE the formula (1) to calculate the eluting efficiency η:

$$\eta = \frac{A_2}{A_1} \times 100\% \qquad \cdots\cdots (1)$$

Where:

η - Eluting efficiency, expressed as a percentage;

A_1 - The activity of the ^{99m}Tc in the generator at the time of eluting, in becquerel (Bq);

A_2 - The activity of the ^{99m}Tc in the eluate, in becquerel (Bq).

6.1.2 Surface radioactive contamination

8 Product marking, label and instruction manual

8.1 Marking

Generator outer packaging shall have the following markings:

a) Radioactive marking;

b) Radioactive transportation level marking;

c) Markings of rainproof, handle with care, and face upwards.

8.2 Label

The label is divided into inner packaging label and outer packaging label. The inner packaging label is attached to the generator surface; AND the outer packaging label is attached to the outer packaging. The label shall have the following information:

a) Product name;

b) Radioactive marking;

c) Approval document number;

d) Specifications;

e) Product lot number;

f) Radioactive activity;

g) Calibration time (or reference time);

h) Validity period;

i) Manufacturer.

8.3 Instruction manual

The generator shall be supplied with the instruction manual at the time of exit-factory. The contents of the instruction manual shall be in accordance with the provisions of the State Food and Drug Administration [2006] No.264.

9 Packaging, transportation and storage

9.1 Packaging

Product packaging is lead can, foam liner, and iron drum in the order in the order from the inside out, AND the surface radioactive pollution levels and radiation levels shall comply with the provisions of GB 11806.

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