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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 13172-20xx
Replaces GB 13172-91

Molybdenum 99 – technetium 99m chromatographic generator (fission)

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Foreword

The present standard is a revision of GB 13172-91 “ ^{99}Mo - $^{99\text{m}}\text{Tc}$ chromatographic generator (fission).” The present standard replaces GB 13172-91 “ ^{99}Mo - $^{99\text{m}}\text{Tc}$ chromatographic generator (fission)” upon announcement. The present standard changes GB 13172-91 primarily with respect to the following:

- a) revises the standard title;
- b) adds five cited regulatory documents including GB 2828 “Sampling procedures and tables for lot-by-lot inspection and counting” and EJ/T 843-94 “Radionuclide activity measurement—Well-type ionization chamber method;”
- c) changes “test” and “determination” in the former document to “inspection;”
- d) deletes article 3.3 of the former standard and adds such terms as “eluant,” “eluate,” “calibration time,” and “aluminium content;”
- e) changes “sodium chloride injection” of the former standard to “ eluant;”
- f) deletes Chapter 4 of the former standard;
- g) adds new product specifications;
- h) deletes 6.1.1 and 6.1.4 of the former standard;
- i) adds technical requirements relating to generator surface radioactive contamination;
- j) adjusts 6.2.9 of the former standard to technical requirements for the generator;
- k) deletes article 7.2 of the former standards;
- l) adds an inspection rules chapter;
- m) splits chapter 8 of the former standard into two chapters: “Marks, labels and instructions for use” and “Packaging, transportation and storage;”
- n) revises some of the language of the former standard.

The present standard was put forward by, and is under the jurisdiction of, the Radioactive Isotopes Technical Subcommittee of the National Nuclear Energy Standardisation Technical Committee.

The entity that drafted the present standard: China Institute of Atomic Energy

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The present standard was first announced on 29 October 1991.

Molybdenum 99 – technetium 99m chromatographic generator (fission)

1 Scope

The present standard specifies the technical requirements, testing methods, inspection rules, marks, inspection certificates, instructions for use, packaging, transportation, and storage for molybdenum 99-technetium 99m chromatographic generators (fission).

The present standard applies to medical molybdenum 99-technetium 99m chromatographic generators which use Al_2O_3 as an adsorbent. It does not apply to other types of technetium 99m generators.

2 Cited regulatory documents

The clauses in the documents below become clauses of the present standard by virtue of being cited by the present standard. If a date is indicated for a cited document, no subsequent revision sheet (not including corrigenda) or amended version shall apply to the present standard. Nevertheless, the parties to agreements based on the present standard are encouraged to study whether the most recent versions of these documents can be used. If no date is indicated for a cited document, then the most recent version applies to the present standard.

GB 11806	Regulations for the safe transport of radioactive material
	People's Republic of China Pharmacopoeia, Part 2 (2005 edition)
GB 2828	Sampling procedures and tables for lot-by-lot inspection and counting
EJ/T 843-1994	Radionuclide activity measurement—Well-type ionization chamber method
EJ/T 845-1994	Methods of determining the pH of radiopharmaceuticals
GSYJZ [2006] No. 264	“Detailed standard for radiopharmaceutical package inserts”

3 Terms and definitions

The following terms and definitions apply to the present standard.

3.1

molybdenum 99-technetium 99m chromatographic generator (fission)

Refers to a device that adsorbs fission molybdenum 99 to an Al_2O_3 chromatographic column from which, as appropriate, the daughter nuclide technetium 99m, a decay product of molybdenum 99, may be eluted with an eluent.

3.2

eluent

The solution that is used to elute technetium 99m from the generator. In the present standard, it especially refers to sodium chloride injection.

3.3

eluate

The technetium 99m-containing solution that is eluted from the generator using eluent.

3.4

calibration time

The time corresponding to the product specification.

3.5

aluminium concentration

Aluminium content in unit volume eluate; unit is $\mu\text{g}/\text{mL}$.

3.6

elution efficiency

The ratio in percentage terms of the activity of technetium 99m eluted using a certain volume of eluant to the activity of technetium 99m present in the generator at the start of elution.

4 Product specifications

The product has the following specifications:

11.1 GBq; 18.5 GBq; 29.6 GBq; 37 GBq, and above 37 GBq.

5 Technical requirements

5.1 Technical requirements of the generator

5.1.1 Elution efficiency

Elution efficiency for 10 mL eluant shall be at least 90%.

5.1.2 Surface radioactive contamination

Radioactive contamination of the generator surface shall be less than 0.4 Bq/cm².

5.1.3 Expiration date

The expiration date of this product is 15 days after production.

5.2 Eluant technical requirements

5.2.1 Appearance

Shall be a colourless, clear liquid.

5.2.2 pH

Shall be between 4.0 and 7.0.

5.2.3 Aluminium content

Shall be no greater than 10 µg/mL.

5.2.4 Radionuclide purity

Radioactive impurity activity relative to total radioactivity shall not exceed the specifications below:

⁹⁹ Mo	$1 \times 10^{-1}\%$
¹³¹ I	$5 \times 10^{-3}\%$
¹⁰³ Ru	$5 \times 10^{-3}\%$
⁸⁹ Sr	$6 \times 10^{-5}\%$
⁹⁰ Sr	$6 \times 10^{-6}\%$
α impure nuclide	$1 \times 10^{-7}\%$
other total β and γ nuclides	$1 \times 10^{-2}\%$

5.2.5 Radiochemical purity

The content of Na^{99m}TcO₄ shall be at least 98%.

5.2.6 Activity

The ^{99m}Tc eluted from the generator shall, calculated according to the calibration time, be 90.0% to 110.0% of the nominal quantity.

5.2.7 Bacterial endotoxins

Shall comply with the specifications of People's Republic of China Pharmacopoeia, Part 2 (2005 edition).

5.2.8 Sterility

Shall comply with the specifications of People's Republic of China Pharmacopoeia, Part 2 (2005 edition).

6 Inspection methods

6.1 Generator inspection

6.1.1 Elution efficiency

In accordance with the calibration time and product specifications, calculate the activity A_1 of ^{99m}Tc in the generator at elution. Using 10 mL eluant to elute the generator, determine the activity A_2 of ^{99m}Tc in the eluate. Use the formula below to calculate elution efficiency η :

$$\eta = \frac{A_2}{A_1} \times 100 \%$$

Where:

η —elution efficiency, unit is %;
 A_1 —activity of ^{99m}Tc in the generator at elution, unit is Bq;
 A_2 —activity of ^{99m}Tc in eluate, unit is Bq.

- 6.1.2 Surface radioactive contamination**
 Test using the wipe method.
- 6.1.3 Expiration date**
 Conduct inspection on each technical requirement for the generator within 15 days from the production date.
- 6.2 Eluate inspection**
- 6.2.1 Appearance**
 Inspect with the naked eye after placing a vial filled with 1 mL eluate behind a lead glass shield.
- 6.2.2 pH**
 Test in accordance with the method specified in EJ/T 845-94.
- 6.2.3 Aluminium content**
 Measure in accordance with the specifications of the People's Republic of China Pharmacopoeia, Part 2 (2005 edition).
- 6.2.4 Radionuclide purity**
 Take an appropriate quantity of eluate, measure the amount of radioactive impurity with a γ -spectrum spectrometer, calculate the ratio of impure nuclide activity to total activity in percentage terms.
- 6.2.5 Radiochemical purity**
 Test in accordance with method 1 in People's Republic of China Pharmacopoeia, Part 2 (2005 edition), Appendix XIII.
- 6.2.6 Activity**
 Elute the generator with 10 mL eluant. Collect the eluate, and measure in accordance with the method specified in EJ/T 843-94.
- 6.2.7 Bacterial endotoxins**
 Take an appropriate quantity of eluate. Dilute 15 : 1 with water used for bacterial endotoxin examinations. Inspect in accordance with method E in the People's Republic of China Pharmacopoeia, Part 2 (2005 edition), Appendix XI.
- 6.2.8 Sterility**
 Inspect in accordance with method H in the People's Republic of China Pharmacopoeia, Part 2 (2005 edition), Appendix XI.
- 7 Inspection rules**
- 7.1 Comprehensive inspection**
 All items specified in the technical requirements of the present standard constitute the comprehensive inspection. Comprehensive inspections shall involve at least three samples and be conducted biannually. A comprehensive inspection shall also be conducted in the event of any of the following:
- when the raw materials, structure, or production process of the generator undergoes a relatively major change which might affect product quality;
 - when production is restored after being suspended for more than one year;
 - when a quality supervision department of the state requests a comprehensive inspection.
- 7.2 Pre-shipment inspection**
- 7.2.1** The pre-shipment inspection shall make use of sampling. The sampling procedures and quantities shall be determined in accordance with the specifications of GB 2828.
- 7.2.2** Generator pre-shipment inspection items are as follows:
- radioactivity;
 - surface radioactive contamination.
- 7.2.3 Eluate pre-shipment inspection items are as follows:**
- appearance;

- b) pH;
- c) aluminium content;
- d) radionuclide purity;
- e) radiochemical purity;
- f) activity;
- g) bacterial endotoxins;
- h) sterility.

8 Product marks, labels and instructions for use

8.1 Marks

The outer package of the generator shall have the marks listed below:

- a) radioactivity mark;
- b) radioactive transportation category mark;
- c) "Keep out of rain," "Handle with care," and "This side up" marks.

8.2 Labels

Labels are divided into inner package and outer package labels. Inner package labels are attached to the surface of the generator. Outer package labels are attached to the outer package. Labels shall include the following information:

- a) product name;
- b) radioactivity mark;
- c) approval document number;
- d) specification;
- e) product lot number;
- f) radioactivity;
- g) calibration time;
- h) expiration date;
- i) manufacturer.

8.3 Instructions for use

Generators shall be provided with instructions for use when shipped from the factory. The contents of instructions for use shall comply with the provisions of GSYJZ [2006] No. 264.

9 Packaging, transportation and storage

9.1 Packaging

Product packaging, in an inside-to-outside sequence, shall consist of: lead cylinder, foam padding, and iron-sheet drum. The radioactive contamination level and radiation level of the outer package container surface shall comply with the provisions of GB 11806.

When packaging, enclose the instructions for use in the iron-sheet drum. Seal with lead after packaging is completed.

9.2 Transportation

Products shall be shipped in accordance with the provisions of GB 11806.

9.3 Storage

The product shall be kept at a constant temperature in a clean environment. Please be sure to protect against theft, freezing, tipping over, and vibrations.