ISOTOPE
ROSATOM

$^{188}W/^{188}Re$ generator for radionuclide therapy

GREN-1 rhenium-188 generator is intended for multiple generation of sterile sodium perrenate solution with rhenium-188 used for production of radiopharmaceuticals with the help of special kits of reagents. These RP are used for therapy in hospitals.

Generator design elements are:
- shielding container with radiation (biological) shield;
- sorption column with communications (eluent line and eluate line).

TECHNICAL SPECIFICATION

- Yield of rhenium-188 radionuclide equals to 70 to 90% of tungsten -188 mother radionuclide activity.
- Rhenium-188 radionuclide activity has rated values: 3.7, 5.5, 7.4, 18.5, 37.0 GBq on delivery date. Permissible deviation from rated values of the eluate activity in rhenium-188 – from minus 10 to plus 20 %.
- For generators of 3.7, 5.5, 7.4 GBq the eluent volume is 10 cm^3, and for generator of 18.5 and 37.0 GBq - 20 cm^3, correspondingly.
- Optimal mode of generator elution with maximum accumulation of rhenium-188 radionuclide is once per three days, it is determined by half-life periods of the radionuclide pair.
- Physical and chemical properties of the eluate correspond to the requirements and standards presented in the Table.
- Specified lifetime of generator is determined by its rated activity and amounts to: 40, 80, 110, 150, 200 days for generators of 3.7, 5.5, 7.4, 18.5, 37.0 GBq, correspondingly.
- Evacuated vials are sterile inside and vacuum level should provide obtaining of eluate of 10 to 20 cm^3 with the following column drying.
- Generator should withstand one hundred fifty-fold elutions by eluent of 10 to 20 cm^3 (depending on its rated activity).
- Time period of one elution cycle equals to:
  - (35-50) sec. for vials of 10 ml volume;
  - (75-95) sec. for vials of 20 ml volume.
- Generator weight is not more than 16.0 kg; in transport container – not more than 21.0 kg. Weight of medical shielding container is nor more than 1.2 kg.

KEY ADVANTAGES:

Experienced production facility

Worldwide logistics

Wide fleet of certified containers

ISOTOPE JSC: THE CORE OF ATOMIC TECHNOLOGY FOR LONGER LIVES

Address: 22 Pogodinskaya Str., Moscow 119435, Russia
Tel.: +7 (495) 981 96 16
Website: www.isotop.ru, E-mail: medical@isotop.ru

ISOTOPE
ROSATOM

TRANSPORTATION

Transportation of generator in transport container (Type A) as in radiation package of the III transport category is allowed on specially equipped vehicles or special set aside areas on ships only according to the Rules and Standards.

WARRANTY

• Producer guarantees the generator compliance with the requirements of the specification while meeting the requirements of operating, transportation and storage conditions specified by this specification.

• Warranty life of generator is determined by its rated activity and equals to: **40, 80, 110, 150, 200 days** for generators of **3.7, 5.5, 7.4, 18.5, 37.0 GBq,** correspondingly.

Property	Standard
Appearance	sterile solution
Sodium chloride concentration, mg/ml	9.0 ± 1.0
pH of solution	4.0 ÷ 8.0
Inactive impurity concentration, μg/ml, not more than: - mercury, zinc - aluminum - arcenic, cadmium, antimony, tellurium, iron - copper - barium, bismuth, chromium, molybdenum, nickel, tin, lead - berillium - manganese	 2.5 5.0 1.0 0.05 0.1 0.005 0.01
Radionuclide impurity concentration, % of renium-88 activity, not more than; - tungsten-188 - other γ-emitters (total)	 $1 \cdot 10^{-3}$ $1 \cdot 10^{-3}$
Concentration activity in renium-188, MBq/ml: - by the end of generator service life - on calibration date of 37.0 GBq generator	 370 3700
Relative activity of perrenate-ions 188ReO4 - (radiochemical purity), %, not less than	 99.0
Sterility	sterile
Bacterial endotoxins, EU/ml, not more than	8.75

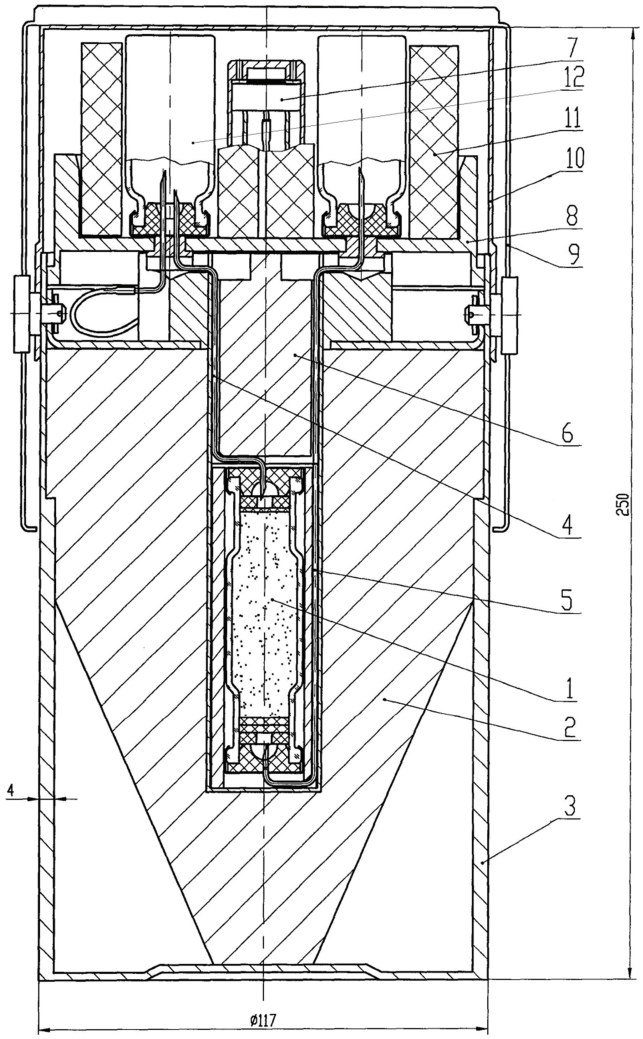
For pricing and availability please inquire

ISOTOPE JSC: THE CORE OF ATOMIC TECHNOLOGY FOR LONGER LIVES

Address: 22 Pogodinskaya Str., Moscow 119435, Russia
Tel.: +7 (495) 981 96 16
Website: www.isotop.ru, E-mail: medical@isotop.ru

ISOTOPE
ROSATOM

GENERATOR DESIGN



7 – air filter (medical felt and membrain)

12 – vial with benzyl alcoho

Figure A.1 – GREN-1 generator designl

11 – preventive foam insert (expandable poly

10 - cover (steel AISI 321)

8 – generator flange (aluminum alloy)

9 – handle for transportation (steel AISI 321)

6 – protector plug (lead)

4 – eluent line (steel AISI 321)

5 – eluate line (steel AISI 321)

1 – sorption column (molybdenum glass)

2 – radiation protection (lead)

3 – generator shielding container (steel AISI321)

Address: 22 Pogodinskaya Str., Moscow 119435, Russia
Tel.: +7 (495) 981 96 16
Website: www.isotop.ru, E-mail: medical@isotop.ru

ISOTOPE JSC: THE CORE OF ATOMIC TECHNOLOGY FOR LONGER LIVES