

# <sup>177</sup>Lutetium Chloride n.c.a.

Non-carrier-added [<sup>177</sup>Lu]Lutetium Chloride solution



Sterile [<sup>177</sup>Lu]Lutetium Chloride solution for radiolabeling

#### PLEASE NOTE:

The product is not intended for direct use in humans and has not been registered as a pharmaceutical product.

#### Full Range Supplier

Eckert & Ziegler Radiopharma GmbH is a full-range supplier of radiopharmaceutical products for diagnostic and therapeutical use. One of our core competences is the production of a non-carrier-added [<sup>177</sup>Lu]Lutetium Chloride solution that can be delivered worldwide to eligible users for non-clinical and clinical trials.

#### GMP Quality and Safety Standards

[<sup>177</sup>Lu]Lutetium Chloride solution is produced in a state-of-the-art GMP production facility. The high purity of our product enables pre-calibration up to ten days. Enhanced vial shielding is used to protect users of unnecessary exposure in accordance with ALARA principle.

We provide [<sup>177</sup>Lu]Lutetium Chloride (<sup>177</sup>Lu]LuCl<sub>3</sub>) as a sterile solution. It is to be used only for *in vitro*-radiolabeling of carrier molecules, which have been specifically developed and authorized for radiolabeling with this radionuclide. It is not meant for direct application to patients.

#### U.S. DMF Type II

Eckert & Ziegler submitted a Type II DMF (#038043) to the U.S. FDA.

*The product has not been registered as a radiopharmaceutical in the European Union. In the USA it is regarded as a drug substance.*

#### Flexible Dispension

We dispense your required volume of sterile [<sup>177</sup>Lu]Lutetium Chloride solution in up to 3 mL V-vials or in 5 mL in a 10R-glass flat bottom vial with activities up to 200 GBq (5.4 Ci).

#### Production Capacity and Raw Material

Eckert & Ziegler implemented efficient processes and resource allocation measures to ensure uninterrupted production and consistent supply to meet the growing global demand for [<sup>177</sup>Lu]Lutetium Chloride (n.c.a.). Moreover, we are currently establishing an own supply of the indispensable precursor material Ytterbium-176, including an efficient recycling process.

#### Reliable Delivery

A broad international logistics network enables us to deliver [<sup>177</sup>Lu]Lutetium Chloride worldwide within four business days. Close proximity to international transportation hubs, a global network of partners and the experienced team ensure optimal logistics.

#### Calibration Solutions

We provide a range of PTB and NIST-traceable [<sup>177</sup>Lu]Lutetium calibrated solutions. In cooperation with the Eckert & Ziegler Nuclitec we also provide a [<sup>177</sup>Lu]Lutetium calibration solution certified by the DAkkS. All our solutions are available on request.

#### CDMO Services and GMP Suites

Eckert & Ziegler also provides a wide range of CDMO services, including the development of radiolabeling and quality control protocols for your Lutetium-based products. With our global network of GMP suites (EMEA, AMERICAS, APAC) we give access to state-of-the-art infrastructure including logistics and a highly experienced staff.

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## Product Specifications (GMP grade)

Product	[ <sup>177</sup> Lu]Lutetium Chloride solution (clear and colorless)
Active ingredient	[ <sup>177</sup> Lu]Lutetium Chloride, 40 GBq/mL
Excipients	Hydrochloric acid (0.04 mol/L)
Half-life	6.65 days
Decay energy	β: E <sub>max</sub> = 498 keV γ: E = 208 keV E = 113 keV
Chemical form	[ <sup>177</sup> Lu]LuCl <sub>3</sub> in 0.04 mol/L hydrochloric acid solution
Specific activity	> 3000 GBq/mg at activity calibration date
Activity	As requested 4 - 200 GBq per vial (activity tolerance ± 10%)
Pre-calibration	Up to 10 days after production
Reference date	[ <sup>177</sup> Lu]Lutetium can be produced to meet specific customer requirements for calibration date
Expiry date	10 days after production
Radiochemical purity	> 99.0 % [ <sup>177</sup> Lu]Lutetium as Lu <sup>3+</sup>
Radionuclide purity	≥ 99.9 % [ <sup>175</sup> Yb]Ytterbium ≤ 0.1 % [ <sup>177m</sup> Lu]Lutetium ≤ 0.07 % All other radionuclide impurities ≤ 0.01 %
Chemical purity	Fe: ≤ 0.50 µg/GBq Cu: ≤ 1.00 µg/GBq Zn: ≤ 1.00 µg/GBq Pb: ≤ 0.50 µg/GBq Yb: ≤ 0.50 µg/GBq
pH	1.0 - 2.0
Packaging	Max. 3 mL in a (3 mL) V-glass vial 5 mL in a 10R-glass flat bottom vial Closure with crimp cap and pharma-grade stopper
Endotoxins	< 20 EU/mL
Sterility	Sterile
Delivery time	Within 4 business days worldwide

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