

 **SHINE**

**Meet the purest
n.c.a. Lu-177.**



99.9% pure. 100% available to ship.

When it comes to supporting the world's need for nuclear medicine, one product shines bright. SHINE Technologies' n.c.a. Lu-177 offers unmatched radionuclidic purity and immediate worldwide shipping to bring life-saving medicine within reach like never before.



Unmatched purity and efficacy
for high specific activity
n.c.a. Lu-177



Meets or exceeds European
Pharmacopeia standards



Efficient weekly global
distribution



Streamlined customs processing
to minimize the risk of study
delays or cancellations

Supporting the creation of hundreds of thousands of doses of cancer-fighting medications.

Our purpose-built facility in Wisconsin, USA offers unprecedented production capacity with the ability to support 100,000 doses of medication per year, and room to expand to 200,000 doses. We plan to add a second therapeutics facility in Europe that will match our US-based production. Because we are one of the few ytterbium-176 (Yb-176) producers outside of Russia, we also offer a separate, reliable alternative to traditional sources, further de-risking supply.

Hope shines.

Lu-177 illuminates hope for patients with cancer with the ability to precisely target tumors and metastases with potent radiation, destroying cancer cells while minimizing harm to healthy tissue. With unparalleled purity and efficacy, our Lu-177 offers new possibilities for patients with advanced or difficult-to-treat cancers, including neuroendocrine tumors and prostate cancer.

- Reliable supply and fast shipping to help research and clinical trials stay on track.
- Helps bring innovative cancer therapies to market faster.
- Rigorous testing of each lot ensures optimal radiolabeling yield and performance.



Routine pairing with
PSMA 617 at $\geq 99\%$



The largest U.S. production
capacity to meet growing
worldwide demand



Optimization of internal
irradiation capabilities
with an eye toward 100%
vertical integration



Eliminates dependence on
Russian sources and aging
nuclear reactors



Operates to cGMP as
defined by ICH Q7 and
FDA 21CFR to ensure
regulatory compliance



Drug Master File (DMF) is
filed with the U.S. FDA



Lighting the way.

SHINE is on track to become the world's first vertically integrated Lu-177 manufacturer. We're continuing to increase capacity and are developing new therapeutic isotopes. We're committed to helping save lives, reducing radioactive waste, and empowering a future in which commercial fusion energy is feasible. We're helping light the way to a brighter future for us all.



Made differently. To make a difference.

Our n.c.a. Lu-177 uses a proprietary process that offers a variety of advantages. These include not only higher purity, but also a longer shelf life and a more eco-friendly outcome.

Product Specifications.



Packaging Options	10 mL flat bottom glass vial 2 mL conical glass vial
Chemical Form	n.c.a. $^{177}\text{LuCl}_3$ in 0.04M HCl solution
Specific Activity	$\geq 3,000$ GBq/mg at SHINE calibration time
Radiochemical Purity	$\geq 99\%$ as $^{177}\text{LuCl}_3$
Radionuclidic Purity	$\geq 99.9\%$ ^{177}Lu
Radioactivity Concentration at SHINE Calibration	1.0 Ci/mL (37 GBq/mL) $\pm 10\%$
Expiry	10 days from the end of synthesis
Standard Calibration	Tuesdays 1200 Central Time (U.S.) at 1.0 Ci/mL
cGMP	Meets ICH-Q7 and FDA 21 CFR
Radiolabeling Yield	 $\geq 99\%$
Chemical Purity	$\text{Fe} \leq 0.25 \mu\text{g/GBq}$ $\text{Cu} \leq 0.5 \mu\text{g/GBq}$ $\text{Zn} \leq 0.5 \mu\text{g/GBq}$ $\text{Pb} \leq 0.5 \mu\text{g/GBq}$ $^{176}\text{Yb} \leq 0.1 \mu\text{g/GBq}$
Production	Every week under cGMP with fresh material
Shipping	 Weekend shipment for arrival at customer locations on Monday
Radioactivity Concentration	1.0 Ci/mL
Lead Time for Delivery	7-14 days; the cutoff is Wednesday at 1400 CT
Minimum Order Size	50mCi (1.85 GBq)



Upcoming Isotopes.

We're mapping out isotope development, made possible by Chrysalis, our state-of-the-art production facility in America's heartland. Once completed, Chrysalis will be the world's most flexible neutron irradiation source, enabling us to produce a wide range of medical isotopes.

Isotope Portfolio:

Lutetium-177 (Lu-177)

Lu-177 delivers precisely targeted radiation therapy to cancer cells, making it effective for treating various cancers, particularly neuroendocrine and prostate.

Ytterbium-176 (Yb-176)

Yb-176 is the essential precursor for producing our high-purity lutetium-177, enabling precise, targeted cancer radiotherapy.



shinefusion.com/isotope-sales-eu
orders@shinefusion.com

Isotope Portfolio Pipeline:

Molybdenum-99 (Mo-99)

Mo-99 is the parent isotope for technetium-99m, the most widely used radioisotope in diagnostic nuclear medicine.

Terbium-161 (Tb-161)

Tb-161's unique radiation profile makes it ideal for treating small tumors while allowing for SPECT imaging.

Iodine-131 (I-131)

I-131 selectively destroys thyroid tissue, offering effective treatment for thyroid cancer and hyperthyroidism.

Xenon-133 (Xe-133)

Xe-133 enables non-invasive imaging of lung function, aiding diagnosis of various respiratory conditions.

Chrysalis, SHINE's flexible neutron irradiation source in Janesville, WI, USA.

