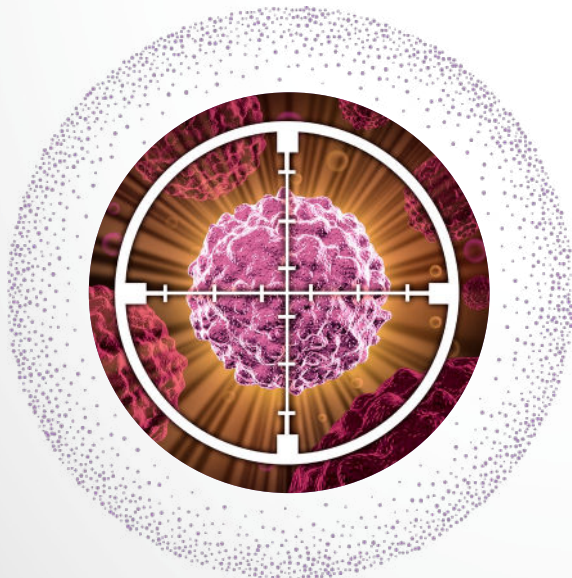


Lutetium (^{177}Lu) chloride

Targeted molecular radiotherapy



Isotopia – About Us

Isotopia Molecular Imaging was established in 2006, and has become an essential supplier for the growing field of nuclear medicine. Driven by the need to expand healthcare providers' power to diagnose and treat cancer, with greater precision and safety, we develop, produce, and supply cutting-edge diagnostic and therapeutic radioactive isotopes and cold kits.

Ensuring our services are efficiently available globally, we're establishing additional production facilities around the globe.

Reliable Global supply chain

Supply



- Consistent supply on weekly basis all year round all around the globe
- Supply to all stages of clinical development from pre-clinical to commercial
- EU production site coming up*



- New production site in Canada:
 - ✓ Shorter time from Irradiation to patient
 - ✓ Save pre calibration costs & reach more patients
 - ✓ De-risk the logistics
 - ✓ Back up and redundancy with the Israel production facility

High Quality



- Fully complies with cGMP regulations
- US FDA DMF and Health Canada MF*
- EU Marketing authorization available*
- Certified Type A package for safe global shipping
- Authorized Manufacturer, Importer, Distributor, Exporter (MIDE)

**Applicable for n.c.a only*

Service



- Gold standard service- Full attentive support, direct communication with our professional team of experts



Tell us what you need



Choose between **c.a** or **n.c.a**



Select **5mL** or **10mL** vial



Get **Lu 177** according to your needs

Lutetium (¹⁷⁷Lu) Solution for Radiolabeling

Specifications

Chemical Form	LuCl ₃ in HCl 0.04N
Packaging	10 mL molded vial closed with fluorotec septum and open top crimp seal 5 mL V-shaped vial closed with fluorotec septum and open top crimp seal

Test	Specification	
	N.C.A	C.A
Appearance	Clear, colorless solution	Clear, colorless solution
pH	1.0 – 2.0	1.0 – 2.0
Identification A (Gamma spectrometry)	Gamma photons with 208 KeV and 113 KeV present	Gamma photons with 208 KeV and 113 KeV present
Identification B (pH)	1.0 – 2.0	1.0 – 2.0
Identification C (iTLC)	The retardation factor of the principal peak in the chromatogram obtained in the test for radiochemical purity is 0.4 to 0.7	The retardation factor of the principal peak in the chromatogram obtained in the test for radiochemical purity is 0.4 to 0.7
Specific Activity (by ICP-OES at end of production)	>3000 GBq/mg (>81 Ci/mg)	>740 GBq/mg (>20 Ci/mg)
Chemical Purity (by ICP- OES at end of shelf life)	Cu ≤ 1.0 µg/GBq Fe ≤ 0.5 µg/GBq Pb ≤ 0.5 µg/GBq Zn ≤ 1.0 µg/GBq Yb ≤ 1.0 µg/GBq	Cu ≤ 1.0 µg/GBq Fe ≤ 0.5 µg/GBq Pb ≤ 0.5 µg/GBq Zn ≤ 1.0 µg/GBq
Radionuclidic Purity (Gamma spectrometry at end of shelf life)	¹⁷⁵ Yb ≤ 0.1%	^{177m} Lu ≤ 0.07%
	The total radioactivity due to other radionuclides impurities ≤ 0.01%	The total radioactivity due to other radionuclides impurities ≤ 0.01%
Radiochemical Purity (by iTLC)	[¹⁷⁷ Lu]lutetium(III) ion ≥99%	[¹⁷⁷ Lu]lutetium(III) ion ≥99%
Bacterial endotoxins	< 35 EU/mL	< 35 EU/mL
Sterility	Sterile (by autoclaving)	Sterile (by autoclaving)



Perfecting Solutions.
Delivering Confidence.



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