

# Lutetium (<sup>177</sup>Lu) chloride Targeted molecular radiotherapy

sotopia



#### 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



- 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\*

- 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



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

#### Tell us what you need



Choose between c.a or n.c.a



5 mL vial (V Shape)

Plexiglass

222

しいが umm 10 mL vial

Get Lu 177 according to your needs

Select 5mL or 10mL vial

Shield

Shield cove

### Lutetium (<sup>177</sup>Lu) Solution for Radiolabeling

#### **Specifications**

Chemical Form	L
Packaging	10 mL molded vial closed with fluorot
	5 mL V-shaped vial closed with fluor

Test	Specification		
Test	N.C.A	C.A	
Appearance	Clear, colorless solution	Clear, colorless solution	
рН	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	<sup>175</sup> Yb ≤ 0.1%	<sup>177™</sup> Lu ≤ 0.07%	
(Gamma spectrometry at end of shelf life)	The total radioactivity due to other radionuclides impurities ≤ 0.01%	The total radioactivity due to other radionuclides impurities ≤ 0.01%	
Radiochemical Purity (by iTLC)	[ <sup>177</sup> Lu]lutetium(III) ion ≥99%	[ <sup>177</sup> Lu]lutetium(III) ion ≥99%	
Bacterial endotoxins	< 35 EU/mL	< 35 EU/mL	
Sterility	Sterile (by autoclaving)	Sterile (by autoclaving)	





#### LuCl3 in HCl 0.04N

otec septum and open top crimp seal rotec septum and open top crimp seal

## Perfecting Solutions. Delivering Confidence.



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