

itG Lu-177 n.c.a.

No-carrier-added Lutetium-177



GMP
certified

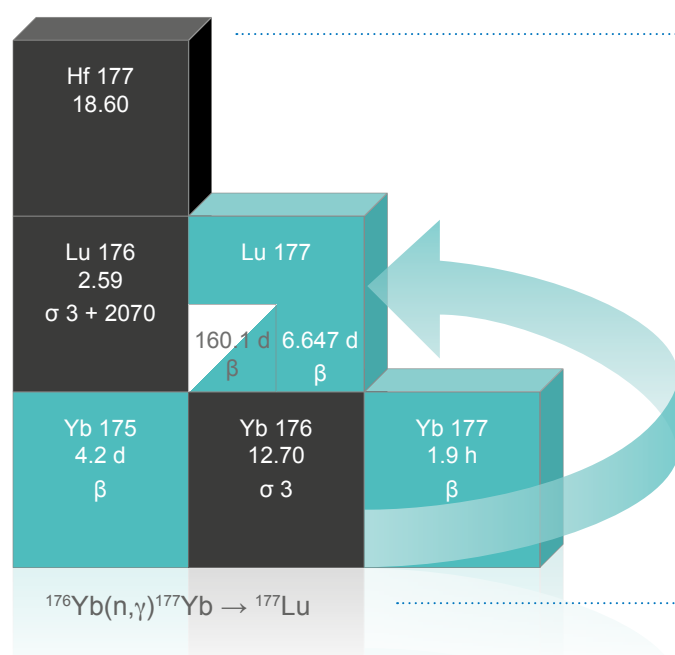
itG Lu-177 n.c.a.

The development of no-carrier-added Lutetium-177 is first-in-class for the efficacy and quality of radionuclides for theranostics in oncology. The superior production route of GMP manufactured itG Lu-177 n.c.a. takes advantage of highly enriched Ytterbium-176 as starting material, thereby providing highest specific activity and an unprecedented level of radionuclidic purity. As a result, the superior performance creates the best pre-conditions for efficient radiolabeling of biomolecules such as peptides and antibodies.

ITG is proud to work side by side with the Australian Nuclear Science and Technology Organisation (Ansto, Australia) and NTP Radioisotopes SOC Ltd. (South Africa) – both strong and reliable partners in the development of medical isotopes. In addition, the technological transfer's strategic alignment guarantees security of supply and daily availability of highly effective Lu-177 n.c.a., 365 days a year. The itm Group and its subsidiary ITG GmbH strive for excellence in establishing an innovative, fully-integrated Lu-177 n.c.a. platform, setting new standards regarding quality, safety and convenience of itG Lu-177 n.c.a.

Key advantages

- › **Significant clinical superiority**
- › **Highest specific activity (> 3,800 GBq/mg)**
- › **No contamination with long-lived Lu-177m**
- › **Availability – 365 days a year**
- › **Sterile / Endotoxin-tested**



Superior production route

No-carrier-added vs. carrier-added

No-carrier-added Lutetium-177 displays superior characteristics when compared to the carrier-added analog. The specific activity of n.c.a. Lutetium-177 is up to 4 to 5 times higher and offers the best preconditions for an efficient radiolabeling reaction. The n.c.a. Lu-177 product is characterized by a significantly longer shelf life than the c.a. Lu-177 variant, which must be used immediately upon receipt. Furthermore, n.c.a. Lutetium-177 provides the highest achievable radionuclidic purity. In comparison, c.a. isotope contains up to 0.1 % metastable Lutetium-177m. This long-lived radionuclide decays with a half-life of 160.1 days and requires costly management and storage of contaminated radioactive waste and waste water.

Product Data

TECHNICAL DATA

Element	Lutetium
Nuclide	^{177}Lu
Half-life	6.647 days
Decay mode	Beta decay
Beta (β^-) energy	$E(\beta^-)_{\text{max}} = 0.498 \text{ MeV}$
Gamma radiation keV (%)	112.9498 (6.17), 208.3662 (10.36)
Chemical form	LuCl_3
Solvent	0.04 M HCl solution
Activity concentration	1.5 – 300 GBq/ml
Activity	0.3 to 600 GBq per vial
Packaging	2ml conical or 10 ml flat bottom glass vial, closure with Flurotec® Coated Brombutyl Stopper

PURITY

Parameter	Value	Method
Specific activity (at production)	> 3,800 GBq/mg	ICP-MS
Specific activity (at expiry)	> 3,000 GBq/mg	ICP-MS
Radionuclidic purity	> 99,9 % ^{177}Lu	γ -Spectroscopy
Radiochemical purity	> 99 % as $^{177}\text{LuCl}_3$	ITLC
Isomeric purity	< 10^{-7} ($^{177\text{m}}\text{Lu}$)	γ -Spectroscopy
Chemical purity	> 99 %	ICP-MS

RELEASE PARAMETERS

Parameter	Value	Method
Microbiological	sterile (final autoclaving)	parametric release, contamination: post-release follow-up
Bacterial endotoxins	< 20 EU/Dose	LAL test
Radiolabeling yield	$\geq 99 \%$	500 MBq ^{177}Lu , 4 μg DOTA-peptide
Radiochemical purity	> 99 % as $^{177}\text{LuCl}_3$	ITLC



ITM Isotopen Technologien München AG

Shaping the Future of Theranostics




Targeting Vector DOTATOC

*Excellent pharmacokinetic
properties for somatostatin
receptor targeting*

Radionuclides

- › Lutetium-177 n.c.a.
- › Yttrium-90
- › Rhenium-188

All products manufactured by 

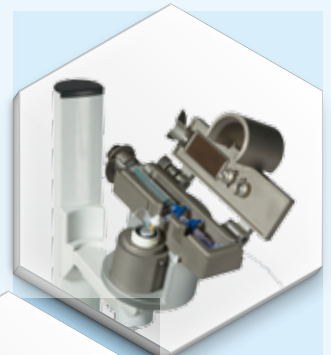
Radiolabeling Platform

*Dedicated hot-cells for
GMP manufacturing of
radiopharmaceuticals*



itG Quality Control Solution

*First-in-class
radio HPLC System*



iQS® Ga-68 Fluidic Labeling Module

*Fast and efficient labeling
of PET/CT tracers*

itG Radionuclide Generators

- › Ge-68 / Ga-68
- › W-188 / Re-188
- › Ac-225 / Bi-213

Medical Devices

- › itm Rhenium-PTA
Endovascular Brachytherapy
- › itm Rhenium-SCT
Epidermal Radioisotope
Therapy

Other products upon request.

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The itm Group is the leading pharmaceutical company for the development, production and worldwide distribution of highly effective radionuclides and medical devices for theranostics. Its commitment to setting industry standards in theranostics is built on robust platform technologies and a well-established global network of strategic and sales partners. The ITM AG and its subsidiaries ITG GmbH, itm OncoBeta GmbH and RP Munich GmbH are renowned for their excellence and precision in R&D and production, as well as for their unprecedented reliability and flexibility in terms of offering global logistic services and customer care, 365 days a year.

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