

### Yttriga radiopharmaceutical precursor, solution

Sterile [<sup>90</sup>Y]Yttrium Chloride solution for radiolabeling of pharmaceuticals



#### Full Range Supplier

Eckert & Ziegler Radiopharma GmbH is a full-range supplier of radiopharmaceutical products for diagnostic and therapeutic use. One of our core competences is the production of a carrier free [<sup>90</sup>Y]Yttrium Chloride solution that can be delivered worldwide.

#### Marketing Authorization

Our [<sup>90</sup>Y]Yttrium Chloride solution is registered as a medicinal product in the European Union under the name of Yttriga (EU/1/05/322/001 and EU/1/05/322/002). A Type II DMF (#17226) is submitted to the U.S. FDA.

*In the USA Yttriga is regarded as a drug substance.*

#### High Quality and Safety Standards

[<sup>90</sup>Y]Yttrium Chloride solution is produced in an approved, state of the art, GMP production facility. The high purity of our product enables pre-calibration up to nine days. Enhanced vial shielding is used to protect users of unnecessary exposure in accordance with ALARA principle.

We provide [<sup>90</sup>Y]Yttrium Chloride ([<sup>90</sup>Y]YCl<sub>3</sub>) as a sterile, endotoxin-free 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.

#### Flexible Dispension

We dispense your required volume of sterile [<sup>90</sup>Y]Yttrium Chloride solution in 3 ml V-vials (0.1 ml to 3 ml) or in 10 ml P6-vials (0.1 ml to 5 ml) with activities up to 300 GBq (8.11 Ci).

#### Reliable Delivery and Production Capacity

An international logistics network enables us to deliver [<sup>90</sup>Y]Yttrium Chloride worldwide within six business days. We have no capacity constraints in our Yttriga production facility.

#### Calibration Solutions

We provide a range of PTB and NIST-traceable [<sup>90</sup>Y]Yttrium calibrated solutions. In cooperation with the Eckert & Ziegler Nuclitec we also provide a [<sup>90</sup>Y]Yttrium calibration solution certified by the DAkkS. All our solutions are available on request.

#### Experts in Radiolabeling

Eckert & Ziegler Radiopharma GmbH also provides GMP radiolabeling services. We can develop radiolabeling and quality control protocols for your products.

## Product Specifications

Product	[ <sup>90</sup> Y]Yttrium Chloride solution, radiopharmaceutical precursor
Active ingredient	[ <sup>90</sup> Y]Yttrium Chloride, 0.1-300 GBq
Excipients	Hydrochloric Acid (0.04 M)
Half-life	64.1 hours
Decay energy	$E_{\max} = 2.28 \text{ MeV}$ , 100 % $\beta^-$
Chemical form	[ <sup>90</sup> Y]YCl <sub>3</sub> in 0.04 M HCl solution
Specific activity	Product is carrier free
Activity	As requested 0.1 – 300 GBq per vial (traceable to PTB and NIST) (activity tolerance $\pm 10 \%$ )
Volume	As requested 0.1-3 ml in 3ml V-vials or 0.1-5 ml in 10 ml P6-vials
Pre-calibration	up to 9 days
Reference date	[ <sup>90</sup> Y]Yttrium can be produced to meet specific customer requirements for calibration date.
Expiry date	Calibration date + 3 days
Radiochemical purity	> 99 % [ <sup>90</sup> Y]Yttrium as Y <sup>3+</sup>
Radionuclide purity	[ <sup>90</sup> Sr]Strontium content < 10 <sup>-5</sup> Bq [ <sup>90</sup> Sr]Strontium/Bq [ <sup>90</sup> Y]Yttrium at reference date $\gamma$ -emitting impurities < 10 <sup>-4</sup> Bq/Bq [ <sup>90</sup> Y]Yttrium at reference date
Endotoxins	< 30 E.U. per dose
Chemical purity	> 95 % corresponds to 2 pmol / 3 kBq [ <sup>90</sup> Y]Yttrium
Packaging	3 ml V-glass vial and 10 ml P6-glass vial. Closure with crimp cap. A unique clear plastic inner shield allows the product to be visible during withdrawal using a syringe, which significantly reduces the hand dose.
Sterility	Sterile
Indications	<i>In vitro</i> -radiolabeling, not intended for direct application to patients.
Contraindication	Pregnancy
Side effects	No side effects known
Warnings	Radioactive, handle in accordance with radiation protection requirements. Prescription only.
Delivery time	Within 6 business days worldwide

### Marketing authorization holder:

Marketing authorisation holder: Eckert & Ziegler Radiopharma GmbH, Robert-Roessle-Str. 10, 13125 Berlin, Germany. Name of medicinal product: Yttriga radiopharmaceutical precursor, solution. Active substance: Yttrium (<sup>90</sup>Y) chloride, 0.1 - 300 GBq. Excipients: hydrochloric acid (0.04 M). Indications: *in vitro* radiolabelling, not intended for direct application to patients. Contraindications: pregnancy, hypersensitivity against the active substance or the excipients. Side effects: no side effects known. Warnings: Keep out of the reach and sight of children, radioactive, handle in accordance with radiation protection requirements. Prescription only

### Drug Master File in the USA:

In the USA the FDA regards the [<sup>90</sup>Y]Yttrium Chloride Solution as a drug substance. Accordingly Eckert & Ziegler Radiopharma GmbH has submitted a Type II DMF. DMF #17226, Drug Master File holder: Eckert & Ziegler Radiopharma GmbH, Robert-Rössle-Str. 10, 13125 Berlin, Germany

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