

By implementation of a new legislative as of July 2016 chemical precursors for radiopharmaceutical preparation have to be manufactured according current GMP guidelines and distributed according to Good Distribution Practice (GDP).

The European Pharmacopoeia published the General Monograph for Chemical Precursors for radiopharmaceutical preparations (European Pharmacopoeia 9.0, General Notices 07/2016:2902). General Notices apply to all monographs and other texts.

Sourcing of such precursors in required quality is challenging for clinical centers.

A new era for GMP grade peptide precursors begins

piCHEM **develops, produces and distributes** precursors for radio-diagnosis and nuclear medicine therapy for more than 25 years.

piCHEM is manufacturing chemical precursors within a **GMP approved quality system according to ICH guidelines** ensuring consistent quality. Molecules are well characterized and tested against its specifications. Shipment is performed in compliance with **GDP** regulations under temperature controlled and monitored conditions as required by national authorities.

The peptides are freeze-dried chemical precursors for radiopharmaceutical preparations to be used in **investigational medicinal products**. The products are delivered with a Certificate of Analysis (**CoA**). In addition the products are accompanied by a Certificate of Compliance (**CoC**) including the certification of origin (**CoO**) signed by a Qualified Person (**QP**). The manufacturing process and the analytical methods as well as the handling stability information are outlined in a Product Data Sheet (**PDS**) delivered with each product.

Many of these molecules are New Chemical Entities (**NCE**) and the manufacturing process and the applied analytical methods are generally validated and all procedures and methods comply with the current ICH or other applicable guidelines.

For clinical trials and for product development applications which require additional Quality Documentation/IMP/DMF or ASMF/DMF - these dossiers are available on request.



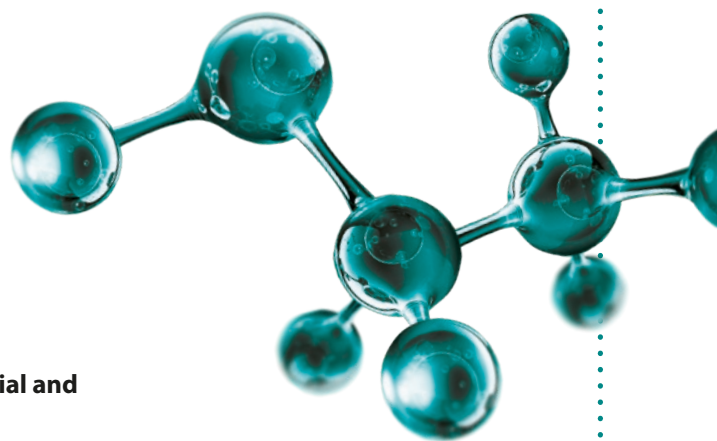
Exemplarily for our comprehensive list of various precursor molecules DOTA-TOC (Edotreotide) is available in 4 different aliquot formulations containing defined net peptide content.

Precursor	Prod.-ID	net peptide content
DOTA-TOC (Edotreotide)	540	50 µg
		115 µg
		350 µg
		1 mg

Each individual dose is freeze dried in 2 R Borosilicate pharma glass type I vials with stoppers and flip-off caps to guarantee metal free and homogeneous quality.

Beside DOTA-TOC many more GMP grade chemical precursors in different filling quantities are available.

Precursor	Prod.-ID
HYNIC-TOC	C62
DOTA-TATE	984
PSMA-I&S	BB1
PSMA-11	AJ0
DOTA-PSMA	Z67



Additionally, qualitative and/or quantitative reference material and cold labelled comparison substances are available:

Product	Prod.-ID
DOTA[⁸⁹ Y]-TATE	AJ2
DOTA-TATE	AF7
DOTA-TOC	AP0
DOTA[⁶⁹ Ga]-TOC	AP2
DOTA[⁶⁹ Ga]-TATE	AP1

Many more reference materials or comparison substances can be provided on request.

Individual designed precursors:

Outside clinical applications customized precursors in R&D grade quality for research purposes or preclinical development are available upon request.

For **more information** and also if you wish **UPDATES on our product pipeline** please contact us.