CMR
CENTER OF MOLECULAR RESEARCH

PEPTIDE PRECURSORS

for radiopharmaceutical preparation

www.isotope-cmr.com

Peptide precursors

Center of Molecular Research (CMR) produce peptide precursors for radiopharmaceutical preparations. Peptide precursors which contain chelating groups can be labeled with radiometals. The others are designed for labelling with fluorine-18. Depending on the used radionuclide precursor, the obtained radiopharmaceuticals are applicable for diagnostic or/and therapeutic purposes.

The CMR peptide products are represented by:

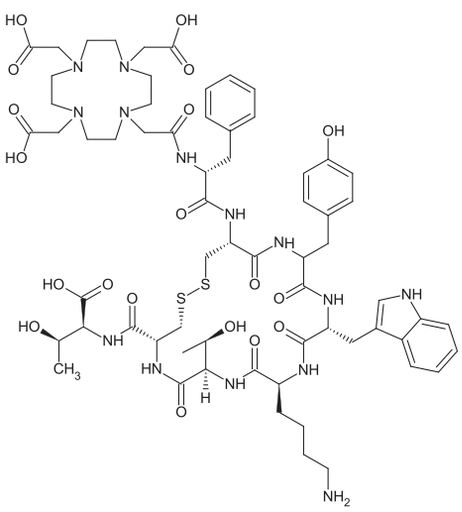
- synthetic analogues of somatostatin;
- ligands for the prostate-specific membrane antigen (PSMA).

Synthetic somatostatin analogues interact with specific somatostatin receptors on cell surfaces. The high concentration of these receptors in neuroendocrine tumors makes them convenient target for the diagnosis.

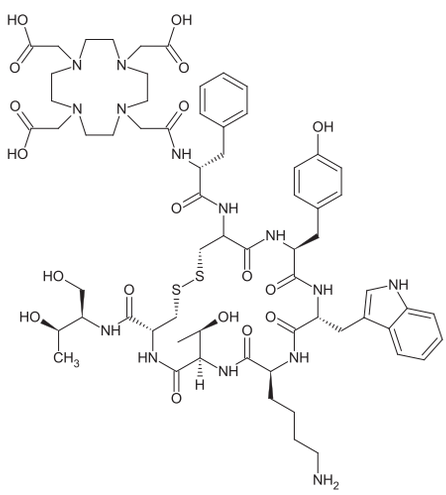
PSMA-ligands bind with PSMA, an enzyme that is highly expressed in prostate cancer cells compared to the normal human body cells. Therefore, some PSMA-ligands are used for diagnostics and/or for radionuclide therapy.

Catalogue number	Name	Formula	Structure #	Mol. weight	CAS №	Usually labelled w/
P002	**DOTA-TATE** acetate	$C_{65}H_{90}N_{14}O_{19}S_2$ (net peptide)	1	1435,6 g/mol (net peptide)	[177943-89-4]	^{68}Ga, ^{177}Lu
P003	**DOTA-TOC** acetate	$C_{65}H_{92}N_{14}O_{18}S_2$ (net peptide)	2	1421,6 g/mol (net peptide)	[204318-14-9]	^{68}Ga
P004	**DOTA-NOC** acetate	$C_{69}H_{94}N_{14}O_{17}S_2$ (net peptide)	3	1455,7 g/mol (net peptide)	[619300-53-7]	^{68}Ga
P005	**PSMA I&T**	$C_{63}H_{92}IN_{11}O_{23}$ (net peptide)	4	1498,4 g/mol (net peptide)	[2192281-54-0]	^{68}Ga, ^{177}Lu
P007	**PSMA-1007** precursor	$C_{52}H_{64}N_9O_{16} \cdot C_2H_3O_2$ (acetate salt)	5	1071,1 g/mol (net peptide)	[not assigned]	^{18}F

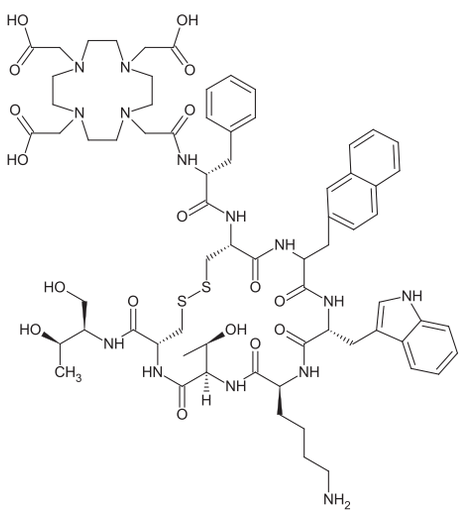
***Standard content — 1.0 mg per vial. Other quantities (0.1–10 mg per vial) are available per request.**



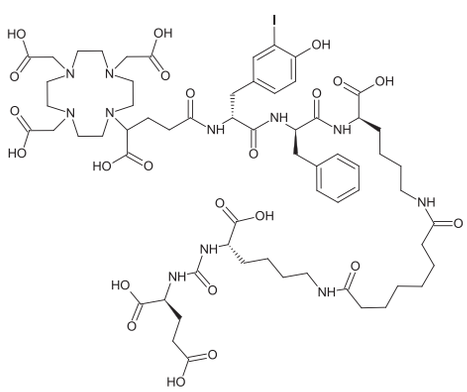
1. DOTA-TATE



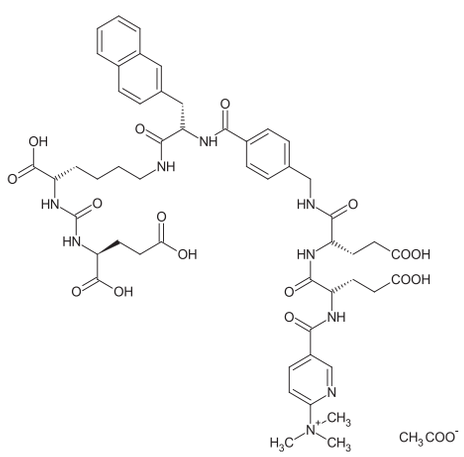
2. DOTA-TOC



3. DOTA-NOC



4. PSMA I&T



5. PSMA-1007 precursor

QUALITY PARAMETERS OF THE PRODUCT

Test	Method / Reference	Specification
Appearance	Visual inspection	White solid
Identification	High-performance liquid chromatography (HPLC)	Retention time of main peak corresponds to retention time of the [substance] peak in the reference solution ± 0.3 min
	Mass spectrometry	[specific value]
Quantitative assay (per vial)	HPLC	[90–110 % of nominal value]
Purity	HPLC	≥ 98.0 %
Bacterial endotoxins	Gel-clot method	≤ 10.0 EU/vial
Sterility*	Direct inoculation method	Sterile (passes test)
Bioburden**	Microbial enumeration tests	TAMC ≤ 10^2 CFU/vial
		TYMC ≤ 10^1 CFU/vial

* Tests of Sterility are performed for sterile products, made in aseptic conditions (class A).

** Tests of Bioburden are performed for other, non-sterile products.

- Retest dates are not less than 18 month from the manufacturing date.
- Products are manufactured in accordance with GMP requirements.
- Packaging in the type I glass vials with bromobutyl rubber stoppers.
- Storage at −20 ± 5 °C. Transportation at 2–8 °C, less than 1 month.

CENTER OF MOLECULAR RESEARCH

info@isotope-cmr.com
www.isotope-cmr.com