



GMP SUBSTANCES

GMP, API GRADE

	DOTATATE 0.25 mg	DOTATATE 0.1 mg	DOTATATE 1.0 mg
Code:	DOT-03	DOT-04	DOT-05
Composition:	DOTATATE trifluoroacetate:		
	0.25 mg/vial (net)	0.1 mg/vial (net)	1.0 mg/vial (net)
Appearance:	White freeze-dried solid		
Primary packaging:	2 mL	2 mL	10 mL
	glass vial sealed with rubber closure and flip-off cap		
Storage:	2-8°C		
Expiry date:	18 months		
Purpose:	<i>Peptide for radiolabelling, e.g. with ⁶⁸Ga, ¹⁷⁷Lu, ⁹⁰Y. The labelling must be performed in the buffer that the recipient must independently prepare. For ¹⁷⁷Lu offered by POLATOM the maximum Lutetium-177 activity is no more than:</i>		
	7.4 GBq.	3.7 GBq.	37 GBq

GMP compliant

PSMA for direct ⁶⁸ Ga labelling	
Code:	PMA-01
Composition:	PSMA-11: 20 µg/vial Sodium Acetate: 60 mg/vial
Primary packaging:	10 mL glass vial sealed with rubber closure and flip-off cap
Storage:	2-8°C
Expiry date:	24 months
Features:	sterile, endotoxin free, freeze-dried solid
Purpose:	for ⁶⁸ Ga labelling (when eluted with 0.05 M ÷ 0.1 M HCL)

GMP compliant

DOTATATE SA 50 µg for direct ⁶⁸Ga radiolabelling offered outside of EU only!

Code:	DOT-06
Composition:	DOTATATE trifluoroacetate – 40 µg/vial Sodium acetate: 60 mg/vial
Primary packaging:	10 mL glass vial sealed with rubber closure and flip-off cap
Storage:	2-8°C
Expiry date:	12 months
Features:	sterile, endotoxin free, freeze-dried solid
Purpose:	for ⁶⁸ Ga labelling (5 mL of ⁶⁸ GaCl ₃ in 0.1M HCl)

DOTATATE SA 40 µg for direct ⁶⁸Ga radiolabelling offered outside of EU only!

Code:	DOT-07
Composition:	DOTATATE trifluoroacetate – 40 µg/vial Sodium acetate: 35 mg/vial
Primary packaging:	10 mL glass vial sealed with rubber closure and flip-off cap
Storage:	2-8°C
Expiry date:	12 months
Features:	sterile, endotoxin free, freeze-dried solid
Purpose:	for ⁶⁸ Ga labelling (4 mL of ⁶⁸ GaCl ₃ in 0.05M HCl)

PSMA-11 1.0 mg

Code:	PMA-00
Composition:	PSMA-11 trifluoroacetate: 1.0 mg/vial (net)
Primary packaging:	2 mL glass vial sealed with rubber closure and flip-off cap
Storage conditions:	15-25°C
Shelf life:	24 months

PSMA-D4 100 µg offered outside of EU only!

Code:	PMA-04
Composition:	PSMA-D4 – 100 µg/vial
Primary packaging:	2.5 mL glass vial sealed with rubber closure and flip-off cap
Storage:	-20 +/- 5°C
Expiry date:	12 months
Features:	sterile, endotoxin free, freeze-dried solid
Purpose:	for ¹⁷⁷ Lu labelling in accordance with procedure of labelling issued by POLATOM

PSMA-T4 (PSMA-HYNIC) - 23 µg for direct ^{99m}Tc radiolabeling

Code:	TCP-01
Composition:	PSMA-HYNIC trifluoroacetate: 20 µg/vial (net) Excipients: Tricine, EDDA, Stannous chloride dihydrate, Disodium phosphate dodecahydrate, Sodium dihydrogen phosphate dihydrate, Nitrogen gas
Primary packaging:	10 mL glass vial sealed with rubber closure and flip-off cap
Storage:	2-8°C
Expiry date:	12 months
Features:	sterile, endotoxin free, freeze-dried solid
Purpose:	for direct preparation of ^{99m} Tc-PSMA-HYNIC without necessity of purification step. Radiochemical purity >90%

PSMA-D4 100 µg for direct ¹⁷⁷Lu radiolabeling offered outside of EU only!

Code:	PMA-03
Composition:	PSMA-D4 – 100 µg/vial Ascorbic acid 50.0 mg/vial, NaOH 7.9 mg
Primary packaging:	2.5 mL glass vial sealed with rubber closure and flip-off cap
Storage:	2-8°C
Expiry date:	12 months
Features:	sterile, endotoxin free, freeze-dried solid
Purpose:	for ¹⁷⁷ Lu labelling in accordance with procedure of labelling issued by POLATOM

Ascorbic acid 50 mg

Code:	ASC-01
Composition:	Ascorbic acid - 50 mg/vial, NaOH – 7.9 mg/vial
Appearance:	White freeze-dried solid
Primary packaging:	2 mL glass vial closed with rubber closures and sealed with white cap type flip-off
Storage:	2-8°C
Expiry date:	24 months
Purpose:	Preparation of buffer solution for ⁹⁰ Y or ¹⁷⁷ Lu labelling