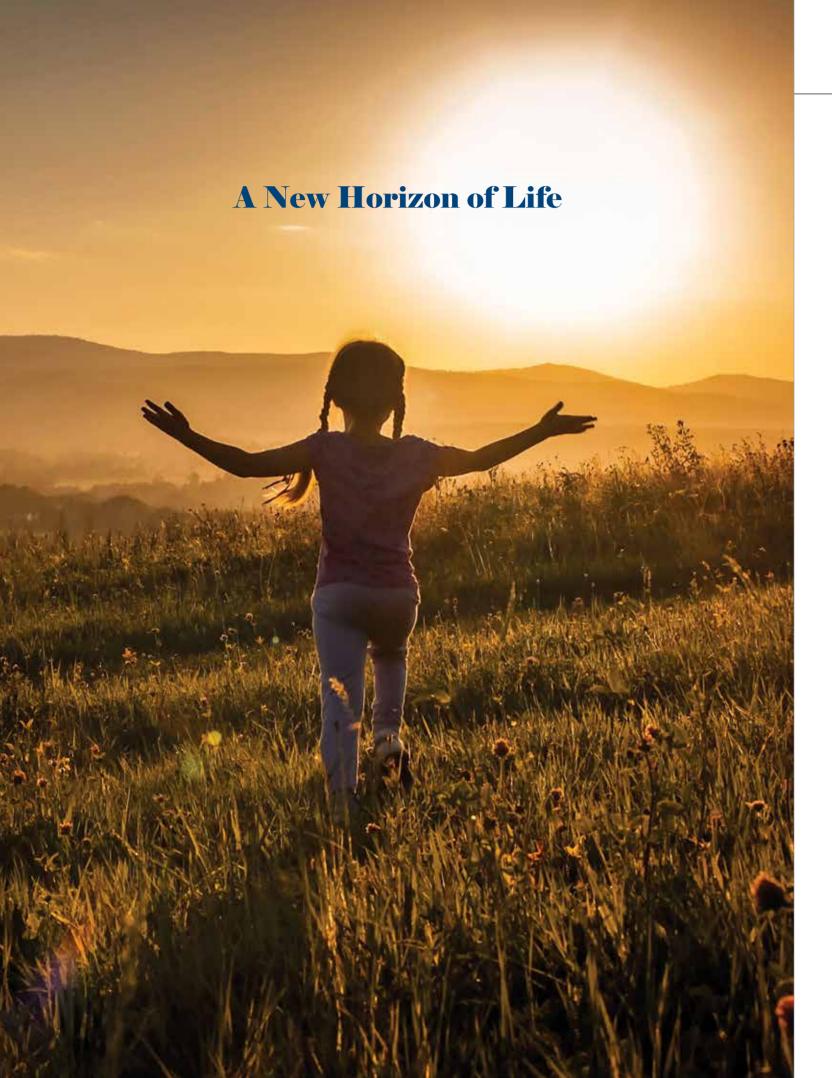


Radioisotope Development & Production For Medical Applications



#### **CONTENTS**



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- DIAGNOSTIC/SPECT
- THERAGNOSTIC





## **DIAGNOSTIC/SPECT**

#### **First Generation**

PARS-MIBI

**PARS-MDP** 

**PARS-DTPA** 

**PARS-DMSA** 

PARS-MAA

PARS-EC

**PARS-ECD** 

PARS-BrIDA

PARS-RBC

**PARS-Phytate** 

**PARS-Antimony TS** 

**PARS-PYP** 

**PARS-Sulfur colloid** 

**PARS-WBC** 

#### **New Generation / Peptide**

**PARS-TECTO PSMA** 

**PARS-TRODAT** 

**PARS-TOC** 

**PARS-TATE** 

PARS-UBI

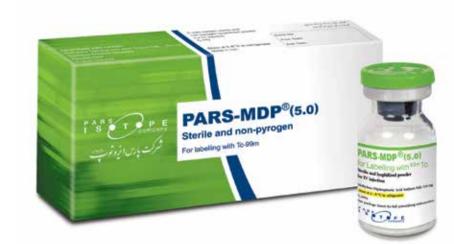
**PARS-BOMBESIN** 





#### PARS-MIBI

(for labelling with 1c-99in)	
Chemical name	Methoxyisobutylisocyanide
Pharmaceutical form	Lyophilized powder
Clinical application	As a diagnostic agent for myocardial perfusion scintigraphy
Packaging	Each package contains 5 vials
Storage conditions	At 2 - 8 °C
Availability	From stock



#### PARS-MDP (for labelling with Tc-99m)

(,	
Chemical name	Methylene diphosphonic acid
Pharmaceutical form	Lyophilized powder
Clinical application	As a diagnostic agent for bone scintigraphy
Packaging	Each package contains 5 vials
Storage conditions	At 2-8 °C
Availability	From stock



## PARS-DTPA (for labelling with Tc-99m)

Chemical name	Diethylene triamine pentaacetate
Pharmaceutical form	Lyophilized powder
Clinical application	As a diagnostic agent for GFR of kidney scintigraphy
Packaging	Each package contains 5 vials
Storage conditions	At 2-8°C
Availability	From stock



## PARS-DMSA (for labelling with Tc-99m)

(	
Chemical name	Dimercaptosuccinic acid
Pharmaceutical form	Lyophilized powder
Clinical application	As a diagnostic agent for morphology of kidney scintigraphy
Packaging	Each package contains 5 vials
Storage conditions	At 2 - 8 °C / keep away from light
Availability	From stock



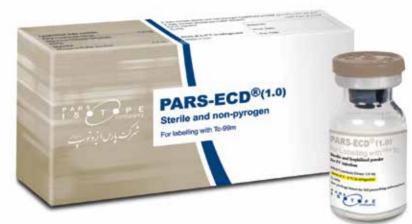
PARS-MAA

(for labelling with 1c-99m)	
Chemical name	Human serum albumin macroaggregates
Pharmaceutical form	Lyophilized powder
Clinical application	As a diagnostic agent for lung scintigraphy
Packaging	Each package contains 5 vials
Storage conditions	At 2-8 °C
Availability	From stock



## PARS-EC (for labelling with Tc-99m)

(	
Chemical name	Ethylene dicysteine
Pharmaceutical form	Lyophilized powder
Clinical application	As a diagnostic agent for ERPF of kidney scintigraphy
Packaging	2 Vial Kit + 2 Vial Buffer (Solution)
Storage conditions	At 2-8 °C
Availability	From stock



PARS-E	CD
(for labelling	with Tc-99m)

(for labelling with 1c-99m)	
Chemical name	Ethyl Cysteinate Dimer
Pharmaceutical form	Lyophilized powder
Clinical application	As a diagnostic agent for regional cerebral blood flow scintigraphy
Packaging	2 Vial Kit + 2 Vial Buffer
Storage conditions	At 2-8°C
Availability	From stock



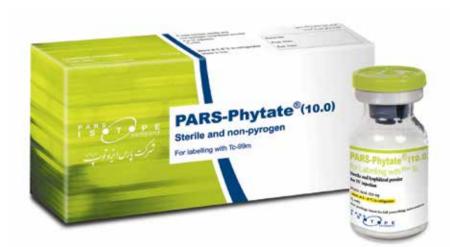
## **PARS-BrIDA**

Trimethyl Bromo-IDA
Lyophilized powder
As a diagnostic agent for hepatobiliary system scintigraphy
Each package contains 5 vials
At 2 - 8 °C
From stock



PA	RS-	RB(	;
for I	ahellin	a with	n Tc-99m)

Chemical name	Stannous Chloride
Pharmaceutical form	Lyophilized powder
Clinical application	As a diagnostic agent for GI bleeding scintigraphy
Packaging	1 Vial kit + 1 Vial ACD (Solution) + 1 Vial Hypochlorite (Solution)
Storage conditions	At 2-8 °C
Availability	From stock



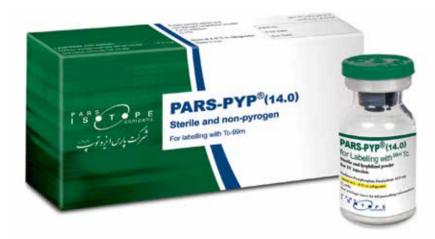
## PARS-Phytate (for labelling with Tc-99m)

(,	
Chemical name	Phytic Acid
Pharmaceutical form	Lyophilized powder
Clinical application	As a diagnostic agent for liver/spleen scintigraphy
Packaging	Each package contains 5 vials
Storage conditions	At 2 - 8 °C
Availability	From stock
Availability	From stock



#### **PARS-Antimony TS**

(for labelling with 1c-99m)	
Chemical name	Antimony Trisulfide
Pharmaceutical form	Solution
Clinical application	As a diagnostic agent for lymphoscintigraphy
Packaging	1 Vial Kit + 1 Vial hydrochloric acid (Solution) + 1 Vial Buffer
Storage conditions	At 2-8°C
Availability	From stock



## PARS-PYP (for labelling with Tc-99m)

Chemical name	Pyrophosphate
Pharmaceutical form	Lyophilized powder
Clinical application	As a diagnostic agent for myocardial infarction scintigraphy
Packaging	Each package contains 5 vials
Storage conditions	At 2 - 8 °C
Availability	From stock



#### PARS-Sulfur colloid

(ioi laboling with to com)	
Chemical name	Sodium thiosulfate anhydrous
Pharmaceutical form	Lyophilized powder
Clinical application	As a diagnostic agent for GI system, liver/spleen scintigraphy
Packaging	Each package contains 5 vials
Storage conditions	At 2-8 °C
Availability	From stock



## PARS-WBC

(101 labelling with 10-9911)	
Chemical name	HMPAO (hexamethylpropyleneamine oxime)
Pharmaceutical form	Lyophilized powder
Clinical application	To detect and localize any occult site of infection
Packaging	Each package contain 4 vials: - 2 colorless vial (Lyophilized powder) - 2 colorless vial (ACD solution)
Storage conditions	At 2-8 °C
Availability	From stock





#### PARS-TECTO PSMA

(for labelling with Tc-99m)	
Chemical name	HYNIC-TECTO-PSMA
Pharmaceutical form	Lyophilized powder
Clinical application	for a SPECT imaging of diagnosing and monitoring the treatment of prostate Carcinoma
Packaging	Each package contains 1 vial
Storage conditions	At -8 to -20 °C / Keep away from light and humidity
Availability	From stock



## PARS-TRODAT

(for labelling with Tc-99m)	
Chemical name	TRODAT-1
Pharmaceutical form	Lyophilized powder
Clinical application	For imaging of dopamine transporters (DAT) in the striatum
Packaging	Each package contains 1 vial
Storage conditions	At -8 to -20 °C / Keep away from light and humidity
Availability	From stock

PARS-TOC

(,	
Chemical name	HYNIC-Tyrosine3-Octreotide
Pharmaceutical form	Lyophilized powder
Clinical application	For localization, staging and therapy follow-up of neuroendocrine tumors
Packaging	Each package contains 1 vial
Storage conditions	At -8 to -20 °C / Keep away from light and humidity
Availability	From stock

PARS-TATE
(for labelling with Tc-99m)

(101 1000000)	
Chemical name	HYNIC-Tyrosine3-Octreotate
Pharmaceutical form	Lyophilized powder
Clinical application	For localization, staging and therapy follow-up of neuroendocrine tumors.
Packaging	Each package contains 1 vial
Storage conditions	At -8 to -20 °C / Keep away from light and humidity
Availability	From stock



## **THERAGNOSTIC**

PARS-LUTO PSMA
PARS-LUTO TATE
PARS-LUTO EDTMP
PARS-HEDP



PARS-UBI (for labelling with Tc-99m)		
Chemical name	HYNIC-Ubiquicidine 29-41	
Pharmaceutical form	Lyophilized powder	
Clinical application	For discrimination between infe and sterile inflammation	ection
Packaging	Each package contains 1 vial	
Storage conditions	At -8 to -20 $^{\circ}\text{C}$ / Keep away from and humidity	m light
Availability	From stock	



PA	RS	-B	ON	ΛB	ES	118	1
(for	lab	ellin	g w	ith	Tc-9	99n	n)

(for labelling with Tc-99m)		
Chemical name	HYNIC-GABA-Bombesin	
Pharmaceutical form	Lyophilized powder	
Clinical application	For localization, staging a follow-up of breast and pr	
Packaging	Each package contains 1	vial
Storage conditions	At -8 to -20 °C / Keep aw and humidity	ay from light
Availability	From stock	



## PARS-LUTO PSMA (for labelling with Lu-177)

(101 labelling with Eu-177)	
Chemical name	DOTA-PSMA
Pharmaceutical form	Lyophilized powder
Clinical application	Theranostics of metastatic prostate cancer
Packaging	Each package contains 1 vial
Storage conditions	At -8 to -20 $^{\circ}\text{C}$ / Keep away from light
Availability	From stock





## PARS-LUTO TATE (for labelling with Lu-177)

(for labelling with Lu-177)	
Chemical name	DOTA-TATE
Pharmaceutical form	Lyophilized powder
Clinical application	Theranostics of neuroendocrine tumors with somatostatin receptors
Packaging	Each package contains 1 vial
Storage conditions	At -8 to -20 °C / Keep away from light
Availability	From stock



#### PARS-LUTO EDTMP

for lah	allina	with	Lu-177
(IUI IAN	eiiiiig	WILLI	Lu-III

(101 laboling With Ea 111)	
Chemical name	ethylenediamine tetra is a phosphonic acid
Pharmaceutical form	Lyophilized powder
Clinical application	relieving bone metastatic pain
Packaging	Each package contains 5 vial
Storage conditions	At 2-8 °C
Availability	From stock



## PARS-HEDP

(101 labelling with Re-100)	
Chemical name	1-Hydroxyethylidene-1,1-diphosphonic acid
Pharmaceutical form	Lyophilized powder
Clinical application	relieve the severe pain of bone metastases
Packaging	Each package contains 5 vial (1 vial HEDP KIT + 1 vial acetate buffer + 1 vial potassium perrhenate + 1 vacuum vial + 1 vial saline 0.9%)
Storage conditions	At 2 - 8 °C
Availability	From stock

# Radionuclide Generators

PARSTEC®II
PARS-KRYPTO
PARS-GalluGEN®
PARS-Rhen®



## PARSTEC®-II

Product name	PARSTEC® II
Pharmaceutical form	Radionuclide generator
Specification	
Medical name	Mo-99/Tc-99m sterile generator
Radionuclide purity	≥99/9%
Radiochemical purity	>95%
Elution pH	4.5 - 7.5 in house
Activity concentration	0.92-4.62 GBq/ml
Other information	
Clinical application	The eluate from the generator can
	be used for cold kit radiolabelling in diagnosis various diseases or used directly in some cases.
Packaging	be used for cold kit radiolabelling in diagnosis various diseases or used
Packaging Storage	be used for cold kit radiolabelling in diagnosis various diseases or used directly in some cases.
0 0	be used for cold kit radiolabelling in diagnosis various diseases or used directly in some cases. Type A packaging

#### Available activities:

PARSTEC®-II is calibrated for 2-6 days after production date. The Tc-99m activities of PARSTEC®-II are 200, 400, 600, 800, 1000, 1200, 1600 and 2000 mCi.



#### Elutable Pertechnetate (mCi activity of Tc-99m at 08:00 am IRST)

	Generator type	PARSTEC II 400	PARSTEC II 600	PARSTEC II 800	PARSTEC II 1000
	Activity Date	200	400	600	800
Production	-6	901	1814	2722	3630
	-5	705	1410	2115	2821
	-4	548	1096	1644	2192
	-3	426	852	1278	1704
	-2	331	662	993	1324
	-1	257	514	772	1029
Calibration	0	200	400	600	800
	+1	155	311	466	621
	+2	121	241	362	483
	+3	94	188	281	375
	+4	73	146	218	292
	+5	57	113	170	227
	+6	44	88	132	176

#### Expirity

The expiration date of PARSTEC®-II is 14 days after production date. The expiration time of the sodium pertechnetate is not later than 6 hours after elution.



## **PARS-KRYPTO**

Rb-81/Kr-81m		
Radionuclide generator		
Specification		
Kr-81m Gas generator		
≥99%		
≥99%		
4.58 h/13 sec		
0.37 GBq/generator		
Other information		
Diagnosis of lung diseases		
Type A packaging		
Room temperature		
Weekly		



#### Physical decay chart:

Rb-81/Kr-81m Generator (half-life Rb-81: 4.6 h)

Hours	Fraction Remaining
0.00 (Calibration Time)	1.000
1.00	0.86
2.00	0.74
3.00	0.63
4.00	0.54
5.00	0.47
6.00	0.40
7.00	0.35
8.00	0.30
9.00	0.25



## **PARS-GalluGEN®**

Product name	PARS - GalluGEN®
Pharmaceutical form	Radionuclide generator
Specification	
Medical name	Ge-68/Ga-68 sterile generator
Radionuclide purity	≥99.9%
Radiochemical purity	≥99.9%
Eluent	3mL, 0.1 M HCI
Available activity	Up to 2.59 GBq
Other information	
Clinical application	Ga-68, one of the most widely used radionuclides in nuclear medicine, is used in PET imaging. Ga-68 is used to label various peptides such as DOTATATE, DOTANOC, PSMA and specifically in the diagnosis of various types of cancers.
Packaging	Tape A packaging
Storage	Room temperature
Availability	On demand



#### Physical decay chart: Ge-68 (half-life: 271 Day)

Day	Fraction Remaining
0.00 (Calibration Time)	1.000
30.00	0.930
60.00	0.865
90.00	0.804
120.00	0.748
150.00	0.696
180.00	0.647
210.00	0.602
240.00	0.560
270.00	0.521
300.00	0.484
330.00	0.450



## **PARS-Rhen**®

Product name	PARS -Rhen®
Pharmaceutical form	Radionuclide generator
Specification	
Medical name	W-188/Re-188 sterile generator
Radionuclide purity	≥99%
Radiochemical purity	≥95%
рН	4-7
Activity concentration	18.5 GBq
Available activity	3.7-37 GBq/ Generator
Other information	
Clinical application	The eluate from the generator can be used in cold kit radiolabelling for therapeutic purposes.
Packaging	Tape A packaging
Storage	Room temperature
Availability	On demand



#### Physical decay chart: W-188 (half-life 70 Day)

i nyolodi debay bilarti iv 100 (ilali ilic 10 Ba)	
Day	Fraction Remaining
0.00	1.000
(Calibration Time)	
10	0.905
20	0.820
30	0.743
40	0.673
50	0.609
60	0.552
70	0.500
80	0.452
90	0.410



# DIAGNOSTIC

# Ready to use Radiopharmaceuticals

#### **SPECT**

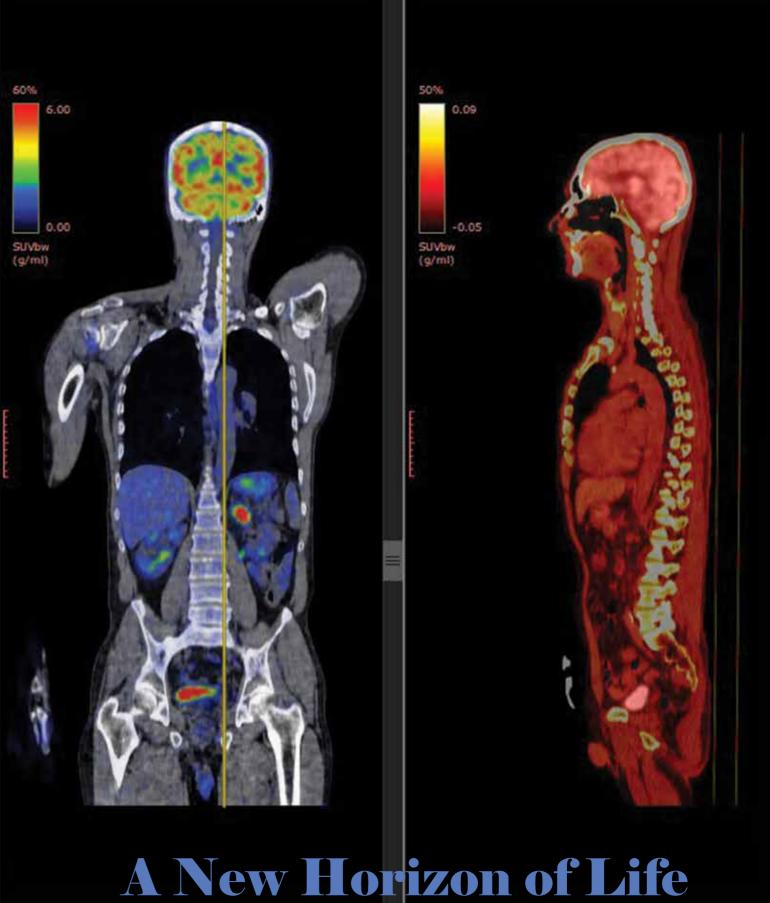
I-131 Capsule
I-131 MIBG Diagnostic
TI-201 Chloride
Ga-67 Citrate

#### PET

F-18 FDG
Ga-68 PSMA
Ga-68 DOTATATE
Ga-68 FAPI
Ga-68 CIXAFOR







## I-131 CAPSULE

Product name	I-131 Capsule-D
Pharmaceutical form	Oral capsule
Specification	
Medical name	Sodium Iodide I-131 Capsule
Radionuclide purity	≥99%
Radiochemical purity	≥95%
Half life	8.02 days
Available activity	1.11, 1.85 MBq/Capsule
Other information	
Clinical application	Estimation of thyroid uptake
	Identification of thyroid remnants
	and metastases (after ablation)
Packaging	Type A packaging
Storage	15-25 °C
Availability	Weekly





## **I-131 MIBG DIAGNOSTIC**

Product name	I-131 MIBG
Pharmaceutical form	Sterile solution for injection
Specification	
Medical name	I-131 Metaiodobenzyl guanidine
Radionuclide purity	≥99%
Radiochemical purity	≥90%
pH	4.5 - 7.5
Half life	8.02 days
Activity concentration	18.5 Mbq/mL
Available activity	37, 74, 111, 148 MBq
Specific activity	1110-2220 MBq/mg (MIBG)
Other information	
Clinical application	Diagnosis of neuroendocrine tumors, especially phaeochromocytoma, neuroblastoma and paraganglioma
Packaging	Type A packaging
Storage	≤ - 15 °C
Availability	Weekly





## **Ga-67 CITRATE**

Product name	Gallium-67 Citrate
Pharmaceutical form	Sterile solution for injection
Specification	
Medical name	Gallium-67 Citrate
Radionuclide purity	≥99%
Radiochemical purity	≥97%
Specific activity	Carrier free
рН	4.5-7.5
Activity concentration	185-370 Mbq/mL
Available activity	185 - 370 MBq on calibration time other activities available on request
Half life	3.26 Day
Other information	
Clinical application	Use in detection of infection, inflammation and various tumors
Packaging	Type A packaging
Storage	Room temperature
Availability	Weekly



## **TI-201 CHLORIDE**

Product name	Thallium-201 Chloride
Pharmaceutical form	Sterile solution for injection
Specification	
Medical name	Thallous chloride
Radionuclide purity	≥99%
Radiochemical purity	≥95%
рН	4.5-7.5
Activity concentration	185-370 MBq/mL
Available activity	185 - 740 MBq/vial, on calibration date Other activities available on request
Half life	3.038 Day
Other information	
Clinical application	Diagnosis of myocardial viability
Packaging	Type A packaging
Storage	Room temperature
Availability	Weekly



## **F-18 FDG**

Product name	F-18 FDG
Pharmaceutical form	Sterile solution for injection
Specification	
Medical name	F-18 Fluorodeoxyglucose
Radionuclide purity	≥99%
Radiochemical purity	≥95%
pH	4.5 - 7.5
Activity concentration	11-17.5 MBq/mL
Half life	110 min
Volume	0.5-15 mL
Available activity	370MBq-74GBq/vial, at calibration time Other activities available on request
Specific activity	Carrier free
Other information	
Clinical application	PET imaging of the whole body using FDG improves the diagnosis and staging of cancer, the selection of appropriate treatment and the evaluation of the therapeutic response.
Packaging	Type A packaging
Storage	Room temperature
Availability	Daily











## Ga-68 PSMA

Product name	Ga-68 PSMA
Pharmaceutical form	Sterile solution for injection
Specification	
Medical name	Ga-68 Prostate-specific membrane antigen
Radionuclide purity	≥99%
Radiochemical purity	≥98%
pH	4-7
Half life	68 min
Volume	10-15 mL
Available activity	185, 370 Mbq/vial, at calibration time
Specific activity	Carrier free
Other information	
Clinical application	Diagnosis of metastatic prostate cancer using PET imaging system
Packaging	Type A
Storage	≤25 °C
Availability	Daily



#### **Ga-68 DOTATATE**

Product name	Ga-68 DOTATATE
Pharmaceutical form	Sterile solution for injection
Specification	
Medical name	Ga-68 DOTA-Octreotate
Radionuclide purity	≥99%
Radiochemical purity	≥98%
рН	4-7
Half life	68 min
Volume	10-15 mL
Available activity	185, 370 Mbq/vial, at calibration time
Specific activity	Carrier free
Other information	
Clinical application	Diagnosis of neuroendocrine tumors using
	PET imaging system
Packaging	Type A
Storage	≤25 °C
Availability	Daily



## Ga-68 FAPI

Product name	Ga-68 FAPI	
Pharmaceutical form	Sterile solution for injection	
Specification		
Medical name	Ga-68 Fibroblast activation protein	
Radionuclide purity	≥99%	
Radiochemical purity	≥98%	
рН	4-7	
Half life	68 min	
Volume	10-15 mL	
Available activity	185, 370 MBq/vial, at calibration time	
Specific activity	Carrier free	
Other information		
Clinical application	detection of tumors and cancer cells expressing fibroblast activation protein using PET imaging system	
Packaging	Type A	
Storage	≤25 °C	
Availability	Daily	



#### **Ga-68 CIXAFOR**

Product name	Ga-68 CIXAFOR
Pharmaceutical form	Sterile solution for injection
Specification	
Medical name	Ga-68 Pentixafor
Radionuclide purity	≥99%
Radiochemical purity	≥98%
pH	4-7
Half life	68 min
Volume	10-15 mL
Available activity	185, 370 MBq/vial, at calibration time
Specific activity	Carrier free
Other information	
Clinical application	detection of tumors and cancer cells expressing CXCR4 receptors using PET imaging system
Packaging	Type A
Storage	≤25 °C
Availability	Daily



# **THERAPEUTIC**

# Ready to use Radiopharmaceuticals

#### • Bone pain palliation:

Sm-153 EDTMP

Lu-177 EDTMP

Re-186 HEDP

Re-188 HEDP

#### • Radiosynovectomy:

P-32 Colloidal chromic phosphate

Re-186 Sulfide colloid

Re-188 Sulfide colloid

Y-90 Hydoxyapatite

#### • Therapeutic:

I-131 Oral solution

I-131 Capsule

I-131 MIBG

Lu-177 DOTATATE

Lu-177 PSMA

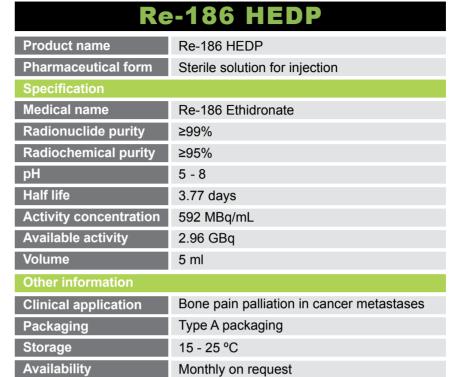


Sm-153 EDTMP	
Product name	Sm-153 EDTMP
Pharmaceutical form	Sterile solution for injection
Specification	
Medical name	Sm-153 Lexidronam
Radionuclide purity	≥99%
Radiochemical purity	≥95%
Volume	3 mL
рН	7-8.5
Half life	1.93 days
Activity concentration	984 MBq/mL
Available activity	2.96 GBq
Other information	
Clinical application	Bone pain palliation in cancer metastases
Packaging	Type A packaging
Storage	-15 °C
Availability	Monthly on request



Lu-177 EDTMP	
Product name	Lu-177 EDTMP
Pharmaceutical form	Sterile solution for injection
Specification	
Medical name	Lu-177 Ethylen diamine tetramethylene phosphonate
Radionuclide purity	≥99%
Radiochemical purity	≥98%
Volume	1.5 mL
рН	7 - 8.5
Half life	6.73 days
<b>Activity concentration</b>	1.726 GBq/mL
Available activity	2.59 GBq
Other information	
Clinical application	Bone pain palliation in cancer metastases
Packaging	Type A packaging
Storage	Bellow -15 °C
Availability	Monthly on request







Re-188 HEDP			
Product name	Re-188 HEDP		
Pharmaceutical form	Sterile solution for injection		
Specification	Specification		
Medical name	Re -188 Ethidronate		
Radionuclide purity	≥99/9%		
Radiochemical purity	≥95%		
Half life	0.7 days		
рН	5 -8		
Activity concentration	592 MBq/mL		
Available activity	2.96 GBq		
Volume	5 ml		
Other information			
Clinical application	Bone pain palliation in cancer metastases		
Packaging	Type A packaging		
Storage	15 - 25 °C		
Availability	Monthly on request		



Y-90 Hydroxyapatite		
Product name	Y-90 HA	
Pharmaceutical form	Sterile white suspension for intra-articular injection	
Specification		
Medical name	Yttrium-90 hydroxyapatite	
Radionuclide purity	≥99%	
Radiochemical purity	≥95%	
Volume	1 mL	
рН	5.5 - 7.5	
Half life	2.67 days	
Activity concentration	185 MBq/mL	
Available activity	0.185 GBq	
Other information		
Clinical application	Therapeutic agent to cure chronic knee synovitis in rheumatoid arthritis, hemophilia or orthopedic troubles	

Type A packaging

Weekly on request

15 - 25 °C



#### P-32 Colloidal chromic phosphate

Product name	P-32 Colloidal chromic phosphate
Pharmaceutical form	Sterile colloid
Specification	
Medical name	P-32 Chromic phosphate colloid
Radionuclide purity	>99%
Radiochemical purity	≥95%
рН	5-6
Half life	14.3 days
Activity concentration	37 MBq/mL for radiosynovectomy usage 370 MBq/mL for liver metastases usage
Available activity	0.185 GBq for radiosynovectomy usage     1.85 GBq for liver metastases usage
Volume	5 mL
Other information	
Clinical application	<ul> <li>Treatment of patients with rheumatoid arthritis (Radiosynovectomy)</li> <li>Treatment of patients with recurrent hemorrhages in the joints due to hemphilia</li> <li>With larger size (20-60 µm) are also used for the treatment of liver metastases</li> </ul>
Packaging	Type A packaging
Storage	15 - 25 °C
Availability	Weekly

<b>Re-186</b>	Sulfide colloid	
Product name	Re-186 Sulfide colloid	
Pharmaceutical form	Sterile colloid	
Specification		
Medical name	Re-186 sulfide	
Radionuclide purity	≥99%	
Radiochemical purity	≥98%	
Specific activity	180 - 280 MBq/mg Re	
рН	5.5 - 7	
Half life	3.77 days	
Activity concentration	800 - 1200 MBq/ml	
Available activity	2.96 GBq	
Other information		
Clinical application	Radiosynovectomy of medium size joints	
Packaging	Type A packaging	
Storage	Room temperature	
Availability	Weekly	



#### Re-188 Sulfide colloid

Product name	Re-188 sulfide colloid
Pharmaceutical form	Sterile Colloid
Specification	
Medical name	Re -188 sulfide
Radionuclide purity	≥99%
Radiochemical purity	≥95%
Volume	3 mL
рН	4.5 - 5.5
Half life	0.7 days
Activity concentration	185 MBq/mL
Available activity	0.555 GBq
Other information	
Clinical a pplication	Radiosynovectomy of large size joints
Packaging	Type A packaging
Storage	15 - 25 °C
Availability	Monthly on request

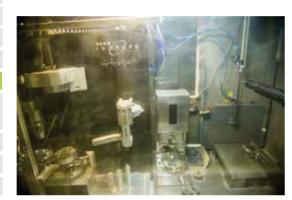


Packaging

Availability

Storage

I-131	CAPSULE
	I-131 Capsule-T
Product name	Oral capsule
Pharmaceutical form	
Specification	Sodium Iodide I-131 Capsule
Medical name	≥99%
Radionuclide purity	≥98%
Radiochemical purity	4-7
рН	68 min
Half life	10-15 mL
Volume	1.85, 3.7, 5.55 GBq/Capsule
Available activity	Carrier free
Specific activity	
Other information	Treatment of thyroid cancer and
Clinical application	hyperthyroidism
Packaging	Type A
Storage	15 - 25 °C
Availability	Weekly



#### I-131 MIBG Therapeutic

Product name	I-131 MIBG Therapeutic
Pharmaceutical form	Sterile solution for injection
Specification	
Medical name	I-131 Metaiodobenzylguanidine
Radionuclide purity	≥99%
Radiochemical purity	≥90%
Specific activity	11.1 - 22.2 GBq/mg (MIBG)
рН	4.5 - 7.5
Half life	8.02 days
Activity concentration	0.185 - 0.555 GBq/mL
Available activity	1.85 - 5.55 GBq
Other information	
Clinical application	Treatment of neuroendocrine tumours, especially, phaeochromocytoma, neuroblastoma, paraganglioma, medullar thyroid carcinoma and carcinoid syndrome
Packaging	Type A packaging
Storage	Below -15 °C
Availability	Weekly



I-13	1 0	ral s	olut	ion

Product name	I-131 Oral solution
Pharmaceutical form	Oral solution
Specification	
Medical name	Sodium iodide I-131 solution
Radionuclide purity	≥99%
Radiochemical purity	≥95%
рН	7.5 - 10
Half life	8.02 days
Activity concentration	0.925, 1.387, 1.850 GBq/mL
available activity	1.85, 3.7, 5.55, 7.4 GBq
Volume	2 - 4 ml
Other information	

## Clinical application

<ul> <li>1 - Therapeutic thyroid applications including:         Treatment of graves disease, toxic multinodular goiter         Treatment of papillary and follicular thyroid carcinoma such as metastatic diseases     </li> <li>2- For various research applications such as radioimmunotherapy</li> </ul>
Type A peakeging

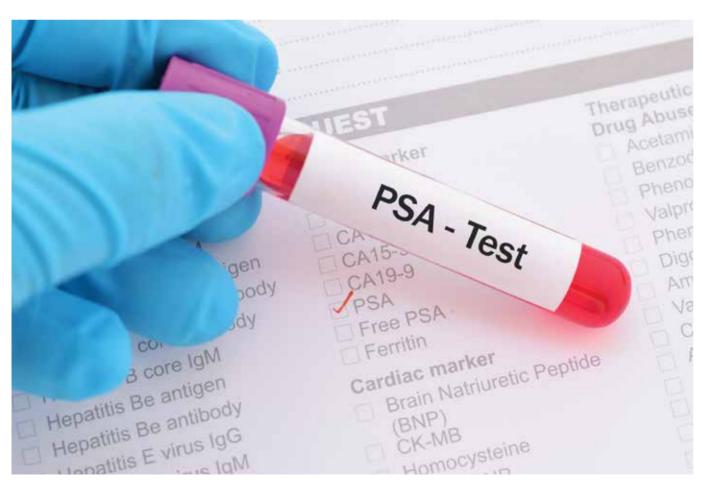
Packaging	туре А раска	
Storage	15 - 25 °C	
Availability	Weekly	

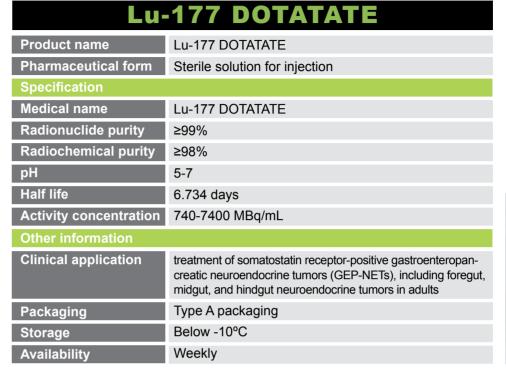




Lu-177 PSMA		
Product name	Lu-177 PSMA	
Pharmaceutical form	Sterile solution for injection	
Specification		
Medical name	Lu-177 PSMA	
Radionuclide purity	≥99%	
Radiochemical purity	≥98%	
рН	5-7	
Half life	6.734 days	
Activity concentration	740-7400 MBq/mL	
Other information		
Clinical application	treatment of prostate cancer, including Metastatic Castration-Resistant Prostate Cancer (mCRPC)	
Packaging	Type A packaging	
Storage	Below -10°C	
Availability	Weekly	











PARS T PE

## **RADIONUCLIDES**

#### **Based on reactor production**

I-131

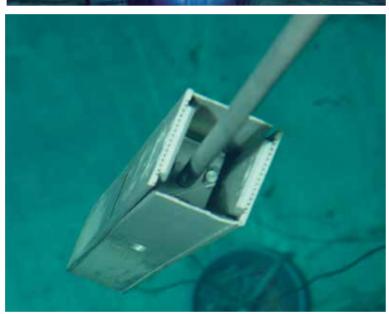
P-32

Sm-153

Re-186

Y-90









#### **Based on cyclotron production**

TI-201

Ga-67

Ge-68

F-18

I-123

**Rb-81** 

In-111

A New Horizon of Life

#### **RADIONUCLIDES**

## **Based on reactor production**

Name	I-131
Radioisotope	lodine 131 (I-131)
chemical formula	Sodium iodide (Na <sup>131</sup> I)
State or form	Soluble in carbonate buffer
Half-life	8.02 d
рН	9-10
Radionuclide purity	> 99%
Storage conditions	room temperature

Name	P-32
Radioisotope	Phosphorus 32 (P-32)
chemical formula	Phosphoric acid(H <sub>3</sub> <sup>32</sup> PO <sub>4</sub> )
State or form	Soluble in HCl 0.1 M
Half-life	14.28 d
рН	Acidic aqueous
Radionuclide purity	> 99%
Storage conditions	room temperature

Name	Sm-153
Radioisotope	Samarium 153 (Sm-153)
chemical formula	Samarium chloride (153SmCl <sub>3</sub> )
State or form	Soluble in HCl 0.1 M
Half-life	1.92 d (46.27 h)
pH	6-7
Radionuclide purity	> 99%
Storage conditions	room temperature

## **Based on reactor production**

Name	Re-186
Radioisotope	Rhenium 186 (Re-186)
Chemical formula	Potassium Perrhenate (K <sup>186</sup> ReO <sub>4</sub> )
State or form	Solution
Half-life	3.77 d
рН	6-7
Radionuclide purity	> 99%
Storage conditions	room temperature

Name	Y-90
Radioisotope	Yttrium 90 (Y-90)
Chemical formula	Yttrium chloride (90YCl <sub>3</sub> )
State or form	Soluble in HCl 0.05 M
Half-life	2.67 d
рН	Acidic aqueous
Radionuclide purity	> 99%
Storage conditions	room temperature



## **RADIONUCLIDES**

## **Based on cyclotron production**

Name	TI-201
Radioisotope	Thallium 201 (TI-201)
Chemical formula	Thallium chloride (201TICI)
State or form	Soluble in normal saline
Half-life	3.04 d (73 h)
pH	4-7
Radionuclide purity	> 99%
Storage conditions	room temperature

Name	Ga-67
Radioisotope	Gallium 67 (Ga-67)
Chemical formula	Gallium citrate (C <sub>6</sub> H <sub>5</sub> <sup>67</sup> GaO <sub>7</sub> )
State or form	Soluble in normal saline
Half-life	3.26 d (78.3 h)
рН	4-7
Radionuclide purity	> 99%
Storage conditions	Room temperature

Name	Ge-68
Radioisotope	Germanium 68 (Ge-68)
Chemical formula	Germanium chloride (68GeCl <sub>3</sub> )
State or form	Soluble in HCl 0.1 M
Half-life	270.95 d
рН	≤ 2
Radionuclide purity	> 99%
Storage conditions	Room temperature



## **Based on cyclotron production**

Name	F-18
Radioisotope	Fluorine 18 (F-18)
Chemical formula	Fluorodeoxyglucose (C <sub>6</sub> H <sub>11</sub> <sup>18</sup> FO <sub>5</sub> )
State or form	Soluble in normal saline
Half-life	110 minutes
рН	4-7
Radionuclide purity	> 99%
Storage conditions	Room temperature

Name	I-123
Radioisotope	lodine 123 (I-123)
Chemical formula	Sodium iodide (Na <sup>123</sup> I)
State or form	Soluble in NaOH
Half-life	13.2 h
рН	9-10
Radionuclide purity	> 99%
Storage conditions	Room temperature

Name	Rb-81
Radioisotope	Rubidium 81 (Rb-81)
Chemical formula	<sup>81</sup> Rb
State or form	Soluble in water
Half-life	4.58 h (274 minutes)
рН	5-7
Radionuclide purity	> 99%
Storage conditions	Room temperature

Name	In-111
Radioisotope	Indium 111 (In-111)
Chemical formula	Indium chloride (111 InCl <sub>3</sub> )
State or form	Soluble in HCl 1 M
Half-life	2.80 d (67.3 h)
рН	≤2
Radionuclide purity	> 99%
Storage conditions	Room temperature

#### **PACKAGING**

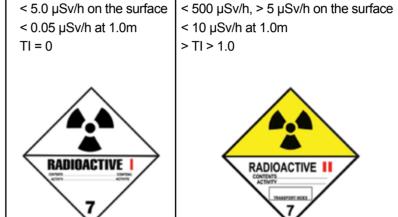
a. I-WHITE Label

Radioac

In Pars Isotope Company, all radioactive products produced with Type A packaging and in accordance with the Regulations for the safe transportation of radioactive materials SSR-6 of the International Atomic Energy Agency and as well as the rules and regulations of the Nuclear Safety Center of the country are transported.

According to the regulations, radioactive packages are classified as Class 7 dangerous goods and the identification number is listed as a UN number.

According to the category, each package must have labels in match with the models provided below:



b. II-YELLOW Label

c. III-YELLOW Label 500  $\mu$ Sv/h, < 2000  $\mu$ Sv/h on the surface  $> 10 \mu Sv/h, < 100 \mu Sv/h$  at 1.0m < TI < 10  $_{c}$  1mSv/h = 1000  $\mu$ Sv/h  $_{c}$ 



On two of these types of labels, a number is entered as the transport index, which is obtained from the following relation.

#### Transport Index (TI):

Determine the maximum radiation level in units of millisieverts per hour (mSv/h) at a distance of one meter from the external surfaces of the package determined shall be multiplied by 100 and the resulting number is the TI.







Radioactive Material













#### **Quality Control and Services**

# Radiopharmaceuticals **Quality Control Department**

The **PARS ISOTOPE** quality control management is equipped with the modern analytical instruments complying to Good Laboratory Practice (GLP) which conducts the control experiments in accordance with the applicable pharmacopoeia monographs.

This management includes the following laboratories:

- Raw materials and incoming items,
- Physicochemical laboratory for reactor-based products,
- Physicochemical laboratory for cyclotron-based products,
- Microbiological laboratories,
- Biological and imaging laboratory with animal house,
- In-Process Quality Control (IPQC) laboratory.

All tests in these laboratories are performed by well-trained and qualified experts in accordance with the requirements of **ISO/IEC 17025** standard. The quality control process in PARS ISOTOPE Company starts from supplying raw materials and items needed to produce the final products and includes in-process controls, control of intermediate products, final product tests, checking the final packaging, product stability tests and conducting research. Quality control laboratories are directly involved in monitoring the quality of all PARS ISOTOPE products and give appropriate feedback by obtaining reliable data in order to maintain the quality characteristics and performance efficacy of radiopharmaceuticals and their continuous improvement processes. The ultimate mission of quality control management in PARS ISOTOPE Company as pointed out in **PIC/S GMP** guide, is to ensure that all necessary and relevant tests are carried out and that materials are not released for use, nor products released for sale, until their quality has been judged satisfactory.





The Secondary Standard Dosimetry Laboratory (SSDL) of Pars Isotope Co. is under the direct supervision of IAEA. This department is responsible for the following duties:

#### **Calibration & QC Services**

- \* Calibration of radiotherapy ionization chambers in standard Co-60 gamma ray field,
- \* Calibration of personal dosemeters and survey meters in Co-60 and Cs-137 gamma ray fields.
- \* Calibration of contamination monitors.
- \* Calibration & dosimetry of brachytherapy sources,
- \* Absolute dosimetry of electron & photon radiation fields of medical linear accelerators and gamma ray field of Co-60 radiotherapy machines,
- \* QC of medical LINACs for radiation field dosimetry, mecanical tests, radiation field safety and radiation protection safety,
- \* QC of nuclear medicine dose calibrators

#### Irradiation

- \* Standard irradiation of samples at all Co-60 gamma ray dose levels,
- \* Standard irradiation of samples in Am-Be neutron fields,
- \* Standard irradiation, reading and annealing of TLDs





PARS T PE company

#### **Quality Control and Services**

#### **PARS-PET Phantom**

#### **Germanium-68 Cylindrical Phantom**

#### An instrument for calibrating PET imaging systems

A positron emission tomography (PET) scanner is one of the most modern, accurate and advanced nuclear medicine imaging systems with unparalleled capabilities in diagnosing different types of cancer, neurological and cardiovascular disease. In order to have a proper functioning imaging system, the machine needs to be calibrated and adjusted on a daily basis. This calibrations require a particular set of tools. The Germanium-68 Cylindrical Phantom is one of the tools that is used to perform the daily functional testing.

PET is a functional imaging technique in which images are taken from different parts of the body using radiation emitted by positron emitting radioactive materials with a short half-life, such as F-18 or Ga-68. These examinations attain different goals including early detection of any possible failures in the components of the device (like the detector module).

The examination also provides other services like 3D normalization, and receiving test images of the PET system.

Germanium-68 cylindrical phantom under the brand name of PARS-PET Phantom is manufactured by Iranian specialists in Parsisotope Company for purposes mentioned above. After passing control and guarantee approvals, this product is sent to nuclear medicine centers for calibrating PET imaging systems.

PARS-PET Phantom	
Product name	Ge-68 Phantom
Shape	Cylindrical
Active height	20, 27 cm
Nominal activity	For 20 cm: 37 MBq (uniformly) For 27 cm: 74 MBq (uniformly)
Useful life time	1 year
Application	For PET imaging system calibration
Packaging	Type A packaging
Storage	15-40 °C
Availability	On request











ISLAMIC REPUBLIC OF IRAN MINISTRY OF HEALTH AND MEDICAL EDUCATION



REF: 665/70302 Date: 7/3/2022

#### GMP CERTIFICATE

Manufacturer: Pars Isotope Company Address: No. 88, West 23rd St., Azadegan Blvd., South Sheykh Bahaie Ave., Tehran, Iran. P.O. 803: 1437663181

Production Lines: Radiopharmaceuticals and Cold Kits

This is to certify that above-mentioned production lines were duly inspected and approved in accordance with Good Manufacturing Practice Principles for pharmaceutical products which are currently in force in the LR of Iran.

The manufacturer plant is subject to regular GMP inspections by the Iranian Food and Drug Administration.

The production lines of Radiopharmaceuticals and Cold Kits are in compliance with the cGMP/GMP standards and relevant principles and regulation.

This certificate is valid for a period of two years.



TABLES CHATTER & BASE



areatory Accreditation Certificate

Pars Isotope Laboratory

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