



# Kit Quality Control Report

## RPH CENTRAL PHARMA

CNPJ: 19.315.658/0001-10

R: Maestro Cardim, 769 - São Paulo/SP

Farm. RT: Priscila Larcher CRF/SP-74.417

Date: From 24/11/2021 To 24/11/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211124-017		24/11/2021	04:04	PM	Butanona Normal Saline	3MM Whatman Sílica gel	190,2 9,1		0,5 151,5	0	pH (Low/Actual/High)	94,072 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211124-026		24/11/2021	07:33	MB	Butanona Normal Saline	3MM Whatman Sílica gel	138,7 3,5		0,8 141,5	0	pH (Low/Actual/High)	97,013 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211124-027		24/11/2021	07:34	MB	Butanona Normal Saline	3MM Whatman Sílica gel	112,8 1,5		2,9 81,2	0	pH (Low/Actual/High)	95,68 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211124-036		24/11/2021	10:28	PM	Butanona Normal Saline	3MM Whatman Sílica gel	171,7 9,7		0,9 142,3	0	pH (Low/Actual/High)	93,097 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20211124-033		24/11/2021	09:39	BB	Citrato de Sódio 0,1M	Sílica gel	32,5		0,6	0	pH (Low/Actual/High)	98,187 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20211124-018	RPH	24/11/2021	04:12	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	979 9		2 641	0	pH (Low/Actual/High)	98,412 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211124-019	RPH	24/11/2021	04:14	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	637 16		3 709	0	pH (Low/Actual/High)	97,324 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211124-037	RPH	24/11/2021	10:36	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	491 6		1 336	0	pH (Low/Actual/High)	98,042 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20211124-016		24/11/2021	04:00	MB	Butanona	3MM Whatman	284		3	0	pH (Low/Actual/High)	98,955 %	Pass 5,00 <= 5,00 <= 7,00
						Límpido/Incolor							
FITATO-99mTc Lot # K-20211124-028		24/11/2021	07:37	MB	Butanona	3MM Whatman	296,1		5	0	pH (Low/Actual/High)	98,339 %	Pass 5,00 <= 5,00 <= 7,00
						Límpido/Incolor							
MAA-99mTc Lot # K-20211124-015		24/11/2021	03:57	PM	Butanona	3MM Whatman	238,1		0,3	0	pH (Low/Actual/High)	99,874 %	Pass 3,00 <= 5,00 <= 6,00
						Turvo/Incolor							

Product:	Manuf:	Calibration D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
MAA-99mTc Lot # K-20211124-030		24/11/2021 07:42	MB	Butanona		3MM Whatman		175,4		0,7	0	99,602 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211124-031		24/11/2021 07:46	MB	Butanona		3MM Whatman		146,7		0,6	0	99,593 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211124-038		24/11/2021 10:45	PM	Butanona		3MM Whatman		105,7		1,5	0	98,601 %	Pass	
												pH (Low/Actual/High)	3,00 <= 3,00 <= 6,00	
												Turvo/Incolor		
MDP-99mTc Lot # K-20211124-012		24/11/2021 03:50	PM	Acetona		3MM Whatman		916		3	0	97,435 %	Pass	
				Normal Saline		3MM Whatman		21		917	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
												Límpido/Incolor		
MDP-99mTc Lot # K-20211124-013		24/11/2021 03:52	PM	Acetona		3MM Whatman		1058		3	0	98,69 %	Pass	
				Normal Saline		3MM Whatman		9		867	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
												Límpido/Incolor		
MDP-99mTc Lot # K-20211124-014		24/11/2021 03:54	PM	Acetona		3MM Whatman		772		1	0	98,048 %	Pass	
				Normal Saline		3MM Whatman		16		862	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
												Límpido/Incolor		
MDP-99mTc Lot # K-20211124-024		24/11/2021 07:01	MB	Acetona		3MM Whatman		348		1	0	98,796 %	Pass	
				Normal Saline		3MM Whatman		3		324	pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80		
												Límpido/Incolor		
MDP-99mTc Lot # K-20211124-025		24/11/2021 07:01	MB	Acetona		3MM Whatman		670		1	0	98,362 %	Pass	
				Normal Saline		3MM Whatman		12		794	pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80		
												Límpido/Incolor		
MDP-99mTc Lot # K-20211124-029		24/11/2021 07:39	MB	Acetona		3MM Whatman		775		2	0	98,928 %	Pass	
				Normal Saline		3MM Whatman		6		731	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
												Límpido/Incolor		
MDP-99mTc Lot # K-20211124-039		24/11/2021 10:52	JS	Acetona		3MM Whatman		1080		2	0	97,888 %	Pass	
				Normal Saline		3MM Whatman		19		967	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
												Límpido/Incolor		
MDP-99mTc Lot # K-20211124-040		24/11/2021 10:56	JS	Acetona		3MM Whatman		958		2	0	98,305 %	Pass	
				Normal Saline		3MM Whatman		4		265	pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80		
												Límpido/Incolor		
MDP-99mTc Lot # K-20211124-041		24/11/2021 11:03	JS	Acetona		3MM Whatman		547		1	0	99,548 %	Pass	
				Normal Saline		3MM Whatman		1		370	pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80		
												Límpido/Incolor		
MIBI-99mTc Lot # K-20211124-004		24/11/2021 01:51	MB	Normal Saline		Sílica gel		660		12	0	97,268 %	Pass	
				Metanol		3MM Whatman		13		1361	pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
												Límpido/Incolor		

Product:	Manuf:	Calibration D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
MIBI-99mTc Lot # K-20211124-005		24/11/2021 01:52 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1005 6		24 1059	0	pH (Low/Actual/High)	97,104 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-006		24/11/2021 01:57 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1033 35		7 1710	0	pH (Low/Actual/High)	97,321 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-007		24/11/2021 02:00 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			774 19		17 628	0	pH (Low/Actual/High)	94,914 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-008		24/11/2021 02:49 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			673 35		9 1522	0	pH (Low/Actual/High)	96,432 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-009		24/11/2021 02:49 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			810 6		8 1433	0	pH (Low/Actual/High)	98,605 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-010		24/11/2021 02:53 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1445 11		8 1917	0	pH (Low/Actual/High)	98,879 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-011		24/11/2021 02:54 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			489 10		2 715	0	pH (Low/Actual/High)	98,213 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-020		24/11/2021 05:08 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2410 14		64 2464	0	pH (Low/Actual/High)	96,848 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-021		24/11/2021 06:46 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			571 5		12 682	0	pH (Low/Actual/High)	97,214 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-023		24/11/2021 06:46 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			415 5		6 708	0	pH (Low/Actual/High)	97,874 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-032		24/11/2021 08:06 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1198 4		2 1369	0	pH (Low/Actual/High)	99,542 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-034		24/11/2021 10:10 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1140 14		10 1663	0	pH (Low/Actual/High)	98,296 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211124-035		24/11/2021 10:14 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1943 1		36 258	0	pH (Low/Actual/High)	97,795 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														

Product:	Manuf:	Calibration	D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
PSMA-177Lu Lot # K-20211124-001	24/11/2021	01:09	BB	Citrato de Sódio 0,1M	Sílica gel				1221		8	0		99,349 %	Pass
								Limpido				pH (Low/Actual/High)	4,00 <= 4,50	<= 5,00	
QC Notes: HPLC: 96,05%															
PSMA-177Lu Lot # K-20211124-002	24/11/2021	01:10	BB	Citrato de Sódio 0,1M	Sílica gel				814		5	0		99,389 %	Pass
								Limpido				pH (Low/Actual/High)	4,00 <= 4,50	<= 5,00	
QC Notes: HPLC: 97,55%															
PSMA-177Lu Lot # K-20211124-003	24/11/2021	01:25	BB	Citrato de Sódio 0,1M	Sílica gel				864		5	0		99,425 %	Pass
								Limpido				pH (Low/Actual/High)	4,00 <= 4,50	<= 5,00	
QC Notes: HPLC: 98,44%															
PSMA-68Ga Lot # K-20211124-022	24/11/2021	06:47	PM	Acetato de amônio 1M:Metanol	Sílica gel				0,13	26,67		0		99,515 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
PSMA-68Ga Lot # K-20211124-042	24/11/2021	12:56	MB	Acetato de amônio 1M:Metanol	Sílica gel				0,8	111,2		0		99,286 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
Tecnécio-99m Lot # E-20211124-001	24/11/2021	01:42	MB	Butanona	3MM Whatman				187	4802		0		96,252 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20211124-002	24/11/2021	01:42	MB	Butanona	3MM Whatman				48	3806		0		98,755 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20211124-004	24/11/2021	02:44	MB	Butanona	3MM Whatman				1	323		0		99,691 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20211124-003	24/11/2021	02:44	MB	Butanona	3MM Whatman				5	730		0		99,32 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20211124-005	24/11/2021	03:48	MB	Butanona	3MM Whatman				1	363		0		99,725 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20211124-006	24/11/2021	05:07	PP	Butanona	3MM Whatman				29	3274		0		99,122 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211124-007	24/11/2021	06:39	MB	Butanona	3MM Whatman				6	1186		0		99,497 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	

Product:	Manuf:	Calibration D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
Tecnécio-99m Lot # E-20211124-009		24/11/2021 06:55	MB	Butanona		3MM Whatman		4		853	0		99,533 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211124-010		24/11/2021 07:28	MB	Butanona		3MM Whatman		7		1755	0		99,603 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211124-011		24/11/2021 08:03	MB	Butanona		3MM Whatman		6		1529	0		99,609 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211124-013		24/11/2021 10:07	PM	Butanona		3MM Whatman		3		362	0		99,178 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211124-014		24/11/2021 10:11	PM	Butanona		3MM Whatman		1		221	0		99,55 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211124-015		24/11/2021 10:46	PM	Butanona		3MM Whatman		25		2255	0		98,904 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211124-016		24/11/2021 10:49	PM	Butanona		3MM Whatman		7		312	0		97,806 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor