



## 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 26/05/2021 To 26/05/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210526-020		26/05/2021	07:28	FS	Butanona Normal Saline	3MM Whatman Sílica gel	65,8 5,9		0,8 66,2	0	pH (Low/Actual/High)	90,616 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210526-023		26/05/2021	07:53	FS	Butanona Normal Saline	3MM Whatman Sílica gel	70 1		2 109	0	pH (Low/Actual/High)	96,313 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210526-026		26/05/2021	08:15	FS	Butanona Normal Saline	3MM Whatman Sílica gel	232 5		3 122,3	0	pH (Low/Actual/High)	94,796 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210526-032		26/05/2021	10:33	WG	Butanona Normal Saline	3MM Whatman Sílica gel	129,8 1,4		4 79,4	0	pH (Low/Actual/High)	95,278 %	Pass
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210526-029		26/05/2021	09:49	JS	Citrato de Sódio 0,1M	Sílica gel	45,6		0,4	0	pH (Low/Actual/High)	99,13 %	Pass
Límpido e Incolor													
DTPA-99mTc Lot # K-20210526-005	RPH	26/05/2021	03:36	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	940 28		40 726	0	pH (Low/Actual/High)	92,205 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210526-022	RPH	26/05/2021	07:40	FS	Acetona Normal Saline	3MM Whatman 3MM Whatman	474 8		3 315	0	pH (Low/Actual/High)	96,894 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210526-033	RPH	26/05/2021	10:39	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	123,7 3		2,6 355	0	pH (Low/Actual/High)	97,103 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20210526-003		26/05/2021	03:09	PP	Butanona	3MM Whatman	626		4	0	pH (Low/Actual/High)	99,365 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20210526-021		26/05/2021	07:32	FS	Butanona	3MM Whatman	450		1	0	pH (Low/Actual/High)	99,778 %	Pass
Límpido/Incolor													
MAA-99mTc Lot # K-20210526-007		26/05/2021	03:47	PP	Butanona	3MM Whatman	397		3	0	pH (Low/Actual/High)	99,25 %	Pass
Turvo/Incolor													

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210526-008		26/05/2021 03:49 PP	Butanona		3MM	Whatman		325		1	0	99,693 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210526-009		26/05/2021 03:50 PP	Butanona		3MM	Whatman		408		8	0	98,077 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210526-025		26/05/2021 08:04 FS	Butanona		3MM	Whatman		117		2	0	98,319 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210526-031		26/05/2021 10:32 JS	Butanona		3MM	Whatman		59		1,9	0	96,88 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210526-035		26/05/2021 11:05 WG	Butanona		3MM	Whatman		298		5	0	98,35 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MDP-99mTc Lot # K-20210526-010		26/05/2021 04:04 PP	Acetona		3MM	Whatman		806		1	0	97,057 %	Pass	
			Normal Saline		3MM	Whatman		15		517	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210526-012		26/05/2021 04:06 PP	Acetona		3MM	Whatman		631		1	0	93,914 %	Pass	
			Normal Saline		3MM	Whatman		31		492	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210526-015		26/05/2021 04:41 PP	Acetona		3MM	Whatman		3771		58	0	97,902 %	Pass	
			Normal Saline		3MM	Whatman		6		1022	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210526-019		26/05/2021 07:27 FS	Acetona		3MM	Whatman		392		2	0	98,227 %	Pass	
			Normal Saline		3MM	Whatman		2		156	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210526-030		26/05/2021 10:25 JS	Acetona		3MM	Whatman		550		1	0	99,196 %	Pass	
			Normal Saline		3MM	Whatman		3		479	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210526-034		26/05/2021 10:56 WG	Acetona		3MM	Whatman		569		2	0	99,195 %	Pass	
			Normal Saline		3MM	Whatman		3,2		700	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210526-001		26/05/2021 02:44 PP	Normal Saline		Sílica gel			2023		4	0	99,707 %	Pass	
			Metanol		3MM	Whatman		2		2095	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210526-002		26/05/2021 02:48 PP	Normal Saline		Sílica gel			2064		7	0	97,901 %	Pass	
			Metanol		3MM	Whatman		5		279	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210526-004	26/05/2021	03:27 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3193 2		43 3052	0	pH (Low/Actual/High)	98,606 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210526-006	26/05/2021	03:44 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2490 10		54 2175	0	pH (Low/Actual/High)	97,42 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210526-011	26/05/2021	04:04 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			824 9		10 1120	0	pH (Low/Actual/High)	98,004 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210526-013	26/05/2021	04:31 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2528 6		28 2330	0	pH (Low/Actual/High)	98,648 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210526-014	26/05/2021	04:40 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			568 26		7 1074	0	pH (Low/Actual/High)	96,419 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210526-017	26/05/2021	07:10 FS	Normal Saline Metanol		Sílica gel 3MM Whatman			487 4		7 817	0	pH (Low/Actual/High)	98,096 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210526-018	26/05/2021	07:15 FS	Normal Saline Metanol		Sílica gel 3MM Whatman			473 9		6 758	0	pH (Low/Actual/High)	97,574 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210526-024	26/05/2021	08:02 FS	Normal Saline Metanol		Sílica gel 3MM Whatman			290 5		5 881	0	pH (Low/Actual/High)	97,741 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210526-027	26/05/2021	09:27 FS	Normal Saline Metanol		Sílica gel 3MM Whatman			345 8		2 603	0	pH (Low/Actual/High)	98,114 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210526-028	26/05/2021	09:35 FS	Normal Saline Metanol		Sílica gel 3MM Whatman			1153 13		3 1924	0	pH (Low/Actual/High)	99,069 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
PSMA-177Lu Lot # K-20210526-016 Master Formulation Record:	26/05/2021	05:39 MP	Citrato de Sódio 0,1M		Sílica gel			813		1	0	pH (Low/Actual/High)	99,877 %	Pass 4,00 <= 4,50 <= 5,00
QC Notes: HPLC 99,88%							Límpido							
PSMA-68Ga Lot # K-20210526-036	26/05/2021	12:38 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,3		42,9	0	pH (Low/Actual/High)	99,306 %	Pass 4,00 <= 5,00 <= 8,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210526-001	26/05/2021	02:37 PP	Butanona		3MM Whatman			7		4030	0	pH (Low/Actual/High)	99,827 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210526-002		26/05/2021 02:44 PP	Butanona		3MM	Whatman		12		3005	0	99,602 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-003		26/05/2021 03:01 PP	Butanona		3MM	Whatman		14		477	0	97,149 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-004		26/05/2021 03:26 PP	Butanona		3MM	Whatman		73		1598	0	95,631 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-005		26/05/2021 03:36 PP	Butanona		3MM	Whatman		11		229	0	95,417 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-006		26/05/2021 04:00 PP	Butanona		3MM	Whatman		9		298	0	97,068 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-007		26/05/2021 04:01 PP	Butanona		3MM	Whatman		13		389	0	96,766 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-009		26/05/2021 04:29 PP	Butanona		3MM	Whatman		17		671	0	97,529 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-008		26/05/2021 04:29 PP	Butanona		3MM	Whatman		20		1652	0	98,804 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-010		26/05/2021 04:38 PP	Butanona		3MM	Whatman		17		350	0	95,368 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-012		26/05/2021 07:03 FS	Butanona		3MM	Whatman		1		258	0	99,614 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-013		26/05/2021 07:12 FS	Butanona		3MM	Whatman		2		705	0	99,717 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-015		26/05/2021 07:25 FS	Butanona		3MM	Whatman		3		286	0	98,962 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-014		26/05/2021 07:25 FS	Butanona		3MM	Whatman		3		617	0	99,516 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210526-016		26/05/2021 07:39 FS	Butanona		3MM	Whatman		3		158	0		98,137 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-017		26/05/2021 07:58 FS	Butanona		3MM	Whatman		1		48	0		97,959 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-018		26/05/2021 08:14 FS	Butanona		3MM	Whatman		2		375	0		99,469 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-019		26/05/2021 09:24 FS	Butanona		3MM	Whatman		4		1638	0		99,756 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-020		26/05/2021 09:32 FS	Butanona		3MM	Whatman		9		1767	0		99,493 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-022		26/05/2021 10:14 FS	Butanona		3MM	Whatman		6		410	0		98,558 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-023		26/05/2021 10:21 FS	Butanona		3MM	Whatman		34		913	0		96,41 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210526-024		26/05/2021 10:54 WG	Butanona		3MM	Whatman		7		1713	0		99,593 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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