



# 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 26/11/2021 To 26/11/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211126-011		26/11/2021	04:05	PM	Butanona Normal Saline	3MM Whatman Sílica gel	207 9,4		2 220,6	0	pH (Low/Actual/High)	94,956 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20211126-023		26/11/2021	08:01	MB	Butanona Normal Saline	3MM Whatman Sílica gel	182,1 0,9		1,8 138,6	0	pH (Low/Actual/High)	98,376 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20211126-024		26/11/2021	08:02	MB	Butanona Normal Saline	3MM Whatman Sílica gel	222,7 5,8		0,8 169,7	0	pH (Low/Actual/High)	96,337 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20211126-025		26/11/2021	08:03	MB	Butanona Normal Saline	3MM Whatman Sílica gel	171,5 6,5		1,5 134	0	pH (Low/Actual/High)	94,507 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20211126-037		26/11/2021	10:39	VS	Butanona Normal Saline	3MM Whatman Sílica gel	654 5		3 164	0	pH (Low/Actual/High)	96,585 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20211126-038		26/11/2021	10:41	VS	Butanona Normal Saline	3MM Whatman Sílica gel	231 5		3 423	0	pH (Low/Actual/High)	97,55 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DOTATOC-68Ga Lot # K-20211126-045		26/11/2021	12:47										%
DTPA-99mTc Lot # K-20211126-010	RPH	26/11/2021	03:54	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	611 8		3 496	0	pH (Low/Actual/High)	97,924 %	Pass
						Límpido/Incolor						3,80 <= 5,00	<= 7,50
DTPA-99mTc Lot # K-20211126-013	RPH	26/11/2021	04:12	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	698 23		3 807	0	pH (Low/Actual/High)	96,801 %	Pass
						Límpido/Incolor						3,80 <= 5,00	<= 7,50
DTPA-99mTc Lot # K-20211126-044	RPH	26/11/2021	12:10	VS	Acetona Normal Saline	3MM Whatman 3MM Whatman	595 12		7 530	0	pH (Low/Actual/High)	96,623 %	Pass
						Límpido/Incolor						3,80 <= 7,00	<= 7,50
FITATO-99mTc Lot # K-20211126-015		26/11/2021	04:50	PM	Butanona	3MM Whatman	595		6	0	pH (Low/Actual/High)	99,002 %	Pass
						Límpido/Incolor						5,00 <= 6,00	<= 7,00

Product:	Manuf:	Calibration D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
FITATO-99mTc Lot # K-20211126-039	26/11/2021	10:56 VS	Butanona		3MM	Whatman		691		6	0	99,139 %	Pass	
												pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00
														Límpido/Incolor
MAA-99mTc Lot # K-20211126-012	26/11/2021	04:10 PM	Butanona		3MM	Whatman		319		1	0	99,688 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211126-026	26/11/2021	08:06 MB	Butanona		3MM	Whatman		153,2		0,8	0	99,481 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211126-027	26/11/2021	08:07 MB	Butanona		3MM	Whatman		151,7		1,7	0	98,892 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211126-040	26/11/2021	11:00 VS	Butanona		3MM	Whatman		786		3	0	99,62 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211126-041	26/11/2021	11:05 VS	Butanona		3MM	Whatman		470		2	0	99,576 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211126-042	26/11/2021	11:07 VS	Butanona		3MM	Whatman		1084		4	0	99,632 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MDP-99mTc Lot # K-20211126-008	26/11/2021	03:47 PM	Acetona		3MM	Whatman		1310		2	0	95,50 %	Pass	
			Normal Saline		3MM	Whatman		25		550		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211126-009	26/11/2021	03:49 PM	Acetona		3MM	Whatman		1165		7	0	99,281 %	Pass	
			Normal Saline		3MM	Whatman		1		823		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211126-016	26/11/2021	06:32 MB	Acetona		3MM	Whatman		685		3	0	99,271 %	Pass	
			Normal Saline		3MM	Whatman		2		680		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211126-028	26/11/2021	08:11 MB	Acetona		3MM	Whatman		442		3	0	98,79 %	Pass	
			Normal Saline		3MM	Whatman		2		371		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211126-029	26/11/2021	08:13 MB	Acetona		3MM	Whatman		667		9	0	98,446 %	Pass	
			Normal Saline		3MM	Whatman		2		896		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211126-036	26/11/2021	10:25 VS	Acetona		3MM	Whatman		1213		4	0	98,865 %	Pass	
			Normal Saline		3MM	Whatman		12		1476		pH (Low/Actual/High)	4,00 <= 7,00	<= 7,80
														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
MDP-99mTc Lot # K-20211126-043		26/11/2021 11:40	VS	Acetona Normal Saline	3MM Whatman 3MM Whatman			1789 1		12 346	0 pH (Low/Actual/High)	99,046 %		Pass 4,00 <= 7,00 <= 7,80
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-001		26/11/2021 01:44	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1333 20		18 1574	0 pH (Low/Actual/High)	97,413 %		Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-002		26/11/2021 01:49	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			826,5 30		1,4 1540	0 pH (Low/Actual/High)	97,92 %		Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-003		26/11/2021 02:37	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			767,4 7,6		15 958,1	0 pH (Low/Actual/High)	97,296 %		Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-004		26/11/2021 02:39	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1211 29		19 1316	0 pH (Low/Actual/High)	96,299 %		Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-005		26/11/2021 02:40	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1222 2		11 1189	0 pH (Low/Actual/High)	98,94 %		Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-006		26/11/2021 02:55	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			860,3 7		9,9 1266	0 pH (Low/Actual/High)	98,312 %		Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-007		26/11/2021 03:38	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1016 15		14 2428	0 pH (Low/Actual/High)	98,027 %		Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-014		26/11/2021 04:33	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1200 3		16 1360	0 pH (Low/Actual/High)	98,464 %		Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-018		26/11/2021 06:59	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			688,4 8		2,9 1624	0 pH (Low/Actual/High)	99,09 %		Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-019		26/11/2021 07:14	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1388 29		22 1832	0 pH (Low/Actual/High)	96,881 %		Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-020		26/11/2021 07:17	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1006 3		10 1540	0 pH (Low/Actual/High)	98,821 %		Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211126-021		26/11/2021 07:27	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			531 11		10 833	0 pH (Low/Actual/High)	96,848 %		Pass 5,00 <= 6,00 <= 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-20211126-022	26/11/2021	07:35	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			921 2		6 1010	0	pH (Low/Actual/High)	99,155 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211126-031	26/11/2021	09:49	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			368 4		4 669	0	pH (Low/Actual/High)	98,33 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211126-032	26/11/2021	09:57	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			349 2		4 586	0	pH (Low/Actual/High)	98,527 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211126-033	26/11/2021	09:58	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			221 6		3 982	0	pH (Low/Actual/High)	98,053 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211126-034	26/11/2021	10:00	VS	Normal Saline Metanol	Sílica gel 3MM Whatman			373 2		4 301	0	pH (Low/Actual/High)	98,279 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211126-035	26/11/2021	10:09	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			1611 2		13 245	0	pH (Low/Actual/High)	98,39 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20211126-017	26/11/2021	06:48	MB	Acetato de amônio 1M:Metanol	Sílica gel			0,06		23,55	0	pH (Low/Actual/High)	99,746 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20211126-030	26/11/2021	09:54	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,3		22,6	0	pH (Low/Actual/High)	98,69 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211126-001	26/11/2021	01:17	MB	Butanona	3MM Whatman			4		1512	0	pH (Low/Actual/High)	99,736 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211126-002	26/11/2021	01:43	MB	Butanona	3MM Whatman			12		1580	0	pH (Low/Actual/High)	99,246 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211126-003	26/11/2021	02:31	MB	Butanona	3MM Whatman			18		1270	0	pH (Low/Actual/High)	98,602 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211126-004	26/11/2021	03:36	PM	Butanona	3MM Whatman			7		611	0	pH (Low/Actual/High)	98,867 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211126-005	26/11/2021	03:45	MB	Butanona	3MM Whatman			1,8		163,4	0	pH (Low/Actual/High)	98,91 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														

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-20211126-006		26/11/2021 04:07 PM	Butanona		3MM Whatman			5		2003	0		99,751 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-007		26/11/2021 04:48 PM	Butanona		3MM Whatman			17		1942	0		99,132 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-009		26/11/2021 06:57 MB	Butanona		3MM Whatman			33		2732	0		98,807 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-010		26/11/2021 07:07 MB	Butanona		3MM Whatman			18		3223	0		99,445 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-011		26/11/2021 07:21 MB	Butanona		3MM Whatman			15		1258	0		98,822 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-012		26/11/2021 07:30 MB	Butanona		3MM Whatman			1		386,4	0		99,742 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-013		26/11/2021 07:48 MB	Butanona		3MM Whatman			5,2		610,7	0		99,156 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-014		26/11/2021 08:09 MB	Butanona		3MM Whatman			2,4		220,7	0		98,924 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-015		26/11/2021 09:32 MB	Butanona		3MM Whatman			8		1470	0		99,459 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-016		26/11/2021 09:33 MB	Butanona		3MM Whatman			27		1231	0		97,854 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-017		26/11/2021 09:47 MB	Butanona		3MM Whatman			12		741	0		98,406 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-019		26/11/2021 10:06 MB	Butanona		3MM Whatman			2		1024	0		99,805 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20211126-020		26/11/2021 10:19 JS	Butanona		3MM Whatman			8		955	0		99,169 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 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-20211126-021		26/11/2021 10:31	JS	Butanona		3MM	Whatman	3		275	0		98,921 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211126-022		26/11/2021 11:36	VS	Butanona		3MM	Whatman	13		398	0		96,837 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
												Límpido e Incolor		