



# 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 21/02/2022 To 21/02/2022

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20220221-028		21/02/2022	08:02	MB	Butanona Normal Saline	3MM Whatman Sílica gel	118,7 6,9		0,8 113,6	0	pH (Low/Actual/High)	93,604 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220221-030		21/02/2022	08:30	MB	Butanona Normal Saline	3MM Whatman Sílica gel	197,4 1,3		1,7 151	0	pH (Low/Actual/High)	98,293 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220221-037		21/02/2022	10:13	VSR	Butanona Normal Saline	3MM Whatman Sílica gel	133 6,3		1,4 131	0	pH (Low/Actual/High)	94,37 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20220221-036		21/02/2022	09:45	VSR	Citrato de Sódio 0,1M	Sílica gel	20,2		0,1	0	pH (Low/Actual/High)	99,507 %	Pass 4,00 <= 6,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20220221-044		21/02/2022	15:42	JS	Citrato de Sódio 0,1M	Sílica gel	19,7		0,2	0	pH (Low/Actual/High)	98,995 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20220221-009	RPH	21/02/2022	03:32	GS	Acetona Normal Saline	3MM Whatman 3MM Whatman	371 12		2 365	0	pH (Low/Actual/High)	96,281 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20220221-010	RPH	21/02/2022	03:35	GS	Acetona Normal Saline	3MM Whatman 3MM Whatman	395 4		1 565	0	pH (Low/Actual/High)	99,044 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20220221-027	RPH	21/02/2022	07:31	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	395 15		4 433	0	pH (Low/Actual/High)	95,649 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20220221-013		21/02/2022	04:09	GS	Butanona	3MM Whatman	535		2	0	pH (Low/Actual/High)	99,628 %	Pass 5,00 <= 5,00 <= 7,00
						Límpido/Incolor							
FITATO-99mTc Lot # K-20220221-033		21/02/2022	09:33	VSR	Butanona	3MM Whatman	346		5	0	pH (Low/Actual/High)	98,575 %	Pass 5,00 <= 6,00 <= 7,00
						Límpido/Incolor							
MAA-99mTc Lot # K-20220221-012		21/02/2022	04:02	GS	Butanona	3MM Whatman	309		3	0	pH (Low/Actual/High)	99,038 %	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-20220221-022		21/02/2022 07:12	MB	Butanona		3MM Whatman		43,7		1	0	97,763 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20220221-023		21/02/2022 07:14	MB	Butanona		3MM Whatman		26,7		1	0	96,39 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20220221-024		21/02/2022 07:16	MB	Butanona		3MM Whatman		107		2	0	98,165 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20220221-025		21/02/2022 07:19	MB	Butanona		3MM Whatman		89		2	0	97,802 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20220221-040		21/02/2022 10:54	VSR	Butanona		3MM Whatman		121		2	0	98,374 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20220221-042		21/02/2022 11:10	YD	Butanona		3MM Whatman		131		2,5	0	98,127 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20220221-007		21/02/2022 03:24	GS	Acetona		3MM Whatman		1265		2	0	99,605 %	Pass	
				Normal Saline		3MM Whatman		2		843		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20220221-008		21/02/2022 03:29	GS	Acetona		3MM Whatman		812		2	0	98,667 %	Pass	
				Normal Saline		3MM Whatman		10		910		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20220221-011		21/02/2022 04:02	GS	Acetona		3MM Whatman		607		7	0	98,478 %	Pass	
				Normal Saline		3MM Whatman		6		1566		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20220221-014		21/02/2022 04:19	GS	Acetona		3MM Whatman		863		2	0	97,615 %	Pass	
				Normal Saline		3MM Whatman		21		954		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20220221-015		21/02/2022 05:00	GS	Acetona		3MM Whatman		903		2	0	98,331 %	Pass	
				Normal Saline		3MM Whatman		17		1157		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20220221-019		21/02/2022 06:43	MB	Acetona		3MM Whatman		1312		6	0	97,687 %	Pass	
				Normal Saline		3MM Whatman		23		1215		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20220221-021		21/02/2022 06:59	MB	Acetona		3MM Whatman		1362		1	0	98,732 %	Pass	
				Normal Saline		3MM Whatman		16		1323		pH (Low/Actual/High)	4,00 <= 6,00	<= 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-20220221-031		21/02/2022 08:45	VSR	Acetona Normal Saline	3MM	Whatman		1,4 0,008	0,012 1,246	0		98,512 %	Pass	pH (Low/Actual/High) 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20220221-034		21/02/2022 09:38	VSR	Acetona Normal Saline	3MM	Whatman		1,344 0,017	0,001 1,325	0		98,659 %	Pass	pH (Low/Actual/High) 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20220221-035		21/02/2022 09:41	VSR	Acetona Normal Saline	3MM	Whatman		768 0,007	2 1,305	0		99,207 %	Pass	pH (Low/Actual/High) 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20220221-001		21/02/2022 01:58	WN	Normal Saline Metanol	Sílica gel 3MM	Whatman		1762 8	33 1878	0		97,737 %	Pass	pH (Low/Actual/High) 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220221-002		21/02/2022 01:59	WN	Normal Saline Metanol	Sílica gel 3MM	Whatman		3572 37	116 3303	0		95,747 %	Pass	pH (Low/Actual/High) 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220221-003		21/02/2022 01:59	WN	Normal Saline Metanol	Sílica gel 3MM	Whatman		1766 19	38 1784	0		96,84 %	Pass	pH (Low/Actual/High) 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220221-004		21/02/2022 02:04	WN	Normal Saline Metanol	Sílica gel 3MM	Whatman		1989 3	38 2071	0		97,981 %	Pass	pH (Low/Actual/High) 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220221-005		21/02/2022 02:09	WN	Normal Saline Metanol	Sílica gel 3MM	Whatman		986 21	18 3287	0		97,572 %	Pass	pH (Low/Actual/High) 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220221-006		21/02/2022 02:10	GS	Normal Saline Metanol	Sílica gel 3MM	Whatman		1867 7	23 1390	0		98,282 %	Pass	pH (Low/Actual/High) 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220221-016		21/02/2022 05:05	GS	Normal Saline Metanol	Sílica gel 3MM	Whatman		1778 7	23 2937	0		98,485 %	Pass	pH (Low/Actual/High) 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220221-018		21/02/2022 06:41	MB	Normal Saline Metanol	Sílica gel 3MM	Whatman		1140 8	15 1331	0		98,104 %	Pass	pH (Low/Actual/High) 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220221-026		21/02/2022 07:27	MB	Normal Saline Metanol	Sílica gel 3MM	Whatman		1278 9	24 2000	0		97,709 %	Pass	pH (Low/Actual/High) 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220221-029		21/02/2022 08:04	MB	Normal Saline Metanol	Sílica gel 3MM	Whatman		1475 3	9 1664	0		99,214 %	Pass	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-20220221-032	21/02/2022	09:09	VSR	Normal Saline Metanol	Sílica gel 3MM Whatman			161,9 1		0,8 200	0	pH (Low/Actual/High)	99,011 %	Pass
													5,00 <= 6,00	<= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20220221-038	21/02/2022	10:46	VSR	Normal Saline Metanol	Sílica gel 3MM Whatman			1,478 0,002		0,026 1,593	0	pH (Low/Actual/High)	98,146 %	Pass
													5,00 <= 5,00	<= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20220221-039	21/02/2022	10:49	VSR	Normal Saline Metanol	Sílica gel 3MM Whatman			0,999 0,007		0,002 1,27	0	pH (Low/Actual/High)	99,252 %	Pass
													5,00 <= 5,00	<= 6,00
														Límpido/Incolor
PIRO-99mTc Lot # K-20220221-020	21/02/2022	06:51	MB	Butanona Normal Saline	3MM Whatman 3MM Whatman			314 15		1 334	0	pH (Low/Actual/High)	95,385 %	Pass
													5,00 <= 5,00	<= 7,00
														Límpido/Incolor
PSMA-68Ga Lot # K-20220221-017	21/02/2022	06:32	MB	Acetato de amônio 1M:Metanol	Sílica gel			0,4		21	0	pH (Low/Actual/High)	98,131 %	Pass
													4,00 <= 5,00	<= 8,00
														Límpido e Incolor
PSMA-68Ga Lot # K-20220221-043	21/02/2022	12:41	YD	Acetato de amônio 1M:Metanol	Sílica gel			0,3		12,3	0	pH (Low/Actual/High)	97,619 %	Pass
													4,00 <= 5,00	<= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-001	21/02/2022	00:30	WN	Butanona	3MM Whatman			8		6843	0	pH (Low/Actual/High)	99,883 %	Pass
													5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-002	21/02/2022	00:32	WN	Butanona	3MM Whatman			1		1064	0	pH (Low/Actual/High)	99,906 %	Pass
													5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-004	21/02/2022	00:36	WN	Butanona	3MM Whatman			8		613	0	pH (Low/Actual/High)	98,712 %	Pass
													5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-005	21/02/2022	00:37	WN	Butanona	3MM Whatman			1		612	0	pH (Low/Actual/High)	99,837 %	Pass
													5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-006	21/02/2022	00:40	WN	Butanona	3MM Whatman			7		865	0	pH (Low/Actual/High)	99,197 %	Pass
													5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-007	21/02/2022	01:48	GS	Butanona	3MM Whatman			7		467	0	pH (Low/Actual/High)	98,523 %	Pass
													5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-008	21/02/2022	01:48	GS	Butanona	3MM Whatman			2		583	0	pH (Low/Actual/High)	99,658 %	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-20220221-009		21/02/2022 01:50	WN	Butanona		3MM Whatman		0,225		10,25	0		97,852 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-010		21/02/2022 03:58	GS	Butanona		3MM Whatman		5		412	0		98,801 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-011		21/02/2022 04:17	GS	Butanona		3MM Whatman		7		255	0		97,328 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-012		21/02/2022 05:00	GS	Butanona		3MM Whatman		6		1430	0		99,582 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-015		21/02/2022 06:38	MB	Butanona		3MM Whatman		113		3783	0		97,10 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-016		21/02/2022 06:51	MB	Butanona		3MM Whatman		22		1322	0		98,363 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-017		21/02/2022 07:24	MB	Butanona		3MM Whatman		22		3605	0		99,393 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-018		21/02/2022 07:54	MB	Butanona		3MM Whatman		24		3528	0		99,324 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-019		21/02/2022 09:03	VSR	Butanona		3MM Whatman		0,01		2,14	0		99,535 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-020		21/02/2022 09:33	VSR	Butanona		3MM Whatman		0,01		3,31	0		99,699 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-022		21/02/2022 10:35	VSR	Butanona		3MM Whatman		0,02		4,11	0		99,516 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220221-024		21/02/2022 14:29	JS	Butanona		3MM Whatman		1		280	0		99,644 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor