



# 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 22/12/2021 To 22/12/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211222-026		22/12/2021	07:32	PM	Butanona Normal Saline	3MM Whatman Sílica gel	247,8 3,7		0,7 147,4	0		97,27 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20211222-027		22/12/2021	07:33	PM	Butanona Normal Saline	3MM Whatman Sílica gel	216,5 9,2		1,4 183,1	0		94,573 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20211222-042		22/12/2021	10:41	JS	Butanona Normal Saline	3MM Whatman Sílica gel	102 1,2		1 42,6	0		96,289 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DOTATOC-68Ga Lot # K-20211222-033		22/12/2021	09:35	JS	Citrato de Sódio 0,1M	Sílica gel	23,8		0,1	0		99,582 %	Pass
						Límpido e Incolor				pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
DTPA-99mTc Lot # K-20211222-013	RPH	22/12/2021	03:41	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	610,3 8,3		3,4 609,2	0		98,102 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 5,00	<= 7,50
DTPA-99mTc Lot # K-20211222-014	RPH	22/12/2021	03:43	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	560,1 6,7		2,3 462,8	0		98,164 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 5,00	<= 7,50
DTPA-99mTc Lot # K-20211222-035	RPH	22/12/2021	09:52	JS	Acetona Normal Saline	3MM Whatman 3MM Whatman	660 15		4 522	0		96,604 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 5,00	<= 7,50
FITATO-99mTc Lot # K-20211222-012		22/12/2021	03:38	MB	Butanona	3MM Whatman	195		1,3	0		99,338 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		5,00 <= 5,00	<= 7,00
FITATO-99mTc Lot # K-20211222-023		22/12/2021	07:04	PM	Butanona	3MM Whatman	129,6		5,9	0		95,646 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		5,00 <= 7,00	<= 7,00
MAA-99mTc Lot # K-20211222-016		22/12/2021	03:52	MB	Butanona	3MM Whatman	135,8		1	0		99,269 %	Pass
						Turvo/Incolor				pH (Low/Actual/High)		3,00 <= 5,00	<= 6,00
MAA-99mTc Lot # K-20211222-017		22/12/2021	03:54	MB	Butanona	3MM Whatman	110,8		0,7	0		99,372 %	Pass
						Turvo/Incolor				pH (Low/Actual/High)		3,00 <= 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
MAA-99mTc Lot # K-20211222-031		22/12/2021 08:19 PM	Butanona			3MM Whatman		132,3		6,8	0		95,111 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211222-036		22/12/2021 09:57 JS	Butanona			3MM Whatman		70		1	0		98,592 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211222-037		22/12/2021 10:00 JS	Butanona			3MM Whatman		110,4		0,9	0		99,191 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211222-038		22/12/2021 10:01 JS	Butanona			3MM Whatman		103		1,7	0		98,376 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211222-039		22/12/2021 10:12 JS	Butanona			3MM Whatman		78		2,7	0		96,654 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211222-040		22/12/2021 10:13 JS	Butanona			3MM Whatman		116		4	0		96,667 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211222-041		22/12/2021 10:14 JS	Butanona			3MM Whatman		176		3,9	0		97,832 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211222-045		22/12/2021 10:58 JS	Butanona			3MM Whatman		155,8		3,3	0		97,926 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211222-046		22/12/2021 11:11 JS	Butanona			3MM Whatman		113		3	0		97,414 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211222-047		22/12/2021 11:13 JS	Butanona			3MM Whatman		247		1	0		99,597 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MDP-99mTc Lot # K-20211222-011		22/12/2021 03:36 MB	Acetona			3MM Whatman		899,5		1	0		99,059 %	Pass
			Normal Saline			3MM Whatman		9		1075		pH (Low/Actual/High)	4,00 <= 4,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211222-018		22/12/2021 04:19 MB	Acetona			3MM Whatman		881,6		0,8	0		96,787 %	Pass
			Normal Saline			3MM Whatman		31,5		977,5		pH (Low/Actual/High)	4,00 <= 4,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211222-019		22/12/2021 04:22 MB	Acetona			3MM Whatman		617,7		6,4	0		97,249 %	Pass
			Normal Saline			3MM Whatman		12,7		723,2		pH (Low/Actual/High)	4,00 <= 4,00 <= 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-20211222-025		22/12/2021 07:17 PM	Acetona Normal Saline		3MM Whatman 3MM Whatman			939 2		1 898	0	pH (Low/Actual/High)	99,671 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211222-030		22/12/2021 08:06 PM	Acetona Normal Saline		3MM Whatman 3MM Whatman			1325 3		5 1240	0	pH (Low/Actual/High)	99,383 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211222-034		22/12/2021 09:45 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			124 2		1 391	0	pH (Low/Actual/High)	98,691 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211222-044		22/12/2021 10:47 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			735 2		4 422	0	pH (Low/Actual/High)	98,987 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-004		22/12/2021 01:43 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1345 67		35 1902	0	pH (Low/Actual/High)	94,061 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-005		22/12/2021 01:45 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			897,7 5		13,1 1294	0	pH (Low/Actual/High)	98,177 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-006		22/12/2021 02:13 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1315 39		24 2056	0	pH (Low/Actual/High)	96,346 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-007		22/12/2021 02:18 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1090 2		15 1997	0	pH (Low/Actual/High)	98,542 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-008		22/12/2021 02:51 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1555 1		17 1739	0	pH (Low/Actual/High)	98,861 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-009		22/12/2021 02:52 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1084 30		17 1367	0	pH (Low/Actual/High)	96,308 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-010		22/12/2021 03:34 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1159 19		6 1664	0	pH (Low/Actual/High)	98,356 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-015		22/12/2021 03:50 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1397 18		13 1872	0	pH (Low/Actual/High)	98,126 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-020		22/12/2021 06:38 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1561 5		18 1634	0	pH (Low/Actual/High)	98,555 %	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
MIBI-99mTc Lot # K-20211222-021		22/12/2021 06:40 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1678 1		20 234	0	pH (Low/Actual/High)	98,397 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-028		22/12/2021 07:36 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1896 2		10 207	0	pH (Low/Actual/High)	98,518 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-029		22/12/2021 07:41 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1608 3		28 1377	0	pH (Low/Actual/High)	98,071 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-032		22/12/2021 09:26 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1035 16		18 948	0	pH (Low/Actual/High)	96,631 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-043		22/12/2021 10:43 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			642 2		5 610	0	pH (Low/Actual/High)	98,90 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211222-048		22/12/2021 11:18 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			266 24		1 1925	0	pH (Low/Actual/High)	98,394 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20211222-024		22/12/2021 07:07 PM	Butanona Normal Saline		3MM Whatman 3MM Whatman			340,2 11,7		2,2 508,6	0	pH (Low/Actual/High)	97,109 %	Pass 5,00 <= 5,00 <= 7,00
Límpido/Incolor														
PSMA-177Lu Lot # K-20211222-001		22/12/2021 01:12 BB	Citrato de Sódio 0,1M		Sílica gel			686		6	0	pH (Low/Actual/High)	99,133 %	Pass 4,00 <= 4,50 <= 5,00
Límpido														
QC Notes: HPLC: 97,06%														
PSMA-177Lu Lot # K-20211222-002		22/12/2021 01:13 BB	Citrato de Sódio 0,1M		Sílica gel			583		2	0	pH (Low/Actual/High)	99,658 %	Pass 4,00 <= 4,50 <= 5,00
Límpido														
QC Notes: HPLC: 98,93%														
PSMA-177Lu Lot # K-20211222-003		22/12/2021 01:29 BB	Citrato de Sódio 0,1M		Sílica gel			1246		2	0	pH (Low/Actual/High)	99,84 %	Pass 4,00 <= 4,50 <= 5,00
Límpido														
QC Notes: HPLC: 97,04%														
PSMA-68Ga Lot # K-20211222-022		22/12/2021 06:53 PM	Acetato de amônio 1M:Metanol		Sílica gel			0,2		23,4	0	pH (Low/Actual/High)	99,153 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20211222-049		22/12/2021 12:45 YD	Acetato de amônio 1M:Metanol		Sílica gel			0,6		15,9	0	pH (Low/Actual/High)	96,364 %	Pass 4,00 <= 5,00 <= 8,00
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-20211222-001		22/12/2021 01:23	BB	Butanona		3MM Whatman		92	3646		0	97,539 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-002		22/12/2021 02:08	MB	Butanona		3MM Whatman		28	2915		0	99,049 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-003		22/12/2021 02:15	MB	Butanona		3MM Whatman		21,9	683,3		0	96,894 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-004		22/12/2021 02:43	MB	Butanona		3MM Whatman		2,1	833,2		0	99,749 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-005		22/12/2021 03:31	MB	Butanona		3MM Whatman		28	1356		0	97,977 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-006		22/12/2021 03:45	MB	Butanona		3MM Whatman		1	751,9		0	99,867 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-007		22/12/2021 04:17	MB	Butanona		3MM Whatman		6,7	453,6		0	98,544 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-008		22/12/2021 06:26	PM	Butanona		3MM Whatman		1	313		0	99,682 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-009		22/12/2021 06:35	PM	Butanona		3MM Whatman		1	281		0	99,645 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-011		22/12/2021 07:13	PM	Butanona		3MM Whatman		1	215		0	99,537 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-012		22/12/2021 07:24	PM	Butanona		3MM Whatman		3	304		0	99,023 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-013		22/12/2021 07:34	PM	Butanona		3MM Whatman		1	594		0	99,832 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211222-014		22/12/2021 07:38	PM	Butanona		3MM Whatman		7	383		0	98,205 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 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-20211222-015		22/12/2021 08:02 PM	Butanona		3MM	Whatman		5		311	0		98,418 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211222-016		22/12/2021 09:15 JS	Butanona		3MM	Whatman		2		1033	0		99,807 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211222-018		22/12/2021 09:41 JS	Butanona		3MM	Whatman		1		482	0		99,793 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211222-020		22/12/2021 10:37 JS	Butanona		3MM	Whatman		3		405	0		99,265 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211222-019		22/12/2021 10:37 JS	Butanona		3MM	Whatman		7		729	0		99,049 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211222-021		22/12/2021 11:08 JS	Butanona		3MM	Whatman		9		643	0		98,62 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			