



# 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 15/12/2021 To 15/12/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211215-015		15/12/2021	04:05	MB	Butanona	3MM Whatman	103,5		2	0	pH (Low/Actual/High)	90,811 %	Pass
					Normal Saline	Silica gel	5,2	66,1	2,00 <= 3,00	<= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20211215-029		15/12/2021	08:06	WG	Butanona	3MM Whatman	137,9		3,1	0	pH (Low/Actual/High)	96,107 %	Pass
					Normal Saline	Silica gel	1,7	98,6	2,00 <= 3,00	<= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20211215-030		15/12/2021	08:07	WG	Butanona	3MM Whatman	93,2		1,4	0	pH (Low/Actual/High)	94,881 %	Pass
					Normal Saline	Silica gel	2,7	71,5	2,00 <= 3,00	<= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20211215-031		15/12/2021	08:09	WG	Butanona	3MM Whatman	93,7		1,2	0	pH (Low/Actual/High)	95,581 %	Pass
					Normal Saline	Silica gel	2	61,4	2,00 <= 3,00	<= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20211215-039		15/12/2021	10:09	WG	Butanona	3MM Whatman	144		2	0	pH (Low/Actual/High)	97,797 %	Pass
					Normal Saline	Silica gel	1,1	131	2,00 <= 3,00	<= 3,00			
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20211215-037		15/12/2021	09:48	WG	Citrato de Sódio 0,1M	Silica gel	44,7		2	0	pH (Low/Actual/High)	95,717 %	Pass
												4,00 <= 7,00	<= 8,00
Límpido e Incolor													
DTPA-99mTc Lot # K-20211215-018	RPH	15/12/2021	04:10	PM	Acetona	3MM Whatman	1111		4	0	pH (Low/Actual/High)	99,162 %	Pass
					Normal Saline	3MM Whatman	4	830	3,80 <= 6,00	<= 7,50			
Límpido/Incolor													
DTPA-99mTc Lot # K-20211215-032	RPH	15/12/2021	08:13	WG	Acetona	3MM Whatman	426		3	0	pH (Low/Actual/High)	97,317 %	Pass
					Normal Saline	3MM Whatman	5	247	3,80 <= 6,00	<= 7,50			
Límpido/Incolor													
DTPA-99mTc Lot # K-20211215-040	RPH	15/12/2021	10:12	WG	Acetona	3MM Whatman	178		2	0	pH (Low/Actual/High)	95,684 %	Pass
					Normal Saline	3MM Whatman	5	151	3,80 <= 6,00	<= 7,50			
Límpido/Incolor													
FITATO-99mTc Lot # K-20211215-017		15/12/2021	04:09	PM	Butanona	3MM Whatman	732		4	0	pH (Low/Actual/High)	99,457 %	Pass
												5,00 <= 6,00	<= 7,00
Límpido/Incolor													
FITATO-99mTc Lot # K-20211215-038		15/12/2021	09:49	WG	Butanona	3MM Whatman	336		2	0	pH (Low/Actual/High)	99,408 %	Pass
												5,00 <= 6,00	<= 7,00
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
MAA-99mTc Lot # K-20211215-019		15/12/2021 04:15	MB	Butanona		3MM Whatman		311,3		4,1	0	98,70 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20211215-025		15/12/2021 07:50	WG	Butanona		3MM Whatman		91,4		2	0	97,859 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20211215-042		15/12/2021 10:45	WG	Butanona		3MM Whatman		96		1	0	98,969 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20211215-043		15/12/2021 10:46	WG	Butanona		3MM Whatman		93,2		0,7	0	99,255 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20211215-044		15/12/2021 10:47	WG	Butanona		3MM Whatman		82,7		1,5	0	98,219 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
QC Notes: ,5														
MAA-99mTc Lot # K-20211215-045		15/12/2021 10:48	WG	Butanona		3MM Whatman		120		3	0	97,561 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20211215-046		15/12/2021 10:49	WG	Butanona		3MM Whatman		234		2	0	99,153 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20211215-047		15/12/2021 10:50	WG	Butanona		3MM Whatman		239		4	0	98,354 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20211215-048		15/12/2021 10:51	WG	Butanona		3MM Whatman		265		2	0	99,251 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20211215-049		15/12/2021 10:51	WG	Butanona		3MM Whatman		98,2		2	0	98,004 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MDP-99mTc Lot # K-20211215-016		15/12/2021 04:07	PM	Acetona		3MM Whatman		1377		12	0	97,787 %	Pass	
				Normal Saline		3MM Whatman		23		1682	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20211215-020		15/12/2021 04:23	PM	Acetona		3MM Whatman		1537		9	0	98,376 %	Pass	
				Normal Saline		3MM Whatman		14		1330	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20211215-026		15/12/2021 07:55	WG	Acetona		3MM Whatman		1286		11	0	98,027 %	Pass	
				Normal Saline		3MM Whatman		8		703	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-20211215-027		15/12/2021 07:56	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			1021 16		9 1411	0	pH (Low/Actual/High)	98,005 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211215-033		15/12/2021 08:37	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			820 4		15 1045	0	pH (Low/Actual/High)	97,822 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211215-036		15/12/2021 09:38	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			832 4		7 698	0	pH (Low/Actual/High)	98,596 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211215-041		15/12/2021 10:35	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			421 3		7 632	0	pH (Low/Actual/High)	97,892 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211215-054		15/12/2021 15:07	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			1244 3		4 1345	0	pH (Low/Actual/High)	99,457 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20211215-001		15/12/2021 01:49	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			970,5 17		12,9 1299	0	pH (Low/Actual/High)	97,396 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211215-002		15/12/2021 01:49	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			989,8 1		14,2 1344	0	pH (Low/Actual/High)	98,511 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211215-008		15/12/2021 02:48	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			853,9 6		16,2 1384	0	pH (Low/Actual/High)	97,706 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211215-009		15/12/2021 03:14	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			836 23		10 1204	0	pH (Low/Actual/High)	96,943 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211215-010		15/12/2021 03:15	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1017 1		18 284	0	pH (Low/Actual/High)	97,91 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211215-011		15/12/2021 03:21	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1112 2		18 1064	0	pH (Low/Actual/High)	98,219 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211215-012		15/12/2021 03:22	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1012 8		13 816	0	pH (Low/Actual/High)	97,761 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211215-013		15/12/2021 03:59	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			300 2		3 232	0	pH (Low/Actual/High)	98,155 %	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-20211215-014		15/12/2021 04:00 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			225 1		3 353	0	pH (Low/Actual/High)	98,402 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211215-021		15/12/2021 06:54 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			850 16		18 1636	0	pH (Low/Actual/High)	96,958 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211215-023		15/12/2021 06:57 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			1178 3		11 1298	0	pH (Low/Actual/High)	98,844 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211215-024		15/12/2021 07:40 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			512 14		15 1323	0	pH (Low/Actual/High)	96,107 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211215-028		15/12/2021 08:04 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			1297 13		20 2222	0	pH (Low/Actual/High)	97,90 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211215-034		15/12/2021 09:30 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			2865 44		55 1854	0	pH (Low/Actual/High)	95,798 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211215-035		15/12/2021 09:33 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			814 34		5 2642	0	pH (Low/Actual/High)	98,119 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211215-050		15/12/2021 10:56 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			832 4		7 632	0	pH (Low/Actual/High)	98,537 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
PSMA-177Lu Lot # K-20211215-003		15/12/2021 02:00 WG	Citrato de Sódio 0,1M		Sílica gel			488		3	0	pH (Low/Actual/High)	99,389 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 95,94%														
PSMA-177Lu Lot # K-20211215-004		15/12/2021 02:00 BB	Citrato de Sódio 0,1M		Sílica gel			987		2	0	pH (Low/Actual/High)	99,798 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 96,25%														
PSMA-177Lu Lot # K-20211215-005		15/12/2021 02:22 BB	Citrato de Sódio 0,1M		Sílica gel			984		3	0	pH (Low/Actual/High)	99,696 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 95,22%														
PSMA-177Lu Lot # K-20211215-006		15/12/2021 02:23 BB	Citrato de Sódio 0,1M		Sílica gel			1248		2	0	pH (Low/Actual/High)	99,84 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 97,87%														

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-20211215-007	15/12/2021	02:24	BB	Citrato de Sódio 0,1M	Sílica gel			711		1	0	99,86 %	Pass	
							Limpido				pH (Low/Actual/High)	4,00 <= 4,50 <= 5,00		
QC Notes: HPLC: 95,36%														
PSMA-68Ga Lot # K-20211215-022	15/12/2021	06:59	WG	Acetato de amônio 1M:Metanol	Sílica gel			1		33,7	0	97,118 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 7,00 <= 8,00		
PSMA-68Ga Lot # K-20211215-051	15/12/2021	12:28	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,5		23,5	0	97,917 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
PSMA-68Ga Lot # K-20211215-052	15/12/2021	13:30	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,3		23,6	0	98,745 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
PSMA-68Ga Lot # K-20211215-053	15/12/2021	14:12	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,2		10,3	0	98,095 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
Tecnécio-99m Lot # E-20211215-001	15/12/2021	01:44	MB	Butanona	3MM Whatman			38		3754	0	98,998 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211215-002	15/12/2021	01:54	MB	Butanona	3MM Whatman			15		2195	0	99,321 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211215-003	15/12/2021	03:09	MB	Butanona	3MM Whatman			5,4		920,3	0	99,417 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211215-004	15/12/2021	03:16	MB	Butanona	3MM Whatman			12		1617	0	99,263 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211215-005	15/12/2021	03:55	PM	Butanona	3MM Whatman			27		1582	0	98,322 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211215-006	15/12/2021	04:03	PM	Butanona	3MM Whatman			12		599	0	98,036 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211215-007	15/12/2021	04:21	PM	Butanona	3MM Whatman			12		414	0	97,183 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211215-008	15/12/2021	06:50	WG	Butanona	3MM Whatman			12		1354	0	99,122 %	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-20211215-010		15/12/2021 07:01	WG	Butanona		3MM Whatman		3		572	0	99,478 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211215-011		15/12/2021 07:37	WG	Butanona		3MM Whatman		2		942	0	99,788 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211215-012		15/12/2021 07:52	WG	Butanona		3MM Whatman		15		2966	0	99,497 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211215-013		15/12/2021 08:02	WG	Butanona		3MM Whatman		33		1786	0	98,186 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211215-014		15/12/2021 08:36	WG	Butanona		3MM Whatman		32		1679	0	98,13 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211215-015		15/12/2021 09:25	WG	Butanona		3MM Whatman		28		3559	0	99,219 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211215-016		15/12/2021 09:26	WG	Butanona		3MM Whatman		12		1883	0	99,367 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211215-017		15/12/2021 09:45	WG	Butanona		3MM Whatman		15		951	0	98,447 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211215-019		15/12/2021 10:31	WG	Butanona		3MM Whatman		5		321	0	98,466 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211215-020		15/12/2021 10:54	WG	Butanona		3MM Whatman		5		321	0	98,466 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211215-024		15/12/2021 15:03	WG	Butanona		3MM Whatman		7		1802	0	99,613 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211215-025		15/12/2021 15:47	JS	Butanona		3MM Whatman		9		903	0	99,013 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	