



# 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 02/07/2021 To 02/07/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210702-025		02/07/2021	07:38	WG	Butanona Normal Saline	3MM Whatman Sílica gel	128,7 5		4,5 100,5	0	pH (Low/Actual/High)	91,882 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210702-026		02/07/2021	07:39	WG	Butanona Normal Saline	3MM Whatman Sílica gel	316 1,2		4 122,9	0	pH (Low/Actual/High)	97,783 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210702-027		02/07/2021	07:40	WG	Butanona Normal Saline	3MM Whatman Sílica gel	213 5		2 194,6	0	pH (Low/Actual/High)	96,565 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210702-028		02/07/2021	07:41	WG	Butanona Normal Saline	3MM Whatman Sílica gel	192,4 4		6 163	0	pH (Low/Actual/High)	94,581 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210702-032		02/07/2021	08:03	WG	Butanona Normal Saline	3MM Whatman Sílica gel	154,7 6		1,2 170,3	0	pH (Low/Actual/High)	95,827 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210702-033		02/07/2021	08:05	WG	Butanona Normal Saline	3MM Whatman Sílica gel	151,1 0,5		0,8 145,8	0	pH (Low/Actual/High)	99,132 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210702-037		02/07/2021	10:43	JS	Butanona Normal Saline	3MM Whatman Sílica gel	121,5 3		1,2 89	0	pH (Low/Actual/High)	95,761 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210702-039		02/07/2021	12:49	JS	Citrato de Sódio 0,1M	Sílica gel	164		1	0	pH (Low/Actual/High)	99,394 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210702-007	RPH	02/07/2021	03:12	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	982 38		2 1178	0	pH (Low/Actual/High)	96,672 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210702-011	RPH	02/07/2021	03:39	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1938 14		51 582	0	pH (Low/Actual/High)	95,087 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210702-012	RPH	02/07/2021	03:44	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1122 33		6 963	0	pH (Low/Actual/High)	96,155 %	Pass 3,80 <= 6,00 <= 7,50
						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
DTPA-99mTc Lot # K-20210702-023	RPH	02/07/2021 07:13	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			397 3		5 251	0	pH (Low/Actual/High)	97,575 %	Pass 3,80 <= 6,00 <= 7,50
							Límpido/Incolor							
DTPA-99mTc Lot # K-20210702-035	RPH	02/07/2021 10:15	JS	Acetona Normal Saline	3MM Whatman 3MM Whatman			396 3		12 511	0	pH (Low/Actual/High)	96,475 %	Pass 3,80 <= 5,00 <= 7,50
							Límpido/Incolor							
FITATO-99mTc Lot # K-20210702-009		02/07/2021 03:17	PP	Butanona	3MM Whatman			989		10	0	pH (Low/Actual/High)	98,999 %	Pass 5,00 <= 6,00 <= 7,00
							Límpido/Incolor							
FITATO-99mTc Lot # K-20210702-024		02/07/2021 07:13	BB	Butanona	3MM Whatman			227		5	0	pH (Low/Actual/High)	97,845 %	Pass 5,00 <= 6,00 <= 7,00
							Límpido/Incolor							
MAA-99mTc Lot # K-20210702-013		02/07/2021 03:46	BB	Butanona	3MM Whatman			136		3	0	pH (Low/Actual/High)	97,842 %	Pass 3,00 <= 6,00 <= 6,00
							Turvo/Incolor							
MAA-99mTc Lot # K-20210702-014		02/07/2021 03:48	PP	Butanona	3MM Whatman			141		2	0	pH (Low/Actual/High)	98,601 %	Pass 3,00 <= 6,00 <= 6,00
							Turvo/Incolor							
MAA-99mTc Lot # K-20210702-015		02/07/2021 03:51	PP	Butanona	3MM Whatman			164		4	0	pH (Low/Actual/High)	97,619 %	Pass 3,00 <= 6,00 <= 6,00
							Turvo/Incolor							
MAA-99mTc Lot # K-20210702-016		02/07/2021 03:53	PP	Butanona	3MM Whatman			65,3		1,3	0	pH (Low/Actual/High)	98,048 %	Pass 3,00 <= 6,00 <= 6,00
							Turvo/Incolor							
MAA-99mTc Lot # K-20210702-017		02/07/2021 03:55	PP	Butanona	3MM Whatman			245		1	0	pH (Low/Actual/High)	99,593 %	Pass 3,00 <= 6,00 <= 6,00
							Turvo/Incolor							
MAA-99mTc Lot # K-20210702-018		02/07/2021 04:10	PP	Butanona	3MM Whatman			124		1	0	pH (Low/Actual/High)	99,20 %	Pass 3,00 <= 6,00 <= 6,00
							Turvo/Incolor							
MAA-99mTc Lot # K-20210702-019		02/07/2021 04:12	PP	Butanona	3MM Whatman			381		5	0	pH (Low/Actual/High)	98,705 %	Pass 3,00 <= 6,00 <= 6,00
							Turvo/Incolor							
MAA-99mTc Lot # K-20210702-038		02/07/2021 11:19	WG	Butanona	3MM Whatman			346		2	0	pH (Low/Actual/High)	99,425 %	Pass 3,00 <= 6,00 <= 6,00
							Turvo/Incolor							
MDP-99mTc Lot # K-20210702-008		02/07/2021 03:14	BB	Acetona Normal Saline	3MM Whatman 3MM Whatman			1924 42		5 1260	0	pH (Low/Actual/High)	96,515 %	Pass 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-20210702-010		02/07/2021 03:37	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman			633 56		12 1277	0		93,938 %	Pass
												pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
														Límpido/Incolor
MDP-99mTc Lot # K-20210702-029		02/07/2021 07:43	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			1188 19		6 1267	0		98,02 %	Pass
												pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
														Límpido/Incolor
MDP-99mTc Lot # K-20210702-030		02/07/2021 07:46	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			2007 23		13 1389	0		97,728 %	Pass
												pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
														Límpido/Incolor
MDP-99mTc Lot # K-20210702-031		02/07/2021 07:47	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			1157 13		2 1002	0		98,547 %	Pass
												pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
														Límpido/Incolor
MIBI-99mTc Lot # K-20210702-001		02/07/2021 02:11	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1876 29		24 1628	0		96,987 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido/Incolor
MIBI-99mTc Lot # K-20210702-002		02/07/2021 02:12	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2156 31		40 2210	0		96,795 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido/Incolor
MIBI-99mTc Lot # K-20210702-003		02/07/2021 02:13	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1120 53		31 3024	0		95,584 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido/Incolor
MIBI-99mTc Lot # K-20210702-004		02/07/2021 02:33	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1669 20		30 2816	0		97,529 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido/Incolor
MIBI-99mTc Lot # K-20210702-005		02/07/2021 02:34	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1743 32		59 1914	0		95,081 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido/Incolor
MIBI-99mTc Lot # K-20210702-006		02/07/2021 02:35	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			933 70		24 3001	0		95,213 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido/Incolor
MIBI-99mTc Lot # K-20210702-021		02/07/2021 06:57	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			2980 1		12 2271	0		99,555 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido/Incolor
MIBI-99mTc Lot # K-20210702-022		02/07/2021 06:58	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1616 16		18 1654	0		97,94 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido/Incolor
PSMA-68Ga Lot # K-20210702-020		02/07/2021 06:44	BB	Acetato de amônio	Sílica gel			1,1		49,2	0		97,813 %	Pass
												pH (Low/Actual/High)	4,00 <= 6,00 <= 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
PSMA-68Ga Lot # K-20210702-034		02/07/2021 09:56	JS	Acetato de amônio	Sílica gel			0,5		58	0	99,145 %	Pass	
												pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00	
												Límpido e Incolor		
PSMA-68Ga Lot # K-20210702-036		02/07/2021 10:32	JS	Acetato de amônio	Sílica gel			0,3		22,8	0	98,701 %	Pass	
												pH (Low/Actual/High)	4,00 <= 6,00 <= 8,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210702-001		02/07/2021 02:06	PP	Butanona	3MM Whatman			13		913	0	98,596 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210702-002		02/07/2021 02:29	PP	Butanona	3MM Whatman			40		2557	0	98,46 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210702-003		02/07/2021 03:35	PP	Butanona	3MM Whatman			2		1022	0	99,805 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210702-004		02/07/2021 03:41	PP	Butanona	3MM Whatman			13		2163	0	99,403 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210702-006		02/07/2021 06:53	WG	Butanona	3MM Whatman			23		2140	0	98,937 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210702-007		02/07/2021 07:08	WG	Butanona	3MM Whatman			12		2437	0	99,51 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210702-008		02/07/2021 07:32	WG	Butanona	3MM Whatman			18		1933	0	99,077 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210702-010		02/07/2021 10:13	WG	Butanona	3MM Whatman			7		486	0	98,58 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210702-013		02/07/2021 11:24	SB	Butanona	3MM Whatman			0,1		1698	0	99,994 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		