



# 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 23/08/2021 To 23/08/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210823-023		23/08/2021	07:22	JS	Butanona Normal Saline	3MM Whatman Sílica gel	403 8		5 157	0	pH (Low/Actual/High)	93,926 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210823-024		23/08/2021	07:23	JS	Butanona Normal Saline	3MM Whatman Sílica gel	102,6 5		4,7 108,3	0	pH (Low/Actual/High)	91,207 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210823-028		23/08/2021	07:53	JS	Butanona Normal Saline	3MM Whatman Sílica gel	71,5 3,9		0,1 85	0	pH (Low/Actual/High)	95,473 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210823-029		23/08/2021	07:58	JS	Butanona Normal Saline	3MM Whatman Sílica gel	26,4 0,2		0,6 32	0	pH (Low/Actual/High)	97,157 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210823-030		23/08/2021	08:03	JS	Butanona Normal Saline	3MM Whatman Sílica gel	83,5 2		0,1 119	0	pH (Low/Actual/High)	98,227 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210823-040		23/08/2021	10:36	JS	Butanona Normal Saline	3MM Whatman Sílica gel	69,1 1		1,1 54	0	pH (Low/Actual/High)	96,615 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210823-034		23/08/2021	09:47	YD	Citrato de Sódio 0,1M	Sílica gel	10,21		0,1	0	pH (Low/Actual/High)	99,03 %	Pass 4,00 <= 6,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210823-039		23/08/2021	10:29	JS	Citrato de Sódio 0,1M	Sílica gel	9,78		0,5	0	pH (Low/Actual/High)	95,136 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210823-053		23/08/2021	15:48	JS	Citrato de Sódio 0,1M	Sílica gel	10,6		0,4	0	pH (Low/Actual/High)	96,364 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210823-054		23/08/2021	16:33	JS	Citrato de Sódio 0,1M	Sílica gel	15,3		0,2	0	pH (Low/Actual/High)	98,71 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DTPA-99mTc Lot # K-20210823-007	RPH	23/08/2021	03:27	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1006 11		14 709	0	pH (Low/Actual/High)	97,10 %	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-20210823-008	RPH	23/08/2021 03:29 PP	Acetona Normal Saline		3MM Whatman 3MM Whatman			811 20		3 787	0 pH (Low/Actual/High)	97,153 % 3,80 <= 6,00 <= 7,50	Pass	
							Límpido/Incolor							
DTPA-99mTc Lot # K-20210823-037	RPH	23/08/2021 10:07 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			750 4		2 261	0 pH (Low/Actual/High)	98,225 % 3,80 <= 6,00 <= 7,50	Pass	
							Límpido/Incolor							
FITATO-99mTc Lot # K-20210823-009		23/08/2021 03:33 PP	Butanona		3MM Whatman			1254		4	0 pH (Low/Actual/High)	99,682 % 5,00 <= 6,00 <= 7,00	Pass	
							Límpido/Incolor							
FITATO-99mTc Lot # K-20210823-010		23/08/2021 03:34 PP	Butanona		3MM Whatman			592		5	0 pH (Low/Actual/High)	99,162 % 5,00 <= 6,00 <= 7,00	Pass	
							Límpido/Incolor							
FITATO-99mTc Lot # K-20210823-035		23/08/2021 10:00 YD	Butanona		3MM Whatman			125,2		0,8	0 pH (Low/Actual/High)	99,365 % 5,00 <= 6,00 <= 7,00	Pass	
							Límpido/Incolor							
MAA-99mTc Lot # K-20210823-011		23/08/2021 03:50 PP	Butanona		3MM Whatman			184		2	0 pH (Low/Actual/High)	98,925 % 3,00 <= 6,00 <= 6,00	Pass	
							Turvo/Incolor							
MAA-99mTc Lot # K-20210823-012		23/08/2021 03:53 PP	Butanona		3MM Whatman			184		1	0 pH (Low/Actual/High)	99,459 % 3,00 <= 6,00 <= 6,00	Pass	
							Turvo/Incolor							
MAA-99mTc Lot # K-20210823-013		23/08/2021 03:55 PP	Butanona		3MM Whatman			305		9	0 pH (Low/Actual/High)	97,134 % 3,00 <= 6,00 <= 6,00	Pass	
							Turvo/Incolor							
MAA-99mTc Lot # K-20210823-014		23/08/2021 03:57 PP	Butanona		3MM Whatman			196		4	0 pH (Low/Actual/High)	98,00 % 3,00 <= 6,00 <= 6,00	Pass	
							Turvo/Incolor							
MAA-99mTc Lot # K-20210823-015		23/08/2021 03:59 PP	Butanona		3MM Whatman			207		7	0 pH (Low/Actual/High)	96,729 % 3,00 <= 6,00 <= 6,00	Pass	
							Turvo/Incolor							
MAA-99mTc Lot # K-20210823-016		23/08/2021 04:02 PP	Butanona		3MM Whatman			166		1	0 pH (Low/Actual/High)	99,401 % 3,00 <= 6,00 <= 6,00	Pass	
							Turvo/Incolor							
MAA-99mTc Lot # K-20210823-032		23/08/2021 08:20 JS	Butanona		3MM Whatman			108		0,4	0 pH (Low/Actual/High)	99,631 % 3,00 <= 5,00 <= 6,00	Pass	
							Turvo/Incolor							
MAA-99mTc Lot # K-20210823-041		23/08/2021 10:42 JS	Butanona		3MM Whatman			104		1,5	0 pH (Low/Actual/High)	98,578 % 3,00 <= 5,00 <= 6,00	Pass	
							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-20210823-042		23/08/2021 10:45 JS	Butanona		3MM	Whatman		120		1	0	99,174 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210823-043		23/08/2021 10:47 JS	Butanona		3MM	Whatman		80		1,8	0	97,80 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210823-044		23/08/2021 10:51 JS	Butanona		3MM	Whatman		71,4		1,5	0	97,942 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MAA-99mTc Lot # K-20210823-045		23/08/2021 10:57 JS	Butanona		3MM	Whatman		91,4		1,7	0	98,174 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210823-046		23/08/2021 10:59 JS	Butanona		3MM	Whatman		55		2,3	0	95,986 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210823-047		23/08/2021 11:01 JS	Butanona		3MM	Whatman		93		0,6	0	99,359 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210823-048		23/08/2021 11:04 JS	Butanona		3MM	Whatman		129		1,3	0	99,002 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210823-049		23/08/2021 11:10 JS	Butanona		3MM	Whatman		307		4	0	98,714 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210823-050		23/08/2021 11:13 JS	Butanona		3MM	Whatman		242		2	0	99,18 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210823-051		23/08/2021 12:14 JS	Butanona		3MM	Whatman		107		1,1	0	98,982 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MDP-99mTc Lot # K-20210823-017		23/08/2021 04:14 PP	Acetona		3MM	Whatman		1583		3	0	98,095 %	Pass	
			Normal Saline		3MM	Whatman		14		802	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210823-018		23/08/2021 04:16 PP	Acetona		3MM	Whatman		1801		8	0	98,047 %	Pass	
			Normal Saline		3MM	Whatman		16		1043	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210823-025		23/08/2021 07:27 JS	Acetona		3MM	Whatman		800		8	0	98,307 %	Pass	
			Normal Saline		3MM	Whatman		4		565	pH (Low/Actual/High)	4,00 <= 5,00 <= 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-20210823-026		23/08/2021 07:40 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			1030 4		5 549	0	pH (Low/Actual/High)	98,794 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210823-036		23/08/2021 10:02 YD	Acetona Normal Saline		3MM Whatman 3MM Whatman			499 1		1 589	0	pH (Low/Actual/High)	99,631 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210823-038		23/08/2021 10:18 YD	Acetona Normal Saline		3MM Whatman 3MM Whatman			569 5		1 473	0	pH (Low/Actual/High)	98,779 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20210823-001		23/08/2021 02:14 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2506 42		29 2426	0	pH (Low/Actual/High)	97,154 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210823-002		23/08/2021 02:16 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1491 65		18 2099	0	pH (Low/Actual/High)	95,803 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210823-003		23/08/2021 02:22 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1622 53		22 1395	0	pH (Low/Actual/High)	95,002 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210823-004		23/08/2021 02:24 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			788 51		14 1689	0	pH (Low/Actual/High)	95,323 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210823-005		23/08/2021 03:22 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1960 60		21 2330	0	pH (Low/Actual/High)	96,429 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210823-006		23/08/2021 03:23 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1072 61		11 2136	0	pH (Low/Actual/High)	96,208 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210823-020		23/08/2021 06:55 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1482 1		20 211	0	pH (Low/Actual/High)	98,197 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210823-021		23/08/2021 06:56 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1343 11		13 1355	0	pH (Low/Actual/High)	98,236 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210823-027		23/08/2021 07:52 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1361 16		15 879	0	pH (Low/Actual/High)	97,122 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210823-031		23/08/2021 08:06 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1598 3		22 208	0	pH (Low/Actual/High)	97,22 %	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-20210823-033	23/08/2021	09:37	BB	Normal Saline Metanol	Sílica gel 3MM Whatman			869 4		23 244	0	pH (Low/Actual/High)	95,809 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
PIRO-99mTc Lot # K-20210823-022	23/08/2021	07:10	JS	Butanona Normal Saline	3MM Whatman 3MM Whatman			180,5 1,1		1,3 106	0	pH (Low/Actual/High)	98,258 %	Pass 5,00 <= 6,00 <= 7,00
														Límpido/Incolor
PSMA-68Ga Lot # K-20210823-019	23/08/2021	06:52	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,4		28,5	0	pH (Low/Actual/High)	98,616 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
PSMA-68Ga Lot # K-20210823-052	23/08/2021	12:57	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,3		7,25	0	pH (Low/Actual/High)	96,026 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210823-001	23/08/2021	02:01	PP	Butanona	3MM Whatman			22		721	0	pH (Low/Actual/High)	97,039 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210823-002	23/08/2021	02:03	PP	Butanona	3MM Whatman			1		660	0	pH (Low/Actual/High)	99,849 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210823-003	23/08/2021	03:17	PP	Butanona	3MM Whatman			1		642	0	pH (Low/Actual/High)	99,844 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210823-004	23/08/2021	04:07	PP	Butanona	3MM Whatman			6		833	0	pH (Low/Actual/High)	99,285 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210823-005	23/08/2021	06:50	JS	Butanona	3MM Whatman			14		586	0	pH (Low/Actual/High)	97,667 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210823-007	23/08/2021	07:18	JS	Butanona	3MM Whatman			2		814	0	pH (Low/Actual/High)	99,755 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210823-008	23/08/2021	07:38	JS	Butanona	3MM Whatman			0		382	0	pH (Low/Actual/High)	100,00 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210823-009	23/08/2021	07:55	JS	Butanona	3MM Whatman			9		2000	0	pH (Low/Actual/High)	99,552 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210823-010	23/08/2021	09:33	YD	Butanona	3MM Whatman			1		373	0	pH (Low/Actual/High)	99,733 %	Pass 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-20210823-012		23/08/2021 10:15	YD	Butanona		3MM Whatman		2		246	0		99,194 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210823-014		23/08/2021 10:33	JS	Butanona		3MM Whatman		1		723	0		99,862 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210823-015		23/08/2021 12:01	JS	Butanona		3MM Whatman		2		804	0		99,752 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			