



# 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 25/11/2021 To 25/11/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211125-013		25/11/2021	04:06	PM	Butanona Normal Saline	3MM Whatman Sílica gel	143,3 0,7		3,4 113,2	0	pH (Low/Actual/High)	97,068 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211125-028		25/11/2021	08:02	PM	Butanona Normal Saline	3MM Whatman Sílica gel	188,7 5,8		0,2 144,4	0	pH (Low/Actual/High)	96,033 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211125-041		25/11/2021	10:50	VS	Butanona Normal Saline	3MM Whatman Sílica gel	196 4		4 113	0	pH (Low/Actual/High)	94,581 %	Pass
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20211125-020		25/11/2021	06:53	BB	Citrato de Sódio 0,1M	Sílica gel	11,8		0,4	0	pH (Low/Actual/High)	96,721 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20211125-025		25/11/2021	07:45	BB	Citrato de Sódio 0,1M	Sílica gel	17,74		0,2	0	pH (Low/Actual/High)	98,885 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20211125-051		25/11/2021	13:00	VS	Citrato de Sódio 0,1M	Sílica gel	212		2	0	pH (Low/Actual/High)	99,065 %	Pass
Límpido e Incolor													
DTPA-99mTc Lot # K-20211125-015	RPH	25/11/2021	04:11	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	494 20		2 565	0	pH (Low/Actual/High)	96,178 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20211125-044	RPH	25/11/2021	10:59	VS	Acetona Normal Saline	3MM Whatman 3MM Whatman	394 3		7 395	0	pH (Low/Actual/High)	97,501 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20211125-012		25/11/2021	03:43	PM	Butanona	3MM Whatman	1303		9	0	pH (Low/Actual/High)	99,314 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20211125-024		25/11/2021	07:35	MB	Butanona	3MM Whatman	576		6	0	pH (Low/Actual/High)	98,969 %	Pass
Límpido/Incolor													
MAA-99mTc Lot # K-20211125-014		25/11/2021	04:09	PM	Butanona	3MM Whatman	316,1		2,2	0	pH (Low/Actual/High)	99,309 %	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-20211125-029		25/11/2021 08:10 PM	Butanona		3MM	Whatman		89,9		1,1	0	98,791 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20211125-045		25/11/2021 12:04 VS	Butanona		3MM	Whatman		230		5	0	97,872 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20211125-047		25/11/2021 12:42 VS	Butanona		3MM	Whatman		277		6	0	97,88 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20211125-049		25/11/2021 12:44 VS	Butanona		3MM	Whatman		261		5	0	98,12 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MDP-99mTc Lot # K-20211125-008		25/11/2021 03:00 MB	Acetona		3MM	Whatman		566		5	0	98,116 %	Pass	
			Normal Saline		3MM	Whatman		5		491	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20211125-007		25/11/2021 03:00 MB	Acetona		3MM	Whatman		578		5	0	98,766 %	Pass	
			Normal Saline		3MM	Whatman		2		530	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20211125-009		25/11/2021 03:36 MB	Acetona		3MM	Whatman		833		1	0	99,266 %	Pass	
			Normal Saline		3MM	Whatman		5		809	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20211125-010		25/11/2021 03:39 MB	Acetona		3MM	Whatman		867		2	0	99,467 %	Pass	
			Normal Saline		3MM	Whatman		2		659	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20211125-011		25/11/2021 03:41 PM	Acetona		3MM	Whatman		867		17	0	97,383 %	Pass	
			Normal Saline		3MM	Whatman		10		1431	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20211125-017		25/11/2021 04:56 PM	Acetona		3MM	Whatman		733		1	0	99,403 %	Pass	
			Normal Saline		3MM	Whatman		4		865	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20211125-027		25/11/2021 07:58 PM	Acetona		3MM	Whatman		595		2	0	99,179 %	Pass	
			Normal Saline		3MM	Whatman		3		614	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20211125-043		25/11/2021 10:54 VS	Acetona		3MM	Whatman		122		1	0	96,573 %	Pass	
			Normal Saline		3MM	Whatman		4		149	pH (Low/Actual/High)	4,00 <= 7,00	<= 7,80	
											Límpido/Incolor			
MIBI-99mTc Lot # K-20211125-001		25/11/2021 01:42 MB	Normal Saline		Sílica gel			1124		8	0	97,87 %	Pass	
			Metanol		3MM	Whatman		19		1316	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-20211125-002		25/11/2021 01:46 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			889 32		5 1460	0 pH (Low/Actual/High)	97,296 %		Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-004		25/11/2021 01:54 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1032 8		11 1407	0 pH (Low/Actual/High)	98,38 %		Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-005		25/11/2021 02:57 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1175 39		26 1284	0 pH (Low/Actual/High)	94,887 %		Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-006		25/11/2021 02:58 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1638 32		26 1961	0 pH (Low/Actual/High)	96,832 %		Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-016		25/11/2021 04:23 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1712 8		21 1738	0 pH (Low/Actual/High)	98,33 %		Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-018		25/11/2021 06:44 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1258 24		22 1110	0 pH (Low/Actual/High)	96,165 %		Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-019		25/11/2021 06:47 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			953 47		18 1858	0 pH (Low/Actual/High)	95,679 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-021		25/11/2021 07:02 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1086 12		19 1203	0 pH (Low/Actual/High)	97,293 %		Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-030		25/11/2021 08:15 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1037 22		9 1730	0 pH (Low/Actual/High)	97,884 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-031		25/11/2021 08:54 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			788 6		3 821	0 pH (Low/Actual/High)	98,895 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-037		25/11/2021 10:24 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			262 5		2 213	0 pH (Low/Actual/High)	96,949 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-042		25/11/2021 10:47 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			198 4		5 287	0 pH (Low/Actual/High)	96,162 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211125-046		25/11/2021 12:13 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			920 1		8 176	0 pH (Low/Actual/High)	98,573 %		Pass 5,00 <= 6,00 <= 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-20211125-048	25/11/2021	12:38	VS	Normal Saline Metanol		Sílica gel 3MM Whatman			497 2		4 295	0 pH (Low/Actual/High)	98,528 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor															
MIBI-99mTc Lot # K-20211125-050	25/11/2021	12:44	VS	Normal Saline Metanol		Sílica gel 3MM Whatman			143 5		4 518	0 pH (Low/Actual/High)	96,323 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor															
MIBI-99mTc Lot # K-20211125-052	25/11/2021	13:24	MB	Normal Saline Metanol		Sílica gel 3MM Whatman			388 2		6 424	0 pH (Low/Actual/High)	98,008 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor															
MIBI-99mTc Lot # K-20211125-053	25/11/2021	13:36	MB	Normal Saline Metanol		Sílica gel 3MM Whatman			167 1		2 341	0 pH (Low/Actual/High)	98,524 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor															
Octreo-99mTc Lot # K-20211125-026	25/11/2021	07:55	PM	Butanona Cittrato de Sódio 0,1M		Sílica gel Sílica gel			179,1 159,8		0,8 9,9	0 pH (Low/Actual/High)	93,261 %	Pass	5,00 <= 6,00 <= 7,00
Límpido/Incolor															
				Metanol/ Acetato Amônio 1M		Sílica gel			1		216				
PSMA-68Ga Lot # K-20211125-032	25/11/2021	09:55	JS	Acetato de amônio 1M:Metanol		Sílica gel			0,21		19,48	0 pH (Low/Actual/High)	98,933 %	Pass	4,00 <= 5,00 <= 8,00
Límpido e Incolor															
Tecnécio-99m Lot # E-20211125-001	25/11/2021	01:40	MB	Butanona		3MM Whatman			30		3298	0 pH (Low/Actual/High)	99,099 %	Pass	5,00 <= 5,00 <= 6,00
Límpido e Incolor															
Tecnécio-99m Lot # E-20211125-002	25/11/2021	01:40	MB	Butanona		3MM Whatman			96		3070	0 pH (Low/Actual/High)	96,968 %	Pass	5,00 <= 5,00 <= 6,00
Límpido e Incolor															
Tecnécio-99m Lot # E-20211125-004	25/11/2021	02:53	MB	Butanona		3MM Whatman			9		1187	0 pH (Low/Actual/High)	99,247 %	Pass	5,00 <= 5,00 <= 6,00
Límpido e Incolor															
Tecnécio-99m Lot # E-20211125-003	25/11/2021	02:53	MB	Butanona		3MM Whatman			1		541	0 pH (Low/Actual/High)	99,815 %	Pass	5,00 <= 5,00 <= 6,00
Límpido e Incolor															
Tecnécio-99m Lot # E-20211125-005	25/11/2021	03:34	MB	Butanona		3MM Whatman			6		1522	0 pH (Low/Actual/High)	99,607 %	Pass	5,00 <= 5,00 <= 6,00
Límpido e Incolor															
Tecnécio-99m Lot # E-20211125-006	25/11/2021	04:04	MB	Butanona		3MM Whatman			6		1507	0 pH (Low/Actual/High)	99,603 %	Pass	5,00 <= 5,00 <= 6,00
Límpido e Incolor															
Tecnécio-99m Lot # E-20211125-007	25/11/2021	04:21	PM	Butanona		3MM Whatman			4		548	0 pH (Low/Actual/High)	99,275 %	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-20211125-008		25/11/2021 06:42 PM	Butanona		3MM Whatman			4		461	0		99,14 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-010		25/11/2021 07:00 PM	Butanona		3MM Whatman			1		201	0		99,505 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-011		25/11/2021 07:25 PM	Butanona		3MM Whatman			20		1989	0		99,004 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-013		25/11/2021 08:03 PM	Butanona		3MM Whatman			6		406	0		98,544 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-014		25/11/2021 08:12 PM	Butanona		3MM Whatman			27		898	0		97,081 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-015		25/11/2021 08:49 PM	Butanona		3MM Whatman			2		265	0		99,251 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-016		25/11/2021 09:51 VS	Butanona		3MM Whatman			5		245	0		98,00 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-018		25/11/2021 10:28 VS	Butanona		3MM Whatman			6		685	0		99,132 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-019		25/11/2021 10:45 VS	Butanona		3MM Whatman			3		940	0		99,682 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-020		25/11/2021 11:17 VS	Butanona		3MM Whatman			15		486	0		97,006 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-021		25/11/2021 12:08 VS	Butanona		3MM Whatman			4		261	0		98,491 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-022		25/11/2021 12:34 VS	Butanona		3MM Whatman			2		158	0		98,75 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211125-023		25/11/2021 12:36 VS	Butanona		3MM Whatman			12		631	0		98,134 %	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-20211125-025		25/11/2021 13:21 VS	Butanona		3MM Whatman			6		214	0	97,273 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211125-026		25/11/2021 13:32 VS	Butanona		3MM Whatman			5		307	0	98,397 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
TRODAT-99mTc Lot # K-20211125-022		25/11/2021 07:30 MB	Normal Saline		Sílica gel			67,3		1,1	0	94,143 %	Pass	
			Butanona		3MM Whatman			4,1		92,4	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211125-023		25/11/2021 07:31 MB	Normal Saline		Sílica gel			108		1	0	98,554 %	Pass	
			Butanona		3MM Whatman			0,7		131,7	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211125-033		25/11/2021 10:17 VS	Normal Saline		Sílica gel			161,2		2,1	0	97,701 %	Pass	
			Butanona		3MM Whatman			1,4		136,8	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211125-034		25/11/2021 10:19 VS	Normal Saline		Sílica gel			136,8		2,1	0	97,451 %	Pass	
			Butanona		3MM Whatman			1,3		124,1	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211125-035		25/11/2021 10:20 VS	Normal Saline		Sílica gel			142,6		1,2	0	97,424 %	Pass	
			Butanona		3MM Whatman			1,9		107,2	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211125-036		25/11/2021 10:22 VS	Normal Saline		Sílica gel			164,7		1,1	0	98,055 %	Pass	
			Butanona		3MM Whatman			3		231,1	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211125-038		25/11/2021 10:34 VS	Normal Saline		Sílica gel			142,4		2,7	0	96,097 %	Pass	
			Butanona		3MM Whatman			2,3		110,3	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211125-039		25/11/2021 10:35 VS	Normal Saline		Sílica gel			177,2		2,7	0	96,916 %	Pass	
			Butanona		3MM Whatman			2,8		174,1	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211125-040		25/11/2021 10:36 VS	Normal Saline		Sílica gel			126,5		2	0	95,99 %	Pass	
			Butanona		3MM Whatman			2,9		115,3	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							