



# 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 23/12/2021 To 23/12/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211223-011		23/12/2021	04:03	MB	Butanona Normal Saline	3MM Whatman Sílica gel	149,6 7,7		1,4 103,8	0	pH (Low/Actual/High)	92,167 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211223-022		23/12/2021	07:33	PM	Butanona Normal Saline	3MM Whatman Sílica gel	301,3 7,2		2,1 180,2	0	pH (Low/Actual/High)	95,466 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211223-039		23/12/2021	10:40	JS	Butanona Normal Saline	3MM Whatman Sílica gel	70 4,4		1,2 90,8	0	pH (Low/Actual/High)	93,693 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20211223-019		23/12/2021	06:54	PM	Citrato de Sódio 0,1M	Sílica gel	32,8		0,5	0	pH (Low/Actual/High)	98,498 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20211223-043		23/12/2021	12:38	JS	Citrato de Sódio 0,1M	Sílica gel	45,5		0,4	0	pH (Low/Actual/High)	99,129 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20211223-008	RPH	23/12/2021	03:29	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	763 22,2		2,1 599,1	0	pH (Low/Actual/High)	96,152 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211223-010	RPH	23/12/2021	03:58	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	630,2 39,4		1,1 619,3	0	pH (Low/Actual/High)	93,844 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211223-021	RPH	23/12/2021	07:09	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	626 11		2 503	0	pH (Low/Actual/High)	97,541 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211223-030	RPH	23/12/2021	09:21	JS	Acetona Normal Saline	3MM Whatman 3MM Whatman	247 2		4 283	0	pH (Low/Actual/High)	97,705 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20211223-006		23/12/2021	03:23	MB	Butanona	3MM Whatman	377,6		2,7	0	pH (Low/Actual/High)	99,29 %	Pass 5,00 <= 6,00 <= 7,00
						Límpido/Incolor							
FITATO-99mTc Lot # K-20211223-023		23/12/2021	07:35	PM	Butanona	3MM Whatman	706		8	0	pH (Low/Actual/High)	98,88 %	Pass 5,00 <= 7,00 <= 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-20211223-013		23/12/2021 04:06	MB	Butanona		3MM Whatman		108,7		1	0	99,088 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211223-014		23/12/2021 04:08	MB	Butanona		3MM Whatman		163,9		2,8	0	98,32 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211223-015		23/12/2021 04:11	MB	Butanona		3MM Whatman		209		5	0	97,664 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211223-027		23/12/2021 08:26	PM	Butanona		3MM Whatman		268		9	0	96,751 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211223-042		23/12/2021 12:25	JS	Butanona		3MM Whatman		112		1,7	0	98,505 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20211223-004		23/12/2021 03:13	MB	Acetona		3MM Whatman		1203		2	0	98,206 %	Pass	
				Normal Saline		3MM Whatman		19		1148		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211223-005		23/12/2021 03:15	MB	Acetona		3MM Whatman		1292		19	0	98,022 %	Pass	
				Normal Saline		3MM Whatman		6		1128		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211223-007		23/12/2021 03:27	MB	Acetona		3MM Whatman		703,8		1,4	0	98,321 %	Pass	
				Normal Saline		3MM Whatman		10,3		685,2		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211223-009		23/12/2021 03:54	MB	Acetona		3MM Whatman		1185		3	0	99,043 %	Pass	
				Normal Saline		3MM Whatman		8		1128		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211223-016		23/12/2021 04:30	MB	Acetona		3MM Whatman		1078		4	0	99,63 %	Pass	
				Normal Saline		3MM Whatman		0		961		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211223-020		23/12/2021 07:06	PM	Acetona		3MM Whatman		1877		2	0	99,677 %	Pass	
				Normal Saline		3MM Whatman		2		921		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211223-024		23/12/2021 07:41	PM	Acetona		3MM Whatman		1737		7	0	98,54 %	Pass	
				Normal Saline		3MM Whatman		14		1308		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211223-026		23/12/2021 07:58	PM	Acetona		3MM Whatman		667		2	0	95,779 %	Pass	
				Normal Saline		3MM Whatman		20		490		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-20211223-031		23/12/2021 09:23 JS	Acetona Normal Saline		3MM Whatman			764 5		2 679	0	pH (Low/Actual/High)	99,008 %	Pass
							Límpido/Incolor					4,00 <= 5,00 <= 7,80		
MIBI-99mTc Lot # K-20211223-001		23/12/2021 02:05 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1332 4		26 1992	0	pH (Low/Actual/High)	97,885 %	Pass
							Límpido/Incolor					5,00 <= 5,00 <= 6,00		
MIBI-99mTc Lot # K-20211223-002		23/12/2021 02:11 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1632 5		19 1742	0	pH (Low/Actual/High)	98,563 %	Pass
							Límpido/Incolor					5,00 <= 5,00 <= 6,00		
MIBI-99mTc Lot # K-20211223-003		23/12/2021 03:03 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1393 4		29 2004	0	pH (Low/Actual/High)	97,761 %	Pass
							Límpido/Incolor					5,00 <= 5,00 <= 6,00		
MIBI-99mTc Lot # K-20211223-017		23/12/2021 06:38 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1472 1		28 255	0	pH (Low/Actual/High)	97,743 %	Pass
							Límpido/Incolor					5,00 <= 5,00 <= 6,00		
MIBI-99mTc Lot # K-20211223-018		23/12/2021 06:44 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1830 4		2 1978	0	pH (Low/Actual/High)	99,689 %	Pass
							Límpido/Incolor					5,00 <= 5,00 <= 6,00		
MIBI-99mTc Lot # K-20211223-025		23/12/2021 07:51 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1411 3		14 199	0	pH (Low/Actual/High)	97,532 %	Pass
							Límpido/Incolor					5,00 <= 5,00 <= 6,00		
MIBI-99mTc Lot # K-20211223-028		23/12/2021 08:43 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1222 22		16 1380	0	pH (Low/Actual/High)	97,138 %	Pass
							Límpido/Incolor					5,00 <= 5,00 <= 6,00		
MIBI-99mTc Lot # K-20211223-029		23/12/2021 09:17 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			577 6		6 483	0	pH (Low/Actual/High)	97,744 %	Pass
							Límpido/Incolor					5,00 <= 5,00 <= 6,00		
MIBI-99mTc Lot # K-20211223-040		23/12/2021 11:37 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			976 4		19 853	0	pH (Low/Actual/High)	97,624 %	Pass
							Límpido/Incolor					5,00 <= 6,00 <= 6,00		
MIBI-99mTc Lot # K-20211223-041		23/12/2021 11:37 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			771 5		11 595	0	pH (Low/Actual/High)	97,76 %	Pass
							Límpido/Incolor					5,00 <= 5,00 <= 6,00		
PSMA-68Ga Lot # K-20211223-032		23/12/2021 09:38 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,3		38	0	pH (Low/Actual/High)	99,217 %	Pass
							Límpido e Incolor					4,00 <= 5,00 <= 8,00		
Tecnécio-99m Lot # E-20211223-001		23/12/2021 01:41 MB	Butanona		3MM Whatman			18		3186	0	pH (Low/Actual/High)	99,438 %	Pass
							Límpido e Incolor					5,00 <= 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
Tecnécio-99m Lot # E-20211223-002		23/12/2021 02:01	MB	Butanona		3MM Whatman		21	3526		0	99,408 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-003		23/12/2021 02:58	MB	Butanona		3MM Whatman		6	1036		0	99,424 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-004		23/12/2021 03:11	MB	Butanona		3MM Whatman		5	1698		0	99,706 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-005		23/12/2021 03:25	MB	Butanona		3MM Whatman		2	2191		0	99,909 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-006		23/12/2021 03:51	MB	Butanona		3MM Whatman		19	1675		0	98,878 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-007		23/12/2021 06:24	PM	Butanona		3MM Whatman		8	524		0	98,496 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-008		23/12/2021 06:35	PM	Butanona		3MM Whatman		9	434		0	97,968 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-009		23/12/2021 06:41	PM	Butanona		3MM Whatman		1	469		0	99,787 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-011		23/12/2021 07:21	PM	Butanona		3MM Whatman		7	487		0	98,583 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-012		23/12/2021 07:38	PM	Butanona		3MM Whatman		8	218		0	96,46 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-013		23/12/2021 07:48	PM	Butanona		3MM Whatman		18	1864		0	99,044 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-014		23/12/2021 08:36	PM	Butanona		3MM Whatman		16	660		0	97,633 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211223-015		23/12/2021 09:12	JS	Butanona		3MM Whatman		5	162		0	97,006 %	Pass	
												pH (Low/Actual/High)	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-20211223-016		23/12/2021 09:18 JS	Butanona		3MM Whatman			4		204	0	98,077 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211223-018		23/12/2021 10:23 JS	Butanona		3MM Whatman			9		244	0	96,443 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211223-019		23/12/2021 11:00 JS	Butanona		3MM Whatman			2		289	0	99,313 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211223-020		23/12/2021 11:32 JS	Butanona		3MM Whatman			1,2		104	0	98,859 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211223-021		23/12/2021 11:32 JS	Butanona		3MM Whatman			2		1458	0	99,863 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
											Límpido e Incolor			
TRODAT-99mTc Lot # K-20211223-033		23/12/2021 10:30 JS	Normal Saline		Sílica gel			116		4	0	95,128 %	Pass	
			Butanona		3MM Whatman			7		448	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20211223-034		23/12/2021 10:31 JS	Normal Saline		Sílica gel			58,7		1,7	0	96,185 %	Pass	
			Butanona		3MM Whatman			1		99	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20211223-035		23/12/2021 10:32 JS	Normal Saline		Sílica gel			115		3,8	0	91,872 %	Pass	
			Butanona		3MM Whatman			2,1		40,5	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20211223-036		23/12/2021 10:32 JS	Normal Saline		Sílica gel			135		5	0	92,634 %	Pass	
			Butanona		3MM Whatman			2		50,7	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20211223-037		23/12/2021 10:33 JS	Normal Saline		Sílica gel			140,8		5	0	92,27 %	Pass	
			Butanona		3MM Whatman			4		89	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20211223-038		23/12/2021 10:34 JS	Normal Saline		Sílica gel			790		1	0	98,987 %	Pass	
			Butanona		3MM Whatman			6		671	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			