



# 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 19/11/2021 To 19/11/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211119-023		19/11/2021	07:32	PM	Butanona Normal Saline	3MM Whatman Sílica gel	73,3 3,9		1,4 49,6	0	pH (Low/Actual/High)	90,836 %	Pass <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20211119-024		19/11/2021	07:33	WG	Butanona Normal Saline	3MM Whatman Sílica gel	86,8 2		0,9 131,1	0	pH (Low/Actual/High)	97,471 %	Pass <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20211119-025		19/11/2021	07:34	WG	Butanona Normal Saline	3MM Whatman Sílica gel	68,9 2,6		0,6 60,6	0	pH (Low/Actual/High)	95,023 %	Pass <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20211119-026		19/11/2021	07:38	WG	Butanona Normal Saline	3MM Whatman Sílica gel	77,4 2		1,1 74,7	0	pH (Low/Actual/High)	95,991 %	Pass <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20211119-028		19/11/2021	08:06	WG	Butanona Normal Saline	3MM Whatman Sílica gel	98,5 2,8		3 111,4	0	pH (Low/Actual/High)	94,592 %	Pass <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20211119-029		19/11/2021	08:07	WG	Butanona Normal Saline	3MM Whatman Sílica gel	168,9 2,9		1,6 172,1	0	pH (Low/Actual/High)	97,404 %	Pass <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20211119-037		19/11/2021	10:35	MB	Butanona Normal Saline	3MM Whatman Sílica gel	110,2 2,1		0,3 106,3	0	pH (Low/Actual/High)	97,791 %	Pass <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20211119-038		19/11/2021	10:36	MB	Butanona Normal Saline	3MM Whatman Sílica gel	102 3,5		1,5 119,2	0	pH (Low/Actual/High)	95,698 %	Pass <= 3,00 <= 3,00
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20211119-049		19/11/2021	12:47	JS	Citrato de Sódio 0,1M	Sílica gel	17,28		0,43	0	pH (Low/Actual/High)	97,572 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20211119-050		19/11/2021	15:41	VS	Citrato de Sódio 0,1M	Sílica gel	53,4		0,4	0	pH (Low/Actual/High)	99,257 %	Pass 4,00 <= 7,00 <= 8,00
Límpido e Incolor													
DTPA-99mTc Lot # K-20211119-014	RPH	19/11/2021	04:18	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	931 42		33 1220	0	pH (Low/Actual/High)	93,249 %	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-20211119-018	RPH	19/11/2021 05:08	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman			320 9		5 277	0	pH (Low/Actual/High)	95,315 %	Pass 3,80 <= 5,00 <= 7,50
Límpido/Incolor														
DTPA-99mTc Lot # K-20211119-035	RPH	19/11/2021 09:58	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			232 0		1 247	0	pH (Low/Actual/High)	99,571 %	Pass 3,80 <= 5,00 <= 7,50
Límpido/Incolor														
DTPA-99mTc Lot # K-20211119-044	RPH	19/11/2021 11:31	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			140 4		3 149	0	pH (Low/Actual/High)	95,288 %	Pass 3,80 <= 5,00 <= 7,50
Límpido/Incolor														
FITATO-99mTc Lot # K-20211119-007		19/11/2021 03:33	PM	Butanona	3MM Whatman			242		3	0	pH (Low/Actual/High)	98,776 %	Pass 5,00 <= 5,00 <= 7,00
Límpido/Incolor														
FITATO-99mTc Lot # K-20211119-039		19/11/2021 10:39	MB	Butanona	3MM Whatman			574		4	0	pH (Low/Actual/High)	99,308 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
MAA-99mTc Lot # K-20211119-013		19/11/2021 04:16	PP	Butanona	3MM Whatman			2713		10	0	pH (Low/Actual/High)	99,633 %	Pass 3,00 <= 6,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211119-030		19/11/2021 08:24	WG	Butanona	3MM Whatman			101,8		2	0	pH (Low/Actual/High)	98,073 %	Pass 3,00 <= 6,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211119-031		19/11/2021 08:26	WG	Butanona	3MM Whatman			62,1		3	0	pH (Low/Actual/High)	95,392 %	Pass 3,00 <= 6,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211119-041		19/11/2021 10:49	MB	Butanona	3MM Whatman			256		2	0	pH (Low/Actual/High)	99,225 %	Pass 3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211119-042		19/11/2021 10:51	MB	Butanona	3MM Whatman			132,6		2,5	0	pH (Low/Actual/High)	98,15 %	Pass 3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211119-047		19/11/2021 11:41	MB	Butanona	3MM Whatman			149		2	0	pH (Low/Actual/High)	98,675 %	Pass 3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211119-046		19/11/2021 11:41	MB	Butanona	3MM Whatman			118		2,8	0	pH (Low/Actual/High)	97,682 %	Pass 3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MDP-99mTc Lot # K-20211119-010		19/11/2021 03:55	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman			1141 11		5 969	0	pH (Low/Actual/High)	98,441 %	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-20211119-011	19/11/2021	03:58 PP	Acetona Normal Saline		3MM Whatman 3MM Whatman			1229 12		3 1548	0	pH (Low/Actual/High)	98,987 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211119-016	19/11/2021	04:42 PP	Acetona Normal Saline		3MM Whatman 3MM Whatman			1739 7		6 1562	0	pH (Low/Actual/High)	99,21 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211119-017	19/11/2021	05:03 PP	Acetona Normal Saline		3MM Whatman 3MM Whatman			647 4		2 760	0	pH (Low/Actual/High)	99,168 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211119-021	19/11/2021	07:02 PM	Acetona Normal Saline		3MM Whatman 3MM Whatman			775 6		1 809	0	pH (Low/Actual/High)	99,135 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211119-027	19/11/2021	07:53 WG	Acetona Normal Saline		3MM Whatman 3MM Whatman			751 4		2 598	0	pH (Low/Actual/High)	99,07 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211119-036	19/11/2021	10:04 MB	Acetona Normal Saline		3MM Whatman 3MM Whatman			825 1		4 971	0	pH (Low/Actual/High)	99,415 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211119-043	19/11/2021	10:54 MB	Acetona Normal Saline		3MM Whatman 3MM Whatman			527 6		3 459	0	pH (Low/Actual/High)	98,144 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-001	19/11/2021	01:43 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			1166 3		11 1611	0	pH (Low/Actual/High)	98,88 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-002	19/11/2021	01:47 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			1048 25		6 1912	0	pH (Low/Actual/High)	98,14 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-003	19/11/2021	02:17 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			1313 2		18 1589	0	pH (Low/Actual/High)	98,522 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-004	19/11/2021	02:18 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1092 19		17 1704	0	pH (Low/Actual/High)	97,364 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-005	19/11/2021	02:19 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1278 26		18 1592	0	pH (Low/Actual/High)	97,004 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-006	19/11/2021	02:37 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			871 3		32 1772	0	pH (Low/Actual/High)	96,287 %	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-20211119-009		19/11/2021 03:41 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1138 13		16 1731	0	pH (Low/Actual/High)	97,868 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-008		19/11/2021 03:41 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1632 9		33 1930	0	pH (Low/Actual/High)	97,554 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-015		19/11/2021 04:30 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2198 32		12 3308	0	pH (Low/Actual/High)	98,499 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-020		19/11/2021 06:58 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1440 2		24 363	0	pH (Low/Actual/High)	97,813 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-022		19/11/2021 07:23 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1445 2		23 286	0	pH (Low/Actual/High)	97,739 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-032		19/11/2021 08:31 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			635 18		5 641	0	pH (Low/Actual/High)	96,487 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-034		19/11/2021 09:52 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			963 11		3 874	0	pH (Low/Actual/High)	98,447 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-040		19/11/2021 10:43 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			471 3		5 318	0	pH (Low/Actual/High)	98,015 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-045		19/11/2021 11:26 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			546 6		7 540	0	pH (Low/Actual/High)	97,635 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211119-048		19/11/2021 11:46 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1204 1		7 242	0	pH (Low/Actual/High)	99,01 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20211119-012		19/11/2021 04:00 PP	Butanona Normal Saline		3MM Whatman 3MM Whatman			1403 16		8 567	0	pH (Low/Actual/High)	96,689 %	Pass 5,00 <= 7,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20211119-019		19/11/2021 06:30 YD	Acetato de amônio 1M:Metanol		Sílica gel			0,03		12,1	0	pH (Low/Actual/High)	99,753 %	Pass 4,00 <= 6,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20211119-033		19/11/2021 09:40 JS	Acetato de amônio 1M:Metanol		Sílica gel			1		24,5	0	pH (Low/Actual/High)	96,078 %	Pass 4,00 <= 5,00 <= 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
Tecnécio-99m Lot # E-20211119-001		19/11/2021 01:38	MB	Butanona		3MM Whatman		16	2850		0	99,442 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-002		19/11/2021 01:40	MB	Butanona		3MM Whatman		6	1664		0	99,641 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-003		19/11/2021 02:11	PM	Butanona		3MM Whatman		2	631		0	99,684 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-004		19/11/2021 02:35	PM	Butanona		3MM Whatman		7	224		0	96,97 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-005		19/11/2021 03:35	PM	Butanona		3MM Whatman		5	710		0	99,301 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-006		19/11/2021 03:35	PM	Butanona		3MM Whatman		1	226		0	99,559 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-007		19/11/2021 03:52	PP	Butanona		3MM Whatman		54	2914		0	98,181 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-008		19/11/2021 03:52	PP	Butanona		3MM Whatman		29	637		0	95,646 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-009		19/11/2021 04:28	PP	Butanona		3MM Whatman		14	4567		0	99,694 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-010		19/11/2021 04:40	PP	Butanona		3MM Whatman		2	2931		0	99,932 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-012		19/11/2021 06:49	PM	Butanona		3MM Whatman		7	1270		0	99,452 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-013		19/11/2021 07:01	PM	Butanona		3MM Whatman		4	617		0	99,356 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211119-014		19/11/2021 07:20	PM	Butanona		3MM Whatman		5	281		0	98,252 %	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-20211119-015		19/11/2021 07:35 PM	Butanona		3MM	Whatman		2		495	0		99,598 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211119-016		19/11/2021 07:43 PM	Butanona		3MM	Whatman		1		289	0		99,655 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211119-017		19/11/2021 07:51 PM	Butanona		3MM	Whatman		5		402	0		98,771 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211119-018		19/11/2021 08:22 WG	Butanona		3MM	Whatman		6		198,6	0		97,067 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211119-020		19/11/2021 09:48 WG	Butanona		3MM	Whatman		14		926	0		98,511 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211119-021		19/11/2021 10:01 MB	Butanona		3MM	Whatman		19		758	0		97,555 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211119-022		19/11/2021 10:31 MB	Butanona		3MM	Whatman		36		1184	0		97,049 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211119-023		19/11/2021 10:47 MB	Butanona		3MM	Whatman		33		978	0		96,736 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211119-024		19/11/2021 11:21 MB	Butanona		3MM	Whatman		15		1301	0		98,86 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211119-025		19/11/2021 11:27 MB	Butanona		3MM	Whatman		8		643	0		98,771 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211119-026		19/11/2021 11:37 MB	Butanona		3MM	Whatman		1		158	0		99,371 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211119-028		19/11/2021 15:04 VS	Butanona		3MM	Whatman		1		483	0		99,793 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		