



# 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 16/06/2021 To 16/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210616-018		16/06/2021	04:18	PP	Butanona Normal Saline	3MM Whatman Sílica gel	268 10		2 196	0	pH (Low/Actual/High)	94,405 % 2,00 <= 3,00 <= 3,00	Pass
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210616-029		16/06/2021	07:33	FN	Butanona Normal Saline	3MM Whatman Sílica gel	181 7		1 136	0	pH (Low/Actual/High)	94,555 % 2,00 <= 3,00 <= 3,00	Pass
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210616-030		16/06/2021	07:34	FN	Butanona Normal Saline	3MM Whatman Sílica gel	167 5		2 120	0	pH (Low/Actual/High)	94,817 % 2,00 <= 3,00 <= 3,00	Pass
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210616-043		16/06/2021	10:39	WG	Butanona Normal Saline	3MM Whatman Sílica gel	213 2,1		1 105,9	0	pH (Low/Actual/High)	97,588 % 2,00 <= 3,00 <= 3,00	Pass
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210616-036		16/06/2021	09:50	JS	Citrato de Sódio 0,1M	Sílica gel	42,9		0,4	0	pH (Low/Actual/High)	99,076 % 4,00 <= 5,00 <= 8,00	Pass
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210616-007	RPH	16/06/2021	03:13	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	634 20		4 504	0	pH (Low/Actual/High)	95,556 % 3,80 <= 6,00 <= 7,50	Pass
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210616-028	RPH	16/06/2021	07:17	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	810 5		3 1330	0	pH (Low/Actual/High)	99,256 % 3,80 <= 6,00 <= 7,50	Pass
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210616-038	RPH	16/06/2021	09:53	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	704 4		64 502	0	pH (Low/Actual/High)	90,876 % 3,80 <= 6,00 <= 7,50	Pass
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210616-006		16/06/2021	03:11	PP	Butanona	3MM Whatman	341		1	0	pH (Low/Actual/High)	99,708 % 5,00 <= 6,00 <= 7,00	Pass
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210616-027		16/06/2021	07:14	FN	Butanona	3MM Whatman	252		3	0	pH (Low/Actual/High)	98,824 % 5,00 <= 6,00 <= 7,00	Pass
						Límpido/Incolor							
MAA-99mTc Lot # K-20210616-011		16/06/2021	03:54	PP	Butanona	3MM Whatman	358		1	0	pH (Low/Actual/High)	99,721 % 3,00 <= 6,00 <= 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-20210616-012		16/06/2021 03:56 PP	Butanona		3MM Whatman			173		2	0	98,857 %		Pass
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210616-013		16/06/2021 03:58 PP	Butanona		3MM Whatman			127		3	0	97,692 %		Pass
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210616-014		16/06/2021 04:00 PP	Butanona		3MM Whatman			213		2	0	99,07 %		Pass
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210616-016		16/06/2021 04:15 PP	Butanona		3MM Whatman			302		1	0	99,67 %		Pass
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210616-017		16/06/2021 04:17 PP	Butanona		3MM Whatman			171		8	0	95,531 %		Pass
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210616-022		16/06/2021 04:28 PP	Butanona		3MM Whatman			326		12	0	96,45 %		Pass
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210616-032		16/06/2021 07:49 FN	Butanona		3MM Whatman			114		2	0	98,276 %		Pass
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210616-037		16/06/2021 09:51 JS	Butanona		3MM Whatman			212		2	0	99,065 %		Pass
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210616-045		16/06/2021 11:23 WG	Butanona		3MM Whatman			289		1	0	99,655 %		Pass
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MDP-99mTc Lot # K-20210616-020		16/06/2021 04:22 PP	Acetona		3MM Whatman			1214		10	0	98,292 %		Pass
			Normal Saline		3MM Whatman			11		1224	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210616-021		16/06/2021 04:25 PP	Acetona		3MM Whatman			1174		62	0	94,35 %		Pass
			Normal Saline		3MM Whatman			9		1410	pH (Low/Actual/High)	4,00 <= 7,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210616-023		16/06/2021 04:33 PP	Acetona		3MM Whatman			1364		64	0	95,386 %		Pass
			Normal Saline		3MM Whatman			1		758	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210616-024		16/06/2021 04:58 PP	Acetona		3MM Whatman			777		2	0	97,084 %		Pass
			Normal Saline		3MM Whatman			10		366	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-20210616-033	16/06/2021	07:52 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			783 5		2 847	0 pH (Low/Actual/High)	99,158 %		Pass 4,00 <= 6,00 <= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210616-034	16/06/2021	07:57 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			975 3		1 700	0 pH (Low/Actual/High)	99,471 %		Pass 4,00 <= 6,00 <= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210616-035	16/06/2021	08:19 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			567 5		2 472	0 pH (Low/Actual/High)	98,60 %		Pass 4,00 <= 6,00 <= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210616-042	16/06/2021	10:34 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			460 4		3 493	0 pH (Low/Actual/High)	98,547 %		Pass 4,00 <= 6,00 <= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210616-044	16/06/2021	10:44 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			1190 11		6 563	0 pH (Low/Actual/High)	97,582 %		Pass 4,00 <= 6,00 <= 7,80
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210616-001	16/06/2021	01:26 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2400 10		99 2188	0 pH (Low/Actual/High)	95,583 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210616-004	16/06/2021	02:53 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1901 8		29 2117	0 pH (Low/Actual/High)	98,121 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210616-005	16/06/2021	02:54 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1262 63		16 2008	0 pH (Low/Actual/High)	95,706 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210616-008	16/06/2021	03:25 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2393 51		51 2586	0 pH (Low/Actual/High)	95,979 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210616-009	16/06/2021	03:36 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2502 32		48 3522	0 pH (Low/Actual/High)	97,217 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210616-010	16/06/2021	03:43 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3088 23		64 2027	0 pH (Low/Actual/High)	96,848 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210616-015	16/06/2021	04:11 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3119 101		54 3657	0 pH (Low/Actual/High)	95,611 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210616-019	16/06/2021	04:20 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1746 15		23 426	0 pH (Low/Actual/High)	95,298 %		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-20210616-025	16/06/2021	07:03	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			798 7		1 1010	0	pH (Low/Actual/High)	99,187 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210616-026	16/06/2021	07:04	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			386 5		2 483	0	pH (Low/Actual/High)	98,46 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210616-031	16/06/2021	07:44	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			514 2		7 524	0	pH (Low/Actual/High)	98,276 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210616-039	16/06/2021	10:14	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			1756 2		10 623	0	pH (Low/Actual/High)	99,114 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210616-040	16/06/2021	10:19	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			563 1		9 445	0	pH (Low/Actual/High)	98,202 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210616-041	16/06/2021	10:26	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			325 3		4 215	0	pH (Low/Actual/High)	97,408 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210616-046	16/06/2021	11:24	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			494 9		17 820	0	pH (Low/Actual/High)	95,588 %	Pass
Límpido/Incolor														
PSMA-177Lu Lot # K-20210616-002	16/06/2021	02:02	BB	Citrato de Sódio 0,1M	Sílica gel			186		1	0	pH (Low/Actual/High)	99,465 %	Pass
Límpido														
QC Notes: HPLC: 99,13%														
PSMA-177Lu Lot # K-20210616-003	16/06/2021	02:25	BB	Citrato de Sódio 0,1M	Sílica gel			354		2	0	pH (Low/Actual/High)	99,438 %	Pass
Límpido														
QC Notes: HPLC: 96,99														
PSMA-68Ga Lot # K-20210616-047	16/06/2021	12:40	JS	Acetato de amônio	Sílica gel			0,3		23,9	0	pH (Low/Actual/High)	98,76 %	Pass
Límpido e Incolor														
Tecnécio-99m Lot # E-20210616-001	16/06/2021	01:23	PP	Butanona	3MM Whatman			20		2340	0	pH (Low/Actual/High)	99,153 %	Pass
Límpido e Incolor														
Tecnécio-99m Lot # E-20210616-002	16/06/2021	02:48	PP	Butanona	3MM Whatman			24		551	0	pH (Low/Actual/High)	95,826 %	Pass
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-20210616-003		16/06/2021 02:48	PP	Butanona		3MM Whatman		6		615	0	99,034 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-004		16/06/2021 03:08	PP	Butanona		3MM Whatman		1		632	0	99,842 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-005		16/06/2021 03:22	PP	Butanona		3MM Whatman		2		286	0	99,306 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-006		16/06/2021 03:33	PP	Butanona		3MM Whatman		4		782	0	99,491 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-007		16/06/2021 03:40	PP	Butanona		3MM Whatman		2		305	0	99,349 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-008		16/06/2021 03:52	PP	Butanona		3MM Whatman		4		597	0	99,334 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-009		16/06/2021 04:08	PP	Butanona		3MM Whatman		31		614	0	95,194 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-010		16/06/2021 04:17	PP	Butanona		3MM Whatman		56		1285	0	95,824 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-011		16/06/2021 04:20	PP	Butanona		3MM Whatman		5		166	0	97,076 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-012		16/06/2021 04:23	PP	Butanona		3MM Whatman		2		138	0	98,571 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-013		16/06/2021 04:27	PP	Butanona		3MM Whatman		3		949	0	99,685 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-014		16/06/2021 04:31	PP	Butanona		3MM Whatman		5		385	0	98,718 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210616-016		16/06/2021 07:01	FN	Butanona		3MM Whatman		1		262	0	99,62 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 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-20210616-015		16/06/2021 07:01	FN	Butanona		3MM Whatman		1		1375	0	99,927 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-017		16/06/2021 07:11	FN	Butanona		3MM Whatman		2		693	0	99,712 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-018		16/06/2021 07:40	FN	Butanona		3MM Whatman		3		1242	0	99,759 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-019		16/06/2021 07:50	FN	Butanona		3MM Whatman		2		563	0	99,646 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-020		16/06/2021 07:54	FN	Butanona		3MM Whatman		1		249	0	99,60 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-021		16/06/2021 08:16	FN	Butanona		3MM Whatman		2		177	0	98,883 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-022		16/06/2021 09:48	PP	Butanona		3MM Whatman		3		864	0	99,654 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-024		16/06/2021 09:57	PP	Butanona		3MM Whatman		1		191	0	99,479 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-025		16/06/2021 10:09	PP	Butanona		3MM Whatman		1		118	0	99,16 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-026		16/06/2021 10:11	PP	Butanona		3MM Whatman		2		122	0	98,387 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-027		16/06/2021 10:22	JS	Butanona		3MM Whatman		5		484	0	98,978 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-028		16/06/2021 10:31	JS	Butanona		3MM Whatman		1		399	0	99,75 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210616-029		16/06/2021 10:37	JS	Butanona		3MM Whatman		2		159	0	98,758 %	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		16/06/2021 11:20	WG	Butanona				17		971	0		98,279 %	Pass
Lot # E-20210616-030												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor