



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 09/06/2021 To 09/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210609-025		09/06/2021	07:37	FN	Butanona Normal Saline	3MM Whatman Sílica gel	78,9 11,9		1,1 162,2	0	pH (Low/Actual/High)	91,79 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210609-026		09/06/2021	07:38	FN	Butanona Normal Saline	3MM Whatman Sílica gel	117,3 6,6		1,2 78,1	0	pH (Low/Actual/High)	91,195 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210609-038		09/06/2021	10:25	WG	Butanona Normal Saline	3MM Whatman Sílica gel	200 2,4		2 167	0	pH (Low/Actual/High)	97,593 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210609-033		09/06/2021	09:59	BB	Citrato de Sódio 0,1M	Sílica gel	8,68		0,3	0	pH (Low/Actual/High)	96,659 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210609-045		09/06/2021	11:05	JS	Citrato de Sódio 0,1M	Sílica gel	25,3		0,3	0	pH (Low/Actual/High)	98,828 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DTPA-99mTc Lot # K-20210609-005	RPH	09/06/2021	03:12	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	382 26		1 317	0	pH (Low/Actual/High)	92,159 %	Pass 3,80 <= 7,00 <= 7,50
Límpido/Incolor													
DTPA-99mTc Lot # K-20210609-027	RPH	09/06/2021	07:42	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	330 15		3 241	0	pH (Low/Actual/High)	93,24 %	Pass 3,80 <= 6,00 <= 7,50
Límpido/Incolor													
DTPA-99mTc Lot # K-20210609-037	RPH	09/06/2021	10:21	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	383 7		8 360	0	pH (Low/Actual/High)	96,047 %	Pass 3,80 <= 6,00 <= 7,50
Límpido/Incolor													
FITATO-99mTc Lot # K-20210609-006		09/06/2021	03:39	PP	Butanona	3MM Whatman	233		2	0	pH (Low/Actual/High)	99,149 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor													
FITATO-99mTc Lot # K-20210609-030		09/06/2021	08:14	FN	Butanona	3MM Whatman	203		2	0	pH (Low/Actual/High)	99,024 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor													
FITATO-99mTc Lot # K-20210609-035		09/06/2021	10:19	WG	Butanona	3MM Whatman	347		4	0	pH (Low/Actual/High)	98,86 %	Pass 5,00 <= 6,00 <= 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-20210609-010		09/06/2021 03:49 PP	Butanona		3MM	Whatman		507		3	0	99,412 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210609-011		09/06/2021 04:09 PP	Butanona		3MM	Whatman		257		3	0	98,846 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210609-012		09/06/2021 04:11 BB	Butanona		3MM	Whatman		360		3	0	99,174 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210609-013		09/06/2021 04:13 PP	Butanona		3MM	Whatman		257		12	0	95,539 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210609-015		09/06/2021 04:19 PP	Butanona		3MM	Whatman		275		4	0	98,566 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210609-016		09/06/2021 04:21 PP	Butanona		3MM	Whatman		72,6	0,7		0	99,045 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210609-017		09/06/2021 04:23 PP	Butanona		3MM	Whatman		134		7	0	95,035 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210609-043		09/06/2021 10:53 WG	Butanona		3MM	Whatman		126,2	0,8		0	99,37 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MDP-99mTc Lot # K-20210609-009		09/06/2021 03:46 PP	Acetona		3MM	Whatman		1229		15	0	95,593 %	Pass	
			Normal Saline		3MM	Whatman		29		877	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210609-018		09/06/2021 04:28 PP	Acetona		3MM	Whatman		1231		45	0	95,333 %	Pass	
			Normal Saline		3MM	Whatman		10		867	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210609-028		09/06/2021 07:45 FN	Acetona		3MM	Whatman		1041		2	0	99,193 %	Pass	
			Normal Saline		3MM	Whatman		7		1131	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210609-029		09/06/2021 08:08 FN	Acetona		3MM	Whatman		935		5	0	98,789 %	Pass	
			Normal Saline		3MM	Whatman		8		1170	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210609-032		09/06/2021 08:28 FN	Acetona		3MM	Whatman		688		1	0	97,922 %	Pass	
			Normal Saline		3MM	Whatman		15		761	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-20210609-044		09/06/2021 10:57	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			761 34		5 907	0 pH (Low/Actual/High)	95,734 %	Pass	4,00 <= 6,00 <= 7,80
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-002		09/06/2021 02:52	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1947 89		38 2943	0 pH (Low/Actual/High)	95,15 %	Pass	5,00 <= 6,00 <= 6,00
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-001		09/06/2021 02:54	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1382 103		18 2714	0 pH (Low/Actual/High)	95,058 %	Pass	5,00 <= 6,00 <= 6,00
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-003		09/06/2021 02:58	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1501 56		20 2629	0 pH (Low/Actual/High)	96,599 %	Pass	5,00 <= 6,00 <= 6,00
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-004		09/06/2021 03:03	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			4042 23		38 2695	0 pH (Low/Actual/High)	98,222 %	Pass	5,00 <= 6,00 <= 6,00
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-007		09/06/2021 03:41	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			3239 37		37 2703	0 pH (Low/Actual/High)	97,52 %	Pass	5,00 <= 6,00 <= 6,00
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-008		09/06/2021 03:44	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1911 17		52 2854	0 pH (Low/Actual/High)	96,759 %	Pass	5,00 <= 6,00 <= 6,00
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-014		09/06/2021 04:17	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			3337 74		74 2557	0 pH (Low/Actual/High)	95,018 %	Pass	5,00 <= 6,00 <= 6,00
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-019		09/06/2021 04:30	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			3620 54		59 1917	0 pH (Low/Actual/High)	95,657 %	Pass	5,00 <= 6,00 <= 6,00
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-020		09/06/2021 07:11	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			695 4		8 781	0 pH (Low/Actual/High)	98,352 %	Pass	5,00 <= 6,00 <= 6,00
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-021		09/06/2021 07:14	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			786 15		12 705	0 pH (Low/Actual/High)	96,413 %	Pass	5,00 <= 6,00 <= 6,00
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-023		09/06/2021 07:32	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			587 6		10 537	0 pH (Low/Actual/High)	97,22 %	Pass	5,00 <= 6,00 <= 6,00
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210609-031		09/06/2021 08:19	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			1025 8		13 804	0 pH (Low/Actual/High)	97,762 %	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-20210609-036		09/06/2021	10:21	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			334 2		4 377	0 pH (Low/Actual/High)	98,289 %		Pass
													5,00 <= 6,00		<= 6,00
															Límpido/Incolor
MIBI-99mTc Lot # K-20210609-039		09/06/2021	10:26	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			563 9		9 517	0 pH (Low/Actual/High)	96,716 %		Pass
													5,00 <= 6,00		<= 6,00
															Límpido/Incolor
MIBI-99mTc Lot # K-20210609-041		09/06/2021	10:33	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			497 25		4 858	0 pH (Low/Actual/High)	96,37 %		Pass
													5,00 <= 6,00		<= 6,00
															Límpido/Incolor
MIBI-99mTc Lot # K-20210609-042		09/06/2021	10:48	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			443 22		9 671	0 pH (Low/Actual/High)	94,834 %		Pass
													5,00 <= 6,00		<= 6,00
															Límpido/Incolor
PIRO-99mTc Lot # K-20210609-040		09/06/2021	10:28	WG	Butanona Normal Saline	3MM Whatman 3MM Whatman			616 9		6 267	0 pH (Low/Actual/High)	95,775 %		Pass
													5,00 <= 6,00		<= 7,00
															Límpido/Incolor
PSMA-177Lu Lot # K-20210609-022		09/06/2021	07:14	MP	Citrato de Sódio 0,1M	Sílica gel			155,6		0,7	0 pH (Low/Actual/High)	99,552 %		Pass
													4,00 <= 4,50		<= 5,00
															Límpido
QC Notes: HPLC: 98,21%															
PSMA-177Lu Lot # K-20210609-024		09/06/2021	07:32	FN	Citrato de Sódio 0,1M	Sílica gel			81,3		0,6	0 pH (Low/Actual/High)	99,267 %		Pass
													4,00 <= 4,50		<= 5,00
															Límpido
QC Notes: HPLC: 97,71%															
PSMA-68Ga Lot # K-20210609-046		09/06/2021	12:54	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,3		39,2	0 pH (Low/Actual/High)	99,241 %		Pass
													4,00 <= 5,00		<= 8,00
															Límpido e Incolor
Tecnécio-99m Lot # E-20210609-001		09/06/2021	02:44	PP	Butanona	3MM Whatman			22		4161	0 pH (Low/Actual/High)	99,474 %		Pass
													5,00 <= 6,00		<= 6,00
															Límpido e Incolor
Tecnécio-99m Lot # E-20210609-002		09/06/2021	02:51	PP	Butanona	3MM Whatman			47		3887	0 pH (Low/Actual/High)	98,805 %		Pass
													5,00 <= 6,00		<= 6,00
															Límpido e Incolor
Tecnécio-99m Lot # E-20210609-003		09/06/2021	02:56	PP	Butanona	3MM Whatman			15		717	0 pH (Low/Actual/High)	97,951 %		Pass
													5,00 <= 6,00		<= 6,00
															Límpido e Incolor
Tecnécio-99m Lot # E-20210609-004		09/06/2021	03:00	PP	Butanona	3MM Whatman			2		1100	0 pH (Low/Actual/High)	99,819 %		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-20210609-005		09/06/2021 03:08 PP	Butanona		3MM Whatman			2		1100	0		99,819 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210609-006		09/06/2021 03:08 PP	Butanona		3MM Whatman			3		863	0		99,654 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210609-007		09/06/2021 03:39 PP	Butanona		3MM Whatman			17		1153	0		98,547 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210609-008		09/06/2021 03:42 PP	Butanona		3MM Whatman			27		2031	0		98,688 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210609-009		09/06/2021 04:04 PP	Butanona		3MM Whatman			8		579	0		98,637 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210609-010		09/06/2021 04:07 PP	Butanona		3MM Whatman			9		632	0		98,596 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210609-011		09/06/2021 04:15 PP	Butanona		3MM Whatman			62		3998	0		98,473 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210609-012		09/06/2021 04:26 PP	Butanona		3MM Whatman			18		856	0		97,941 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210609-014		09/06/2021 07:07 FN	Butanona		3MM Whatman			3		212	0		98,605 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210609-013		09/06/2021 07:07 FN	Butanona		3MM Whatman			2		835	0		99,761 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210609-015		09/06/2021 07:29 FN	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-20210609-016		09/06/2021 07:34 FN	Butanona		3MM Whatman			3		993	0		99,699 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210609-017		09/06/2021 07:43 FN	Butanona		3MM Whatman			3		854	0		99,65 %	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-20210609-018	09/06/2021	08:05	FN	Butanona		3MM Whatman		1		555	0	99,82 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210609-019	09/06/2021	08:17	FN	Butanona		3MM Whatman		3		347	0	99,143 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210609-020	09/06/2021	08:25	FN	Butanona		3MM Whatman		3		897	0	99,667 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210609-022	09/06/2021	10:12	BB	Butanona		3MM Whatman		1		851	0	99,883 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210609-023	09/06/2021	10:15	BB	Butanona		3MM Whatman		2		795	0	99,749 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210609-024	09/06/2021	10:23	BB	Butanona		3MM Whatman		4		673	0	99,409 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210609-025	09/06/2021	10:29	WG	Butanona		3MM Whatman		23		803	0	97,215 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210609-026	09/06/2021	10:46	WG	Butanona		3MM Whatman		0,8		103,9	0	99,236 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210609-027	09/06/2021	10:50	WG	Butanona		3MM Whatman		10		944	0	98,952 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
TRODAT-99mTc Lot # K-20210609-034	09/06/2021	10:15	WG	Normal Saline		Sílica gel		82,9		2,7	0	96,606 %	Pass	
				Butanona		3MM Whatman		0,3		124,8	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							