



# 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 24/06/2021 To 24/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210624-010		24/06/2021	04:02	PP	Butanona Normal Saline	3MM Whatman Sílica gel	1073 32		3 2558	0	pH (Low/Actual/High)	98,486 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210624-019		24/06/2021	07:37	WG	Butanona Normal Saline	3MM Whatman Sílica gel	199 2,3		3 164,9	0	pH (Low/Actual/High)	97,139 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210624-020		24/06/2021	07:38	WG	Butanona Normal Saline	3MM Whatman Sílica gel	156,7 5,3		1 122,3	0	pH (Low/Actual/High)	95,212 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210624-023		24/06/2021	08:01	WG	Butanona Normal Saline	3MM Whatman Sílica gel	126 0,2		0,7 107,1	0	pH (Low/Actual/High)	99,261 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210624-035		24/06/2021	11:14	WG	Butanona Normal Saline	3MM Whatman Sílica gel	296 2		5 231	0	pH (Low/Actual/High)	97,481 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210624-015		24/06/2021	07:01	JS	Citrato de Sódio 0,1M	Sílica gel	25,1		0,2	0	pH (Low/Actual/High)	99,209 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210624-038		24/06/2021	13:08	JS	Citrato de Sódio 0,1M	Sílica gel	36,2		0,3	0	pH (Low/Actual/High)	99,178 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210624-008	RPH	24/06/2021	03:56	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	928 35		5 1210	0	pH (Low/Actual/High)	96,653 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210624-014	RPH	24/06/2021	04:28	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	256 18		3 380	0	pH (Low/Actual/High)	94,319 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210624-021	RPH	24/06/2021	07:40	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	217 2,2		2 122,9	0	pH (Low/Actual/High)	97,328 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210624-036	RPH	24/06/2021	11:16	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	347 28		3 505	0	pH (Low/Actual/High)	93,89 %	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
FITATO-99mTc Lot # K-20210624-009	24/06/2021	03:58	PP	Butanona		3MM Whatman		361		2	0	99,449 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 7,00	
												Límpido/Incolor		
FITATO-99mTc Lot # K-20210624-018	24/06/2021	07:27	WG	Butanona		3MM Whatman		452		3	0	99,341 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00 <= 7,00	
												Límpido/Incolor		
MAA-99mTc Lot # K-20210624-011	24/06/2021	04:02	PP	Butanona		3MM Whatman		71		2	0	97,26 %	Pass	
												pH (Low/Actual/High)	3,00 <= 3,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20210624-012	24/06/2021	04:06	PP	Butanona		3MM Whatman		126		4	0	96,923 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20210624-013	24/06/2021	04:08	PP	Butanona		3MM Whatman		143		2	0	98,621 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20210624-037	24/06/2021	11:19	WG	Butanona		3MM Whatman		143,1		0,8	0	99,444 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00	
												Turvo/Incolor		
MDP-99mTc Lot # K-20210624-004	24/06/2021	03:16	PP	Acetona		3MM Whatman		794		1	0	97,887 %	Pass	
				Normal Saline		3MM Whatman		18		888		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20210624-005	24/06/2021	03:19	PP	Acetona		3MM Whatman		1215		2	0	98,135 %	Pass	
				Normal Saline		3MM Whatman		31		1792		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20210624-007	24/06/2021	03:54	PP	Acetona		3MM Whatman		844		1	0	95,485 %	Pass	
				Normal Saline		3MM Whatman		70		1522		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20210624-017	24/06/2021	07:13	WG	Acetona		3MM Whatman		824		8	0	98,818 %	Pass	
				Normal Saline		3MM Whatman		3		1358		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20210624-034	24/06/2021	11:03	WG	Acetona		3MM Whatman		434		4	0	96,033 %	Pass	
				Normal Saline		3MM Whatman		31		984		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210624-001	24/06/2021	01:42	BB	Normal Saline		Sílica gel		1079		30	0	96,052 %	Pass	
				Metanol		3MM Whatman		25		1986		pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210624-002	24/06/2021	02:57	PP	Normal Saline		Sílica gel		1286		25	0	96,393 %	Pass	
				Metanol		3MM Whatman		36		2081		pH (Low/Actual/High)	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-20210624-003	24/06/2021	03:02	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2382 21		51 2516	0	pH (Low/Actual/High)	97,076 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210624-006	24/06/2021	03:51	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			742 7		16 507	0	pH (Low/Actual/High)	96,527 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210624-016	24/06/2021	07:04	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1853 7		39 2511	0	pH (Low/Actual/High)	97,661 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210624-022	24/06/2021	07:43	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			823 2		4 1005	0	pH (Low/Actual/High)	99,318 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210624-025	24/06/2021	10:07	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			1186 10		5 717	0	pH (Low/Actual/High)	98,205 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210624-026	24/06/2021	10:22	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			995 5		12 973	0	pH (Low/Actual/High)	98,297 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210624-027	24/06/2021	10:31	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			1028 6		12 671	0	pH (Low/Actual/High)	97,96 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210624-039	24/06/2021	14:10	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1115 8		2 1094	0	pH (Low/Actual/High)	99,095 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
PSMA-68Ga Lot # K-20210624-024	24/06/2021	09:40	JS	Acetato de amônio	Sílica gel			0,4		59,3	0	pH (Low/Actual/High)	99,33 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
PSMA-68Ga Lot # K-20210624-028	24/06/2021	10:38	JS	Acetato de amônio	Sílica gel			0,5		82,9	0	pH (Low/Actual/High)	99,40 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210624-001	24/06/2021	01:39	BB	Butanona	3MM Whatman			2		297	0	pH (Low/Actual/High)	99,331 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210624-002	24/06/2021	02:15	PP	Butanona	3MM Whatman			3		165	0	pH (Low/Actual/High)	98,214 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210624-003	24/06/2021	02:56	PP	Butanona	3MM Whatman			22		1075	0	pH (Low/Actual/High)	97,995 %	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-20210624-004		24/06/2021 02:59	PP	Butanona		3MM Whatman		9		687	0	98,707 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-005		24/06/2021 03:14	PP	Butanona		3MM Whatman		6		857	0	99,305 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-006		24/06/2021 03:49	PP	Butanona		3MM Whatman		2		552	0	99,639 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-007		24/06/2021 03:49	PP	Butanona		3MM Whatman		38		1059	0	96,536 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-008		24/06/2021 04:00	PP	Butanona		3MM Whatman		2		705	0	99,717 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-009		24/06/2021 04:25	PP	Butanona		3MM Whatman		23		474	0	95,372 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-011		24/06/2021 07:01	WG	Butanona		3MM Whatman		2		216	0	99,083 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-012		24/06/2021 07:12	WG	Butanona		3MM Whatman		22		492	0	95,72 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-013		24/06/2021 07:16	WG	Butanona		3MM Whatman		3		210	0	98,592 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-014		24/06/2021 07:38	WG	Butanona		3MM Whatman		11		553	0	98,05 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-015		24/06/2021 07:41	WG	Butanona		3MM Whatman		8		211	0	96,347 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-017		24/06/2021 10:03	JS	Butanona		3MM Whatman		1		223	0	99,554 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210624-018		24/06/2021 10:20	JS	Butanona		3MM Whatman		2,5		192,7	0	98,719 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	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-20210624-019	24/06/2021	10:24	JS	Butanona	3MM	Whatman		2		460	0	99,567 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20210624-020	24/06/2021	10:24	JS	Butanona	3MM	Whatman		4		690	0	99,424 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210624-022	24/06/2021	10:55	JS	Butanona	3MM	Whatman		3		751	0	99,602 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210624-023	24/06/2021	11:01	JS	Butanona	3MM	Whatman		7		188	0	96,41 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210624-024	24/06/2021	11:12	WG	Butanona	3MM	Whatman		36		1380	0	97,458 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210624-026	24/06/2021	14:07	WG	Butanona	3MM	Whatman		64		1411	0	95,661 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
TRODAT-99mTc Lot # K-20210624-029	24/06/2021	10:51	WG	Normal Saline	Sílica gel			123,8		2,5	0	92,911 %	Pass	
				Butanona	3MM	Whatman		7		130	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20210624-030	24/06/2021	10:52	WG	Normal Saline	Sílica gel			157,9		2	0	95,255 %	Pass	
				Butanona	3MM	Whatman		5		138,1	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20210624-031	24/06/2021	10:53	WG	Normal Saline	Sílica gel			93,3		1	0	92,98 %	Pass	
				Butanona	3MM	Whatman		5		78,9	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20210624-032	24/06/2021	10:54	JS	Normal Saline	Sílica gel			23,6		0,2	0	96,753 %	Pass	
				Butanona	3MM	Whatman		0,9		36,5	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20210624-033	24/06/2021	10:58	JS	Normal Saline	Sílica gel			59,6		0,3	0	99,117 %	Pass	
				Butanona	3MM	Whatman		0,2		52,1	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
							Límpido/Incolor							