



# 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 26/08/2021 To 26/08/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210826-025		26/08/2021	07:59	FN	Butanona Normal Saline	3MM Whatman Sílica gel	177,1 4,4		2,3 129,1	0	pH (Low/Actual/High)	95,422 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210826-026		26/08/2021	08:01	FN	Butanona Normal Saline	3MM Whatman Sílica gel	178,5 5,8		0,5 163,4	0	pH (Low/Actual/High)	96,293 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210826-036		26/08/2021	10:09	YD	Butanona Normal Saline	3MM Whatman Sílica gel	109,5 2,5		0,9 57,2	0	pH (Low/Actual/High)	94,997 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210826-017		26/08/2021	07:02	FN	Citrato de Sódio 0,1M	Sílica gel	20,62		0,23	0	pH (Low/Actual/High)	98,897 %	Pass 4,00 <= 6,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210826-050		26/08/2021	12:32	JS	Citrato de Sódio 0,1M	Sílica gel	14,3		0,2	0	pH (Low/Actual/High)	98,621 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210826-051		26/08/2021	13:22	JS	Citrato de Sódio 0,1M	Sílica gel	12,9		0,2	0	pH (Low/Actual/High)	98,473 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210826-052		26/08/2021	15:38	YD	Citrato de Sódio 0,1M	Sílica gel	9,23		0,02	0	pH (Low/Actual/High)	99,784 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210826-053		26/08/2021	16:23	JS	Citrato de Sódio 0,1M	Sílica gel	19,5		0,2	0	pH (Low/Actual/High)	98,985 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210826-008	RPH	26/08/2021	03:36	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	732 29		3 753	0	pH (Low/Actual/High)	95,883 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210826-014	RPH	26/08/2021	04:04	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1585 39		10 969	0	pH (Low/Actual/High)	95,504 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210826-022	RPH	26/08/2021	07:36	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	621 13		3 590	0	pH (Low/Actual/High)	97,363 %	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-20210826-028	RPH	26/08/2021 09:14	PP	Acetona Normal Saline	3MM	Whatman		431 6		1 265	0	pH (Low/Actual/High)	97,554 %	Pass 3,80 <= 6,00 <= 7,50
												Límpido/Incolor		
FITATO-99mTc Lot # K-20210826-004		26/08/2021 03:23	PP	Butanona	3MM	Whatman		141		6	0	pH (Low/Actual/High)	95,918 %	Pass 5,00 <= 6,00 <= 7,00
												Límpido/Incolor		
FITATO-99mTc Lot # K-20210826-030		26/08/2021 09:34	YD	Butanona	3MM	Whatman		436		1	0	pH (Low/Actual/High)	99,771 %	Pass 5,00 <= 6,00 <= 7,00
												Límpido/Incolor		
MAA-99mTc Lot # K-20210826-009		26/08/2021 03:53	PP	Butanona	3MM	Whatman		266		1	0	pH (Low/Actual/High)	99,625 %	Pass 3,00 <= 6,00 <= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210826-010		26/08/2021 03:55	PP	Butanona	3MM	Whatman		120		1	0	pH (Low/Actual/High)	99,174 %	Pass 3,00 <= 6,00 <= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210826-011		26/08/2021 03:57	PP	Butanona	3MM	Whatman		90		1	0	pH (Low/Actual/High)	98,901 %	Pass 3,00 <= 6,00 <= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210826-012		26/08/2021 03:58	PP	Butanona	3MM	Whatman		175		3	0	pH (Low/Actual/High)	98,315 %	Pass 3,00 <= 6,00 <= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210826-013		26/08/2021 04:01	PP	Butanona	3MM	Whatman		117		2	0	pH (Low/Actual/High)	98,319 %	Pass 3,00 <= 6,00 <= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210826-023		26/08/2021 07:40	FN	Butanona	3MM	Whatman		333		5	0	pH (Low/Actual/High)	98,521 %	Pass 3,00 <= 6,00 <= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210826-029		26/08/2021 09:24	PP	Butanona	3MM	Whatman		301		2	0	pH (Low/Actual/High)	99,34 %	Pass 3,00 <= 6,00 <= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210826-032		26/08/2021 09:52	YD	Butanona	3MM	Whatman		121,7		0,7	0	pH (Low/Actual/High)	99,428 %	Pass 3,00 <= 5,00 <= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210826-033		26/08/2021 09:53	YD	Butanona	3MM	Whatman		111,1		1,1	0	pH (Low/Actual/High)	99,02 %	Pass 3,00 <= 5,00 <= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210826-039		26/08/2021 10:27	YD	Butanona	3MM	Whatman		59,5		1	0	pH (Low/Actual/High)	98,347 %	Pass 3,00 <= 5,00 <= 6,00
												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-20210826-040		26/08/2021 10:33	YD	Butanona		3MM Whatman		125		1,5	0	98,814 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210826-047		26/08/2021 11:15	JS	Butanona		3MM Whatman		76		0,2	0	99,738 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MDP-99mTc Lot # K-20210826-005		26/08/2021 03:31	PP	Acetona		3MM Whatman		530		2	0	98,267 %	Pass	
				Normal Saline		3MM Whatman		9		654	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210826-006		26/08/2021 03:32	PP	Acetona		3MM Whatman		1159		3	0	97,073 %	Pass	
				Normal Saline		3MM Whatman		38		1386	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210826-015		26/08/2021 04:06	PP	Acetona		3MM Whatman		1123		7	0	97,477 %	Pass	
				Normal Saline		3MM Whatman		23		1185	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210826-020		26/08/2021 07:23	FN	Acetona		3MM Whatman		669,5		2,1	0	99,219 %	Pass	
				Normal Saline		3MM Whatman		4,3		914,1	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210826-021		26/08/2021 07:26	FN	Acetona		3MM Whatman		1019		5	0	99,414 %	Pass	
				Normal Saline		3MM Whatman		1		1026	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210826-027		26/08/2021 08:54	PP	Acetona		3MM Whatman		444		1	0	99,453 %	Pass	
				Normal Saline		3MM Whatman		1		309	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210826-001		26/08/2021 02:41	GS	Normal Saline		Sílica gel		805		9	0	97,038 %	Pass	
				Metanol		3MM Whatman		29		1533	pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210826-002		26/08/2021 02:49	PP	Normal Saline		Sílica gel		1027		9	0	98,703 %	Pass	
				Metanol		3MM Whatman		10		2327	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210826-003		26/08/2021 02:58	PP	Normal Saline		Sílica gel		1443		16	0	98,251 %	Pass	
				Metanol		3MM Whatman		11		1676	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210826-016		26/08/2021 04:09	PP	Normal Saline		Sílica gel		2238		30	0	97,677 %	Pass	
				Metanol		3MM Whatman		28		2770	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210826-018		26/08/2021 07:11	FN	Normal Saline		Sílica gel		556		10	0	97,867 %	Pass	
				Metanol		3MM Whatman		2		544	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-20210826-024	26/08/2021	07:57 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			576 7		12 715	0	pH (Low/Actual/High)	96,99 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210826-031	26/08/2021	09:50 YD	Normal Saline Metanol		Sílica gel 3MM Whatman			1324 1		18 1162	0	pH (Low/Actual/High)	98,573 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210826-038	26/08/2021	10:16 YD	Normal Saline Metanol		Sílica gel 3MM Whatman			792 3		9 509	0	pH (Low/Actual/High)	98,29 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210826-045	26/08/2021	10:55 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			426 1		7 469	0	pH (Low/Actual/High)	98,171 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210826-046	26/08/2021	11:09 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			279 10		1 717	0	pH (Low/Actual/High)	98,267 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210826-048	26/08/2021	11:19 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			169 5		2 223	0	pH (Low/Actual/High)	96,637 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210826-049	26/08/2021	11:28 YD	Normal Saline Metanol		Sílica gel 3MM Whatman			630 0,6		5 193,4	0	pH (Low/Actual/High)	98,903 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
PIRO-99mTc Lot # K-20210826-007	26/08/2021	03:34 PP	Butanona Normal Saline		3MM Whatman 3MM Whatman			818 35		1 412	0	pH (Low/Actual/High)	92,048 %	Pass 5,00 <= 6,00 <= 7,00
							Límpido/Incolor							
PSMA-68Ga Lot # K-20210826-035	26/08/2021	10:04 YD	Acetato de amônio 1M:Metanol		Sílica gel			0,7		37,1	0	pH (Low/Actual/High)	98,148 %	Pass 4,00 <= 6,00 <= 8,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210826-001	26/08/2021	02:26 GS	Butanona		3MM Whatman			10		1563	0	pH (Low/Actual/High)	99,364 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210826-002	26/08/2021	02:39 PP	Butanona		3MM Whatman			6		1730	0	pH (Low/Actual/High)	99,654 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210826-003	26/08/2021	02:55 PP	Butanona		3MM Whatman			9		487	0	pH (Low/Actual/High)	98,185 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210826-004	26/08/2021	03:04 PP	Butanona		3MM Whatman			1		636	0	pH (Low/Actual/High)	99,843 %	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-20210826-005		26/08/2021 03:19 PP	Butanona		3MM	Whatman		4		621	0	99,36 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-006		26/08/2021 03:28 PP	Butanona		3MM	Whatman		4		732	0	99,457 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-007		26/08/2021 03:51 PP	Butanona		3MM	Whatman		24		760	0	96,939 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-008		26/08/2021 04:02 PP	Butanona		3MM	Whatman		17		325	0	95,029 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-010		26/08/2021 07:09 FN	Butanona		3MM	Whatman		1,5		289,3	0	99,484 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-011		26/08/2021 07:18 FN	Butanona		3MM	Whatman		3,4		288,6	0	98,836 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-012		26/08/2021 07:19 FN	Butanona		3MM	Whatman		0,3		91,82	0	99,674 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-013		26/08/2021 07:26 FN	Butanona		3MM	Whatman		3		876	0	99,659 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-014		26/08/2021 07:51 FN	Butanona		3MM	Whatman		1		220	0	99,548 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-015		26/08/2021 08:52 PP	Butanona		3MM	Whatman		2		432	0	99,539 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-016		26/08/2021 09:12 PP	Butanona		3MM	Whatman		1		347	0	99,713 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-017		26/08/2021 09:31 PP	Butanona		3MM	Whatman		16		332	0	95,402 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210826-018		26/08/2021 09:39 PP	Butanona		3MM	Whatman		14		413	0	96,721 %	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-20210826-019	26/08/2021	09:56 YD	Butanona		3MM	Whatman		0,4		102	0		99,609 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210826-021	26/08/2021	10:13 YD	Butanona		3MM	Whatman		0,1		84,5	0		99,882 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210826-022	26/08/2021	10:23 YD	Butanona		3MM	Whatman		1		211	0		99,528 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210826-023	26/08/2021	10:39 JS	Butanona		3MM	Whatman		1,5		88,4	0		98,331 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210826-024	26/08/2021	10:52 YD	Butanona		3MM	Whatman		1		507	0		99,803 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210826-025	26/08/2021	11:06 YD	Butanona		3MM	Whatman		0,6		96,2	0		99,38 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210826-026	26/08/2021	11:12 BB	Butanona		3MM	Whatman		1		225	0		99,558 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210826-027	26/08/2021	11:16 JS	Butanona		3MM	Whatman		1		31	0		96,875 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210826-028	26/08/2021	11:26 JS	Butanona		3MM	Whatman		6		194	0		97,00 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
TRODAT-99mTc Lot # K-20210826-034	26/08/2021	10:04 MP	Normal Saline		Sílica gel			132		3	0		96,958 %	Pass
			Butanona		3MM	Whatman		1		121		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210826-037	26/08/2021	10:11 MP	Normal Saline		Sílica gel			107		4	0		94,533 %	Pass
			Butanona		3MM	Whatman		3		158		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210826-041	26/08/2021	10:47 JS	Normal Saline		Sílica gel			99		0,9	0		95,395 %	Pass
			Butanona		3MM	Whatman		3		78		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210826-042	26/08/2021	10:48 JS	Normal Saline		Sílica gel			63		3	0		93,631 %	Pass
			Butanona		3MM	Whatman		1,3		70		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														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
TRODAT-99mTc		26/08/2021 10:49	JS	Normal Saline	Silica gel			108		3	0	94,944 %	Pass	
Lot # K-20210826-043				Butanona	3MM Whatman			2		83	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			
TRODAT-99mTc		26/08/2021 10:50	JS	Normal Saline	Silica gel			61		2	0	96,124 %	Pass	
Lot # K-20210826-044				Butanona	3MM Whatman			1,2		170	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			