



# 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 16/08/2021 To 16/08/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210816-023		16/08/2021	07:37	FN	Butanona	3MM Whatman	144,2		2,5	0	pH (Low/Actual/High)	91,258 %	Pass
					Normal Saline	Silica gel	10,1		133,4	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20210816-024		16/08/2021	07:39	FN	Butanona	3MM Whatman	172,4		2,2	0	pH (Low/Actual/High)	91,551 %	Pass
					Normal Saline	Silica gel	13,5		174,3	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20210816-045		16/08/2021	10:18	LG	Butanona	3MM Whatman	107		2	0	pH (Low/Actual/High)	95,892 %	Pass
					Normal Saline	Silica gel	1,5		64,5	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20210816-047		16/08/2021	10:45	LG	Butanona	3MM Whatman	67		1	0	pH (Low/Actual/High)	92,647 %	Pass
					Normal Saline	Silica gel	7		112	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210816-039		16/08/2021	09:51	LG	Citrato de Sódio 0,1M	Silica gel	12,7		0,3	0	pH (Low/Actual/High)	97,692 %	Pass
												4,00 <= 5,00 <= 8,00	
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210816-052		16/08/2021	15:44	JS	Citrato de Sódio 0,1M	Silica gel	42,8		0,4	0	pH (Low/Actual/High)	99,074 %	Pass
												4,00 <= 7,00 <= 8,00	
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210816-053		16/08/2021	16:39	JS	Citrato de Sódio 0,1M	Silica gel	9,9		0,1	0	pH (Low/Actual/High)	99,00 %	Pass
												4,00 <= 7,00 <= 8,00	
Límpido e Incolor													
DTPA-99mTc Lot # K-20210816-016	RPH	16/08/2021	04:15	PP	Acetona	3MM Whatman	1076		23	0	pH (Low/Actual/High)	96,175 %	Pass
					Normal Saline	3MM Whatman	11		624	3,80 <= 6,00 <= 7,50			
Límpido/Incolor													
DTPA-99mTc Lot # K-20210816-046	RPH	16/08/2021	10:42	LG	Acetona	3MM Whatman	64		0,1	0	pH (Low/Actual/High)	95,889 %	Pass
					Normal Saline	3MM Whatman	7		170	3,80 <= 5,00 <= 7,50			
Límpido/Incolor													
FITATO-99mTc Lot # K-20210816-011		16/08/2021	03:44	PP	Butanona	3MM Whatman	141		3	0	pH (Low/Actual/High)	97,917 %	Pass
												5,00 <= 6,00 <= 7,00	
Límpido/Incolor													
FITATO-99mTc Lot # K-20210816-022		16/08/2021	07:19	FN	Butanona	3MM Whatman	177,5		2,2	0	pH (Low/Actual/High)	98,776 %	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
FITATO-99mTc Lot # K-20210816-035		16/08/2021 09:08	LG	Butanona		3MM Whatman		97		0	0	100,00 %	Pass	
												pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00
												Límpido/Incolor		
MAA-99mTc Lot # K-20210816-012		16/08/2021 03:54	PP	Butanona		3MM Whatman		196		4	0	98,00 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210816-013		16/08/2021 03:56	PP	Butanona		3MM Whatman		185		5	0	97,368 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210816-014		16/08/2021 03:58	PP	Butanona		3MM Whatman		292		3	0	98,983 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210816-015		16/08/2021 03:59	PP	Butanona		3MM Whatman		137		3	0	97,857 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210816-027		16/08/2021 08:04	FN	Butanona		3MM Whatman		135,1		1,7	0	98,757 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210816-028		16/08/2021 08:07	FN	Butanona		3MM Whatman		99,9		1,2	0	98,813 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210816-029		16/08/2021 08:08	FN	Butanona		3MM Whatman		246		1	0	99,595 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210816-030		16/08/2021 08:11	FN	Butanona		3MM Whatman		149,2		0,2	0	99,866 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210816-031		16/08/2021 08:13	PP	Butanona		3MM Whatman		134		1	0	99,259 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210816-032		16/08/2021 08:24	PP	Butanona		3MM Whatman		123		1	0	99,194 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210816-037		16/08/2021 09:47	LG	Butanona		3MM Whatman		111		1	0	99,107 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210816-038		16/08/2021 09:49	LG	Butanona		3MM Whatman		100		1,5	0	98,522 %	Pass	
												pH (Low/Actual/High)	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-20210816-040		16/08/2021 09:52 LG	Butanona		3MM	Whatman		170		0,5	0		99,707 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210816-041		16/08/2021 09:59 LG	Butanona		3MM	Whatman		68		1	0		98,551 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210816-043		16/08/2021 10:14 LG	Butanona		3MM	Whatman		70		1	0		98,592 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210816-048		16/08/2021 10:51 LG	Butanona		3MM	Whatman		59		0,3	0		99,494 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210816-049		16/08/2021 11:01 JS	Butanona		3MM	Whatman		14,3		0,2	0		98,621 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210816-050		16/08/2021 11:04 LG	Butanona		3MM	Whatman		86		1	0		98,851 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MDP-99mTc Lot # K-20210816-008		16/08/2021 03:39 PP	Acetona		3MM	Whatman		1258		67	0		94,119 %	Pass
			Normal Saline		3MM	Whatman		8		962		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210816-009		16/08/2021 03:40 PP	Acetona		3MM	Whatman		922		1	0		99,173 %	Pass
			Normal Saline		3MM	Whatman		9		1243		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210816-010		16/08/2021 03:42 PP	Acetona		3MM	Whatman		1138		10	0		97,46 %	Pass
			Normal Saline		3MM	Whatman		14		825		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210816-020		16/08/2021 07:15 FN	Acetona		3MM	Whatman		1472		1	0		98,585 %	Pass
			Normal Saline		3MM	Whatman		16		1172		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210816-021		16/08/2021 07:16 FN	Acetona		3MM	Whatman		970		1	0		98,24 %	Pass
			Normal Saline		3MM	Whatman		17		1009		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210816-025		16/08/2021 07:54 PP	Acetona		3MM	Whatman		1075		40	0		95,936 %	Pass
			Normal Saline		3MM	Whatman		4		835		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210816-036		16/08/2021 09:45 LG	Acetona		3MM	Whatman		361		1	0		99,724 %	Pass
			Normal Saline		3MM	Whatman		0		267		pH (Low/Actual/High)	4,00 <= 5,00 <= 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
MIBI-99mTc Lot # K-20210816-001	16/08/2021	02:10 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			977 2		29 1666	0	pH (Low/Actual/High)	96,997 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210816-002	16/08/2021	02:19 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1086 60		28 2471	0	pH (Low/Actual/High)	95,116 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210816-003	16/08/2021	02:20 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2821 30		34 1900	0	pH (Low/Actual/High)	97,255 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210816-004	16/08/2021	02:41 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2757 15		85 2670	0	pH (Low/Actual/High)	96,45 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210816-005	16/08/2021	02:42 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1569 38		29 2087	0	pH (Low/Actual/High)	96,397 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210816-006	16/08/2021	02:46 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1762 25		57 2062	0	pH (Low/Actual/High)	95,669 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210816-007	16/08/2021	02:47 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1039 18		18 2221	0	pH (Low/Actual/High)	97,493 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210816-017	16/08/2021	06:54 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1934 7		30 1683	0	pH (Low/Actual/High)	98,058 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210816-018	16/08/2021	06:54 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1076 15		21 1735	0	pH (Low/Actual/High)	97,229 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210816-033	16/08/2021	09:01 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			865 8		36 1228	0	pH (Low/Actual/High)	95,357 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210816-034	16/08/2021	09:05 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			956 3		22 601	0	pH (Low/Actual/High)	97,254 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210816-019	16/08/2021	06:56 BB	Acetato de amônio 1M:Metanol		Sílica gel			0,2		11,1	0	pH (Low/Actual/High)	98,23 %	Pass 4,00 <= 4,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210816-051	16/08/2021	12:52 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,2		36,5	0	pH (Low/Actual/High)	99,455 %	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-20210816-001		16/08/2021 01:34 PP	Butanona			3MM Whatman		48		4149	0	98,856 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210816-002		16/08/2021 02:11 PP	Butanona			3MM Whatman		38		4170	0	99,097 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210816-003		16/08/2021 02:37 PP	Butanona			3MM Whatman		2		707	0	99,718 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210816-004		16/08/2021 02:44 PP	Butanona			3MM Whatman		5		1266	0	99,607 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210816-005		16/08/2021 03:37 PP	Butanona			3MM Whatman		5		5206	0	99,904 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210816-006		16/08/2021 03:52 PP	Butanona			3MM Whatman		3		943	0	99,683 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210816-007		16/08/2021 06:49 FN	Butanona			3MM Whatman		2		1093	0	99,817 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210816-009		16/08/2021 07:12 FN	Butanona			3MM Whatman		1		438	0	99,772 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210816-010		16/08/2021 07:35 FN	Butanona			3MM Whatman		7		1239	0	99,438 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210816-011		16/08/2021 08:54 LG	Butanona			3MM Whatman		4		375	0	98,945 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210816-012		16/08/2021 09:14 LG	Butanona			3MM Whatman		0		1740	0	100,00 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210816-014		16/08/2021 10:04 LG	Butanona			3MM Whatman		10		381	0	97,442 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
TRODAT-99mTc Lot # K-20210816-042		16/08/2021 10:02 LG	Normal Saline			Sílica gel		56		1	0	97,376 %	Pass	
			Butanona			3MM Whatman		0,5		57	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							