



# 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 20/05/2021 To 20/05/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210520-027		20/05/2021	08:07	MP	Butanona	3MM Whatman	293		5	0		92,072 %	Pass
					Normal Saline	Silica gel	9		135	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
					Límpido/Incolor								
DMSA-99mTc Lot # K-20210520-035		20/05/2021	10:24	SB	Butanona	3MM Whatman	194,3		4,7	0		94,816 %	Pass
					Normal Saline	Silica gel	5,3		182,5	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
					Límpido/Incolor								
DOTATOC-68Ga Lot # K-20210520-021		20/05/2021	06:53	MP	Citrato de Sódio 0,1M	Silica gel	32,6		0,3	0		99,088 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
					Límpido e Incolor								
DOTATOC-68Ga Lot # K-20210520-042		20/05/2021	12:41	JS	Citrato de Sódio 0,1M	Silica gel	45,9		0,8	0		98,287 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
					Límpido e Incolor								
DTPA-99mTc Lot # K-20210520-008	RPH	20/05/2021	03:33	PP	Acetona	3MM Whatman	829		31	0		96,098 %	Pass
					Normal Saline	3MM Whatman	3		1005	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
					Límpido/Incolor								
DTPA-99mTc Lot # K-20210520-014	RPH	20/05/2021	04:10	PP	Acetona	3MM Whatman	876		2	0		96,831 %	Pass
					Normal Saline	3MM Whatman	36		1188	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
					Límpido/Incolor								
DTPA-99mTc Lot # K-20210520-025	RPH	20/05/2021	07:41	MP	Acetona	3MM Whatman	599		3	0		94,607 %	Pass
					Normal Saline	3MM Whatman	44		855	pH (Low/Actual/High)	3,80 <= 5,00	<= 7,50	
					Límpido/Incolor								
DTPA-99mTc Lot # K-20210520-034	RPH	20/05/2021	10:20	SB	Acetona	3MM Whatman	722		4	0		99,157 %	Pass
					Normal Saline	3MM Whatman	2		684	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
					Límpido/Incolor								
FITATO-99mTc Lot # K-20210520-003		20/05/2021	03:20	PP	Butanona	3MM Whatman	641		2	0		99,689 %	Pass
										pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00	
					Límpido/Incolor								
FITATO-99mTc Lot # K-20210520-030		20/05/2021	08:40	MP	Butanona	3MM Whatman	779		1	0		99,872 %	Pass
										pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
					Límpido/Incolor								
HYNIC-iPSMA-Sn-99mTc Lot # K-20210520-019 Master Formulation Record:		20/05/2021	06:17	MP	Butanona	Silica gel	60,67		2	0		96,139 %	Pass
					Metanol/Acetato de Amonio 1	Silica gel	0,3		44,5	pH (Low/Actual/High)	6,00 <= 6,00	<= 7,50	

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210520-005		20/05/2021	03:27	PP	Butanona		3MM	Whatman	238		3	0	98,755 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MAA-99mTc Lot # K-20210520-006		20/05/2021	03:28	PP	Butanona		3MM	Whatman	399		1	0	99,75 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MAA-99mTc Lot # K-20210520-007		20/05/2021	03:29	PP	Butanona		3MM	Whatman	527		2	0	99,622 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MAA-99mTc Lot # K-20210520-010		20/05/2021	04:04	PP	Butanona		3MM	Whatman	189		3	0	98,438 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MAA-99mTc Lot # K-20210520-011		20/05/2021	04:05	PP	Butanona		3MM	Whatman	274		1	0	99,636 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MAA-99mTc Lot # K-20210520-012		20/05/2021	04:06	PP	Butanona		3MM	Whatman	320		3	0	99,071 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MAA-99mTc Lot # K-20210520-013		20/05/2021	04:08	PP	Butanona		3MM	Whatman	406		18	0	95,755 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MAA-99mTc Lot # K-20210520-018		20/05/2021	05:12	MP	Butanona		3MM	Whatman	109		3	0	97,321 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MAA-99mTc Lot # K-20210520-037		20/05/2021	10:42	SB	Butanona		3MM	Whatman	409		5	0	98,792 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MAA-99mTc Lot # K-20210520-038		20/05/2021	10:50	SB	Butanona		3MM	Whatman	326		5	0	98,489 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MAA-99mTc Lot # K-20210520-040		20/05/2021	10:58	SB	Butanona		3MM	Whatman	43,7		0,2	0	99,544 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MAA-99mTc Lot # K-20210520-041		20/05/2021	11:16	JS	Butanona		3MM	Whatman	34,9		0,9	0	97,486 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
												Turvo/Incolor			
MDP-99mTc Lot # K-20210520-004		20/05/2021	03:27	PP	Acetona		3MM	Whatman	1565		3	0	97,837 %	Pass	
					Normal Saline		3MM	Whatman	40		1989	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
												Limpido/Incolor			

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210520-016		20/05/2021 04:24 PP	Acetona Normal Saline		3MM Whatman 3MM Whatman			919 10		15 820	0 pH (Low/Actual/High)	97,189 % 4,00 <= 7,00 <= 7,80	Pass	
Límpido/Incolor														
MDP-99mTc Lot # K-20210520-015		20/05/2021 04:24 PP	Acetona Normal Saline		3MM Whatman 3MM Whatman			897 9		22 553	0 pH (Low/Actual/High)	96,005 % 4,00 <= 6,00 <= 7,80	Pass	
Límpido/Incolor														
MDP-99mTc Lot # K-20210520-020		20/05/2021 06:34 MP	Acetona Normal Saline		3MM Whatman 3MM Whatman			1044 18		2 948	0 pH (Low/Actual/High)	97,945 % 4,00 <= 6,00 <= 7,80	Pass	
Límpido/Incolor														
MDP-99mTc Lot # K-20210520-023		20/05/2021 07:25 MP	Acetona Normal Saline		3MM Whatman 3MM Whatman			474 9		1 565	0 pH (Low/Actual/High)	98,222 % 4,00 <= 6,00 <= 7,80	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210520-001		20/05/2021 02:45 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1701 3		13 3040	0 pH (Low/Actual/High)	99,143 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210520-002		20/05/2021 02:48 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2378 15		38 2950	0 pH (Low/Actual/High)	97,921 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210520-009		20/05/2021 03:55 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2625 14		30 2506	0 pH (Low/Actual/High)	98,315 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210520-017		20/05/2021 04:26 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2404 40		12 3471	0 pH (Low/Actual/High)	98,364 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210520-022		20/05/2021 07:07 MP	Normal Saline Metanol		Sílica gel 3MM Whatman			1042 19		20 1736	0 pH (Low/Actual/High)	97,034 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210520-024		20/05/2021 07:25 MP	Normal Saline Metanol		Sílica gel 3MM Whatman			652 8		9 662	0 pH (Low/Actual/High)	97,444 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210520-026		20/05/2021 07:59 MP	Normal Saline Metanol		Sílica gel 3MM Whatman			807 9		16 1241	0 pH (Low/Actual/High)	97,336 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210520-028		20/05/2021 08:03 MP	Normal Saline Metanol		Sílica gel 3MM Whatman			632 8		9 1125	0 pH (Low/Actual/High)	97,89 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210520-031		20/05/2021 10:04 SB	Normal Saline Metanol		Sílica gel 3MM Whatman			1201 5		9 1475	0 pH (Low/Actual/High)	98,918 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210520-033	20/05/2021	10:08	SB	Normal Saline Metanol	Sílica gel 3MM Whatman			691 1		7 885	0	pH (Low/Actual/High)	98,884 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210520-039	20/05/2021	10:56	SB	Normal Saline Metanol	Sílica gel 3MM Whatman			684 4		2 825	0	pH (Low/Actual/High)	99,226 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
PSMA-68Ga Lot # K-20210520-032	20/05/2021	10:08	SB	Acetato de amônio 1M:Metanol	Sílica gel			2		65,4	0	pH (Low/Actual/High)	97,033 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210520-001	20/05/2021	02:38	PP	Butanona	3MM Whatman			2		821	0	pH (Low/Actual/High)	99,757 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210520-002	20/05/2021	02:44	PP	Butanona	3MM Whatman			22		1127	0	pH (Low/Actual/High)	98,085 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210520-003	20/05/2021	03:06	PP	Butanona	3MM Whatman			3		832	0	pH (Low/Actual/High)	99,641 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210520-004	20/05/2021	03:17	PP	Butanona	3MM Whatman			12		633	0	pH (Low/Actual/High)	98,14 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210520-005	20/05/2021	03:24	PP	Butanona	3MM Whatman			11		497	0	pH (Low/Actual/High)	97,835 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210520-007	20/05/2021	03:31	PP	Butanona	3MM Whatman			4		182	0	pH (Low/Actual/High)	97,849 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210520-006	20/05/2021	03:31	PP	Butanona	3MM Whatman			12		653	0	pH (Low/Actual/High)	98,195 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210520-008	20/05/2021	03:51	PP	Butanona	3MM Whatman			2		3444	0	pH (Low/Actual/High)	99,942 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210520-009	20/05/2021	04:19	PP	Butanona	3MM Whatman			100		2099	0	pH (Low/Actual/High)	95,452 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210520-010	20/05/2021	04:20	PP	Butanona	3MM Whatman			7		4907	0	pH (Low/Actual/High)	99,858 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210520-011		20/05/2021 04:21	PP	Butanona		3MM Whatman		1		483	0	99,793 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-012		20/05/2021 06:10	MP	Butanona		3MM Whatman		7		814	0	99,147 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-014		20/05/2021 07:03	MP	Butanona		3MM Whatman		13		671	0	98,099 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-015		20/05/2021 07:21	MP	Butanona		3MM Whatman		19		1170	0	98,402 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-017		20/05/2021 07:23	MP	Butanona		3MM Whatman		1		1473	0	99,932 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-016		20/05/2021 07:23	MP	Butanona		3MM Whatman		2		332	0	99,401 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-018		20/05/2021 07:39	MP	Butanona		3MM Whatman		6		484	0	98,776 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-019		20/05/2021 07:55	MP	Butanona		3MM Whatman		1		352	0	99,717 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-020		20/05/2021 07:55	MP	Butanona		3MM Whatman		4		280	0	98,592 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-021		20/05/2021 08:02	MP	Butanona		3MM Whatman		4		845	0	99,529 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-022		20/05/2021 09:50	PP	Butanona		3MM Whatman		2		660	0	99,698 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-023		20/05/2021 10:06	PP	Butanona		3MM Whatman		5		477	0	98,963 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210520-026		20/05/2021 10:14	SB	Butanona		3MM Whatman		6		1277	0	99,532 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

Printed: 20/05/2021 17:46:18

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-20210520-027	20/05/2021	10:33	SB	Butanona	3MM	Whatman		1		840	0		99,881 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210520-028	20/05/2021	10:53	SB	Butanona	3MM	Whatman		10		1187	0		99,165 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
TRODAT-99mTc Lot # K-20210520-036	20/05/2021	10:29	SB	Normal Saline	Sílica gel			160		2	0		94,968 %	Pass
				Butanona	3MM	Whatman		9		228		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														Límpido/Incolor

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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