



# 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 17/05/2021 To 17/05/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210517-023		17/05/2021	07:33	JS	Butanona	3MM Whatman	131		3	0		92,917 %	Pass
					Normal Saline	Silica gel	9		176,8	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
					Límpido/Incolor								
DMSA-99mTc Lot # K-20210517-026		17/05/2021	08:02	JS	Butanona	3MM Whatman	206		4	0		93,591 %	Pass
					Normal Saline	Silica gel	10		212	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
					Límpido/Incolor								
DMSA-99mTc Lot # K-20210517-031		17/05/2021	10:37	WG	Butanona	3MM Whatman	215		1	0		98,932 %	Pass
					Normal Saline	Silica gel	1,1		180,6	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
					Límpido/Incolor								
DOTATOC-68Ga Lot # K-20210517-029		17/05/2021	10:02	WG	Citrato de Sódio 0,1M	Silica gel	25,8		1,1	0		95,911 %	Pass
										pH (Low/Actual/High)	4,00 <= 7,00 <= 8,00		
					Límpido e Incolor								
DOTATOC-68Ga Lot # K-20210517-033		17/05/2021	11:00	WG	Citrato de Sódio 0,1M	Silica gel	34,1		0,2	0		99,417 %	Pass
										pH (Low/Actual/High)	4,00 <= 7,00 <= 8,00		
					Límpido e Incolor								
DTPA-99mTc Lot # K-20210517-011	RPH	17/05/2021	04:02	PP	Acetona	3MM Whatman	733		11	0		96,998 %	Pass
					Normal Saline	3MM Whatman	11		711	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
					Límpido/Incolor								
DTPA-99mTc Lot # K-20210517-030	RPH	17/05/2021	10:13	WG	Acetona	3MM Whatman	305		6	0		92,943 %	Pass
					Normal Saline	3MM Whatman	14		259	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
					Límpido/Incolor								
DTPA-99mTc Lot # K-20210517-034	RPH	17/05/2021	11:15	WG	Acetona	3MM Whatman	699		4	0		98,934 %	Pass
					Normal Saline	3MM Whatman	3		601	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
					Límpido/Incolor								
FITATO-99mTc Lot # K-20210517-010		17/05/2021	03:42	PP	Butanona	3MM Whatman	273		1	0		99,635 %	Pass
										pH (Low/Actual/High)	5,00 <= 6,00 <= 7,00		
					Límpido/Incolor								
FITATO-99mTc Lot # K-20210517-024		17/05/2021	07:36	JS	Butanona	3MM Whatman	507		18	0		96,571 %	Pass
										pH (Low/Actual/High)	5,00 <= 7,00 <= 7,00		
					Límpido/Incolor								
HYNIC-iPSMA-Sn-99mTc Lot # K-20210517-018 Master Formulation Record:		17/05/2021	06:37	MP	Butanona	Silica gel	151		4	0		95,112 %	Pass
					Metanol/Acetato de Amonio 1	Silica gel	6		254	pH (Low/Actual/High)	6,00 <= 6,50 <= 7,50		

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

Printed: 17/05/2021 17:39:45

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-20210517-014		17/05/2021 04:50	PP	Butanona		3MM Whatman		210		1	0	99,526 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210517-015		17/05/2021 04:53	PP	Butanona		3MM Whatman		205		1	0	99,515 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210517-016		17/05/2021 04:54	PP	Butanona		3MM Whatman		222		1	0	99,552 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210517-025		17/05/2021 07:37	JS	Butanona		3MM Whatman		192		3	0	98,462 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210517-032		17/05/2021 10:55	WG	Butanona		3MM Whatman		215		34	0	86,345 %	Fail	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210517-035		17/05/2021 11:23	WG	Butanona		3MM Whatman		83,8		0,6	0	99,289 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MDP-99mTc Lot # K-20210517-006		17/05/2021 03:25	PP	Acetona		3MM Whatman		826		4	0	97,836 %	Pass	
				Normal Saline		3MM Whatman		20		1169	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210517-007		17/05/2021 03:32	PP	Acetona		3MM Whatman		1023		5	0	98,219 %	Pass	
				Normal Saline		3MM Whatman		12		915	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210517-008		17/05/2021 03:35	PP	Acetona		3MM Whatman		561		6	0	97,463 %	Pass	
				Normal Saline		3MM Whatman		10		666	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210517-012		17/05/2021 04:11	PP	Acetona		3MM Whatman		315		1	0	99,191 %	Pass	
				Normal Saline		3MM Whatman		2		404	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210517-020		17/05/2021 06:50	JS	Acetona		3MM Whatman		1313		3	0	94,598 %	Pass	
				Normal Saline		3MM Whatman		49		898	pH (Low/Actual/High)	4,00 <= 7,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210517-022		17/05/2021 07:11	JS	Acetona		3MM Whatman		1245		6	0	97,83 %	Pass	
				Normal Saline		3MM Whatman		21		1221	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210517-027		17/05/2021 08:17	JS	Acetona		3MM Whatman		2290		20	0	98,858 %	Pass	
				Normal Saline		3MM Whatman		4		1444	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			

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

Printed: 17/05/2021 17:39:45

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-20210517-028	17/05/2021	10:01	WG	Acetona Normal Saline	3MM	Whatman		1704 2		4 1324	0 pH (Low/Actual/High)	99,615 %		Pass 5,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20210517-001	17/05/2021	02:19	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		1818 3		34 349	0 pH (Low/Actual/High)	97,312 %		Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210517-002	17/05/2021	02:23	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		234 102		345 255	0 pH (Low/Actual/High)	11,843 %		Fail 5,00 <= 5,50 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210517-003	17/05/2021	02:30	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		209 9		2 343	0 pH (Low/Actual/High)	96,495 %		Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210517-004	17/05/2021	02:31	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		277 2		5 362	0 pH (Low/Actual/High)	97,677 %		Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210517-005	17/05/2021	03:24	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		307 38		4 3016	0 pH (Low/Actual/High)	97,47 %		Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210517-009	17/05/2021	03:36	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		359 5		2 1977	0 pH (Low/Actual/High)	99,194 %		Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210517-013	17/05/2021	04:42	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		513 29		4 587	0 pH (Low/Actual/High)	94,519 %		Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210517-019	17/05/2021	06:40	MP	Normal Saline Metanol	Sílica gel 3MM	Whatman		921 24		15 1330	0 pH (Low/Actual/High)	96,625 %		Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210517-021	17/05/2021	07:04	MP	Normal Saline Metanol	Sílica gel 3MM	Whatman		1513 28		34 1651	0 pH (Low/Actual/High)	96,135 %		Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210517-017	17/05/2021	06:34	MP	Acetato de amônio 1M:Metanol	Sílica gel			0,5		36,6	0 pH (Low/Actual/High)	98,652 %		Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210517-036	17/05/2021	12:28	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,7		49,9	0 pH (Low/Actual/High)	98,617 %		Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210517-001	17/05/2021	02:17	PP	Butanona	3MM	Whatman		9		1144	0 pH (Low/Actual/High)	99,219 %		Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														

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

Printed: 17/05/2021 17:39:46

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-20210517-002		17/05/2021 02:24 PP	Butanona		3MM	Whatman		16		375	0		95,908 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-003		17/05/2021 03:22 PP	Butanona		3MM	Whatman		21		1912	0		98,914 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-005		17/05/2021 03:30 PP	Butanona		3MM	Whatman		8		1363	0		99,416 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-004		17/05/2021 03:30 PP	Butanona		3MM	Whatman		3		1074	0		99,721 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-006		17/05/2021 03:35 PP	Butanona		3MM	Whatman		10		1234	0		99,196 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-007		17/05/2021 04:40 PP	Butanona		3MM	Whatman		1		1227	0		99,919 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-009		17/05/2021 06:37 MP	Butanona		3MM	Whatman		10		2566	0		99,612 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-010		17/05/2021 07:02 JS	Butanona		3MM	Whatman		6		1298	0		99,54 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-011		17/05/2021 07:59 JS	Butanona		3MM	Whatman		2		2870	0		99,93 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-012		17/05/2021 09:58 WG	Butanona		3MM	Whatman		5		3589	0		99,861 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-014		17/05/2021 10:46 WG	Butanona		3MM	Whatman		17		2497	0		99,324 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-017		17/05/2021 13:19 SB	Butanona		3MM	Whatman		4		236	0		98,333 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210517-018		17/05/2021 13:26 SB	Butanona		3MM	Whatman		3,6		624	0		99,426 %	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: 17/05/2021 17:39:46