



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 17/11/2021 To 17/11/2021

Product:	Manuf:	Calibration D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211117-029		17/11/2021 07:35	JS	Butanona Normal Saline	3MM Whatman Sílica gel	123 3		1,4 93	0		95,75 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20211117-030		17/11/2021 08:03	JS	Butanona Normal Saline	3MM Whatman Sílica gel	148 1		1,7 133	0		98,118 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20211117-039		17/11/2021 10:59	WG	Butanona Normal Saline	3MM Whatman Sílica gel	239 6		2 116,6	0		94,276 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DOTATOC-68Ga Lot # K-20211117-038		17/11/2021 09:49	FL	Citrato de Sódio 0,1M	Sílica gel	1113		50	0		95,701 %	Pass
					Límpido e Incolor				pH (Low/Actual/High)		4,00 <= 6,00	<= 8,00
DOTATOC-68Ga Lot # K-20211117-052		17/11/2021 15:51	JS	Citrato de Sódio 0,1M	Sílica gel	25,8		0,2	0		99,231 %	Pass
					Límpido e Incolor				pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
DTPA-99mTc Lot # K-20211117-017	RPH	17/11/2021 04:10	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1406 56		14 1001	0		93,716 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
DTPA-99mTc Lot # K-20211117-018	RPH	17/11/2021 04:12	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1204 31		4 1015	0		96,705 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
DTPA-99mTc Lot # K-20211117-027	RPH	17/11/2021 07:02	JS	Acetona Normal Saline	3MM Whatman 3MM Whatman	123 1		2 65	0		96,885 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 5,00	<= 7,50
DTPA-99mTc Lot # K-20211117-051	RPH	17/11/2021 12:52	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	374 2		5 298	0		98,014 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
FITATO-99mTc Lot # K-20211117-020		17/11/2021 04:30	PP	Butanona	3MM Whatman	370		12	0		96,859 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		5,00 <= 7,00	<= 7,00
MAA-99mTc Lot # K-20211117-019		17/11/2021 04:27	PP	Butanona	3MM Whatman	156		4	0		97,50 %	Pass
					Turvo/Incolor				pH (Low/Actual/High)		3,00 <= 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
MAA-99mTc Lot # K-20211117-032		17/11/2021 08:16	WG	Butanona		3MM Whatman		147,3		2,2	0		98,528 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211117-033		17/11/2021 08:18	WG	Butanona		3MM Whatman		245		1,4	0		99,432 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211117-040		17/11/2021 11:06	WG	Butanona		3MM Whatman		51,6		0,2	0		99,614 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211117-041		17/11/2021 11:08	WG	Butanona		3MM Whatman		122		1,4	0		98,865 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211117-042		17/11/2021 11:10	WG	Butanona		3MM Whatman		236		1	0		99,578 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211117-045		17/11/2021 11:46	WG	Butanona		3MM Whatman		270		2	0		99,265 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211117-046		17/11/2021 11:49	WG	Butanona		3MM Whatman		161,1		1,9	0		98,834 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211117-047		17/11/2021 11:51	WG	Butanona		3MM Whatman		175,2		4,1	0		97,713 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211117-048		17/11/2021 11:53	WG	Butanona		3MM Whatman		351		3	0		99,153 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20211117-014		17/11/2021 03:54	PP	Acetona		3MM Whatman		2057		10	0		98,621 %	Pass
				Normal Saline		3MM Whatman		14		1550		pH (Low/Actual/High)	4,00 <= 7,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211117-016		17/11/2021 04:08	PP	Acetona		3MM Whatman		2446		8	0		98,457 %	Pass
				Normal Saline		3MM Whatman		19		1542		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211117-023		17/11/2021 06:41	BB	Acetona		3MM Whatman		206		3	0		98,204 %	Pass
				Normal Saline		3MM Whatman		7		1935		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211117-026		17/11/2021 06:50	BB	Acetona		3MM Whatman		1299		4	0		99,352 %	Pass
				Normal Saline		3MM Whatman		3		878		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
MDP-99mTc Lot # K-20211117-028		17/11/2021 07:30	JS	Acetona Normal Saline	3MM	Whatman		124 3		4 183	0	pH (Low/Actual/High)	95,262 %	Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20211117-035		17/11/2021 09:14	WG	Acetona Normal Saline	3MM	Whatman		968 12		4 834	0	pH (Low/Actual/High)	98,17 %	Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20211117-036		17/11/2021 09:17	WG	Acetona Normal Saline	3MM	Whatman		504 2		6 388	0	pH (Low/Actual/High)	98,311 %	Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20211117-043		17/11/2021 11:14	WG	Acetona Normal Saline	3MM	Whatman		737 9		14 669	0	pH (Low/Actual/High)	96,808 %	Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20211117-050		17/11/2021 12:42	WG	Acetona Normal Saline	3MM	Whatman		487 9		2 578	0	pH (Low/Actual/High)	98,058 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20211117-004		17/11/2021 01:41	PP	Normal Saline Metanol	Sílica gel 3MM			3361 48		35 3594	0	pH (Low/Actual/High)	97,651 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20211117-006		17/11/2021 01:59	PP	Normal Saline Metanol	Sílica gel 3MM			866 3		16 882	0	pH (Low/Actual/High)	97,847 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20211117-007		17/11/2021 02:41	PP	Normal Saline Metanol	Sílica gel 3MM			1351 17		12 1881	0	pH (Low/Actual/High)	98,224 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20211117-008		17/11/2021 02:49	PP	Normal Saline Metanol	Sílica gel 3MM			1017 10		26 2096	0	pH (Low/Actual/High)	97,032 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20211117-009		17/11/2021 02:50	PP	Normal Saline Metanol	Sílica gel 3MM			1300 34		12 1980	0	pH (Low/Actual/High)	97,397 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20211117-010		17/11/2021 02:58	PP	Normal Saline Metanol	Sílica gel 3MM			1718 11		38 2452	0	pH (Low/Actual/High)	97,389 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20211117-011		17/11/2021 03:36	PP	Normal Saline Metanol	Sílica gel 3MM			4982 121		69 4783	0	pH (Low/Actual/High)	96,167 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20211117-012		17/11/2021 03:37	PP	Normal Saline Metanol	Sílica gel 3MM			4042 118		35 3548	0	pH (Low/Actual/High)	95,923 %	Pass
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-20211117-013		17/11/2021 03:40 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2119 22		23 1032	0	pH (Low/Actual/High)	96,839 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211117-015		17/11/2021 04:06 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2633 35		3 2300	0	pH (Low/Actual/High)	98,387 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211117-022		17/11/2021 06:31 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			1324 40		40 2302	0	pH (Low/Actual/High)	95,36 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211117-021		17/11/2021 06:31 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			2734 8		69 2978	0	pH (Low/Actual/High)	97,27 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211117-025		17/11/2021 06:47 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			316 2		4 281	0	pH (Low/Actual/High)	98,043 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211117-031		17/11/2021 08:00 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			805 7		10 930	0	pH (Low/Actual/High)	98,026 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211117-034		17/11/2021 08:22 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1042 5		12 377	0	pH (Low/Actual/High)	97,553 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211117-037		17/11/2021 09:26 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			688 17		7 591	0	pH (Low/Actual/High)	96,197 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211117-044		17/11/2021 11:15 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			1449 10		6 1333	0	pH (Low/Actual/High)	98,843 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
PSMA-177Lu Lot # K-20211117-001		17/11/2021 01:27 BB	Citrato de Sódio 0,1M		Sílica gel			536		2	0	pH (Low/Actual/High)	99,628 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 96,57%														
PSMA-177Lu Lot # K-20211117-002		17/11/2021 01:36 BB	Citrato de Sódio 0,1M		Sílica gel			697		1	0	pH (Low/Actual/High)	99,857 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 97,85%														
PSMA-177Lu Lot # K-20211117-003		17/11/2021 01:43 BB	Citrato de Sódio 0,1M		Sílica gel			538		3	0	pH (Low/Actual/High)	99,445 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 97,50%														

Product:	Manuf:	Calibration D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
PSMA-177Lu Lot # K-20211117-005	17/11/2021	01:55 BB	Citrato de Sódio 0,1M	Sílica gel				1149		1	0	99,913 %	Pass	
							Limpido				pH (Low/Actual/High)	4,00 <= 4,50 <= 5,00		
QC Notes: HPLC: 97,82%														
PSMA-68Ga Lot # K-20211117-024	17/11/2021	06:45 BB	Acetato de amônio 1M:Metanol	Sílica gel				0,7		44,2	0	98,441 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
PSMA-68Ga Lot # K-20211117-049	17/11/2021	12:33 JS	Acetato de amônio 1M:Metanol	Sílica gel				0,1		28,8	0	99,654 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
Tecnécio-99m Lot # E-20211117-001	17/11/2021	01:36 YD	Butanona	3MM Whatman				3		2555	0	99,883 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211117-002	17/11/2021	01:56 YD	Butanona	3MM Whatman				14		2583	0	99,461 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211117-003	17/11/2021	02:42 PP	Butanona	3MM Whatman				1		1795	0	99,944 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211117-004	17/11/2021	02:44 PP	Butanona	3MM Whatman				2		54	0	96,429 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211117-005	17/11/2021	03:32 PP	Butanona	3MM Whatman				8		1411	0	99,436 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211117-006	17/11/2021	03:32 PP	Butanona	3MM Whatman				6		1156	0	99,484 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211117-007	17/11/2021	04:04 PP	Butanona	3MM Whatman				23		2639	0	99,136 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211117-008	17/11/2021	04:24 PP	Butanona	3MM Whatman				23		4576	0	99,50 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211117-009	17/11/2021	06:18 BB	Butanona	3MM Whatman				19		811	0	97,711 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211117-010	17/11/2021	06:44 BB	Butanona	3MM Whatman				39		1783	0	97,859 %	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-20211117-012		17/11/2021 06:55	BB	Butanona		3MM Whatman		6		2235	0		99,732 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211117-013		17/11/2021 07:56	JS	Butanona		3MM Whatman		6		1722	0		99,653 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211117-014		17/11/2021 08:12	JS	Butanona		3MM Whatman		3		1094	0		99,727 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211117-015		17/11/2021 08:50	FL	Butanona		3MM Whatman		2		1158	0		99,828 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211117-016		17/11/2021 09:11	WG	Butanona		3MM Whatman		6		500	0		98,814 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211117-017		17/11/2021 09:23	WG	Butanona		3MM Whatman		3		251	0		98,819 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211117-019		17/11/2021 10:54	WG	Butanona		3MM Whatman		17		1438	0		98,832 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211117-020		17/11/2021 11:10	WG	Butanona		3MM Whatman		18		1766	0		98,991 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211117-021		17/11/2021 11:32	WG	Butanona		3MM Whatman		21		743	0		97,251 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211117-023		17/11/2021 12:45	WG	Butanona		3MM Whatman		0,5		199,3	0		99,75 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			