



# 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 17/01/2022 To 17/01/2022

Product:	Manuf:	Calibration D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20220117-021		17/01/2022 07:33	MB	Butanona Normal Saline	3MM Whatman Sílica gel	231 5,3		2 127,7	0	pH (Low/Actual/High)	95,157 %	Pass 2,00 <= 3,00 <= 3,00
					Límpido/Incolor							
DMSA-99mTc Lot # K-20220117-023		17/01/2022 08:05	GS	Butanona Normal Saline	3MM Whatman Sílica gel	211 10,7		1 172,7	0	pH (Low/Actual/High)	93,694 %	Pass 2,00 <= 3,00 <= 3,00
					Límpido/Incolor							
DMSA-99mTc Lot # K-20220117-032		17/01/2022 10:17	PM	Butanona Normal Saline	3MM Whatman Sílica gel	300 2		4 215	0	pH (Low/Actual/High)	97,763 %	Pass 2,00 <= 3,00 <= 3,00
					Límpido/Incolor							
DOTATOC-68Ga Lot # K-20220117-029		17/01/2022 09:57	PM	Citrato de Sódio 0,1M	Sílica gel	61,6		0,4	0	pH (Low/Actual/High)	99,355 %	Pass 4,00 <= 6,00 <= 8,00
					Límpido e Incolor							
DTPA-99mTc Lot # K-20220117-007	RPH	17/01/2022 03:41	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	978 12		23 850	0	pH (Low/Actual/High)	96,31 %	Pass 3,80 <= 7,00 <= 7,50
					Límpido/Incolor							
DTPA-99mTc Lot # K-20220117-008	RPH	17/01/2022 03:43	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	889 4		22 777	0	pH (Low/Actual/High)	97,073 %	Pass 3,80 <= 7,00 <= 7,50
					Límpido/Incolor							
DTPA-99mTc Lot # K-20220117-017	RPH	17/01/2022 06:43	GS	Acetona Normal Saline	3MM Whatman 3MM Whatman	488,9 30		6,5 1040	0	pH (Low/Actual/High)	95,884 %	Pass 3,80 <= 5,00 <= 7,50
					Límpido/Incolor							
DTPA-99mTc Lot # K-20220117-035	RPH	17/01/2022 10:55	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	748 4		2 653	0	pH (Low/Actual/High)	99,125 %	Pass 3,80 <= 6,00 <= 7,50
					Límpido/Incolor							
FITATO-99mTc Lot # K-20220117-009		17/01/2022 03:45	FN	Butanona	3MM Whatman	806		5	0	pH (Low/Actual/High)	99,383 %	Pass 5,00 <= 6,00 <= 7,00
					Límpido/Incolor							
FITATO-99mTc Lot # K-20220117-026		17/01/2022 08:49	PM	Butanona	3MM Whatman	591		3	0	pH (Low/Actual/High)	99,495 %	Pass 5,00 <= 7,00 <= 7,00
					Límpido/Incolor							
FITATO-99mTc Lot # K-20220117-038		17/01/2022 13:57	WG	Butanona	3MM Whatman	239		2,2	0	pH (Low/Actual/High)	99,088 %	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
MAA-99mTc Lot # K-20220117-012		17/01/2022 04:12	FN	Butanona		3MM Whatman		512		2	0	99,611 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20220117-024		17/01/2022 08:14	GS	Butanona		3MM Whatman		329		3	0	99,096 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20220117-033		17/01/2022 10:46	PM	Butanona		3MM Whatman		422		19	0	95,692 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20220117-034		17/01/2022 10:48	PM	Butanona		3MM Whatman		340		15	0	95,775 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MDP-99mTc Lot # K-20220117-010		17/01/2022 03:47	FN	Acetona		3MM Whatman		1239		4	0	98,707 %	Pass	
				Normal Saline		3MM Whatman		15		1530	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20220117-011		17/01/2022 03:50	FN	Acetona		3MM Whatman		1612		8	0	99,323 %	Pass	
				Normal Saline		3MM Whatman		3		1635	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20220117-016		17/01/2022 06:30	GS	Acetona		3MM Whatman		1400		1	0	97,708 %	Pass	
				Normal Saline		3MM Whatman		24		1057	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20220117-019		17/01/2022 07:23	GS	Acetona		3MM Whatman		1116		3	0	98,725 %	Pass	
				Normal Saline		3MM Whatman		11		1081	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20220117-020		17/01/2022 07:25	MB	Acetona		3MM Whatman		680		2	0	97,943 %	Pass	
				Normal Saline		3MM Whatman		16		891	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20220117-025		17/01/2022 08:28	MB	Acetona		3MM Whatman		1547		5	0	99,245 %	Pass	
				Normal Saline		3MM Whatman		5		1151	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20220117-031		17/01/2022 10:14	PM	Acetona		3MM Whatman		1798		4	0	98,817 %	Pass	
				Normal Saline		3MM Whatman		20		2061	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20220117-036		17/01/2022 11:08	PM	Acetona		3MM Whatman		1063		7	0	98,889 %	Pass	
				Normal Saline		3MM Whatman		5		1090	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MIBI-99mTc Lot # K-20220117-001		17/01/2022 02:28	FN	Normal Saline		Sílica gel		2910		20	0	98,36 %	Pass	
				Metanol		3MM Whatman		2		207	pH (Low/Actual/High)	5,00 <= 5,00	<= 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-20220117-002		17/01/2022 02:31 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1679 10		22 2290	0	pH (Low/Actual/High)	98,272 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220117-003		17/01/2022 02:32 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			2580 30		25 2160	0	pH (Low/Actual/High)	97,67 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220117-004		17/01/2022 02:52 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			2368 3		33 2456	0	pH (Low/Actual/High)	98,504 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220117-005		17/01/2022 02:53 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			2173 10		36 2713	0	pH (Low/Actual/High)	98,003 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220117-006		17/01/2022 03:38 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			2044 23		34 2719	0	pH (Low/Actual/High)	97,525 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220117-013		17/01/2022 06:22 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1519 36		28 1145	0	pH (Low/Actual/High)	95,142 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220117-014		17/01/2022 06:27 GS	Normal Saline Metanol		Sílica gel 3MM Whatman			210 5		5 219	0	pH (Low/Actual/High)	95,442 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220117-015		17/01/2022 06:28 GS	Normal Saline Metanol		Sílica gel 3MM Whatman			1646 2		33 222	0	pH (Low/Actual/High)	97,142 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220117-027		17/01/2022 09:28 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1568 7		10 1810	0	pH (Low/Actual/High)	98,981 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220117-028		17/01/2022 09:30 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1292 40		18 1697	0	pH (Low/Actual/High)	96,323 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220117-030		17/01/2022 10:11 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			2763 51		59 3795	0	pH (Low/Actual/High)	96,583 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20220117-022		17/01/2022 07:50 GS	Butanona Normal Saline		3MM Whatman 3MM Whatman			478 7		1 441	0	pH (Low/Actual/High)	98,229 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20220117-018		17/01/2022 06:51 GS	Acetato de amônio 1M:Metanol		Sílica gel			0,3		39,7	0	pH (Low/Actual/High)	99,25 %	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
PSMA-68Ga Lot # K-20220117-037		17/01/2022 12:41	MB	Acetato de amônio 1M:Metanol	Sílica gel			1,1		41,3	0		97,406 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00	
PSMA-68Ga Lot # K-20220117-039		17/01/2022 14:13	WG	Acetato de amônio 1M:Metanol	Sílica gel			0,3		12,3	0		97,619 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	4,00 <= 7,00 <= 8,00	
Tecnécio-99m Lot # E-20220117-001		17/01/2022 02:17	FN	Butanona		3MM Whatman		4		2098	0		99,81 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20220117-002		17/01/2022 02:20	FN	Butanona		3MM Whatman		4		1866	0		99,786 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20220117-003		17/01/2022 02:49	FN	Butanona		3MM Whatman		4		2980	0		99,866 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20220117-004		17/01/2022 03:36	FN	Butanona		3MM Whatman		4		2987	0		99,866 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20220117-005		17/01/2022 04:09	FN	Butanona		3MM Whatman		2		1225	0		99,837 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20220117-006		17/01/2022 06:19	MB	Butanona		3MM Whatman		13		1862	0		99,307 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20220117-007		17/01/2022 06:23	MB	Butanona		3MM Whatman		40		2207	0		98,22 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20220117-009		17/01/2022 07:17	GS	Butanona		3MM Whatman		2		517	0		99,615 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20220117-010		17/01/2022 07:31	GS	Butanona		3MM Whatman		1		434	0		99,77 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20220117-011		17/01/2022 08:47	MB	Butanona		3MM Whatman		8		707	0		98,881 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20220117-012		17/01/2022 09:12	MB	Butanona		3MM Whatman		1		846	0		99,882 %	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-20220117-013	17/01/2022	09:14	MB	Butanona		3MM Whatman		1		398	0	99,749 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20220117-015	17/01/2022	10:03	PM	Butanona		3MM Whatman		2		7313	0	99,973 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220117-016	17/01/2022	10:33	PM	Butanona		3MM Whatman		96		2308	0	96,007 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220117-017	17/01/2022	10:44	PM	Butanona		3MM Whatman		50		2066	0	97,637 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220117-018	17/01/2022	10:53	PM	Butanona		3MM Whatman		100		2440	0	96,063 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220117-019	17/01/2022	11:06	PM	Butanona		3MM Whatman		20		2250	0	99,119 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220117-020	17/01/2022	11:35	PM	Butanona		3MM Whatman		17		1824	0	99,077 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220117-021	17/01/2022	11:38	PM	Butanona		3MM Whatman		20		1857	0	98,934 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220117-023	17/01/2022	13:48	WG	Butanona		3MM Whatman		11		539	0	98,00 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	