



# 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 11/06/2021 To 11/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc		11/06/2021	07:43	FN	Butanona	3MM Whatman	148		1	0		93,079 %	Pass
Lot # K-20210611-029					Normal Saline	Silica gel	13		195	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		11/06/2021	07:44	FN	Butanona	3MM Whatman	275		3	0		93,658 %	Pass
Lot # K-20210611-030					Normal Saline	Silica gel	7		126	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		11/06/2021	07:48	FN	Butanona	3MM Whatman	138,8		0,6	0		93,75 %	Pass
Lot # K-20210611-032					Normal Saline	Silica gel	7,1		114,9	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		11/06/2021	08:04	FN	Butanona	3MM Whatman	102,7		0,7	0		96,755 %	Pass
Lot # K-20210611-034					Normal Saline	Silica gel	3,1		117,6	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		11/06/2021	08:06	FN	Butanona	3MM Whatman	296		6	0		96,301 %	Pass
Lot # K-20210611-035					Normal Saline	Silica gel	5		287	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		11/06/2021	08:07	FN	Butanona	3MM Whatman	115,8		0,4	0		96,147 %	Pass
Lot # K-20210611-036					Normal Saline	Silica gel	4,6		126,5	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		11/06/2021	10:36	JS	Butanona	3MM Whatman	136		1,4	0		95,358 %	Pass
Lot # K-20210611-039					Normal Saline	Silica gel	5		133	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DOTATOC-68Ga		11/06/2021	12:57	JS	Citrato de Sódio 0,1M	Silica gel	29,7		0,4	0		98,671 %	Pass
Lot # K-20210611-040										pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
						Límpido e Incolor							
DTPA-99mTc	RPH	11/06/2021	03:37	PP	Acetona	3MM Whatman	687		1	0		94,614 %	Pass
Lot # K-20210611-011					Normal Saline	3MM Whatman	50		904	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	11/06/2021	03:39	PP	Acetona	3MM Whatman	1008		2	0		97,082 %	Pass
Lot # K-20210611-012					Normal Saline	3MM Whatman	25		894	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	11/06/2021	04:01	PP	Acetona	3MM Whatman	1372		11	0		97,493 %	Pass
Lot # K-20210611-013					Normal Saline	3MM Whatman	12		689	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
						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
DTPA-99mTc Lot # K-20210611-038	RPH	11/06/2021 10:15	WG	Acetona Normal Saline	3MM	Whatman		494 10		6 602	0		97,166 %	Pass
												pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50
												Límpido/Incolor		
FITATO-99mTc Lot # K-20210611-014		11/06/2021 03:43	PP	Butanona	3MM	Whatman		607		10	0		98,379 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
												Límpido/Incolor		
FITATO-99mTc Lot # K-20210611-026		11/06/2021 07:32	FN	Butanona	3MM	Whatman		110,7		0,3	0		99,73 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
												Límpido/Incolor		
MAA-99mTc Lot # K-20210611-015		11/06/2021 03:45	PP	Butanona	3MM	Whatman		255		5	0		98,077 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210611-016		11/06/2021 03:47	PP	Butanona	3MM	Whatman		268		3	0		98,893 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210611-017		11/06/2021 03:49	PP	Butanona	3MM	Whatman		217		2	0		99,087 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210611-018		11/06/2021 04:08	PP	Butanona	3MM	Whatman		375		1	0		99,734 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210611-019		11/06/2021 04:10	PP	Butanona	3MM	Whatman		120		4	0		96,774 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210611-027		11/06/2021 07:34	FN	Butanona	3MM	Whatman		136,4		1	0		99,272 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210611-031		11/06/2021 07:46	FN	Butanona	3MM	Whatman		87		1	0		98,864 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210611-033		11/06/2021 07:54	FN	Butanona	3MM	Whatman		82		2	0		97,619 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20210611-009		11/06/2021 03:32	PP	Acetona Normal Saline	3MM	Whatman		891 22		2 1674	0		98,479 %	Pass
												pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210611-010		11/06/2021 03:34	PP	Acetona Normal Saline	3MM	Whatman		1524 10		4 1642	0		99,133 %	Pass
												pH (Low/Actual/High)	4,00 <= 6,00	<= 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-20210611-024		11/06/2021 07:22 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			243 5		1 289	0	pH (Low/Actual/High)	97,889 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210611-025		11/06/2021 07:25 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			266 2		1 209	0	pH (Low/Actual/High)	98,678 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20210611-001		11/06/2021 02:12 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3223 26		7 1299	0	pH (Low/Actual/High)	97,821 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210611-002		11/06/2021 02:13 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1885 3		31 1964	0	pH (Low/Actual/High)	98,23 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210611-003		11/06/2021 02:17 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1722 38		3 2399	0	pH (Low/Actual/High)	98,267 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210611-004		11/06/2021 02:18 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1228 28		20 3394	0	pH (Low/Actual/High)	97,579 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210611-005		11/06/2021 02:51 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3942 54		125 3473	0	pH (Low/Actual/High)	95,395 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210611-006		11/06/2021 02:54 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1821 13		21 2659	0	pH (Low/Actual/High)	98,373 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210611-007		11/06/2021 02:55 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1276 34		22 2184	0	pH (Low/Actual/High)	96,772 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210611-008		11/06/2021 02:58 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1657 12		19 2395	0	pH (Low/Actual/High)	98,368 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210611-020		11/06/2021 06:33 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1922 22		12 1832	0	pH (Low/Actual/High)	98,193 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210611-021		11/06/2021 06:34 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1440 14		22 1980	0	pH (Low/Actual/High)	97,793 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210611-023		11/06/2021 07:20 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			465 12		3 573	0	pH (Low/Actual/High)	97,308 %	Pass 5,00 <= 6,00 <= 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
PSMA-68Ga Lot # K-20210611-022		11/06/2021 06:52	BB	Acetato de amônio 1M:Metanol	Sílica gel			0,4	21,1		0	98,14 %	Pass	
												pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00
														Límpido e Incolor
PSMA-68Ga Lot # K-20210611-028		11/06/2021 07:37	FN	Acetato de amônio 1M:Metanol	Sílica gel			0,2	26		0	99,237 %	Pass	
												pH (Low/Actual/High)	4,00 <= 6,00	<= 8,00
														Límpido e Incolor
PSMA-68Ga Lot # K-20210611-037		11/06/2021 09:45	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,3	39,2		0	99,241 %	Pass	
												pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210611-001		11/06/2021 02:01	PP	Butanona	3MM Whatman			7	821		0	99,155 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210611-002		11/06/2021 02:48	PP	Butanona	3MM Whatman			34	3799		0	99,113 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210611-003		11/06/2021 03:29	PP	Butanona	3MM Whatman			19	1919		0	99,02 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210611-004		11/06/2021 03:32	PP	Butanona	3MM Whatman			12	1594		0	99,253 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210611-005		11/06/2021 03:35	PP	Butanona	3MM Whatman			46	1725		0	97,403 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210611-006		11/06/2021 06:29	FN	Butanona	3MM Whatman			1	683		0	99,854 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210611-008		11/06/2021 07:16	FN	Butanona	3MM Whatman			2	827		0	99,759 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210611-009		11/06/2021 07:25	FN	Butanona	3MM Whatman			2	1366		0	99,854 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210611-010		11/06/2021 07:29	FN	Butanona	3MM Whatman			1	389		0	99,744 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210611-012		11/06/2021 07:40	WG	Butanona	3MM Whatman			20	574		0	96,633 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														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		11/06/2021 10:13	WG	Butanona		3MM	Whatman	12		1494	0		99,203 %	Pass
Lot # E-20210611-014											pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
														Límpido e Incolor