



# 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 03/01/2022 To 03/01/2022

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20220103-010		03/01/2022	04:01	MB	Butanona Normal Saline	3MM Whatman Sílica gel	155,5 4,6		4 93,6	0	pH (Low/Actual/High)	92,808 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220103-019		03/01/2022	07:33	GS	Butanona Normal Saline	3MM Whatman Sílica gel	155,2 10		0,5 148	0	pH (Low/Actual/High)	93,35 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220103-025		03/01/2022	08:03	GS	Butanona Normal Saline	3MM Whatman Sílica gel	173,3 4,9		1,9 125,2	0	pH (Low/Actual/High)	95,149 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220103-029		03/01/2022	08:57	MB	Butanona Normal Saline	3MM Whatman Sílica gel	116 1,5		0,6 83,4	0	pH (Low/Actual/High)	97,719 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220103-031		03/01/2022	10:27	MB	Butanona Normal Saline	3MM Whatman Sílica gel	91,2 4,2		0,8 83,2	0	pH (Low/Actual/High)	94,325 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220103-032		03/01/2022	10:30	MB	Butanona Normal Saline	3MM Whatman Sílica gel	107,2 2,8		3,1 175,1	0	pH (Low/Actual/High)	95,616 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20220103-030		03/01/2022	09:56	VS	Citrato de Sódio 0,1M	Sílica gel	857		11	0	pH (Low/Actual/High)	98,733 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DTPA-99mTc Lot # K-20220103-006	RPH	03/01/2022	03:43	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	680 13		3 668	0	pH (Low/Actual/High)	97,652 %	Pass 3,80 <= 5,00 <= 7,50
Límpido/Incolor													
DTPA-99mTc Lot # K-20220103-018	RPH	03/01/2022	07:25	GS	Acetona Normal Saline	3MM Whatman 3MM Whatman	351 18		1 414	0	pH (Low/Actual/High)	95,549 %	Pass 3,80 <= 5,00 <= 7,50
Límpido/Incolor													
DTPA-99mTc Lot # K-20220103-035	RPH	03/01/2022	12:01	VS	Acetona Normal Saline	3MM Whatman 3MM Whatman	192,1 5		2,8 147,6	0	pH (Low/Actual/High)	95,287 %	Pass 3,80 <= 6,00 <= 7,50
Límpido/Incolor													
FITATO-99mTc Lot # K-20220103-007		03/01/2022	03:46	MB	Butanona	3MM Whatman	418		2	0	pH (Low/Actual/High)	99,524 %	Pass 5,00 <= 5,00 <= 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
FITATO-99mTc Lot # K-20220103-023		03/01/2022 07:57	GS	Butanona		3MM Whatman		360		4	0		98,901 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
														Límpido/Incolor
MAA-99mTc Lot # K-20220103-011		03/01/2022 04:18	MB	Butanona		3MM Whatman		325		5	0		98,485 %	Pass
											pH (Low/Actual/High)	3,00 <= 4,00	<= 6,00	
														Turvo/Incolor
MAA-99mTc Lot # K-20220103-021		03/01/2022 07:43	GS	Butanona		3MM Whatman		1530		1	0		99,935 %	Pass
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
														Turvo/Incolor
MAA-99mTc Lot # K-20220103-022		03/01/2022 07:45	GS	Butanona		3MM Whatman		734		1	0		99,864 %	Pass
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
														Turvo/Incolor
MAA-99mTc Lot # K-20220103-033		03/01/2022 11:04	MB	Butanona		3MM Whatman		827		6	0		99,28 %	Pass
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
														Turvo/Incolor
MAA-99mTc Lot # K-20220103-034		03/01/2022 11:06	MB	Butanona		3MM Whatman		986		5	0		99,495 %	Pass
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
														Turvo/Incolor
MAA-99mTc Lot # K-20220103-036		03/01/2022 12:26	VS	Butanona		3MM Whatman		523		5	0		99,053 %	Pass
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
														Turvo/Incolor
MDP-99mTc Lot # K-20220103-005		03/01/2022 03:40	MB	Acetona		3MM Whatman		1134		8	0		97,702 %	Pass
				Normal Saline		3MM Whatman		15		924	pH (Low/Actual/High)	4,00 <= 4,00	<= 7,80	
														Límpido/Incolor
MDP-99mTc Lot # K-20220103-009		03/01/2022 03:57	MB	Acetona		3MM Whatman		1117		8	0		97,444 %	Pass
				Normal Saline		3MM Whatman		19		1011	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
														Límpido/Incolor
MDP-99mTc Lot # K-20220103-012		03/01/2022 06:18	PM	Acetona		3MM Whatman		1147		3	0		99,677 %	Pass
				Normal Saline		3MM Whatman		1		1611	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
														Límpido/Incolor
MDP-99mTc Lot # K-20220103-017		03/01/2022 07:03	GS	Acetona		3MM Whatman		934		4	0		98,955 %	Pass
				Normal Saline		3MM Whatman		7		1125	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
														Límpido/Incolor
MDP-99mTc Lot # K-20220103-024		03/01/2022 08:00	GS	Acetona		3MM Whatman		1071		27	0		96,982 %	Pass
				Normal Saline		3MM Whatman		4		712	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
														Límpido/Incolor
MDP-99mTc Lot # K-20220103-026		03/01/2022 08:06	GS	Acetona		3MM Whatman		531		3	0		97,848 %	Pass
				Normal Saline		3MM Whatman		10		619	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
MIBI-99mTc Lot # K-20220103-001		03/01/2022 02:36	BB	Normal Saline Metanol	Sílica gel 3MM Whatman			766 62		23 2215	0	pH (Low/Actual/High)	94,362 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220103-002		03/01/2022 02:37	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1151 8		50 2064	0	pH (Low/Actual/High)	95,451 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220103-003		03/01/2022 02:44	BB	Normal Saline Metanol	Sílica gel 3MM Whatman			460 14		26 1326	0	pH (Low/Actual/High)	93,605 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220103-004		03/01/2022 02:45	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1263 32		45 2048	0	pH (Low/Actual/High)	95,021 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220103-008		03/01/2022 03:48	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1347 18		31 1901	0	pH (Low/Actual/High)	96,812 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220103-013		03/01/2022 06:23	BB	Normal Saline Metanol	Sílica gel 3MM Whatman			1153 5		22 2437	0	pH (Low/Actual/High)	97,923 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220103-014		03/01/2022 06:26	BB	Normal Saline Metanol	Sílica gel 3MM Whatman			1971 25		28 1644	0	pH (Low/Actual/High)	97,101 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220103-015		03/01/2022 06:36	GS	Normal Saline Metanol	Sílica gel 3MM Whatman			291 18		7 1457	0	pH (Low/Actual/High)	96,431 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220103-027		03/01/2022 08:36	GS	Normal Saline Metanol	Sílica gel 3MM Whatman			1233 2		37 215	0	pH (Low/Actual/High)	96,165 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220103-028		03/01/2022 08:40	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1210 93		60 2972	0	pH (Low/Actual/High)	92,241 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20220103-020		03/01/2022 07:36	GS	Butanona Normal Saline	3MM Whatman 3MM Whatman			372 20		1 278	0	pH (Low/Actual/High)	93,02 %	Pass 5,00 <= 5,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20220103-016		03/01/2022 06:53	PM	Acetato de amônio 1M:Metanol	Sílica gel			2,7		77,5	0	pH (Low/Actual/High)	96,633 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20220103-037		03/01/2022 12:35	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,1		43,2	0	pH (Low/Actual/High)	99,769 %	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
Tecnécio-99m Lot # E-20220103-001		03/01/2022 02:31	MB	Butanona		3MM Whatman		3		118	0	97,521 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-002		03/01/2022 02:38	MB	Butanona		3MM Whatman		18		1568	0	98,865 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-003		03/01/2022 03:37	MB	Butanona		3MM Whatman		6		728	0	99,183 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-004		03/01/2022 03:55	MB	Butanona		3MM Whatman		25		5199	0	99,521 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-005		03/01/2022 06:21	BB	Butanona		3MM Whatman		7		5684	0	99,877 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-006		03/01/2022 06:33	PM	Butanona		3MM Whatman		1		566	0	99,824 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-008		03/01/2022 07:30	GS	Butanona		3MM Whatman		1		209	0	99,524 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-009		03/01/2022 08:34	GS	Butanona		3MM Whatman		7		464	0	98,514 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-010		03/01/2022 08:55	GS	Butanona		3MM Whatman		6		410	0	98,558 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-011		03/01/2022 09:50	VS	Butanona		3MM Whatman		9		857	0	98,961 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-013		03/01/2022 09:55	VS	Butanona		3MM Whatman		6		201	0	97,101 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-014		03/01/2022 10:32	MB	Butanona		3MM Whatman		5		1528	0	99,674 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20220103-015		03/01/2022 10:40	MB	Butanona		3MM Whatman		3		435	0	99,315 %	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-20220103-016		03/01/2022 11:07	MB	Butanona		3MM Whatman		2		855	0			99,767 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20220103-017		03/01/2022 11:39	VS	Butanona		3MM Whatman		4		1768	0			99,774 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20220103-018		03/01/2022 12:00	MB	Butanona		3MM Whatman		4		657	0			99,395 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20220103-022		03/01/2022 12:02	VS	Butanona		3MM Whatman		5		853	0			99,417 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20220103-019		03/01/2022 12:04	VS	Butanona		3MM Whatman		2		1970	0			99,899 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20220103-020		03/01/2022 12:07	VS	Butanona		3MM Whatman		3		1629	0			99,816 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20220103-021		03/01/2022 12:12	VS	Butanona		3MM Whatman		3		731	0			99,591 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor