



# 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 04/06/2021 To 04/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210604-032		04/06/2021	07:33	WG	Butanona Normal Saline	3MM Whatman Sílica gel	98,5 1,8		3,1 58,5	0	pH (Low/Actual/High)	93,964 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210604-033		04/06/2021	07:34	WG	Butanona Normal Saline	3MM Whatman Sílica gel	128,7 2		3,5 104,8	0	pH (Low/Actual/High)	95,48 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210604-034		04/06/2021	07:35	WG	Butanona Normal Saline	3MM Whatman Sílica gel	181,4 7,3		4,6 153,6	0	pH (Low/Actual/High)	92,99 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210604-039		04/06/2021	08:01	WG	Butanona Normal Saline	3MM Whatman Sílica gel	212 1,4		2 157,4	0	pH (Low/Actual/High)	98,184 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210604-040		04/06/2021	08:02	WG	Butanona Normal Saline	3MM Whatman Sílica gel	172,7 1,8		0,3 162,2	0	pH (Low/Actual/High)	98,729 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210604-041		04/06/2021	08:13	WG	Butanona Normal Saline	3MM Whatman Sílica gel	168,9 3		3,9 104,7	0	pH (Low/Actual/High)	94,958 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210604-045		04/06/2021	10:15	WG	Butanona Normal Saline	3MM Whatman Sílica gel	142,7 15		0,2 184	0	pH (Low/Actual/High)	92,322 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210604-048		04/06/2021	10:39	WG	Butanona Normal Saline	3MM Whatman Sílica gel	102,6 6,5		1 93,4	0	pH (Low/Actual/High)	92,528 %	Pass
						Límpido/Incolor						2,00 <= 3,00	<= 3,00
DOTATOC-68Ga Lot # K-20210604-049		04/06/2021	12:49	JS	Citrato de Sódio 0,1M	Sílica gel	32,6		0,3	0	pH (Low/Actual/High)	99,088 %	Pass
						Límpido e Incolor						4,00 <= 5,00	<= 8,00
DTPA-99mTc Lot # K-20210604-010	RPH	04/06/2021	03:36	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1214 21		1 651	0	pH (Low/Actual/High)	96,793 %	Pass
						Límpido/Incolor						3,80 <= 6,00	<= 7,50
DTPA-99mTc Lot # K-20210604-011	RPH	04/06/2021	03:42	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	953 28		2 589	0	pH (Low/Actual/High)	95,252 %	Pass
						Límpido/Incolor						3,80 <= 6,00	<= 7,50

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-20210604-044	RPH	04/06/2021 10:05	WG	Acetona Normal Saline	3MM	Whatman		788 5		17 547	0		96,982 %	Pass
							Límpido/Incolor					pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50
FITATO-99mTc Lot # K-20210604-020		04/06/2021 04:18	PP	Butanona	3MM	Whatman		266		1	0		99,625 %	Pass
							Límpido/Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
FITATO-99mTc Lot # K-20210604-035		04/06/2021 07:47	WG	Butanona	3MM	Whatman		409		1	0		99,756 %	Pass
							Límpido/Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
MAA-99mTc Lot # K-20210604-013		04/06/2021 03:48	PP	Butanona	3MM	Whatman		202		1	0		99,507 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210604-014		04/06/2021 03:50	PP	Butanona	3MM	Whatman		236		6	0		97,521 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210604-015		04/06/2021 03:52	PP	Butanona	3MM	Whatman		346		9	0		97,465 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210604-016		04/06/2021 03:54	PP	Butanona	3MM	Whatman		225		5	0		97,826 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210604-018		04/06/2021 04:11	PP	Butanona	3MM	Whatman		166		2	0		98,81 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210604-021		04/06/2021 04:20	PP	Butanona	3MM	Whatman		187		4	0		97,906 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210604-022		04/06/2021 04:22	PP	Butanona	3MM	Whatman		240		7	0		97,166 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210604-023		04/06/2021 04:25	PP	Butanona	3MM	Whatman		148		2	0		98,667 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210604-024		04/06/2021 04:27	PP	Butanona	3MM	Whatman		149		1	0		99,333 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210604-025		04/06/2021 04:29	PP	Butanona	3MM	Whatman		130		1	0		99,237 %	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-20210604-036		04/06/2021 07:50	WG	Butanona		3MM Whatman		96,3		1,5	0		98,466 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210604-037		04/06/2021 07:52	WG	Butanona		3MM Whatman		97,8		0,7	0		99,289 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210604-038		04/06/2021 07:55	WG	Butanona		3MM Whatman		46,1		0,9	0		98,085 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210604-046		04/06/2021 10:17	WG	Butanona		3MM Whatman		322		1	0		99,69 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210604-047		04/06/2021 10:18	WG	Butanona		3MM Whatman		197,7		0,3	0		99,848 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20210604-008		04/06/2021 03:31	PP	Acetona		3MM Whatman		1826		20	0		95,31 %	Pass
				Normal Saline		3MM Whatman		37		989		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210604-009		04/06/2021 03:34	PP	Acetona		3MM Whatman		782		1	0		99,811 %	Pass
				Normal Saline		3MM Whatman		1		1641		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210604-012		04/06/2021 03:47	PP	Acetona		3MM Whatman		1926		14	0		99,026 %	Pass
				Normal Saline		3MM Whatman		3		1188		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210604-030		04/06/2021 07:08	FN	Acetona		3MM Whatman		592		2	0		98,907 %	Pass
				Normal Saline		3MM Whatman		6		787		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210604-031		04/06/2021 07:11	FN	Acetona		3MM Whatman		1196		1	0		99,45 %	Pass
				Normal Saline		3MM Whatman		6		1281		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210604-001		04/06/2021 02:14	PP	Normal Saline		Sílica gel		1910		34	0		98,118 %	Pass
				Metanol		3MM Whatman		4		3004		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210604-002		04/06/2021 02:15	PP	Normal Saline		Sílica gel		1632		42	0		96,752 %	Pass
				Metanol		3MM Whatman		24		3222		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210604-003		04/06/2021 02:20	PP	Normal Saline		Sílica gel		1992		38	0		98,062 %	Pass
				Metanol		3MM Whatman		2		3034		pH (Low/Actual/High)	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
MIBI-99mTc Lot # K-20210604-004		04/06/2021 02:26 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3014 26		20 3224	0	pH (Low/Actual/High)	98,541 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210604-005		04/06/2021 02:26 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2097 37		34 3846	0	pH (Low/Actual/High)	97,452 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210604-006		04/06/2021 02:32 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1233 141		19 3638	0	pH (Low/Actual/High)	94,751 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210604-007		04/06/2021 02:42 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1769 17		18 3048	0	pH (Low/Actual/High)	98,438 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210604-017		04/06/2021 04:08 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1642 25		20 1601	0	pH (Low/Actual/High)	97,259 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210604-019		04/06/2021 04:13 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2248 71		30 2467	0	pH (Low/Actual/High)	95,886 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210604-027		04/06/2021 06:56 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1172 20		2 1125	0	pH (Low/Actual/High)	98,083 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210604-028		04/06/2021 06:57 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1239 24		2 1318	0	pH (Low/Actual/High)	98,05 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210604-029		04/06/2021 07:03 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1023 14		12 1324	0	pH (Low/Actual/High)	97,794 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210604-026		04/06/2021 06:38 BB	Acetato de amônio 1M:Metanol		Sílica gel			0,6		37,6	0	pH (Low/Actual/High)	98,429 %	Pass 4,00 <= 7,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210604-042		04/06/2021 09:30 WG	Acetato de amônio 1M:Metanol		Sílica gel			0,6		51,1	0	pH (Low/Actual/High)	98,839 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210604-001		04/06/2021 02:09 PP	Butanona		3MM Whatman			42		1317	0	pH (Low/Actual/High)	96,909 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210604-002		04/06/2021 02:22 PP	Butanona		3MM Whatman			15		1343	0	pH (Low/Actual/High)	98,895 %	Pass 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 Lot # E-20210604-003		04/06/2021 03:30	PP	Butanona		3MM Whatman		9		451	0	98,043 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-004		04/06/2021 03:30	PP	Butanona		3MM Whatman		25		904	0	97,309 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-005		04/06/2021 03:43	PP	Butanona		3MM Whatman		9		389	0	97,739 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-006		04/06/2021 04:04	PP	Butanona		3MM Whatman		18		450	0	96,154 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-007		04/06/2021 04:12	PP	Butanona		3MM Whatman		26		673	0	96,28 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-008		04/06/2021 04:15	PP	Butanona		3MM Whatman		65		1415	0	95,608 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-010		04/06/2021 06:52	FN	Butanona		3MM Whatman		1		653,7	0	99,847 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-011		04/06/2021 07:01	FN	Butanona		3MM Whatman		1		161,4	0	99,384 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-012		04/06/2021 07:28	FN	Butanona		3MM Whatman		2		626	0	99,682 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-013		04/06/2021 07:43	FN	Butanona		3MM Whatman		1		1187	0	99,916 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-015		04/06/2021 10:00	JS	Butanona		3MM Whatman		6		701	0	99,151 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-016		04/06/2021 10:15	WG	Butanona		3MM Whatman		16		1038	0	98,482 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210604-017		04/06/2021 10:23	JS	Butanona		3MM Whatman		3		1609	0	99,814 %	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
TRODAT-99mTc		04/06/2021	10:05	WG	Normal Saline	Silica gel			93,7		2,7	0		94,094 %	Pass
Lot # K-20210604-043					Butanona	3MM Whatman			5		156	pH (Low/Actual/High)		6,50 <= 7,00 <= 8,50	
								Límpido/Incolor							