



# 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 08/06/2021 To 08/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210608-026		08/06/2021	07:44	FN	Butanona Normal Saline	3MM Whatman Sílica gel	82,4 5,7		0,8 76	0	pH (Low/Actual/High)	92,062 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210608-027		08/06/2021	07:45	FN	Butanona Normal Saline	3MM Whatman Sílica gel	166,1 7,8		1,4 151,3	0	pH (Low/Actual/High)	94,262 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210608-020		08/06/2021	06:54	BB	Citrato de Sódio 0,1M	Sílica gel	22,8		0,4	0	pH (Low/Actual/High)	98,276 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210608-029		08/06/2021	07:55	JS	Citrato de Sódio 0,1M	Sílica gel	23,2		0,2	0	pH (Low/Actual/High)	99,145 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210608-043		08/06/2021	13:04	JS	Citrato de Sódio 0,1M	Sílica gel	29,3		0,2	0	pH (Low/Actual/High)	99,322 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210608-004	RPH	08/06/2021	02:56	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	859 21		5 826	0	pH (Low/Actual/High)	96,942 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210608-005	RPH	08/06/2021	03:03	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	289 13		4 609	0	pH (Low/Actual/High)	96,545 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210608-011	RPH	08/06/2021	03:43	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1323 6		6 902	0	pH (Low/Actual/High)	98,888 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210608-024	RPH	08/06/2021	07:23	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	464 15		2 407	0	pH (Low/Actual/High)	96,016 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210608-034	RPH	08/06/2021	09:43	JS	Acetona Normal Saline	3MM Whatman 3MM Whatman	545 2		1 1270	0	pH (Low/Actual/High)	99,66 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210608-003		08/06/2021	02:53	PP	Butanona	3MM Whatman	531		13	0	pH (Low/Actual/High)	97,61 %	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
FITATO-99mTc Lot # K-20210608-025		08/06/2021 07:28 FN	Butanona		3MM	Whatman		146,8		1,2	0		99,189 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
												Límpido/Incolor		
FITATO-99mTc Lot # K-20210608-030		08/06/2021 08:13 FN	Butanona		3MM	Whatman		306		1	0		99,674 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
												Límpido/Incolor		
MAA-99mTc Lot # K-20210608-012		08/06/2021 03:58 PP	Butanona		3MM	Whatman		117		2	0		98,319 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210608-013		08/06/2021 04:00 PP	Butanona		3MM	Whatman		156		2	0		98,734 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210608-014		08/06/2021 04:02 PP	Butanona		3MM	Whatman		217		2	0		99,087 %	Pass
												pH (Low/Actual/High)	3,00 <= 4,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210608-015		08/06/2021 04:05 PP	Butanona		3MM	Whatman		155		5	0		96,875 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210608-016		08/06/2021 04:08 PP	Butanona		3MM	Whatman		251		9	0		96,538 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210608-031		08/06/2021 08:14 FN	Butanona		3MM	Whatman		66,6		1,3	0		98,085 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210608-032		08/06/2021 08:25 FN	Butanona		3MM	Whatman		64		1	0		98,462 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210608-041		08/06/2021 10:49 WG	Butanona		3MM	Whatman		179,6		2,7	0		98,519 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210608-042		08/06/2021 10:49 WG	Butanona		3MM	Whatman		239		4	0		98,354 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20210608-008		08/06/2021 03:19 PP	Acetona		3MM	Whatman		1474		24	0		97,643 %	Pass
			Normal Saline		3MM	Whatman		10		1314		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210608-009		08/06/2021 03:22 PP	Acetona		3MM	Whatman		1799		4	0		97,873 %	Pass
			Normal Saline		3MM	Whatman		22		1133		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-20210608-022		08/06/2021 07:14 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			541 5		13 891	0 pH (Low/Actual/High)	97,095 % 4,00 <= 6,00 <= 7,80	Pass	
Límpido/Incolor														
MDP-99mTc Lot # K-20210608-023		08/06/2021 07:19 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			710 6		1 905	0 pH (Low/Actual/High)	99,201 % 4,00 <= 6,00 <= 7,80	Pass	
Límpido/Incolor														
MDP-99mTc Lot # K-20210608-028		08/06/2021 07:48 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			656 6		8 632	0 pH (Low/Actual/High)	97,855 % 4,00 <= 6,00 <= 7,80	Pass	
Límpido/Incolor														
MDP-99mTc Lot # K-20210608-033		08/06/2021 08:50 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			447 3		3 780	0 pH (Low/Actual/High)	98,95 % 4,00 <= 6,00 <= 7,80	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210608-001		08/06/2021 02:17 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2039 42		51 2868	0 pH (Low/Actual/High)	96,117 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210608-002		08/06/2021 02:21 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1584 49		45 2969	0 pH (Low/Actual/High)	95,614 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210608-006		08/06/2021 03:15 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2931 68		53 3591	0 pH (Low/Actual/High)	96,365 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210608-007		08/06/2021 03:16 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2230 37		27 3417	0 pH (Low/Actual/High)	97,732 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210608-010		08/06/2021 03:24 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2422 35		44 2617	0 pH (Low/Actual/High)	96,896 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210608-017		08/06/2021 06:38 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1510 10		26 1289	0 pH (Low/Actual/High)	97,537 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210608-018		08/06/2021 06:42 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			884 23		12 1184	0 pH (Low/Actual/High)	96,755 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210608-019		08/06/2021 06:47 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1072 2		19 1726	0 pH (Low/Actual/High)	98,143 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210608-035		08/06/2021 09:52 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1552 18		22 1824	0 pH (Low/Actual/High)	97,625 % 5,00 <= 5,00 <= 6,00	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-20210608-036	08/06/2021	09:58	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1454 9		21 1383	0	pH (Low/Actual/High)	97,93 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
PIRO-99mTc Lot # K-20210608-021	08/06/2021	07:11	FN	Butanona Normal Saline	3MM Whatman 3MM Whatman			232 7		2 398	0	pH (Low/Actual/High)	97,417 %	Pass 5,00 <= 6,00 <= 7,00
														Límpido/Incolor
PSMA-68Ga Lot # K-20210608-037	08/06/2021	10:00	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,3		29,2	0	pH (Low/Actual/High)	98,983 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210608-001	08/06/2021	02:13	PP	Butanona	3MM Whatman			62		5112	0	pH (Low/Actual/High)	98,802 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210608-002	08/06/2021	02:18	PP	Butanona	3MM Whatman			11		3728	0	pH (Low/Actual/High)	99,706 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210608-003	08/06/2021	02:57	PP	Butanona	3MM Whatman			10		1091	0	pH (Low/Actual/High)	99,092 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210608-004	08/06/2021	02:58	PP	Butanona	3MM Whatman			44		1075	0	pH (Low/Actual/High)	96,068 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210608-005	08/06/2021	03:12	PP	Butanona	3MM Whatman			11		1672	0	pH (Low/Actual/High)	99,346 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210608-006	08/06/2021	03:12	PP	Butanona	3MM Whatman			22		1845	0	pH (Low/Actual/High)	98,822 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210608-007	08/06/2021	03:22	PP	Butanona	3MM Whatman			52		2398	0	pH (Low/Actual/High)	97,878 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210608-008	08/06/2021	06:27	FN	Butanona	3MM Whatman			1		1612	0	pH (Low/Actual/High)	99,938 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210608-009	08/06/2021	06:39	FN	Butanona	3MM Whatman			1		442	0	pH (Low/Actual/High)	99,774 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210608-011	08/06/2021	07:08	FN	Butanona	3MM Whatman			2		1481	0	pH (Low/Actual/High)	99,865 %	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-20210608-012	08/06/2021	07:15 FN	Butanona		3MM	Whatman		2		1760	0		99,886 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210608-013	08/06/2021	07:39 FN	Butanona		3MM	Whatman		3		1553	0		99,807 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210608-015	08/06/2021	08:09 FN	Butanona		3MM	Whatman		2		1223	0		99,837 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210608-016	08/06/2021	09:49 WG	Butanona		3MM	Whatman		14		878	0		98,43 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210608-017	08/06/2021	09:52 WG	Butanona		3MM	Whatman		3		630	0		99,526 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
TRODAT-99mTc Lot # K-20210608-038	08/06/2021	10:10 WG	Normal Saline		Sílica gel			144,9		4,9	0		94,241 %	Pass
			Butanona		3MM	Whatman		2,1		82,3	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20210608-039	08/06/2021	10:12 WG	Normal Saline		Sílica gel			119,7		4	0		93,599 %	Pass
			Butanona		3MM	Whatman		7		214	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20210608-040	08/06/2021	10:18 WG	Normal Saline		Sílica gel			178,9		3,8	0		95,727 %	Pass
			Butanona		3MM	Whatman		5		223	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							