



# 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 19/07/2021 To 19/07/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210719-023		19/07/2021	07:53	PP	Butanona	3MM Whatman	282		6	0		96,259 %	Pass
					Normal Saline	Silica gel	3		178	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
Límpido/Incolor													
DMSA-99mTc Lot # K-20210719-024		19/07/2021	07:55	PP	Butanona	3MM Whatman	141		7	0		93,096 %	Pass
					Normal Saline	Silica gel	3		135	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
Límpido/Incolor													
DMSA-99mTc Lot # K-20210719-030		19/07/2021	10:49	JS	Butanona	3MM Whatman	95		5	0		92,561 %	Pass
					Normal Saline	Silica gel	3		120	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
Límpido/Incolor													
DMSA-99mTc Lot # K-20210719-032		19/07/2021	10:55	JS	Butanona	3MM Whatman	117		2	0		95,641 %	Pass
					Normal Saline	Silica gel	3		109	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
Límpido/Incolor													
DOTATATE-68Ga Lot # K-20210719-026		19/07/2021	09:48	MP	Citrato de Sódio 0,1M	Silica gel	25,9		0	0		99,458 %	Pass
					Metanol/Acetato de Amonio 1	Silica gel	0,2		36,7	pH (Low/Actual/High)	4,00 <= 4,50	<= 8,00	
Límpido e Incolor													
DOTATATE-68Ga Lot # K-20210719-037		19/07/2021	15:24	MP	Citrato de Sódio 0,1M	Silica gel	24,5		0,1	0		96,419 %	Pass
					Metanol/Acetato de Amonio 1	Silica gel	1		30,5	pH (Low/Actual/High)	4,00 <= 4,50	<= 8,00	
Límpido e Incolor													
DTPA-99mTc Lot # K-20210719-007	RPH	19/07/2021	03:28	FN	Acetona	3MM Whatman	386		6	0		96,122 %	Pass
					Normal Saline	3MM Whatman	10		416	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
Límpido/Incolor													
DTPA-99mTc Lot # K-20210719-028	RPH	19/07/2021	10:07	JS	Acetona	3MM Whatman	479		4	0		96,828 %	Pass
					Normal Saline	3MM Whatman	9		375	pH (Low/Actual/High)	3,80 <= 5,00	<= 7,50	
Límpido/Incolor													
FITATO-99mTc Lot # K-20210719-006		19/07/2021	03:24	FN	Butanona	3MM Whatman	366		1	0		99,728 %	Pass
										pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
Límpido/Incolor													
FITATO-99mTc Lot # K-20210719-017		19/07/2021	07:09	GF	Butanona	3MM Whatman	356		0	0		100,00 %	Pass
										pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
Límpido/Incolor													
MAA-99mTc Lot # K-20210719-009		19/07/2021	03:47	FN	Butanona	3MM Whatman	140,4		2,2	0		98,457 %	Pass
										pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
Turvo/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-20210719-010		19/07/2021 03:49 FN	Butanona		3MM	Whatman		276		4	0		98,571 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210719-011		19/07/2021 03:51 FN	Butanona		3MM	Whatman		290		5	0		98,305 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210719-019		19/07/2021 07:30 GF	Butanona		3MM	Whatman		158		1,9	0		98,812 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210719-020		19/07/2021 07:35 GF	Butanona		3MM	Whatman		100,2		0,8	0		99,208 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210719-025		19/07/2021 08:19 PP	Butanona		3MM	Whatman		394		8	0		98,01 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210719-034		19/07/2021 11:08 JS	Butanona		3MM	Whatman		332		2	0		99,401 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
MDP-99mTc Lot # K-20210719-005		19/07/2021 02:59 FN	Acetona		3MM	Whatman		994		20	0		96,526 %	Pass
			Normal Saline		3MM	Whatman		12		787		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210719-008		19/07/2021 03:41 FN	Acetona		3MM	Whatman		374		2	0		99,256 %	Pass
			Normal Saline		3MM	Whatman		1		470		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210719-016		19/07/2021 06:54 GF	Acetona		3MM	Whatman		486		1	0		97,834 %	Pass
			Normal Saline		3MM	Whatman		8		400		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210719-022		19/07/2021 07:47 GF	Acetona		3MM	Whatman		725		6	0		98,227 %	Pass
			Normal Saline		3MM	Whatman		5		520		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210719-029		19/07/2021 10:22 JS	Acetona		3MM	Whatman		220		6	0		96,188 %	Pass
			Normal Saline		3MM	Whatman		5		427		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210719-033		19/07/2021 11:04 JS	Acetona		3MM	Whatman		243		1	0		98,545 %	Pass
			Normal Saline		3MM	Whatman		3		284		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210719-035		19/07/2021 11:12 JS	Acetona		3MM	Whatman		480		1	0		99,287 %	Pass
			Normal Saline		3MM	Whatman		2		394		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-20210719-001		19/07/2021 02:45 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			227 1		4 270	0	pH (Low/Actual/High)	97,899 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210719-002		19/07/2021 02:48 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			223 1		6 220	0	pH (Low/Actual/High)	96,927 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210719-003		19/07/2021 02:49 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			208 1		3 237	0	pH (Low/Actual/High)	98,158 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210719-004		19/07/2021 02:54 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1768 1		20 200	0	pH (Low/Actual/High)	98,384 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210719-012		19/07/2021 03:55 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			285 6		5 1954	0	pH (Low/Actual/High)	97,97 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210719-014		19/07/2021 06:38 GF	Normal Saline Metanol		Sílica gel 3MM Whatman			671 15		17 1542	0	pH (Low/Actual/High)	96,566 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210719-015		19/07/2021 06:41 GF	Normal Saline Metanol		Sílica gel 3MM Whatman			650 0		27 289	0	pH (Low/Actual/High)	96,012 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210719-021		19/07/2021 07:42 GF	Normal Saline Metanol		Sílica gel 3MM Whatman			900 10		22 1732	0	pH (Low/Actual/High)	97,04 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210719-027		19/07/2021 10:04 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1072 3		32 262	0	pH (Low/Actual/High)	95,969 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210719-031		19/07/2021 10:54 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			843 14		10 1651	0	pH (Low/Actual/High)	97,987 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210719-018		19/07/2021 07:11 GF	Butanona Normal Saline		3MM Whatman 3MM Whatman			330 1		1 458	0	pH (Low/Actual/High)	99,48 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210719-036		19/07/2021 12:50 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,3		64,4	0	pH (Low/Actual/High)	99,536 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210719-001		19/07/2021 02:42 FN	Butanona		3MM Whatman			2		820	0	pH (Low/Actual/High)	99,757 %	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-20210719-002		19/07/2021 02:43	FN	Butanona		3MM Whatman		1		239	0		99,583 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-003		19/07/2021 02:43	FN	Butanona		3MM Whatman		1		506	0		99,803 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-004		19/07/2021 03:00	FN	Butanona		3MM Whatman		2		248	0		99,20 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-005		19/07/2021 03:25	FN	Butanona		3MM Whatman		2		142	0		98,611 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-006		19/07/2021 03:36	FN	Butanona		3MM Whatman		2		487	0		99,591 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-007		19/07/2021 06:35	GF	Butanona		3MM Whatman		1		365	0		99,727 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-008		19/07/2021 06:39	GF	Butanona		3MM Whatman		2		358	0		99,444 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-009		19/07/2021 07:07	GF	Butanona		3MM Whatman		4		700	0		99,432 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-010		19/07/2021 07:38	GF	Butanona		3MM Whatman		0		683	0		100,00 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-012		19/07/2021 09:49	JS	Butanona		3MM Whatman		2		535	0		99,628 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-013		19/07/2021 10:00	JS	Butanona		3MM Whatman		2		385	0		99,483 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-014		19/07/2021 10:19	JS	Butanona		3MM Whatman		5		529	0		99,064 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-015		19/07/2021 10:28	JS	Butanona		3MM Whatman		2		551	0		99,638 %	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 Lot # E-20210719-016		19/07/2021 10:44	JS	Butanona		3MM Whatman		2		147	0			98,658 % Pass
											pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-017		19/07/2021 11:01	JS	Butanona		3MM Whatman		5		357	0			98,619 % Pass
											pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
														Límpido e Incolor
Tecnécio-99m Lot # E-20210719-018		19/07/2021 11:09	JS	Butanona		3MM Whatman		3		491	0			99,393 % Pass
											pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
														Límpido e Incolor