



# 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 27/12/2021 To 27/12/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211227-011		27/12/2021	04:02	MB	Butanona Normal Saline	3MM Whatman Sílica gel	188,7 7,9		1,2 122,8	0	pH (Low/Actual/High)	93,324 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211227-023		27/12/2021	08:01	MB	Butanona Normal Saline	3MM Whatman Sílica gel	157,5 8,3		2,1 124,2	0	pH (Low/Actual/High)	92,42 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211227-024		27/12/2021	08:02	MB	Butanona Normal Saline	3MM Whatman Sílica gel	148,3 8,7		0,9 119	0	pH (Low/Actual/High)	92,584 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211227-033		27/12/2021	11:32	VS	Butanona Normal Saline	3MM Whatman Sílica gel	364 4		2 249	0	pH (Low/Actual/High)	97,873 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211227-034		27/12/2021	11:35	VS	Butanona Normal Saline	3MM Whatman Sílica gel	214 4		3 351	0	pH (Low/Actual/High)	97,491 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20211227-030		27/12/2021	09:43	JS	Citrato de Sódio 0,1M	Sílica gel	23,5		0,3	0	pH (Low/Actual/High)	98,739 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20211227-008	RPH	27/12/2021	03:15	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	443 2		1 418	0	pH (Low/Actual/High)	99,299 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211227-009	RPH	27/12/2021	03:17	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	324 5		2 310	0	pH (Low/Actual/High)	97,799 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211227-029	RPH	27/12/2021	08:58	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	255 4		4 254	0	pH (Low/Actual/High)	96,905 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20211227-010		27/12/2021	03:20	MB	Butanona	3MM Whatman	213		3	0	pH (Low/Actual/High)	98,611 %	Pass 5,00 <= 5,00 <= 7,00
						Límpido/Incolor							
FITATO-99mTc Lot # K-20211227-028		27/12/2021	08:54	MB	Butanona	3MM Whatman	355		2	0	pH (Low/Actual/High)	99,44 %	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
MAA-99mTc Lot # K-20211227-012		27/12/2021 04:06	MB	Butanona		3MM Whatman		271		1	0	99,632 %	Pass	
												pH (Low/Actual/High)	3,00 <= 3,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211227-025		27/12/2021 08:08	MB	Butanona		3MM Whatman		252		1	0	99,605 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211227-036		27/12/2021 12:16	VS	Butanona		3MM Whatman		701		12	0	98,317 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MDP-99mTc Lot # K-20211227-005		27/12/2021 03:10	MB	Acetona		3MM Whatman		535,1		1	0	97,596 %	Pass	
				Normal Saline		3MM Whatman		12,4		546,9		pH (Low/Actual/High)	4,00 <= 4,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211227-006		27/12/2021 03:11	MB	Acetona		3MM Whatman		670,6		2,2	0	98,559 %	Pass	
				Normal Saline		3MM Whatman		7,5		665,6		pH (Low/Actual/High)	4,00 <= 4,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211227-007		27/12/2021 03:13	MB	Acetona		3MM Whatman		565,8		1,5	0	99,564 %	Pass	
				Normal Saline		3MM Whatman		1		581,7		pH (Low/Actual/High)	4,00 <= 4,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211227-018		27/12/2021 07:24	PM	Acetona		3MM Whatman		1849		6	0	96,759 %	Pass	
				Normal Saline		3MM Whatman		51		1697		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211227-019		27/12/2021 07:26	PM	Acetona		3MM Whatman		215		7	0	95,39 %	Pass	
				Normal Saline		3MM Whatman		25		1691		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211227-022		27/12/2021 07:52	MB	Acetona		3MM Whatman		1572		6	0	97,984 %	Pass	
				Normal Saline		3MM Whatman		22		1323		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211227-027		27/12/2021 08:49	MB	Acetona		3MM Whatman		1009		1	0	99,322 %	Pass	
				Normal Saline		3MM Whatman		5		859		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211227-035		27/12/2021 11:39	VS	Acetona		3MM Whatman		1447		5	0	98,174 %	Pass	
				Normal Saline		3MM Whatman		4		266		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MIBI-99mTc Lot # K-20211227-001		27/12/2021 02:43	BB	Normal Saline		Sílica gel		866		29	0	95,54 %	Pass	
				Metanol		3MM Whatman		13		1053		pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido/Incolor		
MIBI-99mTc Lot # K-20211227-002		27/12/2021 02:44	BB	Normal Saline		Sílica gel		8586		20	0	98,683 %	Pass	
				Metanol		3MM Whatman		19		1733		pH (Low/Actual/High)	5,00 <= 5,00 <= 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-20211227-003		27/12/2021 02:56	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1425 9		38 1748	0	pH (Low/Actual/High)	96,89 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211227-004		27/12/2021 02:57	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1685 3		27 1642	0	pH (Low/Actual/High)	98,241 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211227-013		27/12/2021 06:23	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1267 6		30 241	0	pH (Low/Actual/High)	95,258 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211227-014		27/12/2021 06:24	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			3323 32		94 3764	0	pH (Low/Actual/High)	96,406 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211227-015		27/12/2021 06:37	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			945 12		21 1598	0	pH (Low/Actual/High)	97,081 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211227-016		27/12/2021 06:38	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			225 12		9 1108	0	pH (Low/Actual/High)	95,082 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211227-026		27/12/2021 08:11	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1460 15		20 859	0	pH (Low/Actual/High)	96,932 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211227-031		27/12/2021 10:04	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			358 5		14 346	0	pH (Low/Actual/High)	94,812 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211227-032		27/12/2021 10:40	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			1156 5		28 1165	0	pH (Low/Actual/High)	97,208 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20211227-020		27/12/2021 07:45	MB	Butanona Normal Saline	3MM Whatman 3MM Whatman			338 2		1 382	0	pH (Low/Actual/High)	99,184 %	Pass 5,00 <= 5,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20211227-017		27/12/2021 06:53	PM	Acetato de amônio 1M:Metanol	Sílica gel			1,1		56,8	0	pH (Low/Actual/High)	98,10 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211227-001		27/12/2021 02:36	MB	Butanona	3MM Whatman			3,6		138	0	pH (Low/Actual/High)	97,458 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211227-002		27/12/2021 02:46	MB	Butanona	3MM Whatman			12		3632	0	pH (Low/Actual/High)	99,671 %	Pass 5,00 <= 5,00 <= 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-20211227-003		27/12/2021 03:05	MB	Butanona		3MM Whatman		1		100	0	99,01 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-004		27/12/2021 03:06	MB	Butanona		3MM Whatman		5		480	0	98,969 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-005		27/12/2021 04:00	MB	Butanona		3MM Whatman		7		746	0	99,07 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-006		27/12/2021 06:20	PM	Butanona		3MM Whatman		2		293	0	99,322 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-007		27/12/2021 06:30	PM	Butanona		3MM Whatman		3		827	0	99,639 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-008		27/12/2021 06:31	PM	Butanona		3MM Whatman		3		233	0	98,729 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-010		27/12/2021 07:00	PM	Butanona		3MM Whatman		13		1986	0	99,35 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-011		27/12/2021 07:40	PM	Butanona		3MM Whatman		1		289	0	99,655 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-012		27/12/2021 08:05	MB	Butanona		3MM Whatman		11		778	0	98,606 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-014		27/12/2021 09:50	MB	Butanona		3MM Whatman		1		355	0	99,719 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-016		27/12/2021 10:04	JS	Butanona		3MM Whatman		1		1226	0	99,919 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-015		27/12/2021 10:04	JS	Butanona		3MM Whatman		2		387	0	99,486 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211227-017		27/12/2021 10:12	JS	Butanona		3MM Whatman		3		256	0	98,842 %	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-20211227-018	27/12/2021	11:11 VS	Butanona		3MM	Whatman		3		359	0		99,171 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211227-019	27/12/2021	12:13 VS	Butanona		3MM	Whatman		4		1035	0		99,615 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211227-020	27/12/2021	14:35 FL	Butanona		3MM	Whatman		4		1788	0		99,777 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	