



# 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 05/01/2022 To 05/01/2022

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20220105-022		05/01/2022	07:33	PM	Butanona Normal Saline	3MM Whatman Sílica gel	424 5		7 143	0	pH (Low/Actual/High)	94,997 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220105-023		05/01/2022	07:34	PM	Butanona Normal Saline	3MM Whatman Sílica gel	275 9		2 227	0	pH (Low/Actual/High)	95,464 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220105-033		05/01/2022	10:35	PM	Butanona Normal Saline	3MM Whatman Sílica gel	228 10		3 247	0	pH (Low/Actual/High)	94,81 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220105-039		05/01/2022	12:16	JS	Butanona Normal Saline	3MM Whatman Sílica gel	165 7,8		3,3 90,7	0	pH (Low/Actual/High)	90,12 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20220105-030		05/01/2022	09:57	PM	Citrato de Sódio 0,1M	Sílica gel	7,7		0,3	0	pH (Low/Actual/High)	96,25 %	Pass 4,00 <= 6,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20220105-036		05/01/2022	10:48	PM	Citrato de Sódio 0,1M	Sílica gel	26,3		0,9	0	pH (Low/Actual/High)	96,691 %	Pass 4,00 <= 6,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20220105-015	RPH	05/01/2022	04:23	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	445 37		2 389	0	pH (Low/Actual/High)	90,867 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20220105-035	RPH	05/01/2022	10:46	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	457 7		2 419	0	pH (Low/Actual/High)	97,921 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20220105-007		05/01/2022	03:09	MB	Butanona	3MM Whatman	400		2	0	pH (Low/Actual/High)	99,502 %	Pass 5,00 <= 5,00 <= 7,00
						Límpido/Incolor							
FITATO-99mTc Lot # K-20220105-020		05/01/2022	07:18	PM	Butanona	3MM Whatman	1097		2	0	pH (Low/Actual/High)	99,818 %	Pass 5,00 <= 7,00 <= 7,00
						Límpido/Incolor							
MAA-99mTc Lot # K-20220105-012		05/01/2022	04:03	MB	Butanona	3MM Whatman	291		3	0	pH (Low/Actual/High)	98,98 %	Pass 3,00 <= 3,00 <= 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-20220105-025		05/01/2022 07:40 PM	Butanona		3MM	Whatman		193		1	0	99,485 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20220105-026		05/01/2022 07:44 PM	Butanona		3MM	Whatman		219		1	0	99,545 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20220105-027		05/01/2022 07:46 PM	Butanona		3MM	Whatman		235		1	0	99,576 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20220105-028		05/01/2022 07:49 PM	Butanona		3MM	Whatman		408		3	0	99,27 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20220105-037		05/01/2022 11:23 PM	Butanona		3MM	Whatman		210		2	0	99,057 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MDP-99mTc Lot # K-20220105-014		05/01/2022 04:21 MB	Acetona		3MM	Whatman		929		1	0	99,345 %	Pass	
			Normal Saline		3MM	Whatman		6		1089	pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20220105-016		05/01/2022 04:27 MB	Acetona		3MM	Whatman		698		1	0	99,397 %	Pass	
			Normal Saline		3MM	Whatman		4		865	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20220105-021		05/01/2022 07:24 PM	Acetona		3MM	Whatman		1778		1	0	99,513 %	Pass	
			Normal Saline		3MM	Whatman		8		1849	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20220105-024		05/01/2022 07:36 PM	Acetona		3MM	Whatman		1181		5	0	97,22 %	Pass	
			Normal Saline		3MM	Whatman		5		207	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20220105-029		05/01/2022 08:09 PM	Acetona		3MM	Whatman		214		3	0	98,171 %	Pass	
			Normal Saline		3MM	Whatman		6		1337	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20220105-034		05/01/2022 10:38 PM	Acetona		3MM	Whatman		1584		3	0	99,611 %	Pass	
			Normal Saline		3MM	Whatman		3		1500	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MIBI-99mTc Lot # K-20220105-005		05/01/2022 02:46 MB	Normal Saline		Sílica gel			1283		15	0	97,294 %	Pass	
			Metanol		3MM	Whatman		26		1651	pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
							Límpido/Incolor							
MIBI-99mTc Lot # K-20220105-006		05/01/2022 02:51 MB	Normal Saline		Sílica gel			1780		45	0	96,933 %	Pass	
			Metanol		3MM	Whatman		13		2150	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-20220105-008		05/01/2022 03:27	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1396 10		16 1821	0	pH (Low/Actual/High)	98,321 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20220105-009		05/01/2022 03:28	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1207 9		6 2158	0	pH (Low/Actual/High)	99,09 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20220105-010		05/01/2022 03:57	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1566 30		15 1948	0	pH (Low/Actual/High)	97,535 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20220105-011		05/01/2022 03:59	BB	Normal Saline Metanol	Sílica gel 3MM Whatman			1517 18		26 1887	0	pH (Low/Actual/High)	97,37 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20220105-013		05/01/2022 04:17	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1795 56		33 2141	0	pH (Low/Actual/High)	95,646 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20220105-018		05/01/2022 07:02	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1339 30		25 1345	0	pH (Low/Actual/High)	95,985 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20220105-019		05/01/2022 07:07	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			206 1		1 312	0	pH (Low/Actual/High)	99,197 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20220105-031		05/01/2022 10:17	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1251 53		23 1781	0	pH (Low/Actual/High)	95,305 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20220105-032		05/01/2022 10:17	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1905 7		21 222	0	pH (Low/Actual/High)	95,853 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20220105-038		05/01/2022 11:36	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			902 12		13 1040	0	pH (Low/Actual/High)	97,439 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
PSMA-177Lu Lot # K-20220105-001		05/01/2022 01:28	BB	Citrato de Sódio 0,1M	Sílica gel			740		2	0	pH (Low/Actual/High)	99,73 %	Pass 4,00 <= 4,50 <= 5,00
														Límpido
QC Notes: HPLC: 99,4%														
PSMA-177Lu Lot # K-20220105-002		05/01/2022 01:49	BB	Citrato de Sódio 0,1M	Sílica gel			582		3	0	pH (Low/Actual/High)	99,487 %	Pass 4,00 <= 4,50 <= 5,00
														Límpido
QC Notes: HPLC: 97,72%														

Product:	Manuf:	Calibration D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
PSMA-177Lu Lot # K-20220105-003		05/01/2022 02:17 BB	Citrato de Sódio 0,1M		Sílica gel			649		3	0	99,54 %		Pass
							Límpido				pH (Low/Actual/High)	4,00 <= 4,50 <= 5,00		
QC Notes: HPLC: 98,4%														
PSMA-177Lu Lot # K-20220105-004		05/01/2022 02:33 BB	Citrato de Sódio 0,1M		Sílica gel			796		0	0	100,00 %		Pass
							Límpido				pH (Low/Actual/High)	4,00 <= 4,50 <= 5,00		
QC Notes: HPLC: 97%														
PSMA-68Ga Lot # K-20220105-017		05/01/2022 06:52 PM	Acetato de amônio 1M:Metanol		Sílica gel			1,9		40,5	0	95,519 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
PSMA-68Ga Lot # K-20220105-040		05/01/2022 12:56 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,4		26,7	0	98,524 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
PSMA-68Ga Lot # K-20220105-041		05/01/2022 15:45 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,9		26,6	0	96,727 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
Tecnécio-99m Lot # E-20220105-001		05/01/2022 02:33 MB	Butanona		3MM Whatman			19		712	0	97,401 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20220105-002		05/01/2022 02:48 MB	Butanona		3MM Whatman			3		109	0	97,321 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20220105-003		05/01/2022 03:01 MB	Butanona		3MM Whatman			11		513	0	97,901 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20220105-004		05/01/2022 03:23 MB	Butanona		3MM Whatman			2		158	0	98,75 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20220105-005		05/01/2022 03:25 MB	Butanona		3MM Whatman			11		471	0	97,718 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20220105-006		05/01/2022 03:55 MB	Butanona		3MM Whatman			46		2054	0	97,81 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20220105-007		05/01/2022 03:57 MB	Butanona		3MM Whatman			2		1462	0	99,863 %		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-20220105-008		05/01/2022 04:15	MB	Butanona		3MM Whatman		10		2322	0		99,571 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-009		05/01/2022 04:18	MB	Butanona		3MM Whatman		4		2687	0		99,851 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-011		05/01/2022 06:59	PM	Butanona		3MM Whatman		58		1993	0		97,172 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-012		05/01/2022 07:05	PM	Butanona		3MM Whatman		128		3700	0		96,656 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-013		05/01/2022 07:21	PM	Butanona		3MM Whatman		9		251	0		96,538 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-014		05/01/2022 07:30	PM	Butanona		3MM Whatman		11		259	0		95,926 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-015		05/01/2022 08:07	PM	Butanona		3MM Whatman		3		217	0		98,636 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-017		05/01/2022 10:10	PM	Butanona		3MM Whatman		5		1971	0		99,747 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-018		05/01/2022 10:11	PM	Butanona		3MM Whatman		3		1724	0		99,826 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-019		05/01/2022 10:30	PM	Butanona		3MM Whatman		9		1123	0		99,205 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-020		05/01/2022 10:30	PM	Butanona		3MM Whatman		3		225	0		98,684 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-022		05/01/2022 11:34	MB	Butanona		3MM Whatman		9		228	0		96,203 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220105-023		05/01/2022 12:14	JS	Butanona		3MM Whatman		31		904	0		96,684 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor