



# 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 28/12/2021 To 28/12/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211228-011		28/12/2021	04:00	MB	Butanona Normal Saline	3MM Whatman Sílica gel	192,3 5,5		2,4 122,4	0	pH (Low/Actual/High)	94,467 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211228-012		28/12/2021	04:01	MB	Butanona Normal Saline	3MM Whatman Sílica gel	186,4 9,7		0,9 141,8	0	pH (Low/Actual/High)	93,117 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211228-022		28/12/2021	07:31	PM	Butanona Normal Saline	3MM Whatman Sílica gel	290,8 6,6		2,2 176,2	0	pH (Low/Actual/High)	95,639 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211228-023		28/12/2021	07:32	PM	Butanona Normal Saline	3MM Whatman Sílica gel	291,3 8,1		4,1 232,3	0	pH (Low/Actual/High)	95,243 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211228-035		28/12/2021	10:21	JS	Butanona Normal Saline	3MM Whatman Sílica gel	131 4,8		1,4 94	0	pH (Low/Actual/High)	94,084 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20211228-018		28/12/2021	06:58	PM	Citrato de Sódio 0,1M	Sílica gel	56		0,7	0	pH (Low/Actual/High)	98,765 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20211228-028		28/12/2021	09:48	VS	Citrato de Sódio 0,1M	Sílica gel	285		8	0	pH (Low/Actual/High)	97,27 %	Pass 4,00 <= 6,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20211228-047		28/12/2021	12:48	YD	Citrato de Sódio 0,1M	Sílica gel	25,4		0,3	0	pH (Low/Actual/High)	98,833 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20211228-009	RPH	28/12/2021	03:37	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	517,1 7,4		3 459,5	0	pH (Low/Actual/High)	97,838 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211228-021	RPH	28/12/2021	07:28	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	928 26		9 663	0	pH (Low/Actual/High)	95,266 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211228-039	RPH	28/12/2021	10:46	JS	Acetona Normal Saline	3MM Whatman 3MM Whatman	438 9		1 337	0	pH (Low/Actual/High)	97,171 %	Pass 3,80 <= 6,00 <= 7,50
						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-20211228-003		28/12/2021 02:39 MB	Butanona			3MM Whatman		293,6		5,3	0		98,227 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 7,00
														Límpido/Incolor
FITATO-99mTc Lot # K-20211228-024		28/12/2021 07:34 PM	Butanona			3MM Whatman		292		2	0		99,32 %	Pass
												pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00
														Límpido/Incolor
MAA-99mTc Lot # K-20211228-010		28/12/2021 03:59 MB	Butanona			3MM Whatman		222		2	0		99,107 %	Pass
												pH (Low/Actual/High)	3,00 <= 3,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211228-026		28/12/2021 07:50 PM	Butanona			3MM Whatman		185,5		3,2	0		98,304 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211228-041		28/12/2021 11:32 YD	Butanona			3MM Whatman		99		4	0		96,117 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211228-042		28/12/2021 11:38 JS	Butanona			3MM Whatman		133,5		3	0		97,802 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211228-043		28/12/2021 11:38 YD	Butanona			3MM Whatman		106,9		4,4	0		96,047 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211228-044		28/12/2021 11:43 YD	Butanona			3MM Whatman		27,1		0,9	0		96,786 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211228-045		28/12/2021 11:56 YD	Butanona			3MM Whatman		42,4		1,2	0		97,248 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211228-046		28/12/2021 11:58 YD	Butanona			3MM Whatman		65,6		0,6	0		99,094 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MDP-99mTc Lot # K-20211228-005		28/12/2021 02:59 MB	Acetona			3MM Whatman		1065		7	0		99,03 %	Pass
			Normal Saline			3MM Whatman		4		1258		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211228-008		28/12/2021 03:33 MB	Acetona			3MM Whatman		1221		35	0		95,128 %	Pass
			Normal Saline			3MM Whatman		24		1127		pH (Low/Actual/High)	4,00 <= 4,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211228-016		28/12/2021 06:38 PM	Acetona			3MM Whatman		1496		2	0		97,098 %	Pass
			Normal Saline			3MM Whatman		40		1405		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-20211228-017		28/12/2021 06:40 PM	Acetona Normal Saline		3MM Whatman 3MM Whatman			1417 2		14 1308	0	pH (Low/Actual/High)	98,869 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211228-034		28/12/2021 10:16 VS	Acetona Normal Saline		3MM Whatman 3MM Whatman			1408 4		6 1818	0	pH (Low/Actual/High)	99,356 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211228-036		28/12/2021 10:19 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			581 2		1 705	0	pH (Low/Actual/High)	99,545 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20211228-001		28/12/2021 02:32 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1409 16		22 2243	0	pH (Low/Actual/High)	97,754 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211228-002		28/12/2021 02:33 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1301 35		20 2054	0	pH (Low/Actual/High)	96,811 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211228-004		28/12/2021 02:57 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1001 8		11 1773	0	pH (Low/Actual/High)	98,464 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211228-006		28/12/2021 03:03 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1403 12		24 1960	0	pH (Low/Actual/High)	97,71 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211228-007		28/12/2021 03:31 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			964 6		18 1068	0	pH (Low/Actual/High)	97,608 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211228-013		28/12/2021 06:22 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1850 2		31 370	0	pH (Low/Actual/High)	97,814 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211228-015		28/12/2021 06:29 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			268 4		3 285	0	pH (Low/Actual/High)	97,509 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211228-025		28/12/2021 07:44 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			243 7		4 286	0	pH (Low/Actual/High)	95,991 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211228-027		28/12/2021 08:43 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			1113 4		2 1562	0	pH (Low/Actual/High)	99,565 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211228-038		28/12/2021 10:25 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			347 1		9 393	0	pH (Low/Actual/High)	97,218 %	Pass 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-20211228-040	28/12/2021	11:28 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1147 12		12 935	0	pH (Low/Actual/High)	97,697 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
PIRO-99mTc Lot # K-20211228-019	28/12/2021	07:23 PM	Butanona Normal Saline		3MM Whatman 3MM Whatman			786 22		2 944	0	pH (Low/Actual/High)	97,469 %	Pass 5,00 <= 5,00 <= 7,00
														Límpido/Incolor
PIRO-99mTc Lot # K-20211228-020	28/12/2021	07:24 PM	Butanona Normal Saline		3MM Whatman 3MM Whatman			495 3		2 500	0	pH (Low/Actual/High)	99,001 %	Pass 5,00 <= 5,00 <= 7,00
														Límpido/Incolor
Tecnécio-99m Lot # E-20211228-001	28/12/2021	02:27 MB	Butanona		3MM Whatman			3		178	0	pH (Low/Actual/High)	98,343 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211228-002	28/12/2021	02:28 MB	Butanona		3MM Whatman			1		25,2	0	pH (Low/Actual/High)	96,183 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211228-003	28/12/2021	02:54 MB	Butanona		3MM Whatman			3		279	0	pH (Low/Actual/High)	98,936 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211228-004	28/12/2021	03:01 MB	Butanona		3MM Whatman			5,6		476,8	0	pH (Low/Actual/High)	98,839 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211228-005	28/12/2021	03:28 MB	Butanona		3MM Whatman			27		1689	0	pH (Low/Actual/High)	98,427 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211228-006	28/12/2021	03:48 MB	Butanona		3MM Whatman			10		623	0	pH (Low/Actual/High)	98,42 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211228-007	28/12/2021	06:20 PM	Butanona		3MM Whatman			2		797	0	pH (Low/Actual/High)	99,75 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211228-008	28/12/2021	06:26 PM	Butanona		3MM Whatman			2		576	0	pH (Low/Actual/High)	99,654 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211228-009	28/12/2021	06:29 PM	Butanona		3MM Whatman			1		1835	0	pH (Low/Actual/High)	99,946 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211228-011	28/12/2021	07:19 PM	Butanona		3MM Whatman			2		219	0	pH (Low/Actual/High)	99,095 %	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-20211228-012	28/12/2021	07:42 PM	Butanona		3MM	Whatman		6		401	0	98,526 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211228-013	28/12/2021	07:47 PM	Butanona		3MM	Whatman		5		1095	0	99,545 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211228-015	28/12/2021	10:00 VS	Butanona		3MM	Whatman		10		848	0	98,834 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211228-016	28/12/2021	10:15 VS	Butanona		3MM	Whatman		11		723	0	98,501 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211228-017	28/12/2021	11:26 JS	Butanona		3MM	Whatman		2		1261	0	99,842 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211228-019	28/12/2021	14:03 FL	Butanona		3MM	Whatman		0,75		851,25	0	99,912 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211228-020	28/12/2021	14:41 FL	Butanona		3MM	Whatman		1,45		918	0	99,842 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
TRODAT-99mTc Lot # K-20211228-029	28/12/2021	10:13 VS	Normal Saline		Sílica gel			130,8		2	0	97,201 %	Pass	
			Butanona		3MM	Whatman		3		229	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211228-030	28/12/2021	10:14 VS	Normal Saline		Sílica gel			251,3		2	0	98,333 %	Pass	
			Butanona		3MM	Whatman		2		226	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211228-031	28/12/2021	10:15 VS	Normal Saline		Sílica gel			153,2		2,1	0	97,457 %	Pass	
			Butanona		3MM	Whatman		3		249	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211228-032	28/12/2021	10:16 VS	Normal Saline		Sílica gel			171,8		2,3	0	97,724 %	Pass	
			Butanona		3MM	Whatman		3		311	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211228-033	28/12/2021	10:17 VS	Normal Saline		Sílica gel			234,1		1,8	0	98,446 %	Pass	
			Butanona		3MM	Whatman		2		251	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							Límpido/Incolor							