



# 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 30/11/2021 To 30/11/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211130-014		30/11/2021	04:02	MB	Butanona Normal Saline	3MM Whatman Sílica gel	170,8 14,4		1,3 168	0	pH (Low/Actual/High)	91,35 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211130-025		30/11/2021	07:46	BB	Butanona Normal Saline	3MM Whatman Sílica gel	163 1,5		1,9 166,5	0	pH (Low/Actual/High)	97,955 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211130-026		30/11/2021	07:46	PM	Butanona Normal Saline	3MM Whatman Sílica gel	205,2 16,6		2,8 191,1	0	pH (Low/Actual/High)	90,662 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211130-027		30/11/2021	07:47	BB	Butanona Normal Saline	3MM Whatman Sílica gel	220,5 0,6		1,4 72,6	0	pH (Low/Actual/High)	98,549 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20211130-020		30/11/2021	06:47	PM	Citrato de Sódio 0,1M	Sílica gel	19,56		0,03	0	pH (Low/Actual/High)	99,847 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20211130-030		30/11/2021	09:31	BB	Citrato de Sódio 0,1M	Sílica gel	24,4		0,4	0	pH (Low/Actual/High)	98,387 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20211130-055		30/11/2021	12:35	VS	Citrato de Sódio 0,1M	Sílica gel	584		3	0	pH (Low/Actual/High)	99,489 %	Pass 4,00 <= 7,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20211130-058		30/11/2021	15:43	JS	Citrato de Sódio 0,1M	Sílica gel	32,8		0,1	0	pH (Low/Actual/High)	99,696 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20211130-011	RPH	30/11/2021	03:53	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	404 26		2 380	0	pH (Low/Actual/High)	93,103 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211130-012	RPH	30/11/2021	03:55	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	458 12		2 484	0	pH (Low/Actual/High)	97,146 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211130-024	RPH	30/11/2021	07:20	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	691 7		24 624	0	pH (Low/Actual/High)	95,534 %	Pass 3,80 <= 5,00 <= 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
DTPA-99mTc Lot # K-20211130-040	RPH	30/11/2021 10:44	VS	Acetona Normal Saline	3MM	Whatman		194 4		2 908	0	pH (Low/Actual/High)	98,541 %	Pass
													3,80 <= 6,00	<= 7,50
														Límpido/Incolor
FITATO-99mTc Lot # K-20211130-013		30/11/2021 03:57	MB	Butanona	3MM	Whatman		314		1	0	pH (Low/Actual/High)	99,683 %	Pass
													5,00 <= 5,00	<= 7,00
														Límpido/Incolor
FITATO-99mTc Lot # K-20211130-041		30/11/2021 10:48	VS	Butanona	3MM	Whatman		261		3	0	pH (Low/Actual/High)	98,864 %	Pass
													5,00 <= 6,00	<= 7,00
														Límpido/Incolor
MAA-99mTc Lot # K-20211130-015		30/11/2021 04:17	MB	Butanona	3MM	Whatman		532		3	0	pH (Low/Actual/High)	99,439 %	Pass
													3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211130-028		30/11/2021 07:51	PM	Butanona	3MM	Whatman		136		1,9	0	pH (Low/Actual/High)	98,622 %	Pass
													3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211130-043		30/11/2021 11:29	VS	Butanona	3MM	Whatman		561		12	0	pH (Low/Actual/High)	97,906 %	Pass
													3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211130-044		30/11/2021 11:31	VS	Butanona	3MM	Whatman		706		8	0	pH (Low/Actual/High)	98,88 %	Pass
													3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211130-045		30/11/2021 11:33	VS	Butanona	3MM	Whatman		252		10	0	pH (Low/Actual/High)	96,183 %	Pass
													3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211130-046		30/11/2021 11:34	VS	Butanona	3MM	Whatman		637		9	0	pH (Low/Actual/High)	98,607 %	Pass
													3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211130-048		30/11/2021 12:16	VS	Butanona	3MM	Whatman		121		3	0	pH (Low/Actual/High)	97,581 %	Pass
													3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211130-049		30/11/2021 12:18	VS	Butanona	3MM	Whatman		166		4	0	pH (Low/Actual/High)	97,647 %	Pass
													3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211130-051		30/11/2021 12:23	VS	Butanona	3MM	Whatman		695		4	0	pH (Low/Actual/High)	99,428 %	Pass
													3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211130-052		30/11/2021 12:27	VS	Butanona	3MM	Whatman		399		9	0	pH (Low/Actual/High)	97,794 %	Pass
													3,00 <= 5,00	<= 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-20211130-053		30/11/2021 12:31 VS	Butanona		3MM	Whatman		418		5	0	98,818 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20211130-054		30/11/2021 12:34 VS	Butanona		3MM	Whatman		716		3	0	99,583 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20211130-056		30/11/2021 12:49 VS	Butanona		3MM	Whatman		214		4	0	98,165 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20211130-057		30/11/2021 13:04 VS	Butanona		3MM	Whatman		257		2	0	99,228 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MDP-99mTc Lot # K-20211130-008		30/11/2021 03:32 MB	Acetona		3MM	Whatman		800		1	0	99,125 %	Pass	
			Normal Saline		3MM	Whatman		6		794	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211130-009		30/11/2021 03:49 MB	Acetona		3MM	Whatman		969		2	0	99,167 %	Pass	
			Normal Saline		3MM	Whatman		5		792	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211130-010		30/11/2021 03:51 MB	Acetona		3MM	Whatman		798		1	0	98,711 %	Pass	
			Normal Saline		3MM	Whatman		10		849	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211130-019		30/11/2021 05:39 PM	Acetona		3MM	Whatman		969		7	0	98,768 %	Pass	
			Normal Saline		3MM	Whatman		4		773	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211130-023		30/11/2021 07:16 PM	Acetona		3MM	Whatman		1766		13	0	97,993 %	Pass	
			Normal Saline		3MM	Whatman		15		1160	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211130-037		30/11/2021 10:07 VS	Acetona		3MM	Whatman		683		14	0	97,054 %	Pass	
			Normal Saline		3MM	Whatman		7		740	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211130-036		30/11/2021 10:11 VS	Acetona		3MM	Whatman		182		2	0	96,601 %	Pass	
			Normal Saline		3MM	Whatman		4		169	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211130-001		30/11/2021 01:53 MB	Normal Saline		Sílica gel			980		10	0	98,248 %	Pass	
			Metanol		3MM	Whatman		7		936	pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211130-002		30/11/2021 01:57 MB	Normal Saline		Sílica gel			546		6	0	96,98 %	Pass	
			Metanol		3MM	Whatman		11		558	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-20211130-003		30/11/2021 02:21	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			437 5		8 540	0	pH (Low/Actual/High)	97,285 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-004		30/11/2021 02:22	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1023 11		12 1405	0	pH (Low/Actual/High)	98,064 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-005		30/11/2021 02:28	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			657 12		5 988	0	pH (Low/Actual/High)	98,045 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-006		30/11/2021 03:29	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1046 6		9 1358	0	pH (Low/Actual/High)	98,707 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-007		30/11/2021 03:30	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			685 12		10 1094	0	pH (Low/Actual/High)	97,476 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-016		30/11/2021 04:20	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1234 25		9 1353	0	pH (Low/Actual/High)	97,462 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-017		30/11/2021 05:34	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1732 25		26 1818	0	pH (Low/Actual/High)	97,165 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-018		30/11/2021 05:35	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1692 25		18 1468	0	pH (Low/Actual/High)	97,273 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-021		30/11/2021 07:08	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1492 2		22 215	0	pH (Low/Actual/High)	97,625 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-022		30/11/2021 07:09	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1514 35		13 1436	0	pH (Low/Actual/High)	96,769 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-029		30/11/2021 07:54	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1622 1		14 208	0	pH (Low/Actual/High)	98,666 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-031		30/11/2021 09:57	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1229 16		9 1940	0	pH (Low/Actual/High)	98,455 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-042		30/11/2021 11:08	VS	Normal Saline Metanol	Sílica gel 3MM Whatman			289 11		8 541	0	pH (Low/Actual/High)	95,314 %	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-20211130-047	30/11/2021	11:38 VS	Normal Saline Metanol		Silica gel 3MM Whatman			277 11		4 288	0	pH (Low/Actual/High)	94,898 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211130-050	30/11/2021	12:18 VS	Normal Saline Metanol		Silica gel 3MM Whatman			379 13		5 479	0	pH (Low/Actual/High)	96,056 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
Tecnécio-99m Lot # E-20211130-001	30/11/2021	01:38 MB	Butanona		3MM Whatman			1		37,5	0	pH (Low/Actual/High)	97,403 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211130-002	30/11/2021	02:02 MB	Butanona		3MM Whatman			7		670	0	pH (Low/Actual/High)	98,966 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211130-003	30/11/2021	03:25 MB	Butanona		3MM Whatman			5		1135	0	pH (Low/Actual/High)	99,561 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211130-004	30/11/2021	03:47 MB	Butanona		3MM Whatman			15		1155	0	pH (Low/Actual/High)	98,718 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211130-005	30/11/2021	05:29 PM	Butanona		3MM Whatman			11		1569	0	pH (Low/Actual/High)	99,304 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211130-007	30/11/2021	07:03 PM	Butanona		3MM Whatman			1		723	0	pH (Low/Actual/High)	99,862 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211130-008	30/11/2021	07:37 PM	Butanona		3MM Whatman			4		284	0	pH (Low/Actual/High)	98,611 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211130-010	30/11/2021	09:54 PM	Butanona		3MM Whatman			13		664	0	pH (Low/Actual/High)	98,08 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211130-011	30/11/2021	10:03 PM	Butanona		3MM Whatman			1		944	0	pH (Low/Actual/High)	99,894 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211130-012	30/11/2021	10:22 PM	Butanona		3MM Whatman			2		1110	0	pH (Low/Actual/High)	99,82 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211130-013	30/11/2021	10:25 PM	Butanona		3MM Whatman			19		1151	0	pH (Low/Actual/High)	98,376 %	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-20211130-014		30/11/2021 11:05 VS	Butanona		3MM Whatman			2		720	0	99,723 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
											Límpido e Incolor			
Tecnécio-99m Lot # E-20211130-015		30/11/2021 11:56 VS	Butanona		3MM Whatman			5		624	0	99,205 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
											Límpido e Incolor			
TRODAT-99mTc Lot # K-20211130-032		30/11/2021 10:05 VS	Normal Saline		Sílica gel			147,9		2,4	0	98,185 %	Pass	
			Butanona		3MM Whatman			2		915	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20211130-033		30/11/2021 10:06 VS	Normal Saline		Sílica gel			103,8		1,3	0	97,951 %	Pass	
			Butanona		3MM Whatman			1		122,1	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20211130-034		30/11/2021 10:07 VS	Normal Saline		Sílica gel			102,1		2,3	0	97,652 %	Pass	
			Butanona		3MM Whatman			1		691	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20211130-035		30/11/2021 10:08 VS	Normal Saline		Sílica gel			399		2	0	99,112 %	Pass	
			Butanona		3MM Whatman			3		768	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20211130-038		30/11/2021 10:31 VS	Normal Saline		Sílica gel			140,1		2,3	0	97,777 %	Pass	
			Butanona		3MM Whatman			1,2		196,2	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20211130-039		30/11/2021 10:32 VS	Normal Saline		Sílica gel			180		2	0	97,988 %	Pass	
			Butanona		3MM Whatman			2		217	pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50		
											Límpido/Incolor			