



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 23/06/2021 To 23/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210623-027		23/06/2021	07:31	WG	Butanona Normal Saline	3MM Whatman Sílica gel	171 2		3 128	0	pH (Low/Actual/High)	96,737 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210623-028		23/06/2021	07:32	WG	Butanona Normal Saline	3MM Whatman Sílica gel	143 2		0,1 117	0	pH (Low/Actual/High)	98,249 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210623-029		23/06/2021	08:03	WG	Butanona Normal Saline	3MM Whatman Sílica gel	192,9 4,4		0,7 104,8	0	pH (Low/Actual/High)	95,609 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210623-035		23/06/2021	10:28	WG	Butanona Normal Saline	3MM Whatman Sílica gel	155,7 6,1		3,6 102,9	0	pH (Low/Actual/High)	92,144 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210623-031		23/06/2021	09:46	JS	Citrato de Sódio 0,1M	Sílica gel	11,5		0,6	0	pH (Low/Actual/High)	95,041 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210623-036		23/06/2021	10:31	JS	Citrato de Sódio 0,1M	Sílica gel	15,9		0,6	0	pH (Low/Actual/High)	96,364 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210623-040		23/06/2021	11:17	JS	Citrato de Sódio 0,1M	Sílica gel	16,3		0,4	0	pH (Low/Actual/High)	97,605 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210623-006	RPH	23/06/2021	02:37	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	682 17		10 539	0	pH (Low/Actual/High)	95,497 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210623-025	RPH	23/06/2021	07:27	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	386 21		9 413	0	pH (Low/Actual/High)	92,883 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210623-037	RPH	23/06/2021	10:49	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	698 2		13 534	0	pH (Low/Actual/High)	97,798 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210623-007		23/06/2021	02:40	PP	Butanona	3MM Whatman	732		1	0	pH (Low/Actual/High)	99,864 %	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
FITATO-99mTc Lot # K-20210623-024		23/06/2021 07:18	WG	Butanona		3MM Whatman		340		6	0	98,266 %	Pass	
							Límpido/Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
MAA-99mTc Lot # K-20210623-012		23/06/2021 03:58	PP	Butanona		3MM Whatman		438		7	0	98,427 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210623-013		23/06/2021 04:00	PP	Butanona		3MM Whatman		257		3	0	98,846 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210623-014		23/06/2021 04:02	PP	Butanona		3MM Whatman		209		2	0	99,052 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210623-015		23/06/2021 04:04	PP	Butanona		3MM Whatman		160		4	0	97,561 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210623-016		23/06/2021 04:05	PP	Butanona		3MM Whatman		197		6	0	97,044 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210623-038		23/06/2021 10:52	WG	Butanona		3MM Whatman		128		1	0	99,225 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210623-039		23/06/2021 10:54	WG	Butanona		3MM Whatman		200		2	0	99,01 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MDP-99mTc Lot # K-20210623-011		23/06/2021 03:29	PP	Acetona		3MM Whatman		1104		4	0	99,083 %	Pass	
				Normal Saline		3MM Whatman		9		1611	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210623-018		23/06/2021 04:11	PP	Acetona		3MM Whatman		1119		1	0	96,485 %	Pass	
				Normal Saline		3MM Whatman		31		874	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210623-021		23/06/2021 04:38	PP	Acetona		3MM Whatman		673		3	0	97,292 %	Pass	
				Normal Saline		3MM Whatman		19		820	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210623-026		23/06/2021 07:29	WG	Acetona		3MM Whatman		1076		8	0	99,083 %	Pass	
				Normal Saline		3MM Whatman		2		1116	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210623-030		23/06/2021 08:06	WG	Acetona		3MM Whatman		1507		7	0	97,634 %	Pass	
				Normal Saline		3MM Whatman		15		772,9	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-20210623-034		23/06/2021 10:23	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			1750 14		18 867	0	pH (Low/Actual/High)	97,393 %	Pass
														4,00 <= 6,00 <= 7,80
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-003		23/06/2021 01:20	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1235 15		54 1850	0	pH (Low/Actual/High)	95,006 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-004		23/06/2021 02:31	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1683 42		31 3359	0	pH (Low/Actual/High)	96,956 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-005		23/06/2021 02:32	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2054 51		38 4322	0	pH (Low/Actual/High)	97,017 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-008		23/06/2021 03:19	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2127 30		23 2798	0	pH (Low/Actual/High)	97,869 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-009		23/06/2021 03:26	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1949 107		26 2990	0	pH (Low/Actual/High)	95,229 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-010		23/06/2021 03:27	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1889 2		58 2766	0	pH (Low/Actual/High)	96,949 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-017		23/06/2021 04:06	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1810 12		8 2104	0	pH (Low/Actual/High)	98,993 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-019		23/06/2021 04:15	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1273 58		25 2467	0	pH (Low/Actual/High)	95,777 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-020		23/06/2021 04:20	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			975 5		15 945	0	pH (Low/Actual/High)	97,959 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-022		23/06/2021 07:01	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			793 4		7 1611	0	pH (Low/Actual/High)	98,877 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-023		23/06/2021 07:11	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			13626 19		6 2854	0	pH (Low/Actual/High)	99,295 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210623-032		23/06/2021 10:11	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1098 3		5 845	0	pH (Low/Actual/High)	99,193 %	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-20210623-033	23/06/2021	10:15	WG	Normal Saline Metanol	Silica gel			620 18		11 924	0		96,346 %	Pass
							Límpido/Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
PSMA-177Lu Lot # K-20210623-001	23/06/2021	00:55	BB	Citrato de Sódio 0,1M	Silica gel			159,9		0,3	0		99,813 %	Pass
							Límpido					pH (Low/Actual/High)	4,00 <= 4,50 <= 5,00	
QC Notes: HPLC: 97,22														
PSMA-177Lu Lot # K-20210623-002	23/06/2021	01:20	BB	Citrato de Sódio 0,1M	Silica gel			196		2	0		98,99 %	Pass
							Límpido					pH (Low/Actual/High)	4,00 <= 4,50 <= 5,00	
QC Notes: HPLC: 96,76%														
PSMA-68Ga Lot # K-20210623-041	23/06/2021	12:42	JS	Acetato de amônio	Silica gel			0,3		33,2	0		99,104 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00	
Tecnécio-99m Lot # E-20210623-001	23/06/2021	01:04	PP	Butanona	3MM Whatman			5		425	0		98,837 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20210623-003	23/06/2021	02:27	PP	Butanona	3MM Whatman			11		1789	0		99,389 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20210623-002	23/06/2021	02:27	PP	Butanona	3MM Whatman			1		324	0		99,692 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20210623-004	23/06/2021	03:17	PP	Butanona	3MM Whatman			19		1226	0		98,474 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20210623-006	23/06/2021	03:22	PP	Butanona	3MM Whatman			3		781	0		99,617 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20210623-005	23/06/2021	03:22	PP	Butanona	3MM Whatman			10		1046	0		99,053 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20210623-007	23/06/2021	03:56	PP	Butanona	3MM Whatman			18		1213	0		98,538 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20210623-008	23/06/2021	04:03	PP	Butanona	3MM Whatman			67		4921	0		98,657 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 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
Tecnício-99m Lot # E-20210623-009	23/06/2021	04:13	PP	Butanona		3MM	Whatman		9		1371	0	99,348 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-010	23/06/2021	04:17	PP	Butanona		3MM	Whatman		8		444	0	98,23 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-011	23/06/2021	04:36	PP	Butanona		3MM	Whatman		9		356	0	97,534 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-012	23/06/2021	06:59	WG	Butanona		3MM	Whatman		10		584	0	98,316 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-013	23/06/2021	07:09	WG	Butanona		3MM	Whatman		7		246	0	97,233 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-014	23/06/2021	07:16	WG	Butanona		3MM	Whatman		0,6		144	0	99,585 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-015	23/06/2021	07:25	WG	Butanona		3MM	Whatman		6		722	0	99,176 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-016	23/06/2021	08:04	WG	Butanona		3MM	Whatman		12		1281	0	99,072 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-018	23/06/2021	10:08	WG	Butanona		3MM	Whatman		1,8		157	0	98,866 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-019	23/06/2021	10:12	WG	Butanona		3MM	Whatman		4		251	0	98,431 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-020	23/06/2021	10:22	WG	Butanona		3MM	Whatman		5		448	0	98,896 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-022	23/06/2021	10:47	WG	Butanona		3MM	Whatman		16		481	0	96,781 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210623-024	23/06/2021	11:30	WG	Butanona		3MM	Whatman		2		457	0	99,564 %	Pass	
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 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		23/06/2021 13:01	SB	Butanona		3MM	Whatman	20		879	0		97,775 %	Pass
Lot # E-20210623-026												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
														Límpido e Incolor