



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 23/02/2022 To 23/02/2022

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20220223-016		23/02/2022	04:03	MB	Butanona Normal Saline	3MM Whatman Sílica gel	226 11		4 160	0	pH (Low/Actual/High)	91,828 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220223-028		23/02/2022	07:30	MB	Butanona Normal Saline	3MM Whatman Sílica gel	244 11		3 224	0	pH (Low/Actual/High)	94,105 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220223-029		23/02/2022	07:34	MB	Butanona Normal Saline	3MM Whatman Sílica gel	237 9		3 168	0	pH (Low/Actual/High)	93,665 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220223-037		23/02/2022	10:13	VSR	Butanona Normal Saline	3MM Whatman Sílica gel	229 6,9		5 149	0	pH (Low/Actual/High)	93,437 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20220223-033		23/02/2022	09:50	VSR	Citrato de Sódio 0,1M	Sílica gel	27,6		1	0	pH (Low/Actual/High)	96,503 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20220223-044		23/02/2022	15:41	JS	Citrato de Sódio 0,1M	Sílica gel	11		0,2	0	pH (Low/Actual/High)	98,214 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20220223-013	RPH	23/02/2022	03:55	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	690 7		2 809	0	pH (Low/Actual/High)	98,853 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20220223-030	RPH	23/02/2022	07:49	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	365 15		2 374	0	pH (Low/Actual/High)	95,599 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20220223-040	RPH	23/02/2022	11:15	VS	Acetona Normal Saline	3MM Whatman 3MM Whatman	1905 3		4 1797	0	pH (Low/Actual/High)	99,624 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20220223-012		23/02/2022	03:52	MB	Butanona	3MM Whatman	525		3	0	pH (Low/Actual/High)	99,432 %	Pass 5,00 <= 6,00 <= 7,00
						Límpido/Incolor							
FITATO-99mTc Lot # K-20220223-032		23/02/2022	08:15	MB	Butanona	3MM Whatman	704		8	0	pH (Low/Actual/High)	98,876 %	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-20220223-010		23/02/2022 03:45	MB	Butanona		3MM Whatman		213,3		2,6	0		98,796 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20220223-014		23/02/2022 03:56	BB	Butanona		3MM Whatman		196		3	0		98,492 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20220223-036		23/02/2022 10:05	VSR	Butanona		3MM Whatman		69		0,4	0		99,424 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MDP-99mTc Lot # K-20220223-017		23/02/2022 04:07	MB	Acetona		3MM Whatman		979		2	0		99,372 %	Pass
				Normal Saline		3MM Whatman		5		1173		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20220223-018		23/02/2022 04:17	MB	Acetona		3MM Whatman		1342		2	0		99,696 %	Pass
				Normal Saline		3MM Whatman		2		1284		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20220223-019		23/02/2022 04:18	MB	Acetona		3MM Whatman		1366		11	0		97,051 %	Pass
				Normal Saline		3MM Whatman		29		1320		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20220223-020		23/02/2022 05:16	WN	Acetona		3MM Whatman		703		1	0		99,336 %	Pass
				Normal Saline		3MM Whatman		4		763		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20220223-027		23/02/2022 07:22	MB	Acetona		3MM Whatman		1325		3	0		98,874 %	Pass
				Normal Saline		3MM Whatman		12		1321		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20220223-031		23/02/2022 08:11	MB	Acetona		3MM Whatman		1314		4	0		98,105 %	Pass
				Normal Saline		3MM Whatman		23		1422		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20220223-035		23/02/2022 10:00	VSR	Acetona		3MM Whatman		1,04		0,01	0		97,931 %	Pass
				Normal Saline		3MM Whatman		0,017		1,505		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20220223-039		23/02/2022 11:10	VSR	Acetona		3MM Whatman		2,12		0,01	0		97,87 %	Pass
				Normal Saline		3MM Whatman		0,023		1,362		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20220223-041		23/02/2022 11:33	VS	Acetona		3MM Whatman		425		2	0		97,675 %	Pass
				Normal Saline		3MM Whatman		7		370		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MIBI-99mTc Lot # K-20220223-005		23/02/2022 02:08	MB	Normal Saline		Sílica gel		1597		27	0		97,979 %	Pass
				Metanol		3MM Whatman		7		1945		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-20220223-006		23/02/2022 02:12	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1662 47		19 2123	0	pH (Low/Actual/High)	96,704 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-007		23/02/2022 02:12	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1573 19		21 2374	0	pH (Low/Actual/High)	97,889 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-008		23/02/2022 02:43	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1486 40		18 1680	0	pH (Low/Actual/High)	96,478 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-009		23/02/2022 02:47	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1442 61		20 2153	0	pH (Low/Actual/High)	95,877 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-011		23/02/2022 03:49	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1419 50		20 2246	0	pH (Low/Actual/High)	96,432 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-015		23/02/2022 04:03	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1734 26		16 2563	0	pH (Low/Actual/High)	98,081 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-022		23/02/2022 06:53	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1548 16		23 2132	0	pH (Low/Actual/High)	97,791 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-023		23/02/2022 06:59	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1582 4		11 2193	0	pH (Low/Actual/High)	99,127 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-024		23/02/2022 07:00	BB	Normal Saline Metanol	Sílica gel 3MM Whatman			1530 3		41 1329	0	pH (Low/Actual/High)	97,165 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-025		23/02/2022 07:01	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1604 16		23 1571	0	pH (Low/Actual/High)	97,578 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-034		23/02/2022 09:58	VSR	Normal Saline Metanol	Sílica gel 3MM Whatman			96,4 0,5		1 193,2	0	pH (Low/Actual/High)	98,715 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-038		23/02/2022 11:06	VS	Normal Saline Metanol	Sílica gel 3MM Whatman			1348 8		12 452	0	pH (Low/Actual/High)	97,379 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220223-042		23/02/2022 12:07	YD	Normal Saline Metanol	Sílica gel 3MM Whatman			389 4		6 316	0	pH (Low/Actual/High)	97,231 %	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
PIRO-99mTc Lot # K-20220223-026		23/02/2022 07:22	MB	Butanona Normal Saline	3MM Whatman 3MM Whatman			470 3		5 562	0	pH (Low/Actual/High)	98,416 %	Pass 5,00 <= 6,00 <= 7,00
														Límpido/Incolor
PSMA-177Lu Lot # K-20220223-001		23/02/2022 00:21	BB	Citrato de Sódio 0,1M	Sílica gel			732		1	0	pH (Low/Actual/High)	99,864 %	Pass 4,00 <= 4,50 <= 5,00
														Límpido
QC Notes: HPLC: 96,45%														
PSMA-177Lu Lot # K-20220223-002		23/02/2022 00:31	BB	Citrato de Sódio 0,1M	Sílica gel			433		2	0	pH (Low/Actual/High)	99,54 %	Pass 4,00 <= 4,50 <= 5,00
														Límpido
QC Notes: HPLC: 95,30%														
PSMA-177Lu Lot # K-20220223-003		23/02/2022 00:48	BB	Citrato de Sódio 0,1M	Sílica gel			461		2	0	pH (Low/Actual/High)	99,568 %	Pass 4,00 <= 4,50 <= 5,00
														Límpido
QC Notes: HPLC: 99,62%														
PSMA-177Lu Lot # K-20220223-004		23/02/2022 01:02	BB	Citrato de Sódio 0,1M	Sílica gel			341		2	0	pH (Low/Actual/High)	99,417 %	Pass 4,00 <= 4,50 <= 5,00
														Límpido
QC Notes: HPLC: 96,74														
PSMA-68Ga Lot # K-20220223-021		23/02/2022 06:50	MB	Acetato de amônio 1M:Metanol	Sílica gel			0,5		27,6	0	pH (Low/Actual/High)	98,221 %	Pass 4,00 <= 6,00 <= 8,00
														Límpido e Incolor
PSMA-68Ga Lot # K-20220223-043		23/02/2022 12:53	YD	Acetato de amônio 1M:Metanol	Sílica gel			0,3		25,6	0	pH (Low/Actual/High)	98,842 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220223-001		23/02/2022 02:00	MB	Butanona	3MM Whatman			48		3556	0	pH (Low/Actual/High)	98,668 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220223-002		23/02/2022 02:01	MB	Butanona	3MM Whatman			3		1708	0	pH (Low/Actual/High)	99,825 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220223-003		23/02/2022 02:40	MB	Butanona	3MM Whatman			39		1706	0	pH (Low/Actual/High)	97,765 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220223-004		23/02/2022 03:45	MB	Butanona	3MM Whatman			3		2215	0	pH (Low/Actual/High)	99,865 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20220223-005		23/02/2022 04:01	MB	Butanona	3MM Whatman			8		1708	0	pH (Low/Actual/High)	99,534 %	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-20220223-006		23/02/2022 04:04	MB	Butanona		3MM Whatman		1		347	0		99,713 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-007		23/02/2022 04:16	MB	Butanona		3MM Whatman		24		1612	0		98,533 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-008		23/02/2022 06:36	MB	Butanona		3MM Whatman		24		7961	0		99,699 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-010		23/02/2022 06:50	MB	Butanona		3MM Whatman		97		8144	0		98,823 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-011		23/02/2022 07:13	MB	Butanona		3MM Whatman		65		2711	0		97,659 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-012		23/02/2022 08:08	MB	Butanona		3MM Whatman		39		2220	0		98,274 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-014		23/02/2022 09:54	VSR	Butanona		3MM Whatman		0,1		3,07	0		96,845 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-015		23/02/2022 09:55	VSR	Butanona		3MM Whatman		0,019		1,304	0		98,564 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-016		23/02/2022 11:00	VSR	Butanona		3MM Whatman		0,003		1,5	0		99,80 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-017		23/02/2022 11:02	VSR	Butanona		3MM Whatman		0,02		2,19	0		99,095 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-018		23/02/2022 11:50	VS	Butanona		3MM Whatman		5		654	0		99,241 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-020		23/02/2022 13:45	VS	Butanona		3MM Whatman		14		1315	0		98,947 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220223-021		23/02/2022 14:00	VS	Butanona		3MM Whatman		10		1859	0		99,465 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00