



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 31/08/2021 To 31/08/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc		31/08/2021	04:09	PP	Butanona	3MM Whatman	208		2	0		92,97 %	Pass
Lot # K-20210831-014					Normal Saline	Silica gel	11		170	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		31/08/2021	04:11	PP	Butanona	3MM Whatman	323		1	0		91,314 %	Pass
Lot # K-20210831-015					Normal Saline	Silica gel	16		175	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		31/08/2021	07:32	FN	Butanona	3MM Whatman	200		1	0		93,792 %	Pass
Lot # K-20210831-023					Normal Saline	Silica gel	8,8		145,3	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		31/08/2021	07:33	FN	Butanona	3MM Whatman	196,6		0,3	0		95,708 %	Pass
Lot # K-20210831-024					Normal Saline	Silica gel	8,4		194,5	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		31/08/2021	07:34	FN	Butanona	3MM Whatman	240		10	0		91,378 %	Pass
Lot # K-20210831-025					Normal Saline	Silica gel	11		227	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DOTATOC-68Ga		31/08/2021	07:00	FN	Citrato de Sódio 0,1M	Silica gel	19,93		0,75	0		96,373 %	Pass
Lot # K-20210831-019										pH (Low/Actual/High)		4,00 <= 6,00	<= 8,00
						Límpido e Incolor							
DOTATOC-68Ga		31/08/2021	12:43	BB	Citrato de Sódio 0,1M	Silica gel	11,6		0,4	0		96,667 %	Pass
Lot # K-20210831-051										pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
						Límpido e Incolor							
DOTATOC-68Ga		31/08/2021	13:47	BB	Citrato de Sódio 0,1M	Silica gel	9,65		0,4	0		96,02 %	Pass
Lot # K-20210831-052										pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
						Límpido e Incolor							
DTPA-99mTc	RPH	31/08/2021	04:19	PP	Acetona	3MM Whatman	1087		1	0		98,084 %	Pass
Lot # K-20210831-017					Normal Saline	3MM Whatman	12		646	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	31/08/2021	07:54	FN	Acetona	3MM Whatman	548		5	0		96,672 %	Pass
Lot # K-20210831-029					Normal Saline	3MM Whatman	12		483	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	31/08/2021	10:39	BB	Acetona	3MM Whatman	298		1	0		97,372 %	Pass
Lot # K-20210831-041					Normal Saline	3MM Whatman	5		213	pH (Low/Actual/High)		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
FITATO-99mTc Lot # K-20210831-005		31/08/2021 03:35 PP	Butanona		3MM	Whatman		485		5	0		98,98 %	Pass
							Límpido/Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
FITATO-99mTc Lot # K-20210831-031		31/08/2021 08:13 FN	Butanona		3MM	Whatman		429		20	0		95,546 %	Pass
							Límpido/Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
MAA-99mTc Lot # K-20210831-006		31/08/2021 03:37 PP	Butanona		3MM	Whatman		194		2	0		98,98 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210831-007		31/08/2021 03:39 PP	Butanona		3MM	Whatman		86		3	0		96,629 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210831-008		31/08/2021 03:42 PP	Butanona		3MM	Whatman		101		1	0		99,02 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210831-009		31/08/2021 03:44 PP	Butanona		3MM	Whatman		71		2	0		97,26 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210831-010		31/08/2021 03:46 PP	Butanona		3MM	Whatman		96		1	0		98,969 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210831-011		31/08/2021 03:47 PP	Butanona		3MM	Whatman		112		2	0		98,246 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210831-026		31/08/2021 07:47 FN	Butanona		3MM	Whatman		139,5		2,4	0		98,309 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210831-027		31/08/2021 07:49 FN	Butanona		3MM	Whatman		156,3		5,3	0		96,72 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210831-028		31/08/2021 07:50 FN	Butanona		3MM	Whatman		96,2		1,3	0		98,667 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210831-042		31/08/2021 10:42 JS	Butanona		3MM	Whatman		189,5		0,5	0		99,737 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
MAA-99mTc Lot # K-20210831-043		31/08/2021 10:44 JS	Butanona		3MM	Whatman		227		1	0		99,561 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 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
MAA-99mTc Lot # K-20210831-044		31/08/2021 10:47	BB	Butanona		3MM Whatman		121,6		0,6	0		99,509 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20210831-045		31/08/2021 10:49	BB	Butanona		3MM Whatman		86		0,5	0		99,422 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20210831-046		31/08/2021 10:52	JS	Butanona		3MM Whatman		56,5		1	0		98,261 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20210831-047		31/08/2021 11:29	JS	Butanona		3MM Whatman		165		8	0		95,376 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20210831-048		31/08/2021 11:33	JS	Butanona		3MM Whatman		105		3	0		97,222 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20210831-049		31/08/2021 11:35	JS	Butanona		3MM Whatman		377		2,1	0		99,446 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20210831-050		31/08/2021 11:37	JS	Butanona		3MM Whatman		224		2	0		99,115 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MDP-99mTc Lot # K-20210831-013		31/08/2021 03:54	PP	Acetona		3MM Whatman		1364		10	0		98,277 %	Pass
				Normal Saline		3MM Whatman		10		995		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20210831-021		31/08/2021 07:17	FN	Acetona		3MM Whatman		1209		2	0		97,572 %	Pass
				Normal Saline		3MM Whatman		20		864		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20210831-030		31/08/2021 08:00	FN	Acetona		3MM Whatman		951		7	0		96,144 %	Pass
				Normal Saline		3MM Whatman		24		744		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20210831-039		31/08/2021 10:34	JS	Acetona		3MM Whatman		943		10	0		98,651 %	Pass
				Normal Saline		3MM Whatman		3		997		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210831-001		31/08/2021 02:25	PP	Normal Saline		Sílica gel		2734		70	0		95,257 %	Pass
				Metanol		3MM Whatman		80		3481		pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210831-002		31/08/2021 02:34	PP	Normal Saline		Sílica gel		1770		17	0		98,999 %	Pass
				Metanol		3MM Whatman		1		2005		pH (Low/Actual/High)	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-20210831-003		31/08/2021 02:46 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2552 2		40 2778	0	pH (Low/Actual/High)	98,385 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210831-004		31/08/2021 03:30 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			726 12		13 668	0	pH (Low/Actual/High)	96,476 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210831-016		31/08/2021 04:15 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2465 10		36 2756	0	pH (Low/Actual/High)	98,199 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210831-018		31/08/2021 06:56 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1425 9		24 1892	0	pH (Low/Actual/High)	97,87 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210831-020		31/08/2021 07:02 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1968 17		13 1908	0	pH (Low/Actual/High)	98,461 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210831-032		31/08/2021 08:15 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			835 3		17 1474	0	pH (Low/Actual/High)	97,802 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210831-033		31/08/2021 09:47 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1126 6		15 1800	0	pH (Low/Actual/High)	98,353 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210831-034		31/08/2021 09:56 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1767 11		23 1688	0	pH (Low/Actual/High)	98,068 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210831-040		31/08/2021 10:37 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1047 12		11 822	0	pH (Low/Actual/High)	97,521 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
PIRO-99mTc Lot # K-20210831-012		31/08/2021 03:52 PP	Butanona Normal Saline		3MM Whatman 3MM Whatman			507 11		5 504	0	pH (Low/Actual/High)	96,888 %	Pass 5,00 <= 6,00 <= 7,00
							Límpido/Incolor							
PIRO-99mTc Lot # K-20210831-022		31/08/2021 07:24 FN	Butanona Normal Saline		3MM Whatman 3MM Whatman			1013 10		6 616	0	pH (Low/Actual/High)	97,814 %	Pass 5,00 <= 6,00 <= 7,00
							Límpido/Incolor							
PSMA-68Ga Lot # K-20210831-035		31/08/2021 10:02 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,3		23,8	0	pH (Low/Actual/High)	98,755 %	Pass 4,00 <= 5,00 <= 8,00
							Límpido e Incolor							
PSMA-68Ga Lot # K-20210831-053		31/08/2021 15:49 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,2		19,9	0	pH (Low/Actual/High)	99,005 %	Pass 4,00 <= 5,00 <= 8,00
							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-20210831-001		31/08/2021 02:20	PP	Butanona		3MM	Whatman	31	3683		0	99,165 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-002		31/08/2021 02:23	PP	Butanona		3MM	Whatman	54	2436		0	97,831 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-003		31/08/2021 02:43	PP	Butanona		3MM	Whatman	7	566		0	98,778 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-004		31/08/2021 03:27	PP	Butanona		3MM	Whatman	5	129		0	96,269 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-005		31/08/2021 03:32	PP	Butanona		3MM	Whatman	18	1308		0	98,643 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-006		31/08/2021 03:50	PP	Butanona		3MM	Whatman	12	970		0	98,778 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-007		31/08/2021 04:07	PP	Butanona		3MM	Whatman	1	727		0	99,863 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-008		31/08/2021 04:14	PP	Butanona		3MM	Whatman	68	1332		0	95,143 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-009		31/08/2021 04:17	PP	Butanona		3MM	Whatman	11	1119		0	99,027 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-010		31/08/2021 06:52	FN	Butanona		3MM	Whatman	2	1003		0	99,801 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-011		31/08/2021 06:57	FN	Butanona		3MM	Whatman	7	1288		0	99,459 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-013		31/08/2021 07:15	FN	Butanona		3MM	Whatman	5	313		0	98,428 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210831-014		31/08/2021 07:22	FN	Butanona		3MM	Whatman	5	497		0	99,004 %	Pass	
												pH (Low/Actual/High)	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-20210831-015		31/08/2021 07:45	FN	Butanona		3MM Whatman		2		599	0	99,667 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210831-016		31/08/2021 08:10	FN	Butanona		3MM Whatman		4		523	0	99,241 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210831-017		31/08/2021 09:42	JS	Butanona		3MM Whatman		2		238	0	99,167 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210831-018		31/08/2021 09:52	JS	Butanona		3MM Whatman		16		1214	0	98,699 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210831-020		31/08/2021 10:20	JS	Butanona		3MM Whatman		18		1418	0	98,747 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210831-021		31/08/2021 10:32	JS	Butanona		3MM Whatman		1		501	0	99,801 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210831-022		31/08/2021 10:34	BB	Butanona		3MM Whatman		9		1383	0	99,353 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
TRODAT-99mTc Lot # K-20210831-036		31/08/2021 10:26	JS	Normal Saline		Sílica gel		180,7		1,7	0	96,534 %	Pass	
				Butanona		3MM Whatman		2,6		100	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20210831-037		31/08/2021 10:27	JS	Normal Saline		Sílica gel		130,2		8	0	92,392 %	Pass	
				Butanona		3MM Whatman		2,8		151,1	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
											Límpido/Incolor			
TRODAT-99mTc Lot # K-20210831-038		31/08/2021 10:28	JS	Normal Saline		Sílica gel		120,7		3,2	0	94,409 %	Pass	
				Butanona		3MM Whatman		5		161,2	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
											Límpido/Incolor			