



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 02/12/2021 To 02/12/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211202-013		02/12/2021	04:03	MB	Butanona	3MM Whatman	224,5		1,8	0	pH (Low/Actual/High)	92,755 %	Pass
					Normal Saline	Silica gel	9,9		143,6	2,00 <= 3,00		<= 3,00	
Límpido/Incolor													
DMSA-99mTc Lot # K-20211202-028		02/12/2021	07:39	PM	Butanona	3MM Whatman	194,6		6,7	0	pH (Low/Actual/High)	95,266 %	Pass
					Normal Saline	Silica gel	3		210,4	2,00 <= 3,00		<= 3,00	
Límpido/Incolor													
DMSA-99mTc Lot # K-20211202-029		02/12/2021	07:41	PM	Butanona	3MM Whatman	231,1		4,6	0	pH (Low/Actual/High)	93,75 %	Pass
					Normal Saline	Silica gel	6,8		151,4	2,00 <= 3,00		<= 3,00	
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20211202-024		02/12/2021	06:53	PM	Citrato de Sódio 0,1M	Silica gel	34,9		0,2	0	pH (Low/Actual/High)	99,43 %	Pass
										4,00 <= 5,00		<= 8,00	
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20211202-048		02/12/2021	12:32	VS	Citrato de Sódio 0,1M	Silica gel	2474		6	0	pH (Low/Actual/High)	99,758 %	Pass
										4,00 <= 6,00		<= 8,00	
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20211202-050		02/12/2021	15:46	JS	Citrato de Sódio 0,1M	Silica gel	23,6		0,4	0	pH (Low/Actual/High)	98,333 %	Pass
										4,00 <= 5,00		<= 8,00	
Límpido e Incolor													
DTPA-99mTc Lot # K-20211202-010	RPH	02/12/2021	03:51	MB	Acetona	3MM Whatman	415,7		1,8	0	pH (Low/Actual/High)	97,204 %	Pass
					Normal Saline	3MM Whatman	8,4		346,8	3,80 <= 5,00		<= 7,50	
Límpido/Incolor													
DTPA-99mTc Lot # K-20211202-017	RPH	02/12/2021	04:34	MB	Acetona	3MM Whatman	578,8		15,1	0	pH (Low/Actual/High)	95,214 %	Pass
					Normal Saline	3MM Whatman	15,8		688,4	3,80 <= 6,00		<= 7,50	
Límpido/Incolor													
DTPA-99mTc Lot # K-20211202-027	RPH	02/12/2021	07:31	PM	Acetona	3MM Whatman	589		3	0	pH (Low/Actual/High)	99,108 %	Pass
					Normal Saline	3MM Whatman	2		517	3,80 <= 5,00		<= 7,50	
Límpido/Incolor													
DTPA-99mTc Lot # K-20211202-043	RPH	02/12/2021	10:52	VS	Acetona	3MM Whatman	789		11	0	pH (Low/Actual/High)	96,522 %	Pass
					Normal Saline	3MM Whatman	9		419	3,80 <= 6,00		<= 7,50	
Límpido/Incolor													
FITATO-99mTc Lot # K-20211202-009		02/12/2021	03:46	MB	Butanona	3MM Whatman	186,5		1,3	0	pH (Low/Actual/High)	99,308 %	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-20211202-041		02/12/2021 10:48 PM	Butanona		3MM	Whatman		685,5		5,8	0		99,161 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00 <= 7,00	
												Límpido/Incolor		
MAA-99mTc Lot # K-20211202-011		02/12/2021 03:56 MB	Butanona		3MM	Whatman		228,2		1,4	0		99,39 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211202-012		02/12/2021 03:59 MB	Butanona		3MM	Whatman		137,9		0,7	0		99,495 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211202-042		02/12/2021 10:50 PM	Butanona		3MM	Whatman		342,1		2,3	0		99,332 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20211202-049		02/12/2021 12:45 VS	Butanona		3MM	Whatman		3388		12	0		99,647 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
												Turvo/Incolor		
MDP-99mTc Lot # K-20211202-007		02/12/2021 03:06 MB	Acetona		3MM	Whatman		786,6		1,1	0		99,015 %	Pass
			Normal Saline		3MM	Whatman		4,8		563,1		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211202-008		02/12/2021 03:42 MB	Acetona		3MM	Whatman		462,3		1	0		99,444 %	Pass
			Normal Saline		3MM	Whatman		2,4		702,6		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211202-015		02/12/2021 04:11 MB	Acetona		3MM	Whatman		845,6		1,9	0		98,206 %	Pass
			Normal Saline		3MM	Whatman		14,4		902,7		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211202-016		02/12/2021 04:14 MB	Acetona		3MM	Whatman		1027		1	0		98,846 %	Pass
			Normal Saline		3MM	Whatman		11		1030		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211202-018		02/12/2021 06:16 PM	Acetona		3MM	Whatman		417		1	0		98,82 %	Pass
			Normal Saline		3MM	Whatman		4		421		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211202-031		02/12/2021 08:04 PM	Acetona		3MM	Whatman		1182		2	0		97,133 %	Pass
			Normal Saline		3MM	Whatman		34		1226		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211202-032		02/12/2021 08:06 PM	Acetona		3MM	Whatman		1405		6	0		98,562 %	Pass
			Normal Saline		3MM	Whatman		11		1075		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20211202-044		02/12/2021 10:54 VS	Acetona		3MM	Whatman		569		6	0		98,571 %	Pass
			Normal Saline		3MM	Whatman		8		2067		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
MIBI-99mTc Lot # K-20211202-001		02/12/2021 01:55	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			710,1 4	7,4 1326	0		pH (Low/Actual/High)	98,668 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-002		02/12/2021 01:58	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			470,5 6	3,5 1249	0		pH (Low/Actual/High)	98,784 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-003		02/12/2021 02:06	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1222 15,3	15 587,6	0		pH (Low/Actual/High)	96,25 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-004		02/12/2021 02:58	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			487,4 57	5,4 1480	0		pH (Low/Actual/High)	95,196 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-005		02/12/2021 02:59	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			705 11	9 1222	0		pH (Low/Actual/High)	97,847 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-006		02/12/2021 03:03	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1513 26	19 1603	0		pH (Low/Actual/High)	97,164 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-014		02/12/2021 04:09	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			861,3 11	9,2 1292	0		pH (Low/Actual/High)	98,099 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-020		02/12/2021 06:39	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1193 2	3 1835	0		pH (Low/Actual/High)	99,64 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-025		02/12/2021 07:01	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1088 13	22 1522	0		pH (Low/Actual/High)	97,171 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-026		02/12/2021 07:12	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1878 16	37 1680	0		pH (Low/Actual/High)	97,124 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-030		02/12/2021 07:43	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1323 10	6 1275	0		pH (Low/Actual/High)	98,77 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-039		02/12/2021 10:32	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1372 12	18 1250	0		pH (Low/Actual/High)	97,754 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211202-040		02/12/2021 10:41	VS	Normal Saline Metanol	Sílica gel 3MM Whatman			1668 3	1 221	0		pH (Low/Actual/High)	98,601 %	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-20211202-045		02/12/2021 11:46 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			1339 6		4 202	0	pH (Low/Actual/High)	96,818 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211202-046		02/12/2021 12:10 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			2374 6		8 2726	0	pH (Low/Actual/High)	99,445 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211202-047		02/12/2021 12:28 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			3746 8		9 5575	0	pH (Low/Actual/High)	99,617 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
PSMA-68Ga Lot # K-20211202-033		02/12/2021 09:59 PM	Acetato de amônio 1M:Metanol		Sílica gel			0,3		37,2	0	pH (Low/Actual/High)	99,20 %	Pass 4,00 <= 6,00 <= 8,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211202-001		02/12/2021 01:52 MB	Butanona		3MM Whatman			2,8		380,5	0	pH (Low/Actual/High)	99,27 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211202-002		02/12/2021 02:03 MB	Butanona		3MM Whatman			77		2538	0	pH (Low/Actual/High)	97,055 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211202-003		02/12/2021 02:52 MB	Butanona		3MM Whatman			5,8		398,7	0	pH (Low/Actual/High)	98,566 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211202-004		02/12/2021 02:53 MB	Butanona		3MM Whatman			1		1108	0	pH (Low/Actual/High)	99,91 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211202-005		02/12/2021 03:39 MB	Butanona		3MM Whatman			3,7		781,7	0	pH (Low/Actual/High)	99,529 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211202-006		02/12/2021 03:48 MB	Butanona		3MM Whatman			1,7		588,7	0	pH (Low/Actual/High)	99,712 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211202-007		02/12/2021 04:04 MB	Butanona		3MM Whatman			2,2		430,6	0	pH (Low/Actual/High)	99,492 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211202-008		02/12/2021 04:05 MB	Butanona		3MM Whatman			38		3149	0	pH (Low/Actual/High)	98,808 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211202-009		02/12/2021 04:32 MB	Butanona		3MM Whatman			0,8		268,9	0	pH (Low/Actual/High)	99,703 %	Pass 5,00 <= 5,00 <= 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-20211202-010		02/12/2021 06:34 PM	Butanona		3MM	Whatman		15		807	0		98,175 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20211202-011		02/12/2021 06:45 PM	Butanona		3MM	Whatman		2		217	0		99,087 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20211202-013		02/12/2021 07:05 PM	Butanona		3MM	Whatman		4		617	0		99,356 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20211202-014		02/12/2021 07:25 PM	Butanona		3MM	Whatman		8		827	0		99,042 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
Tecnécio-99m Lot # E-20211202-015		02/12/2021 07:36 PM	Butanona		3MM	Whatman		1		502	0		99,801 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20211202-016		02/12/2021 08:01 PM	Butanona		3MM	Whatman		9		641	0		98,615 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20211202-018		02/12/2021 10:17 PM	Butanona		3MM	Whatman		9		678	0		98,69 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20211202-019		02/12/2021 10:38 PM	Butanona		3MM	Whatman		12		510	0		97,701 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20211202-020		02/12/2021 10:44 PM	Butanona		3MM	Whatman		8		238	0		96,748 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20211202-021		02/12/2021 11:40 VS	Butanona		3MM	Whatman		5		2943	0		99,83 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20211202-022		02/12/2021 11:42 VS	Butanona		3MM	Whatman		3		152	0		98,065 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20211202-023		02/12/2021 12:03 VS	Butanona		3MM	Whatman		6		1057	0		99,436 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20211202-024		02/12/2021 12:25 VS	Butanona		3MM	Whatman		6		239	0		97,551 %	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
TRODAT-99mTc Lot # K-20211202-021		02/12/2021 06:51 PM	Normal Saline Butanona		Sílica gel 3MM Whatman			154 8,3		0,7 250	0	pH (Low/Actual/High)	96,334 %	Pass
							Límpido/Incolor					6,50 <= 7,00 <= 8,50		
TRODAT-99mTc Lot # K-20211202-022		02/12/2021 06:52 PM	Normal Saline Butanona		Sílica gel 3MM Whatman			159,9 7,7		2,4 141,8	0	pH (Low/Actual/High)	93,371 %	Pass
							Límpido/Incolor					6,50 <= 7,00 <= 8,50		
TRODAT-99mTc Lot # K-20211202-023		02/12/2021 06:53 PM	Normal Saline Butanona		Sílica gel 3MM Whatman			145,8 7,8		3,9 168,1	0	pH (Low/Actual/High)	92,96 %	Pass
							Límpido/Incolor					6,50 <= 7,00 <= 8,50		
TRODAT-99mTc Lot # K-20211202-034		02/12/2021 10:23 VS	Normal Saline Butanona		Sílica gel 3MM Whatman			268 2		1 347	0	pH (Low/Actual/High)	99,055 %	Pass
							Límpido/Incolor					6,50 <= 7,00 <= 8,50		
TRODAT-99mTc Lot # K-20211202-035		02/12/2021 10:25 VS	Normal Saline Butanona		Sílica gel 3MM Whatman			2469 2,8		1,7 257	0	pH (Low/Actual/High)	98,853 %	Pass
							Límpido/Incolor					6,50 <= 7,00 <= 8,50		
TRODAT-99mTc Lot # K-20211202-036		02/12/2021 10:25 VS	Normal Saline Butanona		Sílica gel 3MM Whatman			1119 1,8		2 1627	0	pH (Low/Actual/High)	99,711 %	Pass
							Límpido/Incolor					6,50 <= 7,00 <= 8,50		
TRODAT-99mTc Lot # K-20211202-037		02/12/2021 10:26 VS	Normal Saline Butanona		Sílica gel 3MM Whatman			1692 3		2,3 266	0	pH (Low/Actual/High)	98,749 %	Pass
							Límpido/Incolor					6,50 <= 7,00 <= 8,50		
TRODAT-99mTc Lot # K-20211202-038		02/12/2021 10:29 VS	Normal Saline Butanona		Sílica gel 3MM Whatman			228 2,8		3 8918	0	pH (Low/Actual/High)	98,67 %	Pass
							Límpido/Incolor					6,50 <= 7,00 <= 8,50		