



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 10/11/2021 To 10/11/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211110-025		10/11/2021	07:34	WG	Butanona	3MM Whatman	143,5		0,9	0	pH (Low/Actual/High)	97,882 %	Pass
					Normal Saline	Silica gel	2,6		171,4	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20211110-030		10/11/2021	08:19	WG	Butanona	3MM Whatman	148,5		3,2	0	pH (Low/Actual/High)	96,061 %	Pass
					Normal Saline	Silica gel	2		107,3	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20211110-040		10/11/2021	10:38	JS	Butanona	3MM Whatman	233		5	0	pH (Low/Actual/High)	94,318 %	Pass
					Normal Saline	Silica gel	1,3		35	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20211110-036		10/11/2021	09:59	PP	Citrato de Sódio 0,1M	Silica gel	1033		4	0	pH (Low/Actual/High)	99,614 %	Pass
										4,00 <= 7,00 <= 8,00			
Límpido e Incolor													
DTPA-99mTc Lot # K-20211110-015	RPH	10/11/2021	04:02	PP	Acetona	3MM Whatman	968		8	0	pH (Low/Actual/High)	97,485 %	Pass
					Normal Saline	3MM Whatman	4		232	3,80 <= 7,00 <= 7,50			
Límpido/Incolor													
DTPA-99mTc Lot # K-20211110-033	RPH	10/11/2021	09:14	PP	Acetona	3MM Whatman	1384		2	0	pH (Low/Actual/High)	97,027 %	Pass
					Normal Saline	3MM Whatman	14		481	3,80 <= 6,00 <= 7,50			
Límpido/Incolor													
DTPA-99mTc Lot # K-20211110-041	RPH	10/11/2021	10:57	JS	Acetona	3MM Whatman	334		11	0	pH (Low/Actual/High)	93,294 %	Pass
					Normal Saline	3MM Whatman	14		384	3,80 <= 5,00 <= 7,50			
Límpido/Incolor													
FITATO-99mTc Lot # K-20211110-014		10/11/2021	04:00	PP	Butanona	3MM Whatman	789		12	0	pH (Low/Actual/High)	98,502 %	Pass
										5,00 <= 5,00 <= 7,00			
Límpido/Incolor													
FITATO-99mTc Lot # K-20211110-028		10/11/2021	07:45	WG	Butanona	3MM Whatman	677		2	0	pH (Low/Actual/High)	99,705 %	Pass
										5,00 <= 6,00 <= 7,00			
Límpido/Incolor													
MAA-99mTc Lot # K-20211110-016		10/11/2021	04:10	PP	Butanona	3MM Whatman	161,7		6	0	pH (Low/Actual/High)	96,422 %	Pass
										3,00 <= 5,00 <= 6,00			
Turvo/Incolor													
MAA-99mTc Lot # K-20211110-026		10/11/2021	07:42	WG	Butanona	3MM Whatman	370		2	0	pH (Low/Actual/High)	99,462 %	Pass
										3,00 <= 6,00 <= 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-20211110-027		10/11/2021 07:42	WG	Butanona		3MM Whatman		290		1	0	99,656 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211110-042		10/11/2021 11:01	JS	Butanona		3MM Whatman		36		1	0	97,297 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211110-046		10/11/2021 11:55	WG	Butanona		3MM Whatman		145,9		2	0	98,648 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211110-047		10/11/2021 11:57	WG	Butanona		3MM Whatman		136,9		0,8	0	99,419 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20211110-011		10/11/2021 03:52	PP	Acetona		3MM Whatman		1879		86	0	94,151 %	Pass	
				Normal Saline		3MM Whatman		28		1874		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211110-012		10/11/2021 03:54	PP	Acetona		3MM Whatman		1223		40	0	96,502 %	Pass	
				Normal Saline		3MM Whatman		5		1508		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211110-022		10/11/2021 07:16	WG	Acetona		3MM Whatman		1737		1	0	99,659 %	Pass	
				Normal Saline		3MM Whatman		3		1057		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211110-024		10/11/2021 07:34	WG	Acetona		3MM Whatman		789		1	0	98,659 %	Pass	
				Normal Saline		3MM Whatman		11		895		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211110-029		10/11/2021 08:14	WG	Acetona		3MM Whatman		1719		1	0	99,754 %	Pass	
				Normal Saline		3MM Whatman		2		1060		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211110-034		10/11/2021 09:24	PP	Acetona		3MM Whatman		557		5	0	98,926 %	Pass	
				Normal Saline		3MM Whatman		2		1081		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211110-035		10/11/2021 09:27	BB	Acetona		3MM Whatman		1553		11	0	97,656 %	Pass	
				Normal Saline		3MM Whatman		34		2038		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211110-038		10/11/2021 10:22	PP	Acetona		3MM Whatman		2110		2	0	95,672 %	Pass	
				Normal Saline		3MM Whatman		58		1312		pH (Low/Actual/High)	4,00 <= 7,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211110-039		10/11/2021 10:35	JS	Acetona		3MM Whatman		371		1	0	98,613 %	Pass	
				Normal Saline		3MM Whatman		15		1326		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-20211110-005		10/11/2021 01:42 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			882 12		22 1253	0 pH (Low/Actual/High)	96,618 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-006		10/11/2021 01:47 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			934 2		16 1283	0 pH (Low/Actual/High)	98,16 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-007		10/11/2021 02:44 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			845 2		11 1630	0 pH (Low/Actual/High)	98,592 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-008		10/11/2021 02:44 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2689 32		68 3017	0 pH (Low/Actual/High)	96,484 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-009		10/11/2021 02:50 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2890 11		33 3954	0 pH (Low/Actual/High)	98,594 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-010		10/11/2021 02:51 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2822 13		22 3125	0 pH (Low/Actual/High)	98,812 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-013		10/11/2021 03:57 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3302 33		126 3972	0 pH (Low/Actual/High)	95,50 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-017		10/11/2021 04:29 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1828 20		87 5308	0 pH (Low/Actual/High)	95,082 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-018		10/11/2021 05:14 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2248 44		6 2816	0 pH (Low/Actual/High)	98,195 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-020		10/11/2021 06:55 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			1760 23		44 2140	0 pH (Low/Actual/High)	96,498 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-021		10/11/2021 07:08 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			2880 20		54 3462	0 pH (Low/Actual/High)	97,585 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-023		10/11/2021 07:20 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			1878 6		30 3194	0 pH (Low/Actual/High)	98,24 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211110-031		10/11/2021 09:03 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2939 56		111 3426	0 pH (Low/Actual/High)	94,752 %	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-20211110-037		10/11/2021 10:15 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			2139 3		223 1005	0 pH (Low/Actual/High)	90,261 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211110-043		10/11/2021 11:23 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			1133 8		12 779	0 pH (Low/Actual/High)	97,935 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211110-044		10/11/2021 11:25 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			732 4		6 489	0 pH (Low/Actual/High)	98,376 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211110-045		10/11/2021 11:41 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			678 11		6 469	0 pH (Low/Actual/High)	96,831 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
PSMA-177Lu Lot # K-20211110-001		10/11/2021 01:04 BB	Citrato de Sódio 0,1M		Sílica gel			133,5		0,2	0 pH (Low/Actual/High)	99,85 %		Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPCL: 97,60%														
PSMA-177Lu Lot # K-20211110-002		10/11/2021 01:04 BB	Citrato de Sódio 0,1M		Sílica gel			337		3	0 pH (Low/Actual/High)	99,118 %		Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 96%														
PSMA-177Lu Lot # K-20211110-003		10/11/2021 01:15 BB	Citrato de Sódio 0,1M		Sílica gel			236		1	0 pH (Low/Actual/High)	99,578 %		Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 95,63%														
PSMA-177Lu Lot # K-20211110-004		10/11/2021 01:33 BB	Citrato de Sódio 0,1M		Sílica gel			379		1	0 pH (Low/Actual/High)	99,737 %		Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 98,09%														
PSMA-68Ga Lot # K-20211110-019		10/11/2021 06:54 WG	Acetato de amônio 1M:Metanol		Sílica gel			1,6		57,8	0 pH (Low/Actual/High)	97,306 %		Pass 4,00 <= 7,00 <= 8,00
							Límpido e Incolor							
PSMA-68Ga Lot # K-20211110-048		10/11/2021 12:36 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,5		37	0 pH (Low/Actual/High)	98,667 %		Pass 4,00 <= 5,00 <= 8,00
							Límpido e Incolor							
PSMA-68Ga Lot # K-20211110-049		10/11/2021 15:31 JS	Acetato de amônio 1M:Metanol		Sílica gel			1,9		65	0 pH (Low/Actual/High)	97,16 %		Pass 4,00 <= 5,00 <= 8,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211110-001		10/11/2021 01:36 YD	Butanona		3MM Whatman			36		1945	0 pH (Low/Actual/High)	98,183 %		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-20211110-002		10/11/2021 01:39 YD	Butanona		3MM Whatman			4		1985	0		99,799 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-003		10/11/2021 02:40 PP	Butanona		3MM Whatman			14		690	0		98,011 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-004		10/11/2021 02:46 PP	Butanona		3MM Whatman			31		2079	0		98,531 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-005		10/11/2021 03:49 PP	Butanona		3MM Whatman			14		1387	0		99,001 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-006		10/11/2021 03:55 PP	Butanona		3MM Whatman			16		6922	0		99,769 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-007		10/11/2021 04:27 PP	Butanona		3MM Whatman			7		1645	0		99,576 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-008		10/11/2021 05:12 PP	Butanona		3MM Whatman			31		1690	0		98,199 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-010		10/11/2021 06:49 WG	Butanona		3MM Whatman			6		3009	0		99,801 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-011		10/11/2021 07:05 WG	Butanona		3MM Whatman			9		1031	0		99,135 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-012		10/11/2021 07:19 WG	Butanona		3MM Whatman			1		4883	0		99,98 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-013		10/11/2021 07:28 WG	Butanona		3MM Whatman			6		1356	0		99,559 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-014		10/11/2021 08:11 WG	Butanona		3MM Whatman			9		2948	0		99,696 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211110-015		10/11/2021 09:00 PP	Butanona		3MM Whatman			26		1538	0		98,338 %	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-20211110-016		10/11/2021 09:05	PP	Butanona		3MM Whatman		6		588	0		98,99 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211110-017		10/11/2021 09:26	PP	Butanona		3MM Whatman		3		775	0		99,614 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211110-019		10/11/2021 10:11	PP	Butanona		3MM Whatman		10		2559	0		99,611 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211110-020		10/11/2021 10:20	PP	Butanona		3MM Whatman		18		2556	0		99,301 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211110-021		10/11/2021 10:30	JS	Butanona		3MM Whatman		3		886	0		99,663 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211110-022		10/11/2021 10:54	JS	Butanona		3MM Whatman		1		436	0		99,771 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211110-023		10/11/2021 11:01	JS	Butanona		3MM Whatman		30		1216	0		97,592 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211110-024		10/11/2021 11:20	WG	Butanona		3MM Whatman		13		1786	0		99,277 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211110-025		10/11/2021 11:38	WG	Butanona		3MM Whatman		9		1878	0		99,523 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211110-026		10/11/2021 11:50	WG	Butanona		3MM Whatman		8		298	0		97,386 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor