



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 03/09/2021 To 03/09/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210903-022		03/09/2021	07:36	JS	Butanona Normal Saline	3MM Whatman Sílica gel	132 1		0,7 141	0	pH (Low/Actual/High)	98,768 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210903-023		03/09/2021	07:38	JS	Butanona Normal Saline	3MM Whatman Sílica gel	75 1,3		4 103,7	0	pH (Low/Actual/High)	93,699 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210903-024		03/09/2021	07:38	JS	Butanona Normal Saline	3MM Whatman Sílica gel	64 3		1,3 41	0	pH (Low/Actual/High)	91,191 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210903-028		03/09/2021	08:08	JS	Butanona Normal Saline	3MM Whatman Sílica gel	95 4		2 182	0	pH (Low/Actual/High)	95,788 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210903-029		03/09/2021	08:11	JS	Butanona Normal Saline	3MM Whatman Sílica gel	21 3		1 68	0	pH (Low/Actual/High)	91,229 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210903-044		03/09/2021	10:21	LG	Butanona Normal Saline	3MM Whatman Sílica gel	92 11		0,5 121	0	pH (Low/Actual/High)	91,126 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210903-050		03/09/2021	12:44	JS	Citrato de Sódio 0,1M	Sílica gel	9,26		0,35	0	pH (Low/Actual/High)	96,358 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210903-051		03/09/2021	14:05	JS	Citrato de Sódio 0,1M	Sílica gel	9,63		0,23	0	pH (Low/Actual/High)	97,667 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210903-052		03/09/2021	16:13	JS	Citrato de Sódio 0,1M	Sílica gel	13,5		0,25	0	pH (Low/Actual/High)	98,182 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DTPA-99mTc Lot # K-20210903-009	RPH	03/09/2021	04:14	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	995 20		2 1673	0	pH (Low/Actual/High)	98,618 %	Pass 3,80 <= 6,00 <= 7,50
Límpido/Incolor													
DTPA-99mTc Lot # K-20210903-010	RPH	03/09/2021	04:16	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1733 12		20 1161	0	pH (Low/Actual/High)	97,836 %	Pass 3,80 <= 6,00 <= 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
DTPA-99mTc Lot # K-20210903-030	RPH	03/09/2021 08:13	JS	Acetona Normal Saline	3MM	Whatman		142 1,4		1,8 103,5	0		97,414 %	Pass
												pH (Low/Actual/High)	3,80 <= 5,00	<= 7,50
														Límpido/Incolor
DTPA-99mTc Lot # K-20210903-039	RPH	03/09/2021 09:53	LG	Acetona Normal Saline	3MM	Whatman		65 11		0,2 104	0		90,128 %	Pass
												pH (Low/Actual/High)	3,80 <= 5,00	<= 7,50
														Límpido/Incolor
FITATO-99mTc Lot # K-20210903-006		03/09/2021 04:05	PP	Butanona	3MM	Whatman		614		3	0		99,514 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
														Límpido/Incolor
FITATO-99mTc Lot # K-20210903-035		03/09/2021 08:22	JS	Butanona	3MM	Whatman		90		2,2	0		97,614 %	Pass
												pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00
														Límpido/Incolor
FITATO-99mTc Lot # K-20210903-047		03/09/2021 10:58	LG	Butanona	3MM	Whatman		395		0	0		100,00 %	Pass
												pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00
														Límpido/Incolor
FITATO-99mTc Lot # K-20210903-048		03/09/2021 10:59	LG	Butanona	3MM	Whatman		277		1	0		99,64 %	Pass
												pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00
														Límpido/Incolor
MAA-99mTc Lot # K-20210903-007		03/09/2021 04:07	PP	Butanona	3MM	Whatman		427		3	0		99,302 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210903-011		03/09/2021 04:18	PP	Butanona	3MM	Whatman		526		6	0		98,872 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210903-012		03/09/2021 04:20	PP	Butanona	3MM	Whatman		499		1	0		99,80 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210903-013		03/09/2021 04:32	PP	Butanona	3MM	Whatman		467		5	0		98,941 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210903-014		03/09/2021 04:33	PP	Butanona	3MM	Whatman		359		8	0		97,82 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210903-015		03/09/2021 04:34	PP	Butanona	3MM	Whatman		407		4	0		99,027 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210903-031		03/09/2021 08:16	JS	Butanona	3MM	Whatman		116		4	0		96,667 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 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-20210903-032		03/09/2021 08:17 JS	Butanona		3MM	Whatman		85		1,7	0	98,039 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210903-033		03/09/2021 08:19 JS	Butanona		3MM	Whatman		84		1	0	98,824 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210903-034		03/09/2021 08:20 JS	Butanona		3MM	Whatman		52		2	0	96,296 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210903-042		03/09/2021 10:16 LG	Butanona		3MM	Whatman		27,5		1	0	96,491 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210903-043		03/09/2021 10:19 LG	Butanona		3MM	Whatman		55,5		1	0	98,23 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MDP-99mTc Lot # K-20210903-017		03/09/2021 04:41 PP	Acetona		3MM	Whatman		1988		12	0	98,316 %	Pass	
			Normal Saline		3MM	Whatman		18		1643	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210903-018		03/09/2021 04:44 PP	Acetona		3MM	Whatman		2366		20	0	92,547 %	Pass	
			Normal Saline		3MM	Whatman		85		1200	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210903-019		03/09/2021 06:26 FN	Acetona		3MM	Whatman		823		2	0	99,53 %	Pass	
			Normal Saline		3MM	Whatman		2		877	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210903-038		03/09/2021 08:43 JS	Acetona		3MM	Whatman		248		9	0	95,74 %	Pass	
			Normal Saline		3MM	Whatman		2		262	pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210903-045		03/09/2021 10:31 LG	Acetona		3MM	Whatman		262		2	0	91,979 %	Pass	
			Normal Saline		3MM	Whatman		30		383	pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80		
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210903-001		03/09/2021 02:43 PP	Normal Saline		Sílica gel			1929		62	0	96,296 %	Pass	
			Metanol		3MM	Whatman		10		1685	pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210903-002		03/09/2021 02:46 BB	Normal Saline		Sílica gel			985		40	0	94,951 %	Pass	
			Metanol		3MM	Whatman		10		862	pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210903-003		03/09/2021 02:53 PP	Normal Saline		Sílica gel			1619		30	0	96,233 %	Pass	
			Metanol		3MM	Whatman		62		3122	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-20210903-004		03/09/2021 03:08 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1861 103		88 2922	0	pH (Low/Actual/High)	92,08 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210903-005		03/09/2021 03:45 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2213 39		16 4481	0	pH (Low/Actual/High)	98,419 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210903-016		03/09/2021 04:38 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			740 23		14 1301	0	pH (Low/Actual/High)	96,406 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210903-021		03/09/2021 07:20 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			214 5		5 229	0	pH (Low/Actual/High)	95,58 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210903-025		03/09/2021 07:44 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			597 13		10 763	0	pH (Low/Actual/High)	96,677 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210903-027		03/09/2021 08:06 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1394 11		2 1508	0	pH (Low/Actual/High)	99,133 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210903-036		03/09/2021 08:25 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			310 1		2,3 652	0	pH (Low/Actual/High)	99,11 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210903-037		03/09/2021 08:37 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			585 15		3 887	0	pH (Low/Actual/High)	97,827 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210903-041		03/09/2021 10:12 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			616 3		6 987	0	pH (Low/Actual/High)	98,732 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210903-049		03/09/2021 11:04 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			141,5 0,3		1 164,5	0	pH (Low/Actual/High)	99,116 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210903-008		03/09/2021 04:13 PP	Butanona Normal Saline		3MM Whatman 3MM Whatman			1032 13		12 593	0	pH (Low/Actual/High)	96,705 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210903-020		03/09/2021 07:00 BB	Acetato de amônio 1M:Metanol		Sílica gel			0,2		9,8	0	pH (Low/Actual/High)	98,00 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210903-026		03/09/2021 07:59 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,3		23,9	0	pH (Low/Actual/High)	98,76 %	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
PSMA-68Ga Lot # K-20210903-040		03/09/2021 10:04	LG	Acetato de amônio 1M:Metanol	Sílica gel			0,8		20,6	0		96,262 %	Pass
												pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-001		03/09/2021 02:23	PP	Butanona		3MM Whatman		101		8155	0		98,777 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-002		03/09/2021 02:50	PP	Butanona		3MM Whatman		11		1283	0		99,15 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-003		03/09/2021 03:05	PP	Butanona		3MM Whatman		9		396	0		97,778 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-004		03/09/2021 03:41	PP	Butanona		3MM Whatman		13		297	0		95,806 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-005		03/09/2021 04:11	PP	Butanona		3MM Whatman		10		908	0		98,911 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-006		03/09/2021 04:30	PP	Butanona		3MM Whatman		13		1193	0		98,922 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-007		03/09/2021 04:36	PP	Butanona		3MM Whatman		100		5467	0		98,204 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-008		03/09/2021 04:39	PP	Butanona		3MM Whatman		12		541	0		97,83 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-009		03/09/2021 04:42	PP	Butanona		3MM Whatman		25		815	0		97,024 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-011		03/09/2021 07:15	FN	Butanona		3MM Whatman		2		865	0		99,769 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-012		03/09/2021 07:34	JS	Butanona		3MM Whatman		1,7		118	0		98,58 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210903-013		03/09/2021 07:34	JS	Butanona		3MM Whatman		1,9		71	0		97,394 %	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-20210903-015		03/09/2021 08:03 JS	Butanona		3MM	Whatman		1		168	0	99,408 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20210903-016		03/09/2021 08:11 JS	Butanona		3MM	Whatman		5		380	0	98,701 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20210903-017		03/09/2021 08:23 JS	Butanona		3MM	Whatman		1,5		38	0	96,203 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20210903-018		03/09/2021 08:35 JS	Butanona		3MM	Whatman		5		123	0	96,094 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210903-019		03/09/2021 08:38 JS	Butanona		3MM	Whatman		2		90	0	97,826 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210903-020		03/09/2021 09:49 LG	Butanona		3MM	Whatman		0,5		78	0	99,363 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20210903-021		03/09/2021 10:03 LG	Butanona		3MM	Whatman		2		241	0	99,177 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210903-023		03/09/2021 10:14 LG	Butanona		3MM	Whatman		1		161,5	0	99,385 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20210903-024		03/09/2021 10:28 LG	Butanona		3MM	Whatman		0,1		29,5	0	99,662 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20210903-025		03/09/2021 10:50 LG	Butanona		3MM	Whatman		0,1		40	0	99,751 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210903-026		03/09/2021 11:02 LG	Butanona		3MM	Whatman		1,5		171	0	99,13 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		