



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 28/05/2021 To 28/05/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210528-019		28/05/2021	07:31	JS	Butanona	3MM Whatman	252		1	0		98,201 %	Pass
					Normal Saline	Silica gel	2,3		161,5	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DMSA-99mTc Lot # K-20210528-020		28/05/2021	07:32	JS	Butanona	3MM Whatman	300		3	0		96,151 %	Pass
					Normal Saline	Silica gel	4		135,9	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DMSA-99mTc Lot # K-20210528-024		28/05/2021	08:02	JS	Butanona	3MM Whatman	166,2		1,8	0		95,547 %	Pass
					Normal Saline	Silica gel	7		200	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DMSA-99mTc Lot # K-20210528-025		28/05/2021	08:03	JS	Butanona	3MM Whatman	95		1	0		96,646 %	Pass
					Normal Saline	Silica gel	4		169	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DMSA-99mTc Lot # K-20210528-026		28/05/2021	08:04	JS	Butanona	3MM Whatman	154		3	0		97,218 %	Pass
					Normal Saline	Silica gel	1,3		148	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DMSA-99mTc Lot # K-20210528-030		28/05/2021	11:19	JS	Butanona	3MM Whatman	592		0,4	0		97,643 %	Pass
					Normal Saline	Silica gel	3,2		136,6	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210528-033		28/05/2021	13:38	JS	Citrato de Sódio 0,1M	Silica gel	24,9		0,3	0		98,81 %	Pass
												pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DTPA-99mTc Lot # K-20210528-009	RPH	28/05/2021	03:54	PP	Acetona	3MM Whatman	761		2	0		99,01 %	Pass
					Normal Saline	3MM Whatman	7		955	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor													
DTPA-99mTc Lot # K-20210528-031	RPH	28/05/2021	11:22	JS	Acetona	3MM Whatman	592		3	0		96,423 %	Pass
					Normal Saline	3MM Whatman	13		410	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor													
FITATO-99mTc Lot # K-20210528-010		28/05/2021	03:57	PP	Butanona	3MM Whatman	559		3	0		99,466 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 7,00
Límpido/Incolor													
FITATO-99mTc Lot # K-20210528-023		28/05/2021	07:47	JS	Butanona	3MM Whatman	199		2	0		99,005 %	Pass
												pH (Low/Actual/High)	5,00 <= 7,00 <= 7,00
Límpido/Incolor													

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210528-011		28/05/2021 04:00	PP	Butanona		3MM Whatman		237		8	0	96,735 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210528-012		28/05/2021 04:02	PP	Butanona		3MM Whatman		394		9	0	97,767 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210528-013		28/05/2021 04:04	PP	Butanona		3MM Whatman		251		5	0	98,047 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210528-015		28/05/2021 04:44	PP	Butanona		3MM Whatman		625		20	0	96,899 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210528-027		28/05/2021 08:06	JS	Butanona		3MM Whatman		170,4		5,8	0	96,708 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210528-028		28/05/2021 08:09	JS	Butanona		3MM Whatman		92,5		2,1	0	97,78 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210528-034		28/05/2021 15:32	JS	Butanona		3MM Whatman		166,5		4,2	0	97,54 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MDP-99mTc Lot # K-20210528-008		28/05/2021 03:50	PP	Acetona		3MM Whatman		1626		2	0	98,644 %	Pass	
				Normal Saline		3MM Whatman		18		1442	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210528-014		28/05/2021 04:11	PP	Acetona		3MM Whatman		1171		2	0	98,581 %	Pass	
				Normal Saline		3MM Whatman		10		791	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210528-021		28/05/2021 07:38	JS	Acetona		3MM Whatman		1017		2	0	99,681 %	Pass	
				Normal Saline		3MM Whatman		1		814	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210528-022		28/05/2021 07:41	JS	Acetona		3MM Whatman		1065		6	0	98,617 %	Pass	
				Normal Saline		3MM Whatman		10		1206	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210528-032		28/05/2021 11:24	JS	Acetona		3MM Whatman		899		3	0	99,429 %	Pass	
				Normal Saline		3MM Whatman		1		419	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MIBI-99mTc Lot # K-20210528-001		28/05/2021 02:19	PP	Normal Saline		Sílica gel		246		6	0	96,282 %	Pass	
				Metanol		3MM Whatman		41		3025	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido/Incolor			

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210528-002		28/05/2021 02:27 PP	Normal Saline Metanol		Silica gel 3MM Whatman			306 3		6 237	0	pH (Low/Actual/High)	96,827 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210528-003		28/05/2021 02:30 PP	Normal Saline Metanol		Silica gel 3MM Whatman			279 1		8 361	0	pH (Low/Actual/High)	96,936 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210528-004		28/05/2021 03:15 PP	Normal Saline Metanol		Silica gel 3MM Whatman			2224 8		6 354	0	pH (Low/Actual/High)	97,521 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210528-005		28/05/2021 03:16 PP	Normal Saline Metanol		Silica gel 3MM Whatman			201 3		3 309	0	pH (Low/Actual/High)	97,568 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210528-006		28/05/2021 03:18 PP	Normal Saline Metanol		Silica gel 3MM Whatman			277 10		6 348	0	pH (Low/Actual/High)	95,087 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210528-007		28/05/2021 03:21 PP	Normal Saline Metanol		Silica gel 3MM Whatman			272 7		3 201	0	pH (Low/Actual/High)	95,544 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210528-017		28/05/2021 07:08 JS	Normal Saline Metanol		Silica gel 3MM Whatman			1927 9		29 1886	0	pH (Low/Actual/High)	98,042 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210528-018		28/05/2021 07:08 JS	Normal Saline Metanol		Silica gel 3MM Whatman			2160 37		23 813	0	pH (Low/Actual/High)	94,593 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
PSMA-68Ga Lot # K-20210528-016		28/05/2021 06:51 JS	Acetato de amônio 1M:Metanol		Silica gel			0,6		70,2	0	pH (Low/Actual/High)	99,153 %	Pass 4,00 <= 5,00 <= 8,00
							Límpido e Incolor							
PSMA-68Ga Lot # K-20210528-029		28/05/2021 09:35 JS	Acetato de amônio 1M:Metanol		Silica gel			0,3		24,5	0	pH (Low/Actual/High)	98,79 %	Pass 4,00 <= 5,00 <= 8,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210528-001		28/05/2021 02:11 PP	Butanona		3MM Whatman			31		1352	0	pH (Low/Actual/High)	97,758 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210528-002		28/05/2021 03:10 PP	Butanona		3MM Whatman			5		283	0	pH (Low/Actual/High)	98,264 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210528-004		28/05/2021 03:46 PP	Butanona		3MM Whatman			10		217	0	pH (Low/Actual/High)	95,595 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210528-005		28/05/2021 03:51	PP	Butanona		3MM Whatman		1		268	0		99,628 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210528-006		28/05/2021 04:04	PP	Butanona		3MM Whatman		7		691	0		98,997 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210528-008		28/05/2021 07:02	JS	Butanona		3MM Whatman		2		2140	0		99,907 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210528-010		28/05/2021 07:28	JS	Butanona		3MM Whatman		2		569	0		99,65 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210528-013		28/05/2021 11:12	BB	Butanona		3MM Whatman		9		1357	0		99,341 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210528-012		28/05/2021 11:45	BB	Butanona		3MM Whatman		9		1169	0		99,236 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210528-015		28/05/2021 15:30	JS	Butanona		3MM Whatman		3		1395	0		99,785 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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