



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 19/05/2021 To 19/05/2021

Product:	Manuf:	Calibration D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210519-022		19/05/2021 07:37	JS	Butanona	3MM Whatman	208		4	0		94,755 %	Pass
				Normal Saline	Silica gel	4		115,1	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor												
DMSA-99mTc Lot # K-20210519-023		19/05/2021 07:41	JS	Butanona	3MM Whatman	139,3		1,8	0		94,075 %	Pass
				Normal Saline	Silica gel	5,1		104,6	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor												
DMSA-99mTc Lot # K-20210519-028		19/05/2021 08:04	JS	Butanona	3MM Whatman	146,5		2,5	0		92,411 %	Pass
				Normal Saline	Silica gel	4,8		76,4	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor												
DMSA-99mTc Lot # K-20210519-034		19/05/2021 10:43	JS	Butanona	3MM Whatman	127,8		1,1	0		94,518 %	Pass
				Normal Saline	Silica gel	4,3		88,6	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor												
DMSA-99mTc Lot # K-20210519-035		19/05/2021 10:45	JS	Butanona	3MM Whatman	143,2		1	0		97,387 %	Pass
				Normal Saline	Silica gel	2,4		122,6	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor												
DOTATOC-68Ga Lot # K-20210519-031		19/05/2021 09:56	JS	Citrato de Sódio 0,1M	Silica gel	22,6		1,1	0	pH (Low/Actual/High)	95,359 %	Pass
Límpido e Incolor												
DOTATOC-68Ga Lot # K-20210519-036		19/05/2021 10:54	JS	Citrato de Sódio 0,1M	Silica gel	26		0,7	0	pH (Low/Actual/High)	97,378 %	Pass
Límpido e Incolor												
DTPA-99mTc Lot # K-20210519-006	RPH	19/05/2021 03:18	PP	Acetona	3MM Whatman	1029		10	0		97,075 %	Pass
				Normal Saline	3MM Whatman	20		999	pH (Low/Actual/High)	3,80 <= 7,00 <= 7,50		
Límpido/Incolor												
DTPA-99mTc Lot # K-20210519-027	RPH	19/05/2021 07:59	JS	Acetona	3MM Whatman	307		3	0		94,169 %	Pass
				Normal Saline	3MM Whatman	16		313	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor												
DTPA-99mTc Lot # K-20210519-033	RPH	19/05/2021 10:17	JS	Acetona	3MM Whatman	628		3	0		95,995 %	Pass
				Normal Saline	3MM Whatman	18		492	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor												
FITATO-99mTc Lot # K-20210519-004		19/05/2021 03:14	PP	Butanona	3MM Whatman	365		2	0	pH (Low/Actual/High)	99,455 %	Pass
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
FITATO-99mTc Lot # K-20210519-017		19/05/2021 07:01 JS	Butanona		3MM	Whatman		187		1,5	0	99,204 %	Pass	
							Límpido/Incolor				pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00	
FITATO-99mTc Lot # K-20210519-037		19/05/2021 10:57 JS	Butanona		3MM	Whatman		793		9	0	98,878 %	Pass	
							Límpido/Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
MAA-99mTc Lot # K-20210519-005		19/05/2021 03:16 PP	Butanona		3MM	Whatman		236		10	0	95,935 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210519-011		19/05/2021 04:11 PP	Butanona		3MM	Whatman		315		9	0	97,222 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210519-010		19/05/2021 04:11 PP	Butanona		3MM	Whatman		286		9	0	96,949 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210519-025		19/05/2021 07:42 JS	Butanona		3MM	Whatman		130,4		0,8	0	99,39 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210519-024		19/05/2021 07:42 JS	Butanona		3MM	Whatman		167,4		3,1	0	98,182 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210519-038		19/05/2021 11:05 JS	Butanona		3MM	Whatman		160,3		1,3	0	99,196 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MDP-99mTc Lot # K-20210519-007		19/05/2021 03:35 PP	Acetona		3MM	Whatman		300		3	0	97,135 %	Pass	
			Normal Saline		3MM	Whatman		12		628	pH (Low/Actual/High)	4,00 <= 7,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210519-008		19/05/2021 03:36 PP	Acetona		3MM	Whatman		944		11	0	98,57 %	Pass	
			Normal Saline		3MM	Whatman		2		718	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210519-021		19/05/2021 07:14 JS	Acetona		3MM	Whatman		191,5		0,6	0	98,362 %	Pass	
			Normal Saline		3MM	Whatman		1,6		119,1	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210519-026		19/05/2021 07:52 JS	Acetona		3MM	Whatman		577		3	0	99,328 %	Pass	
			Normal Saline		3MM	Whatman		2		1290	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210519-030		19/05/2021 09:43 WG	Acetona		3MM	Whatman		1513		4	0	98,63 %	Pass	
			Normal Saline		3MM	Whatman		22		1967	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							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-20210519-001		19/05/2021 02:33 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1897 3		31 2040	0	pH (Low/Actual/High)	98,245 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210519-002		19/05/2021 02:43 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			256 1		5 373	0	pH (Low/Actual/High)	97,817 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210519-003		19/05/2021 02:47 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2020 2		6 2044	0	pH (Low/Actual/High)	99,606 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210519-009		19/05/2021 04:07 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			209 2		3 317	0	pH (Low/Actual/High)	97,958 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210519-012		19/05/2021 04:16 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1081 30		21 1673	0	pH (Low/Actual/High)	96,333 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210519-013		19/05/2021 04:19 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			897 14		11 1521	0	pH (Low/Actual/High)	97,876 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210519-014		19/05/2021 04:33 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2059 4		2 366	0	pH (Low/Actual/High)	98,822 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210519-018		19/05/2021 07:03 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			437 1		5 496	0	pH (Low/Actual/High)	98,668 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210519-020		19/05/2021 07:12 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			531 3		5 506	0	pH (Low/Actual/High)	98,478 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210519-029		19/05/2021 09:35 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			1092 26		11 1766	0	pH (Low/Actual/High)	97,552 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210519-032		19/05/2021 10:10 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			418 7		10 731	0	pH (Low/Actual/High)	96,715 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
PSMA-177Lu Lot # K-20210519-015 Master Formulation Record:		19/05/2021 05:36 MP	Citrato de Sódio 0,1M		Sílica gel			402		2	0	pH (Low/Actual/High)	99,505 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
PSMA-177Lu Lot # K-20210519-016 Master Formulation Record:		19/05/2021 05:36 MP	Citrato de Sódio 0,1M		Sílica gel			192		1	0	pH (Low/Actual/High)	99,482 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							

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
PSMA-68Ga Lot # K-20210519-039		19/05/2021 12:34	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,3		10,4	0		97,196 %	Pass
												pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-001		19/05/2021 02:02	PP	Butanona		3MM Whatman		1		2069	0		99,952 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-002		19/05/2021 02:39	PP	Butanona		3MM Whatman		2		428	0		99,535 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-003		19/05/2021 02:44	PP	Butanona		3MM Whatman		4		427	0		99,072 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-004		19/05/2021 02:52	PP	Butanona		3MM Whatman		30		724	0		96,021 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-005		19/05/2021 03:11	PP	Butanona		3MM Whatman		5		2019	0		99,753 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-006		19/05/2021 03:34	PP	Butanona		3MM Whatman		35		753	0		95,558 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-007		19/05/2021 04:06	PP	Butanona		3MM Whatman		6		183	0		96,825 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-008		19/05/2021 04:13	PP	Butanona		3MM Whatman		12		381	0		96,947 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-009		19/05/2021 04:16	PP	Butanona		3MM Whatman		8		276	0		97,183 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-010		19/05/2021 04:31	PP	Butanona		3MM Whatman		6		142	0		95,946 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-012		19/05/2021 06:59	GF	Butanona		3MM Whatman		5		802	0		99,38 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210519-011		19/05/2021 06:59	GF	Butanona		3MM Whatman		9		746	0		98,808 %	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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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-20210519-013		19/05/2021 07:12 JS	Butanona		3MM	Whatman		2,4	196,6		0	98,794 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210519-014		19/05/2021 07:37 JS	Butanona		3MM	Whatman		2	373		0	99,467 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210519-015		19/05/2021 07:50 JS	Butanona		3MM	Whatman		5	350		0	98,592 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210519-016		19/05/2021 07:51 JS	Butanona		3MM	Whatman		3	206		0	98,565 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210519-017		19/05/2021 09:31 WG	Butanona		3MM	Whatman		13	1654		0	99,22 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210519-018		19/05/2021 09:38 WG	Butanona		3MM	Whatman		6	1054		0	99,434 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210519-019		19/05/2021 09:53 WG	Butanona		3MM	Whatman		7	567		0	98,78 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210519-021		19/05/2021 10:40 JS	Butanona		3MM	Whatman		9	894		0	99,003 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210519-023		19/05/2021 10:57 JS	Butanona		3MM	Whatman		18	1047		0	98,31 %	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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