



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 24/05/2021 To 24/05/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210524-023		24/05/2021	07:34	GF	Butanona	3MM Whatman	57,7		0,3	0		94,502 %	Pass
					Normal Saline	Silica gel	3,8		72,5	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
					Límpido/Incolor								
DMSA-99mTc Lot # K-20210524-024		24/05/2021	07:59	GF	Butanona	3MM Whatman	159		2,9	0		92,954 %	Pass
					Normal Saline	Silica gel	3,5		63,1	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
					Límpido/Incolor								
DMSA-99mTc Lot # K-20210524-029		24/05/2021	10:32	WG	Butanona	3MM Whatman	94,2		1,8	0		93,905 %	Pass
					Normal Saline	Silica gel	4,9		111,2	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
					Límpido/Incolor								
DOTATOC-68Ga Lot # K-20210524-027		24/05/2021	09:48	MP	Citrato de Sódio 0,1M	Silica gel	26		0,6	0		97,744 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
					Límpido e Incolor								
DOTATOC-68Ga Lot # K-20210524-031		24/05/2021	11:03	JS	Citrato de Sódio 0,1M	Silica gel	68,4		3,1	0		95,664 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
					Límpido e Incolor								
DTPA-99mTc Lot # K-20210524-005	RPH	24/05/2021	03:01	PP	Acetona	3MM Whatman	1303		7	0		94,577 %	Pass
					Normal Saline	3MM Whatman	55		1070	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
					Límpido/Incolor								
DTPA-99mTc Lot # K-20210524-030	RPH	24/05/2021	10:38	WG	Acetona	3MM Whatman	298		2	0		99,105 %	Pass
					Normal Saline	3MM Whatman	1		437	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
					Límpido/Incolor								
FITATO-99mTc Lot # K-20210524-006		24/05/2021	03:07	PP	Butanona	3MM Whatman	979		7	0		99,29 %	Pass
										pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
					Límpido/Incolor								
FITATO-99mTc Lot # K-20210524-020		24/05/2021	07:23	GF	Butanona	3MM Whatman	465		1	0		99,785 %	Pass
										pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
					Límpido/Incolor								
MAA-99mTc Lot # K-20210524-012		24/05/2021	04:20	PP	Butanona	3MM Whatman	330		2	0		99,398 %	Pass
										pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
					Turvo/Incolor								
MAA-99mTc Lot # K-20210524-013		24/05/2021	04:21	PP	Butanona	3MM Whatman	301		2	0		99,34 %	Pass
										pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
					Turvo/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-20210524-014		24/05/2021 04:23 PP	Butanona		3MM	Whatman		277		5	0	98,227 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210524-032		24/05/2021 11:11 WG	Butanona		3MM	Whatman		90,1		3	0	96,778 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210524-033		24/05/2021 11:15 WG	Butanona		3MM	Whatman		74,8		1,3	0	98,292 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MDP-99mTc Lot # K-20210524-004		24/05/2021 02:57 PP	Acetona		3MM	Whatman		832		20	0	96,319 %	Pass	
			Normal Saline		3MM	Whatman		9		666	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210524-008		24/05/2021 03:18 PP	Acetona		3MM	Whatman		1821		8	0	94,058 %	Pass	
			Normal Saline		3MM	Whatman		84		1442	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210524-011		24/05/2021 03:50 PP	Acetona		3MM	Whatman		525		20	0	94,98 %	Pass	
			Normal Saline		3MM	Whatman		14		1023	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210524-022		24/05/2021 07:26 GF	Acetona		3MM	Whatman		380		1	0	99,738 %	Pass	
			Normal Saline		3MM	Whatman		0		352	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210524-021		24/05/2021 07:26 GF	Acetona		3MM	Whatman		222		0	0	99,32 %	Pass	
			Normal Saline		3MM	Whatman		2		292	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210524-025		24/05/2021 07:59 GF	Acetona		3MM	Whatman		909		3	0	99,481 %	Pass	
			Normal Saline		3MM	Whatman		1		525	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210524-001		24/05/2021 01:24 PP	Normal Saline		Sílica gel			2018		9	0	96,669 %	Pass	
			Metanol		3MM	Whatman		55		1850	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210524-002		24/05/2021 01:26 PP	Normal Saline		Sílica gel			1570		38	0	95,303 %	Pass	
			Metanol		3MM	Whatman		48		2009	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210524-003		24/05/2021 02:52 PP	Normal Saline		Sílica gel			3011		10	0	99,025 %	Pass	
			Metanol		3MM	Whatman		20		3085	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210524-007		24/05/2021 03:09 PP	Normal Saline		Sílica gel			2029		15	0	98,117 %	Pass	
			Metanol		3MM	Whatman		35		3012	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-20210524-009	24/05/2021	03:26	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2008 8		3 2076	0	pH (Low/Actual/High)	99,467 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210524-010	24/05/2021	03:50	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			301 5		2 3019	0	pH (Low/Actual/High)	99,175 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210524-016	24/05/2021	07:04	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			1250 28		17 1236	0	pH (Low/Actual/High)	96,443 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210524-017	24/05/2021	07:05	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			996 9		21 863	0	pH (Low/Actual/High)	96,903 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210524-026	24/05/2021	08:11	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			761 4		17 969	0	pH (Low/Actual/High)	97,404 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210524-028	24/05/2021	10:28	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			452 2		1 614	0	pH (Low/Actual/High)	99,455 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210524-019	24/05/2021	07:12	GF	Butanona Normal Saline	3MM Whatman 3MM Whatman			256 4,8		1 190,8	0	pH (Low/Actual/High)	97,157 %	Pass 5,00 <= 5,00 <= 7,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210524-018	24/05/2021	07:12	GF	Butanona Normal Saline	3MM Whatman 3MM Whatman			225 1		1 360	0	pH (Low/Actual/High)	99,281 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210524-015	24/05/2021	06:46	GF	Acetato de amônio 1M:Metanol	Sílica gel			0,4		33,8	0	pH (Low/Actual/High)	98,83 %	Pass 4,00 <= 6,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210524-034	24/05/2021	12:39	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,4		45,9	0	pH (Low/Actual/High)	99,136 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210524-001	24/05/2021	01:17	PP	Butanona	3MM Whatman			12		537	0	pH (Low/Actual/High)	97,814 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210524-002	24/05/2021	02:51	PP	Butanona	3MM Whatman			15		322	0	pH (Low/Actual/High)	95,549 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210524-003	24/05/2021	03:06	PP	Butanona	3MM Whatman			10		803	0	pH (Low/Actual/High)	98,77 %	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-20210524-004		24/05/2021 03:18	PP	Butanona		3MM Whatman		20		1498	0		98,682 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210524-006		24/05/2021 07:01	GF	Butanona		3MM Whatman		0		264	0		100,00 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210524-007		24/05/2021 07:09	GF	Butanona		3MM Whatman		3		388	0		99,233 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210524-008		24/05/2021 07:09	GF	Butanona		3MM Whatman		3		714	0		99,582 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210524-009		24/05/2021 07:19	GF	Butanona		3MM Whatman		1		254	0		99,608 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210524-010		24/05/2021 08:09	GF	Butanona		3MM Whatman		6		1311	0		99,544 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210524-012		24/05/2021 10:23	WG	Butanona		3MM Whatman		1		1303	0		99,923 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210524-013		24/05/2021 10:57	WG	Butanona		3MM Whatman		7		896	0		99,225 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor

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