



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 04/08/2021 To 04/08/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210804-021		04/08/2021	07:36	WG	Butanona Normal Saline	3MM Whatman Sílica gel	130,8 4,5		2 111,4	0	pH (Low/Actual/High)	94,611 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210804-022		04/08/2021	07:38	WG	Butanona Normal Saline	3MM Whatman Sílica gel	129,1 0,8		0,4 167,8	0	pH (Low/Actual/High)	99,217 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210804-023		04/08/2021	07:39	WG	Butanona Normal Saline	3MM Whatman Sílica gel	114 3		1 99,3	0	pH (Low/Actual/High)	96,198 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210804-037		04/08/2021	10:52	LG	Butanona Normal Saline	3MM Whatman Sílica gel	112 15		3 191	0	pH (Low/Actual/High)	90,11 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210804-017		04/08/2021	07:04	PL	Citrato de Sódio 0,1M	Sílica gel	15,9		0,2	0	pH (Low/Actual/High)	98,758 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210804-030		04/08/2021	10:02	WG	Citrato de Sódio 0,1M	Sílica gel	20,6		0,1	0	pH (Low/Actual/High)	99,517 %	Pass 4,00 <= 7,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210804-040		04/08/2021	10:57	LG	Citrato de Sódio 0,1M	Sílica gel	25		0,4	0	pH (Low/Actual/High)	98,425 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210804-046		04/08/2021	15:51	WG	Citrato de Sódio 0,1M	Sílica gel	21,9		0,2	0	pH (Low/Actual/High)	99,095 %	Pass 4,00 <= 7,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210804-007	RPH	04/08/2021	02:58	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	246 4		10 280	0	pH (Low/Actual/High)	94,685 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210804-020	RPH	04/08/2021	07:30	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	647 6		1,7 315	0	pH (Low/Actual/High)	97,869 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210804-035	RPH	04/08/2021	10:47	LG	Acetona Normal Saline	3MM Whatman 3MM Whatman	733 34		1 550	0	pH (Low/Actual/High)	94,042 %	Pass 3,80 <= 5,00 <= 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-20210804-036	RPH	04/08/2021 10:49	LG	Acetona Normal Saline	3MM	Whatman		520 13		5 427	0		96,093 %	Pass
												pH (Low/Actual/High)	3,80 <= 5,00	<= 7,50
														Límpido/Incolor
FITATO-99mTc Lot # K-20210804-014		04/08/2021 04:11	FN	Butanona	3MM	Whatman		331		2	0		99,399 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
														Límpido/Incolor
FITATO-99mTc Lot # K-20210804-028		04/08/2021 08:13	LG	Butanona	3MM	Whatman		350		0,2	0		99,943 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
														Límpido/Incolor
MAA-99mTc Lot # K-20210804-012		04/08/2021 04:07	FN	Butanona	3MM	Whatman		127,8		2,2	0		98,308 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210804-024		04/08/2021 08:05	LG	Butanona	3MM	Whatman		161		1,8	0		98,894 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210804-025		04/08/2021 08:07	LG	Butanona	3MM	Whatman		98,9		1,1	0		98,90 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210804-026		04/08/2021 08:09	LG	Butanona	3MM	Whatman		115,4		1,8	0		98,464 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210804-038		04/08/2021 10:54	LG	Butanona	3MM	Whatman		145		3	0		97,973 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210804-039		04/08/2021 10:56	LG	Butanona	3MM	Whatman		139		2,6	0		98,164 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210804-041		04/08/2021 11:09	LG	Butanona	3MM	Whatman		122		1	0		99,187 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210804-042		04/08/2021 11:12	LG	Butanona	3MM	Whatman		69		1	0		98,571 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210804-043		04/08/2021 11:14	LG	Butanona	3MM	Whatman		53		1	0		98,148 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210804-044		04/08/2021 11:19	LG	Butanona	3MM	Whatman		61		1	0		98,387 %	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-20210804-047		04/08/2021 16:01	WG	Butanona		3MM Whatman		99,7		3,7	0	96,422 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MDP-99mTc Lot # K-20210804-011		04/08/2021 04:05	FN	Acetona		3MM Whatman		963		2	0	99,313 %	Pass	
				Normal Saline		3MM Whatman		5		1038		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210804-013		04/08/2021 04:09	FN	Acetona		3MM Whatman		784		3	0	99,52 %	Pass	
				Normal Saline		3MM Whatman		1		1016		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210804-018		04/08/2021 07:23	LG	Acetona		3MM Whatman		650		1,6	0	98,975 %	Pass	
				Normal Saline		3MM Whatman		3,3		420		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210804-027		04/08/2021 08:04	LG	Acetona		3MM Whatman		879		1,5	0	98,242 %	Pass	
				Normal Saline		3MM Whatman		10		620		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210804-029		04/08/2021 09:58	LG	Acetona		3MM Whatman		333,8		1	0	95,207 %	Pass	
				Normal Saline		3MM Whatman		24		510		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210804-031		04/08/2021 10:04	LG	Acetona		3MM Whatman		493		19	0	94,541 %	Pass	
				Normal Saline		3MM Whatman		10		562		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MIBI-99mTc Lot # K-20210804-004		04/08/2021 02:53	FN	Normal Saline		Sílica gel		1144		8	0	98,482 %	Pass	
				Metanol		3MM Whatman		12		1445		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210804-005		04/08/2021 02:54	FN	Normal Saline		Sílica gel		238		4	0	97,161 %	Pass	
				Metanol		3MM Whatman		3		250		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210804-006		04/08/2021 02:56	FN	Normal Saline		Sílica gel		212		2	0	97,738 %	Pass	
				Metanol		3MM Whatman		3		223		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210804-008		04/08/2021 03:19	FN	Normal Saline		Sílica gel		216		4	0	97,31 %	Pass	
				Metanol		3MM Whatman		12		1365		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210804-009		04/08/2021 03:20	FN	Normal Saline		Sílica gel		1475		18	0	98,032 %	Pass	
				Metanol		3MM Whatman		10		1301		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210804-010		04/08/2021 04:04	FN	Normal Saline		Sílica gel		209		2	0	98,212 %	Pass	
				Metanol		3MM Whatman		12		1416		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-20210804-015	04/08/2021	04:23 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1277 10		20 999	0	pH (Low/Actual/High)	97,467 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210804-016	04/08/2021	07:00 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1713 5		28 2323	0	pH (Low/Actual/High)	98,177 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210804-019	04/08/2021	07:28 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			2336 4		12 1196	0	pH (Low/Actual/High)	99,156 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210804-032	04/08/2021	10:18 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			1161 5		21 1313	0	pH (Low/Actual/High)	97,844 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210804-033	04/08/2021	10:31 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			561 1		6 540	0	pH (Low/Actual/High)	98,757 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210804-034	04/08/2021	10:43 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			1080 5		17 1007	0	pH (Low/Actual/High)	97,956 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
PSMA-177Lu Lot # K-20210804-001	04/08/2021	01:24 PL	Citrato de Sódio 0,1M		Sílica gel			127,2		1,2	0	pH (Low/Actual/High)	99,065 %	Pass 4,00 <= 4,50 <= 5,00
														Límpido
PSMA-177Lu Lot # K-20210804-002	04/08/2021	01:24 PL	Citrato de Sódio 0,1M		Sílica gel			179,1		0,6	0	pH (Low/Actual/High)	99,666 %	Pass 4,00 <= 4,50 <= 5,00
														Límpido
PSMA-177Lu Lot # K-20210804-003	04/08/2021	01:57 PL	Citrato de Sódio 0,1M		Sílica gel			241		1	0	pH (Low/Actual/High)	99,587 %	Pass 4,00 <= 4,50 <= 5,00
														Límpido
PSMA-68Ga Lot # K-20210804-045	04/08/2021	12:47 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,1		22,9	0	pH (Low/Actual/High)	99,565 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-001	04/08/2021	01:53 FN	Butanona		3MM Whatman			2		461	0	pH (Low/Actual/High)	99,568 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-002	04/08/2021	02:39 FN	Butanona		3MM Whatman			1		493	0	pH (Low/Actual/High)	99,798 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-003	04/08/2021	02:48 FN	Butanona		3MM Whatman			2		376	0	pH (Low/Actual/High)	99,471 %	Pass 5,00 <= 5,00 <= 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-20210804-004		04/08/2021 02:50	FN	Butanona		3MM Whatman		2		1170	0		99,829 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-005		04/08/2021 03:15	FN	Butanona		3MM Whatman		2		295	0		99,327 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-006		04/08/2021 03:15	FN	Butanona		3MM Whatman		1		264	0		99,623 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-007		04/08/2021 03:16	FN	Butanona		3MM Whatman		1		452	0		99,779 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-008		04/08/2021 03:59	FN	Butanona		3MM Whatman		2		179	0		98,895 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-009		04/08/2021 04:02	FN	Butanona		3MM Whatman		1,6		147,1	0		98,924 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-010		04/08/2021 04:21	FN	Butanona		3MM Whatman		1		225	0		99,558 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-011		04/08/2021 06:53	PP	Butanona		3MM Whatman		20		4097	0		99,514 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-013		04/08/2021 07:22	PP	Butanona		3MM Whatman		1		6181	0		99,984 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-014		04/08/2021 07:25	PP	Butanona		3MM Whatman		78		1848	0		95,95 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-015		04/08/2021 07:33	WG	Butanona		3MM Whatman		12		1895	0		99,371 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-016		04/08/2021 07:40	LG	Butanona		3MM Whatman		2		895	0		99,777 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-017		04/08/2021 09:57	LG	Butanona		3MM Whatman		18		678	0		97,414 %	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-20210804-019		04/08/2021 10:02	LG	Butanona		3MM Whatman		20		468	0		95,902 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-020		04/08/2021 10:16	LG	Butanona		3MM Whatman		19		975	0		98,089 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-021		04/08/2021 10:31	LG	Butanona		3MM Whatman		2		564	0		99,647 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-022		04/08/2021 10:40	LG	Butanona		3MM Whatman		3		414	0		99,281 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-023		04/08/2021 10:45	LG	Butanona		3MM Whatman		2		1383	0		99,856 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210804-027		04/08/2021 15:45	WG	Butanona		3MM Whatman		2		915	0		99,782 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor