



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 12/07/2021 To 12/07/2021

Product:	Manuf:	Calibration D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210712-026		12/07/2021 07:33	FN	Butanona Normal Saline	3MM Whatman Sílica gel	183 12		1 140	0	pH (Low/Actual/High)	91,562 % 2,00 <= 3,00 <= 3,00	Pass
					Límpido/Incolor							
DMSA-99mTc Lot # K-20210712-027		12/07/2021 07:34	FN	Butanona Normal Saline	3MM Whatman Sílica gel	183 10		2 180	0	pH (Low/Actual/High)	93,656 % 2,00 <= 3,00 <= 3,00	Pass
					Límpido/Incolor							
DMSA-99mTc Lot # K-20210712-032		12/07/2021 08:01	FN	Butanona Normal Saline	3MM Whatman Sílica gel	170,5 12		0,3 153,7	0	pH (Low/Actual/High)	92,582 % 2,00 <= 3,00 <= 3,00	Pass
					Límpido/Incolor							
DMSA-99mTc Lot # K-20210712-039		12/07/2021 10:28	JS	Butanona Normal Saline	3MM Whatman Sílica gel	144 2		3 232	0	pH (Low/Actual/High)	97,104 % 2,00 <= 3,00 <= 3,00	Pass
					Límpido/Incolor							
DMSA-99mTc Lot # K-20210712-040		12/07/2021 10:30	JS	Butanona Normal Saline	3MM Whatman Sílica gel	54 5		3 135	0	pH (Low/Actual/High)	91,165 % 2,00 <= 3,00 <= 3,00	Pass
					Límpido/Incolor							
DMSA-99mTc Lot # K-20210712-041		12/07/2021 10:32	JS	Butanona Normal Saline	3MM Whatman Sílica gel	112 1,8		2 170	0	pH (Low/Actual/High)	97,198 % 2,00 <= 3,00 <= 3,00	Pass
					Límpido/Incolor							
DOTATATE-68Ga Lot # K-20210712-035		12/07/2021 09:29	MP	Citrato de Sódio 0,1M Metanol/Acetato de Amonio 1	Sílica gel Sílica gel	35,7 0,9		0,1 48,8	0	pH (Low/Actual/High)	97,91 % 4,00 <= 4,50 <= 8,00	Pass
					Límpido e Incolor							
DOTATATE-68Ga Lot # K-20210712-051		12/07/2021 15:30	MP	Citrato de Sódio 0,1M Metanol/Acetato de Amonio 1	Sílica gel Sílica gel	29 1,2		0,2 59,7	0	pH (Low/Actual/High)	97,345 % 4,00 <= 4,50 <= 8,00	Pass
					Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210712-036		12/07/2021 09:55	JS	Citrato de Sódio 0,1M	Sílica gel	27,1		0,2	0	pH (Low/Actual/High)	99,267 % 4,00 <= 5,00 <= 8,00	Pass
					Límpido e Incolor							
DTPA-99mTc Lot # K-20210712-006	RPH	12/07/2021 03:03	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	495 12		2 487	0	pH (Low/Actual/High)	97,193 % 3,80 <= 6,00 <= 7,50	Pass
					Límpido/Incolor							
DTPA-99mTc Lot # K-20210712-010	RPH	12/07/2021 03:43	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	802 12		2 399	0	pH (Low/Actual/High)	96,832 % 3,80 <= 5,00 <= 7,50	Pass
					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-20210712-031	RPH	12/07/2021 07:51	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman			502 12		13 490	0	pH (Low/Actual/High)	95,085 %	Pass 3,80 <= 6,00 <= 7,50
Límpido/Incolor														
DTPA-99mTc Lot # K-20210712-033	RPH	12/07/2021 08:10	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman			462 12		15 327	0	pH (Low/Actual/High)	93,316 %	Pass 3,80 <= 6,00 <= 7,50
Límpido/Incolor														
DTPA-99mTc Lot # K-20210712-043	RPH	12/07/2021 10:36	MP	Acetona Normal Saline	3MM Whatman 3MM Whatman			249 2		1 316	0	pH (Low/Actual/High)	98,971 %	Pass 3,80 <= 5,00 <= 7,50
Límpido/Incolor														
FITATO-99mTc Lot # K-20210712-007		12/07/2021 03:06	FN	Butanona	3MM Whatman			178		1	0	pH (Low/Actual/High)	99,441 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
FITATO-99mTc Lot # K-20210712-028		12/07/2021 07:38	FN	Butanona	3MM Whatman			81		2	0	pH (Low/Actual/High)	97,59 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
FITATO-99mTc Lot # K-20210712-042		12/07/2021 10:34	JS	Butanona	3MM Whatman			567		5	0	pH (Low/Actual/High)	99,126 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
MAA-99mTc Lot # K-20210712-011		12/07/2021 03:46	FN	Butanona	3MM Whatman			171		2	0	pH (Low/Actual/High)	98,844 %	Pass 3,00 <= 6,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20210712-012		12/07/2021 03:48	FN	Butanona	3MM Whatman			254		3	0	pH (Low/Actual/High)	98,833 %	Pass 3,00 <= 6,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20210712-013		12/07/2021 03:50	FN	Butanona	3MM Whatman			125		1	0	pH (Low/Actual/High)	99,206 %	Pass 3,00 <= 6,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20210712-014		12/07/2021 04:07	FN	Butanona	3MM Whatman			153,6		2,3	0	pH (Low/Actual/High)	98,525 %	Pass 3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20210712-015		12/07/2021 04:09	FN	Butanona	3MM Whatman			115,4		2,5	0	pH (Low/Actual/High)	97,88 %	Pass 3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20210712-016		12/07/2021 04:11	FN	Butanona	3MM Whatman			151,4		3,9	0	pH (Low/Actual/High)	97,489 %	Pass 3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20210712-017		12/07/2021 04:13	FN	Butanona	3MM Whatman			141,1		2,4	0	pH (Low/Actual/High)	98,328 %	Pass 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-20210712-018		12/07/2021 04:16	FN	Butanona		3MM Whatman		88,7		2,9	0	96,834 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210712-019		12/07/2021 04:29	FN	Butanona		3MM Whatman		79,6		2,1	0	97,43 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210712-020		12/07/2021 04:30	FN	Butanona		3MM Whatman		65,2		1,2	0	98,193 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210712-044		12/07/2021 10:37	JS	Butanona		3MM Whatman		258		3	0	98,851 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210712-045		12/07/2021 10:41	JS	Butanona		3MM Whatman		238		4	0	98,347 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210712-046		12/07/2021 10:43	JS	Butanona		3MM Whatman		228		5	0	97,854 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210712-047		12/07/2021 10:46	JS	Butanona		3MM Whatman		193		5	0	97,475 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210712-049		12/07/2021 11:17	WG	Butanona		3MM Whatman		298		5	0	98,35 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210712-052		12/07/2021 16:37	JS	Butanona		3MM Whatman		74,4		3	0	96,124 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MDP-99mTc Lot # K-20210712-005		12/07/2021 03:01	FN	Acetona		3MM Whatman		798		2	0	99,438 %	Pass	
				Normal Saline		3MM Whatman		2		638		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210712-008		12/07/2021 03:38	FN	Acetona		3MM Whatman		1104		2	0	99,041 %	Pass	
				Normal Saline		3MM Whatman		10		1275		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210712-025		12/07/2021 07:04	FN	Acetona		3MM Whatman		1198		1	0	99,674 %	Pass	
				Normal Saline		3MM Whatman		3		1236		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210712-029		12/07/2021 07:40	FN	Acetona		3MM Whatman		456		2	0	97,487 %	Pass	
				Normal Saline		3MM Whatman		13		613		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														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
MDP-99mTc Lot # K-20210712-038	12/07/2021	10:12 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			508 5		2 704	0	pH (Low/Actual/High)	98,903 %	Pass
														4,00 <= 6,00 <= 7,80
														Límpido/Incolor
MIBI-99mTc Lot # K-20210712-001	12/07/2021	02:00 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1822 20		10 1835	0	pH (Low/Actual/High)	98,376 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210712-002	12/07/2021	02:01 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1814 12		10 1854	0	pH (Low/Actual/High)	98,809 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210712-003	12/07/2021	02:17 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1920 6		22 1896	0	pH (Low/Actual/High)	98,552 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210712-004	12/07/2021	02:18 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1399 2		20 1584	0	pH (Low/Actual/High)	98,464 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210712-009	12/07/2021	03:41 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			214 22		3 1688	0	pH (Low/Actual/High)	97,331 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210712-021	12/07/2021	06:35 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1474 12		20 1568	0	pH (Low/Actual/High)	97,902 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210712-022	12/07/2021	06:36 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1421 2		22 218	0	pH (Low/Actual/High)	97,566 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210712-024	12/07/2021	07:01 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1640 12		20 1641	0	pH (Low/Actual/High)	98,069 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210712-030	12/07/2021	07:49 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			214 3		6 250	0	pH (Low/Actual/High)	96,087 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210712-034	12/07/2021	08:19 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			592 7		12 746	0	pH (Low/Actual/High)	97,084 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
PIRO-99mTc Lot # K-20210712-037	12/07/2021	10:04 JS	Butanona Normal Saline		3MM Whatman 3MM Whatman			310 2		1 329	0	pH (Low/Actual/High)	99,074 %	Pass
														5,00 <= 6,00 <= 7,00
														Límpido/Incolor
PSMA-68Ga Lot # K-20210712-023	12/07/2021	06:49 FN	Acetato de amônio		Sílica gel			1		35	0	pH (Low/Actual/High)	97,222 %	Pass
														4,00 <= 6,00 <= 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-20210712-050		12/07/2021 12:54	JS	Acetato de amônio	Sílica gel			0,2	23,6		0		99,16 %	Pass
												pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210712-001		12/07/2021 01:49	FN	Butanona	3MM Whatman			1	242		0		99,588 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210712-002		12/07/2021 02:13	FN	Butanona	3MM Whatman			1	394		0		99,747 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210712-003		12/07/2021 02:59	FN	Butanona	3MM Whatman			2	318		0		99,375 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210712-004		12/07/2021 03:39	FN	Butanona	3MM Whatman			1	524		0		99,81 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210712-005		12/07/2021 06:28	FN	Butanona	3MM Whatman			2	1133		0		99,824 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210712-007		12/07/2021 06:58	FN	Butanona	3MM Whatman			2	1760		0		99,886 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210712-008		12/07/2021 07:28	FN	Butanona	3MM Whatman			3	703		0		99,575 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210712-009		12/07/2021 07:47	FN	Butanona	3MM Whatman			1	414		0		99,759 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210712-012		12/07/2021 10:02	JS	Butanona	3MM Whatman			4	253		0		98,444 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210712-013		12/07/2021 12:37	SB	Butanona	3MM Whatman			3	386		0		99,229 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210712-016		12/07/2021 16:32	JS	Butanona	3MM Whatman			17	822		0		97,974 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
TRODAT-99mTc Lot # K-20210712-048		12/07/2021 10:56	WG	Normal Saline	Sílica gel			162,6	2,9		0		95,385 %	Pass
				Butanona	3MM Whatman			4,4	149,3				pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50
												Límpido/Incolor		