



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 06/09/2021 To 06/09/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210906-022		06/09/2021	07:35	FN	Butanona Normal Saline	3MM Whatman Sílica gel	248 12		11 253	0	pH (Low/Actual/High)	91,225 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210906-023		06/09/2021	07:36	FN	Butanona Normal Saline	3MM Whatman Sílica gel	241 25		3 354	0	pH (Low/Actual/High)	92,174 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210906-030		06/09/2021	08:03	FN	Butanona Normal Saline	3MM Whatman Sílica gel	164,6 8,9		1,5 162	0	pH (Low/Actual/High)	93,889 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210906-039		06/09/2021	10:19	YD	Butanona Normal Saline	3MM Whatman Sílica gel	97,9 6,2		1,5 158	0	pH (Low/Actual/High)	94,715 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210906-047		06/09/2021	10:54	YD	Butanona Normal Saline	3MM Whatman Sílica gel	180,2 6,3		0,4 160,1	0	pH (Low/Actual/High)	95,992 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210906-048		06/09/2021	10:54	YD	Butanona Normal Saline	3MM Whatman Sílica gel	124,8 5,7		1,9 163,9	0	pH (Low/Actual/High)	95,14 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210906-035		06/09/2021	09:43	JS	Citrato de Sódio 0,1M	Sílica gel	11,3		0,31	0	pH (Low/Actual/High)	97,33 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210906-045		06/09/2021	10:31	JS	Citrato de Sódio 0,1M	Sílica gel	15,3		0,35	0	pH (Low/Actual/High)	97,764 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210906-053		06/09/2021	15:43	JS	Citrato de Sódio 0,1M	Sílica gel	14,67		0,33	0	pH (Low/Actual/High)	97,80 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210906-009	RPH	06/09/2021	03:53	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	558 35		1 744	0	pH (Low/Actual/High)	95,328 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210906-036	RPH	06/09/2021	10:02	YD	Acetona Normal Saline	3MM Whatman 3MM Whatman	381 13		1 337	0	pH (Low/Actual/High)	96,024 %	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
FITATO-99mTc Lot # K-20210906-008		06/09/2021 03:49 PP	Butanona		3MM	Whatman		279		4	0		98,587 %	Pass
							Límpido/Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
FITATO-99mTc Lot # K-20210906-025		06/09/2021 07:45 FN	Butanona		3MM	Whatman		398		3	0		99,252 %	Pass
							Límpido/Incolor					pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00
MAA-99mTc Lot # K-20210906-010		06/09/2021 03:57 PP	Butanona		3MM	Whatman		223		27	0		89,20 %	Fail
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210906-011		06/09/2021 03:58 PP	Butanona		3MM	Whatman		73		1	0		98,649 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210906-012		06/09/2021 04:00 PP	Butanona		3MM	Whatman		135		2	0		98,54 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210906-013		06/09/2021 04:02 PP	Butanona		3MM	Whatman		814		23	0		97,252 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210906-014		06/09/2021 05:29 PP	Butanona		3MM	Whatman		287		5	0		98,288 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210906-026		06/09/2021 07:51 FN	Butanona		3MM	Whatman		131,1		0,6	0		99,544 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210906-027		06/09/2021 07:53 FN	Butanona		3MM	Whatman		198,2		0,8	0		99,598 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210906-028		06/09/2021 07:55 FN	Butanona		3MM	Whatman		83,5		0,5	0		99,405 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210906-029		06/09/2021 07:58 FN	Butanona		3MM	Whatman		57,4		0,6	0		98,966 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210906-040		06/09/2021 10:22 YD	Butanona		3MM	Whatman		93,2		0,5	0		99,466 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
MAA-99mTc Lot # K-20210906-041		06/09/2021 10:24 YD	Butanona		3MM	Whatman		66,9		0,6	0		99,111 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00

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-20210906-042		06/09/2021 10:26 YD	Butanona		3MM	Whatman		182		1,2	0		99,345 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210906-043		06/09/2021 10:29 YD	Butanona		3MM	Whatman		136,2		0,05	0		99,963 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210906-044		06/09/2021 10:31 YD	Butanona		3MM	Whatman		118,1		0,5	0		99,578 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210906-046		06/09/2021 10:38 YD	Butanona		3MM	Whatman		125,1		1,5	0		98,815 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210906-049		06/09/2021 11:23 YD	Butanona		3MM	Whatman		186,1		0,8	0		99,572 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210906-050		06/09/2021 11:24 YD	Butanona		3MM	Whatman		186,3		0,3	0		99,839 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210906-051		06/09/2021 11:26 YD	Butanona		3MM	Whatman		178,2		2,2	0		98,78 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MDP-99mTc Lot # K-20210906-006		06/09/2021 03:26 PP	Acetona		3MM	Whatman		1505		22	0		95,781 %	Pass
			Normal Saline		3MM	Whatman		41		1435		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210906-007		06/09/2021 03:28 PP	Acetona		3MM	Whatman		1818		3	0		95,002 %	Pass
			Normal Saline		3MM	Whatman		81		1595		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210906-021		06/09/2021 07:28 FN	Acetona		3MM	Whatman		1182		4	0		97,418 %	Pass
			Normal Saline		3MM	Whatman		24		1045		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210906-024		06/09/2021 07:38 FN	Acetona		3MM	Whatman		1130		1	0		97,85 %	Pass
			Normal Saline		3MM	Whatman		18		855		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210906-033		06/09/2021 09:35 YD	Acetona		3MM	Whatman		682		2	0		98,339 %	Pass
			Normal Saline		3MM	Whatman		13		937		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210906-034		06/09/2021 09:37 YD	Acetona		3MM	Whatman		495		1	0		98,368 %	Pass
			Normal Saline		3MM	Whatman		12		827		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
MIBI-99mTc Lot # K-20210906-001		06/09/2021 02:10 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2366 67		45 2217	0	pH (Low/Actual/High)	95,20 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210906-002		06/09/2021 02:12 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3099 10		17 1757	0	pH (Low/Actual/High)	98,888 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210906-003		06/09/2021 02:46 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3251 44		24 2132	0	pH (Low/Actual/High)	97,245 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210906-004		06/09/2021 02:47 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1010 59		12 2607	0	pH (Low/Actual/High)	96,613 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210906-005		06/09/2021 02:52 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2865 60		61 3351	0	pH (Low/Actual/High)	96,156 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210906-016		06/09/2021 07:03 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1868 10		24 1713	0	pH (Low/Actual/High)	98,151 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210906-017		06/09/2021 07:04 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1270 1		11 214	0	pH (Low/Actual/High)	98,676 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210906-018		06/09/2021 07:09 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			2212 1		4 229	0	pH (Low/Actual/High)	99,385 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210906-019		06/09/2021 07:10 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			221 22		5 1974	0	pH (Low/Actual/High)	96,685 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210906-031		06/09/2021 09:30 YD	Normal Saline Metanol		Sílica gel 3MM Whatman			1134 25		26 1773	0	pH (Low/Actual/High)	96,368 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210906-032		06/09/2021 09:31 YD	Normal Saline Metanol		Sílica gel 3MM Whatman			1932 6		33 1435	0	pH (Low/Actual/High)	97,904 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210906-020		06/09/2021 07:24 FN	Butanona Normal Saline		3MM Whatman 3MM Whatman			396 10		5 300	0	pH (Low/Actual/High)	95,527 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210906-038		06/09/2021 10:15 YD	Butanona Normal Saline		3MM Whatman 3MM Whatman			322 4		2 319	0	pH (Low/Actual/High)	98,144 %	Pass 5,00 <= 6,00 <= 7,00
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
PSMA-68Ga Lot # K-20210906-015	06/09/2021	06:56	FN	Acetato de amônio 1M:Metanol	Sílica gel				0,7	42,7		0		98,387 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 6,00	<= 8,00	
PSMA-68Ga Lot # K-20210906-052	06/09/2021	12:49	JS	Acetato de amônio 1M:Metanol	Sílica gel				0,36	13,6		0		97,421 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
Tecnécio-99m Lot # E-20210906-001	06/09/2021	02:01	PP	Butanona		3MM	Whatman		30	1470		0		98,00 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210906-002	06/09/2021	02:02	PP	Butanona		3MM	Whatman		23	3046		0		99,251 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210906-003	06/09/2021	02:49	PP	Butanona		3MM	Whatman		3	3252		0		99,908 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210906-004	06/09/2021	03:55	PP	Butanona		3MM	Whatman		1	2603		0		99,962 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210906-005	06/09/2021	05:26	PP	Butanona		3MM	Whatman		18	898		0		98,035 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210906-007	06/09/2021	07:00	FN	Butanona		3MM	Whatman		15	1235		0		98,80 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210906-008	06/09/2021	07:06	FN	Butanona		3MM	Whatman		2	487		0		99,591 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210906-009	06/09/2021	07:30	FN	Butanona		3MM	Whatman		3	406		0		99,267 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210906-010	06/09/2021	09:27	YD	Butanona		3MM	Whatman		1	2391		0		99,958 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210906-011	06/09/2021	09:33	YD	Butanona		3MM	Whatman		30	4850		0		99,385 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210906-013	06/09/2021	10:16	YD	Butanona		3MM	Whatman		4	1079		0		99,631 %	Pass
								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	

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		06/09/2021 15:30	JS	Butanona		3MM	Whatman	1		510	0		99,804 %	Pass
Lot # E-20210906-016											pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
														Límpido e Incolor