



# 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 06/08/2021 To 06/08/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc		06/08/2021	07:53	WG	Butanona	3MM Whatman	195		2	0		98,142 %	Pass
Lot # K-20210806-023					Normal Saline	Silica gel	1,2		141,2	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		06/08/2021	07:54	WG	Butanona	3MM Whatman	72,5		2,8	0		95,187 %	Pass
Lot # K-20210806-025					Normal Saline	Silica gel	1		90,4	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		06/08/2021	07:54	WG	Butanona	3MM Whatman	117,8		3	0		95,50 %	Pass
Lot # K-20210806-024					Normal Saline	Silica gel	2		97,2	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		06/08/2021	08:01	WG	Butanona	3MM Whatman	122		4	0		95,915 %	Pass
Lot # K-20210806-026					Normal Saline	Silica gel	0,8		87,1	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		06/08/2021	10:22	LG	Butanona	3MM Whatman	67,3		0	0		95,082 %	Pass
Lot # K-20210806-039					Normal Saline	Silica gel	3		58	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		06/08/2021	10:24	LG	Butanona	3MM Whatman	55		0,3	0		92,791 %	Pass
Lot # K-20210806-040					Normal Saline	Silica gel	4		56	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DTPA-99mTc	RPH	06/08/2021	03:36	FN	Acetona	3MM Whatman	1830		13	0		97,20 %	Pass
Lot # K-20210806-010					Normal Saline	3MM Whatman	15		701	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	06/08/2021	04:08	FN	Acetona	3MM Whatman	388		7	0		94,985 %	Pass
Lot # K-20210806-016					Normal Saline	3MM Whatman	12		358	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	06/08/2021	08:04	WG	Acetona	3MM Whatman	219		1	0		98,007 %	Pass
Lot # K-20210806-029					Normal Saline	3MM Whatman	4		256	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	06/08/2021	10:06	LG	Acetona	3MM Whatman	163		0,4	0		96,706 %	Pass
Lot # K-20210806-037					Normal Saline	3MM Whatman	5		159	pH (Low/Actual/High)		3,80 <= 5,00	<= 7,50
						Límpido/Incolor							
FITATO-99mTc		06/08/2021	03:38	FN	Butanona	3MM Whatman	414		1	0		99,759 %	Pass
Lot # K-20210806-011										pH (Low/Actual/High)		5,00 <= 5,00	<= 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
FITATO-99mTc Lot # K-20210806-022	06/08/2021	07:21	WG	Butanona		3MM Whatman		415		1	0	99,76 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
												Límpido/Incolor		
MAA-99mTc Lot # K-20210806-012	06/08/2021	03:52	FN	Butanona		3MM Whatman		184,5		1,2	0	99,354 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210806-013	06/08/2021	03:54	FN	Butanona		3MM Whatman		193,8		2,9	0	98,526 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210806-014	06/08/2021	03:55	FN	Butanona		3MM Whatman		170,6		1,3	0	99,244 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210806-015	06/08/2021	03:57	FN	Butanona		3MM Whatman		127,8		1,3	0	98,993 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210806-028	06/08/2021	08:02	WG	Butanona		3MM Whatman		163,4		7,4	0	95,667 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210806-036	06/08/2021	10:05	LG	Butanona		3MM Whatman		108		2	0	98,182 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210806-041	06/08/2021	10:39	LG	Butanona		3MM Whatman		46		1	0	97,872 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20210806-008	06/08/2021	03:30	FN	Acetona		3MM Whatman		1062		2	0	98,865 %	Pass	
				Normal Saline		3MM Whatman		10		1046		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210806-009	06/08/2021	03:34	FN	Acetona		3MM Whatman		793		1	0	98,374 %	Pass	
				Normal Saline		3MM Whatman		12		788		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210806-021	06/08/2021	07:18	WG	Acetona		3MM Whatman		1405		11	0	98,562 %	Pass	
				Normal Saline		3MM Whatman		6		902		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210806-027	06/08/2021	07:58	WG	Acetona		3MM Whatman		723		16	0	95,121 %	Pass	
				Normal Saline		3MM Whatman		19		681		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210806-035	06/08/2021	09:54	LG	Acetona		3MM Whatman		446		3	0	98,772 %	Pass	
				Normal Saline		3MM Whatman		2		355		pH (Low/Actual/High)	4,00 <= 5,00	<= 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-20210806-001		06/08/2021 01:56 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1545 4		20 1232	0	pH (Low/Actual/High)	98,398 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-004		06/08/2021 01:57 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			299 5		4 231	0	pH (Low/Actual/High)	96,561 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-003		06/08/2021 01:58 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1630 6		15 1896	0	pH (Low/Actual/High)	98,773 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-005		06/08/2021 02:17 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			390 3		6 220	0	pH (Low/Actual/High)	97,14 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-006		06/08/2021 03:14 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1423 10		20 1377	0	pH (Low/Actual/High)	97,893 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-007		06/08/2021 03:18 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			698 3		8 698	0	pH (Low/Actual/High)	98,439 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-017		06/08/2021 04:10 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1021 2		12 857	0	pH (Low/Actual/High)	98,606 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-019		06/08/2021 06:57 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1939 3		40 2300	0	pH (Low/Actual/High)	97,849 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-020		06/08/2021 07:02 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1603 10		23 2866	0	pH (Low/Actual/High)	98,238 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-030		06/08/2021 08:46 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			908 10		12 902	0	pH (Low/Actual/High)	97,599 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-031		06/08/2021 09:11 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			793 4		10 1079	0	pH (Low/Actual/High)	98,385 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-032		06/08/2021 09:20 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			309 1		5 376	0	pH (Low/Actual/High)	98,142 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210806-033		06/08/2021 09:36 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			309 3		4 364	0	pH (Low/Actual/High)	97,905 %	Pass 5,00 <= 5,00 <= 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
PIRO-99mTc Lot # K-20210806-038	06/08/2021	10:16	LG	Butanona Normal Saline	3MM	Whatman		190 2,5		0,5 180	0	pH (Low/Actual/High)	98,368 %	Pass 5,00 <= 5,00 <= 7,00
														Límpido/Incolor
PSMA-68Ga Lot # K-20210806-018	06/08/2021	06:53	BB	Acetato de amônio 1M:Metanol	Sílica gel			0,3		14	0	pH (Low/Actual/High)	97,902 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
PSMA-68Ga Lot # K-20210806-034	06/08/2021	09:42	LG	Acetato de amônio 1M:Metanol	Sílica gel			0,3		21	0	pH (Low/Actual/High)	98,592 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-001	06/08/2021	01:50	FN	Butanona	3MM	Whatman		1		938	0	pH (Low/Actual/High)	99,894 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-002	06/08/2021	02:11	FN	Butanona	3MM	Whatman		2		783	0	pH (Low/Actual/High)	99,745 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-003	06/08/2021	03:11	FN	Butanona	3MM	Whatman		1		249	0	pH (Low/Actual/High)	99,60 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-004	06/08/2021	03:16	BB	Butanona	3MM	Whatman		6		500	0	pH (Low/Actual/High)	98,814 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-005	06/08/2021	03:27	FN	Butanona	3MM	Whatman		2		296	0	pH (Low/Actual/High)	99,329 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-006	06/08/2021	03:31	FN	Butanona	3MM	Whatman		1		350	0	pH (Low/Actual/High)	99,715 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-007	06/08/2021	04:06	FN	Butanona	3MM	Whatman		1		220	0	pH (Low/Actual/High)	99,548 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-009	06/08/2021	06:55	PP	Butanona	3MM	Whatman		2		560	0	pH (Low/Actual/High)	99,644 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-010	06/08/2021	07:15	WG	Butanona	3MM	Whatman		1		216	0	pH (Low/Actual/High)	99,539 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-011	06/08/2021	07:45	WG	Butanona	3MM	Whatman		2		304,7	0	pH (Low/Actual/High)	99,348 %	Pass 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-20210806-012		06/08/2021 07:45	WG	Butanona		3MM Whatman		10		1965	0		99,494 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-013		06/08/2021 08:44	WG	Butanona		3MM Whatman		1		272	0		99,634 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-014		06/08/2021 09:08	LG	Butanona		3MM Whatman		2		528	0		99,623 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-015		06/08/2021 09:16	LG	Butanona		3MM Whatman		0,5		52,5	0		99,057 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-016		06/08/2021 09:23	LG	Butanona		3MM Whatman		1		145	0		99,315 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-018		06/08/2021 09:50	LG	Butanona		3MM Whatman		2		193	0		98,974 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-019		06/08/2021 10:00	LG	Butanona		3MM Whatman		1		655	0		99,848 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210806-020		06/08/2021 10:55	LG	Butanona		3MM Whatman		1		469	0		99,787 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor