



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 14/07/2021 To 14/07/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc		14/07/2021	04:04	FN	Butanona	3MM Whatman	154,8		1,2	0		92,957 %	Pass
Lot # K-20210714-015					Normal Saline	Silica gel	8,4		125,5	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		14/07/2021	07:32	FN	Butanona	3MM Whatman	143,7		2,3	0		93,28 %	Pass
Lot # K-20210714-022					Normal Saline	Silica gel	8,2		151,2	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		14/07/2021	07:33	FN	Butanona	3MM Whatman	119,3		1,4	0		96,111 %	Pass
Lot # K-20210714-023					Normal Saline	Silica gel	3,1		110,5	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		14/07/2021	07:34	FN	Butanona	3MM Whatman	138,1		10,1	0		91,376 %	Pass
Lot # K-20210714-024					Normal Saline	Silica gel	2,1		114	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		14/07/2021	10:41	FN	Butanona	3MM Whatman	112,5		3	0		92,915 %	Pass
Lot # K-20210714-040					Normal Saline	Silica gel	3,2		68,1	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		14/07/2021	10:42	FN	Butanona	3MM Whatman	193,4		2,1	0		96,209 %	Pass
Lot # K-20210714-041					Normal Saline	Silica gel	3,2		114,6	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DOTATATE-68Ga		14/07/2021	06:43	MP	Citrato de Sódio 0,1M	Silica gel	24,6		0	0		97,835 %	Pass
Lot # K-20210714-016					Metanol/Acetato de Amonio 1	Silica gel	0,5		22,6	pH (Low/Actual/High)		4,00 <= 4,50	<= 8,00
						Límpido e Incolor							
DOTATATE-68Ga		14/07/2021	09:46	MP	Citrato de Sódio 0,1M	Silica gel	64		0,2	0		99,161 %	Pass
Lot # K-20210714-029					Metanol/Acetato de Amonio 1	Silica gel	0,3		56,6	pH (Low/Actual/High)		4,00 <= 4,50	<= 8,00
						Límpido e Incolor							
DOTATOC-68Ga		14/07/2021	10:02	PP	Citrato de Sódio 0,1M	Silica gel	27,8		0,4	0		98,582 %	Pass
Lot # K-20210714-030										pH (Low/Actual/High)		4,00 <= 6,00	<= 8,00
						Límpido e Incolor							
DTPA-99mTc	RPH	14/07/2021	03:42	FN	Acetona	3MM Whatman	610		9	0		96,444 %	Pass
Lot # K-20210714-009					Normal Saline	3MM Whatman	12		559	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	14/07/2021	07:14	FN	Acetona	3MM Whatman	192		3	0		92,051 %	Pass
Lot # K-20210714-020					Normal Saline	3MM Whatman	10		146	pH (Low/Actual/High)		3,80 <= 6,00	<= 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-20210714-035	RPH	14/07/2021	10:28	FN	Acetona Normal Saline	3MM	Whatman		456 20		3 547	0	95,819 %		Pass
								Límpido/Incolor				pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
FITATO-99mTc Lot # K-20210714-010		14/07/2021	03:44	FN	Butanona	3MM	Whatman		397		1	0	99,749 %		Pass
								Límpido/Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 7,00		
FITATO-99mTc Lot # K-20210714-021		14/07/2021	07:19	FN	Butanona	3MM	Whatman		439		2	0	99,546 %		Pass
								Límpido/Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 7,00		
MAA-99mTc Lot # K-20210714-014		14/07/2021	03:58	FN	Butanona	3MM	Whatman		103,8		3,1	0	97,10 %		Pass
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MAA-99mTc Lot # K-20210714-027		14/07/2021	08:04	FN	Butanona	3MM	Whatman		118,7		1,2	0	98,999 %		Pass
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MAA-99mTc Lot # K-20210714-028		14/07/2021	08:07	FN	Butanona	3MM	Whatman		214		2	0	99,074 %		Pass
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MAA-99mTc Lot # K-20210714-036		14/07/2021	10:30	FN	Butanona	3MM	Whatman		64,3		1,7	0	97,424 %		Pass
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MAA-99mTc Lot # K-20210714-037		14/07/2021	10:32	FN	Butanona	3MM	Whatman		164,4		1,2	0	99,275 %		Pass
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MAA-99mTc Lot # K-20210714-038		14/07/2021	10:35	FN	Butanona	3MM	Whatman		177,1		2,5	0	98,608 %		Pass
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MAA-99mTc Lot # K-20210714-039		14/07/2021	10:38	FN	Butanona	3MM	Whatman		758		2	0	99,737 %		Pass
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MAA-99mTc Lot # K-20210714-043		14/07/2021	11:17	JS	Butanona	3MM	Whatman		166		1,3	0	99,223 %		Pass
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210714-046		14/07/2021	14:45	WG	Butanona	3MM	Whatman		145,5		2,4	0	98,377 %		Pass
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MDP-99mTc Lot # K-20210714-013		14/07/2021	03:56	FN	Acetona Normal Saline	3MM	Whatman		1357 5		3 1174	0	99,355 %		Pass
								Límpido/Incolor				pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		

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-20210714-019		14/07/2021 07:11 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			1166 6		2 1238	0 pH (Low/Actual/High)	99,346 %		Pass 4,00 <= 6,00 <= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210714-026		14/07/2021 07:54 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			1085 1		6 820	0 pH (Low/Actual/High)	99,328 %		Pass 4,00 <= 6,00 <= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210714-034		14/07/2021 10:23 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			661 1		2 713	0 pH (Low/Actual/High)	99,558 %		Pass 4,00 <= 6,00 <= 7,80
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210714-003		14/07/2021 01:34 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			691 12		1 733	0 pH (Low/Actual/High)	98,245 %		Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210714-005		14/07/2021 03:02 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1385 10		24 1629	0 pH (Low/Actual/High)	97,687 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210714-006		14/07/2021 03:04 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1994 12		6 1301	0 pH (Low/Actual/High)	98,786 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210714-007		14/07/2021 03:16 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1771 20		14 1779	0 pH (Low/Actual/High)	98,104 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210714-008		14/07/2021 03:20 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1528 6		20 1253	0 pH (Low/Actual/High)	98,231 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210714-011		14/07/2021 03:51 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1720 5		20 1741	0 pH (Low/Actual/High)	98,564 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210714-017		14/07/2021 06:51 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1282 10		6 1224	0 pH (Low/Actual/High)	98,724 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210714-018		14/07/2021 06:59 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			635 10		7 697	0 pH (Low/Actual/High)	97,495 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210714-025		14/07/2021 07:47 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			872 2		10 877	0 pH (Low/Actual/High)	98,639 %		Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210714-031		14/07/2021 10:14 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1027 3		10 852	0 pH (Low/Actual/High)	98,685 %		Pass 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-20210714-032	14/07/2021	10:16 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1229 3		26 903	0	pH (Low/Actual/High)	97,597 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210714-033	14/07/2021	10:20 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			579 1		3 913	0	pH (Low/Actual/High)	99,375 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210714-042	14/07/2021	10:48 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			544 3		9 647	0	pH (Low/Actual/High)	97,911 %	Pass
														5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210714-044	14/07/2021	11:19 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			621 4		2 567	0	pH (Low/Actual/High)	98,978 %	Pass
														5,00 <= 5,00 <= 6,00
														Límpido/Incolor
PSMA-177Lu Lot # K-20210714-001	14/07/2021	00:48 MP	Citrato de Sódio 0,1M		Sílica gel			1160		3	0	pH (Low/Actual/High)	99,742 %	Pass
														4,00 <= 4,50 <= 5,00
														Límpido
														QC Notes: HPLC: 99,34%
PSMA-177Lu Lot # K-20210714-002	14/07/2021	01:18 MP	Citrato de Sódio 0,1M		Sílica gel			163,9		0,8	0	pH (Low/Actual/High)	99,514 %	Pass
														4,00 <= 4,50 <= 5,00
														Límpido
														QC Notes: HPLC: 96,28%
PSMA-177Lu Lot # K-20210714-004	14/07/2021	01:19 MP	Citrato de Sódio 0,1M		Sílica gel			146,1		0,7	0	pH (Low/Actual/High)	99,523 %	Pass
														4,00 <= 4,50 <= 5,00
														Límpido
														QC Notes: HPLC: 98,75%
PSMA-68Ga Lot # K-20210714-045	14/07/2021	12:55 JS	Acetato de amônio		Sílica gel			0,2		36,2	0	pH (Low/Actual/High)	99,451 %	Pass
														4,00 <= 5,00 <= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210714-001	14/07/2021	01:26 FN	Butanona		3MM Whatman			1		320	0	pH (Low/Actual/High)	99,688 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210714-002	14/07/2021	02:59 FN	Butanona		3MM Whatman			2		981	0	pH (Low/Actual/High)	99,797 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210714-003	14/07/2021	03:00 FN	Butanona		3MM Whatman			3		527	0	pH (Low/Actual/High)	99,434 %	Pass
														5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210714-004	14/07/2021	03:13 FN	Butanona		3MM Whatman			3		328	0	pH (Low/Actual/High)	99,094 %	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-20210714-005		14/07/2021 03:18 FN	Butanona		3MM Whatman			1		218	0	99,543 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-006		14/07/2021 03:49 FN	Butanona		3MM Whatman			1		112	0	99,115 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-007		14/07/2021 03:49 FN	Butanona		3MM Whatman			1		498	0	99,80 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-009		14/07/2021 06:49 FN	Butanona		3MM Whatman			3		1223	0	99,755 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-010		14/07/2021 06:57 FN	Butanona		3MM Whatman			6		434	0	98,636 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-011		14/07/2021 07:07 FN	Butanona		3MM Whatman			1		251	0	99,603 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-012		14/07/2021 07:12 FN	Butanona		3MM Whatman			2		1033	0	99,807 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-013		14/07/2021 07:45 FN	Butanona		3MM Whatman			2		544	0	99,634 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-014		14/07/2021 07:51 FN	Butanona		3MM Whatman			2		344	0	99,422 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-017		14/07/2021 10:12 WG	Butanona		3MM Whatman			11		410	0	97,387 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-018		14/07/2021 10:15 WG	Butanona		3MM Whatman			2		644	0	99,69 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-019		14/07/2021 10:17 WG	Butanona		3MM Whatman			1		376	0	99,735 %		Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210714-020		14/07/2021 10:21 WG	Butanona		3MM Whatman			2		296	0	99,329 %		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 Lot # E-20210714-021		14/07/2021 10:25	FN	Butanona		3MM Whatman		1		109	0		99,091 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210714-022		14/07/2021 10:46	FN	Butanona		3MM Whatman		1		217	0		99,541 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210714-023		14/07/2021 11:15	JS	Butanona		3MM Whatman		2		125	0		98,425 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210714-025		14/07/2021 14:42	WG	Butanona		3MM Whatman		4		805	0		99,506 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
											Límpido e Incolor			