



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 05/08/2021 To 05/08/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210805-013		05/08/2021	04:01	FN	Butanona Normal Saline	3MM Whatman Sílica gel	123,3 6		0,5 138	0	pH (Low/Actual/High)	95,429 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210805-025		05/08/2021	08:01	WG	Butanona Normal Saline	3MM Whatman Sílica gel	113,8 0,2		2 62,6	0	pH (Low/Actual/High)	97,954 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210805-026		05/08/2021	08:02	WG	Butanona Normal Saline	3MM Whatman Sílica gel	145,5 3,5		1,4 67,9	0	pH (Low/Actual/High)	94,145 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210805-042		05/08/2021	11:04	JS	Butanona Normal Saline	3MM Whatman Sílica gel	77,8 4		0,3 96,7	0	pH (Low/Actual/High)	95,644 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210805-018		05/08/2021	07:02	BB	Citrato de Sódio 0,1M	Sílica gel	16,1		0,1	0	pH (Low/Actual/High)	99,383 %	Pass <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210805-044		05/08/2021	12:44	JS	Citrato de Sódio 0,1M	Sílica gel	23,9		0,1	0	pH (Low/Actual/High)	99,583 %	Pass <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210805-045		05/08/2021	15:47	JS	Citrato de Sódio 0,1M	Sílica gel	17,3		0,2	0	pH (Low/Actual/High)	98,857 %	Pass <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210805-008	RPH	05/08/2021	03:24	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	253 5		2 234	0	pH (Low/Actual/High)	97,124 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210805-021	RPH	05/08/2021	07:30	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	393 1		2 325	0	pH (Low/Actual/High)	99,187 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210805-029	RPH	05/08/2021	10:09	LG	Acetona Normal Saline	3MM Whatman 3MM Whatman	90,5 7,7		1 98	0	pH (Low/Actual/High)	91,622 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210805-007		05/08/2021	03:19	FN	Butanona	3MM Whatman	277		12	0	pH (Low/Actual/High)	95,848 %	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
FITATO-99mTc Lot # K-20210805-015	05/08/2021	04:15 FN	Butanona		3MM	Whatman		456		3	0		99,346 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
											Límpido/Incolor			
FITATO-99mTc Lot # K-20210805-022	05/08/2021	07:34 WG	Butanona		3MM	Whatman		407		5	0		98,786 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
											Límpido/Incolor			
MAA-99mTc Lot # K-20210805-009	05/08/2021	03:48 FN	Butanona		3MM	Whatman		154,2		5	0		96,859 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210805-010	05/08/2021	03:50 FN	Butanona		3MM	Whatman		158,8		7	0		95,778 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210805-011	05/08/2021	03:54 FN	Butanona		3MM	Whatman		112,9		4	0		96,578 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210805-014	05/08/2021	04:02 FN	Butanona		3MM	Whatman		155,5		2,2	0		98,605 %	Pass
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210805-023	05/08/2021	07:57 WG	Butanona		3MM	Whatman		128,3		2,2	0		98,314 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210805-024	05/08/2021	07:59 WG	Butanona		3MM	Whatman		135,6		2,5	0		98,19 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210805-030	05/08/2021	10:11 LG	Butanona		3MM	Whatman		34,6		1	0		97,191 %	Pass
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210805-031	05/08/2021	10:13 LG	Butanona		3MM	Whatman		51		1,3	0		97,514 %	Pass
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MDP-99mTc Lot # K-20210805-005	05/08/2021	03:14 FN	Acetona		3MM	Whatman		1195		2	0		99,56 %	Pass
			Normal Saline		3MM	Whatman		3		1097	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210805-006	05/08/2021	03:16 FN	Acetona		3MM	Whatman		534		1	0		98,517 %	Pass
			Normal Saline		3MM	Whatman		7		533	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210805-012	05/08/2021	03:58 FN	Acetona		3MM	Whatman		587		6	0		98,409 %	Pass
			Normal Saline		3MM	Whatman		4		687	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-20210805-019		05/08/2021 07:22	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			842 5		4 875	0 pH (Low/Actual/High)	98,959 %	Pass	4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210805-039		05/08/2021 10:43	LG	Acetona Normal Saline	3MM Whatman 3MM Whatman			463 18		1 399	0 pH (Low/Actual/High)	95,468 %	Pass	4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20210805-001		05/08/2021 02:32	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			1319 10		22 1756	0 pH (Low/Actual/High)	97,793 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210805-002		05/08/2021 02:33	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			998 12		8 1336	0 pH (Low/Actual/High)	98,315 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210805-003		05/08/2021 03:03	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			1649 4		8 1465	0 pH (Low/Actual/High)	99,245 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210805-004		05/08/2021 03:06	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			1541 12		20 1675	0 pH (Low/Actual/High)	98,007 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210805-016		05/08/2021 06:53	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			712 5		10 887	0 pH (Low/Actual/High)	98,054 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210805-017		05/08/2021 07:00	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1663 17		37 1973	0 pH (Low/Actual/High)	96,969 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210805-027		05/08/2021 09:34	LG	Normal Saline Metanol	Sílica gel 3MM Whatman			581 12		10 806	0 pH (Low/Actual/High)	96,841 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210805-032		05/08/2021 10:15	LG	Normal Saline Metanol	Sílica gel 3MM Whatman			340 1		3 339	0 pH (Low/Actual/High)	98,831 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210805-040		05/08/2021 10:51	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			462 4		2 414	0 pH (Low/Actual/High)	98,612 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210805-041		05/08/2021 10:57	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			55 1		1,1 353	0 pH (Low/Actual/High)	97,757 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210805-043		05/08/2021 11:09	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			493 7		4 435	0 pH (Low/Actual/High)	97,611 %	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
PIRO-99mTc Lot # K-20210805-020	05/08/2021	07:25	WG	Butanona Normal Saline	3MM	Whatman		124,8 3	0,8 147,9	0		pH (Low/Actual/High)	97,375 %	Pass 5,00 <= 6,00 <= 7,00
														Límpido/Incolor
PSMA-68Ga Lot # K-20210805-028	05/08/2021	09:55	LG	Acetato de amônio 1M:Metanol	Sílica gel			0,01	14,68	0		pH (Low/Actual/High)	99,932 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-001	05/08/2021	02:27	FN	Butanona	3MM	Whatman		2	552	0		pH (Low/Actual/High)	99,639 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-002	05/08/2021	02:28	FN	Butanona	3MM	Whatman		1	449	0		pH (Low/Actual/High)	99,778 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-003	05/08/2021	03:00	FN	Butanona	3MM	Whatman		2	431	0		pH (Low/Actual/High)	99,538 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-004	05/08/2021	03:04	FN	Butanona	3MM	Whatman		0,1	62,2	0		pH (Low/Actual/High)	99,839 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-005	05/08/2021	03:12	FN	Butanona	3MM	Whatman		0,6	143,5	0		pH (Low/Actual/High)	99,584 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-006	05/08/2021	03:20	FN	Butanona	3MM	Whatman		2	453	0		pH (Low/Actual/High)	99,56 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-007	05/08/2021	03:52	FN	Butanona	3MM	Whatman		1	212	0		pH (Low/Actual/High)	99,531 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-008	05/08/2021	03:57	FN	Butanona	3MM	Whatman		2	1376	0		pH (Low/Actual/High)	99,855 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-009	05/08/2021	06:49	PP	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-20210805-010	05/08/2021	06:56	PP	Butanona	3MM	Whatman		2	253	0		pH (Low/Actual/High)	99,216 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-012	05/08/2021	07:19	PP	Butanona	3MM	Whatman		2	187	0		pH (Low/Actual/High)	98,942 %	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-20210805-013	05/08/2021	07:23	WG	Butanona		3MM Whatman		8		861	0		99,079 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-014	05/08/2021	08:12	WG	Butanona		3MM Whatman		22		1531	0		98,583 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-015	05/08/2021	09:18	LG	Butanona		3MM Whatman		8		259	0		97,004 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-016	05/08/2021	09:31	WG	Butanona		3MM Whatman		0,8		146,7	0		99,458 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-018	05/08/2021	10:12	LG	Butanona		3MM Whatman		6		653	0		99,09 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-019	05/08/2021	10:19	LG	Butanona		3MM Whatman		2		98,5	0		98,01 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-020	05/08/2021	10:41	LG	Butanona		3MM Whatman		2		107	0		98,165 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-021	05/08/2021	10:46	LG	Butanona		3MM Whatman		1		113	0		99,123 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-022	05/08/2021	10:54	LG	Butanona		3MM Whatman		1,5		143	0		98,962 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210805-023	05/08/2021	11:02	JS	Butanona		3MM Whatman		1		108	0		99,083 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
TRODAT-99mTc Lot # K-20210805-033	05/08/2021	10:29	JS	Normal Saline		Sílica gel		140		2,5	0		96,747 %	Pass
				Butanona		3MM Whatman		1,2		78,9		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210805-034	05/08/2021	10:30	JS	Normal Saline		Sílica gel		66,1		1,6	0		96,446 %	Pass
				Butanona		3MM Whatman		1		83		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210805-035	05/08/2021	10:31	JS	Normal Saline		Sílica gel		117		2	0		97,746 %	Pass
				Butanona		3MM Whatman		0,6		104		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														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
TRODAT-99mTc Lot # K-20210805-036		05/08/2021 10:32 JS	Normal Saline Butanona		Sílica gel 3MM Whatman			59 1,4		0,3 98	0 pH (Low/Actual/High)		98,086 %	Pass
							Límpido/Incolor					6,50 <= 7,00 <= 8,50		
TRODAT-99mTc Lot # K-20210805-037		05/08/2021 10:38 JS	Normal Saline Butanona		Sílica gel 3MM Whatman			146 3		2 181	0 pH (Low/Actual/High)		97,018 %	Pass
							Límpido/Incolor					6,50 <= 7,00 <= 8,50		
TRODAT-99mTc Lot # K-20210805-038		05/08/2021 10:39 JS	Normal Saline Butanona		Sílica gel 3MM Whatman			104 0,9		1 79	0 pH (Low/Actual/High)		97,921 %	Pass
							Límpido/Incolor					6,50 <= 7,00 <= 8,50		