



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 30/08/2021 To 30/08/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210830-018		30/08/2021	07:31	FN	Butanona Normal Saline	3MM Whatman Sílica gel	206 12		1 213	0	pH (Low/Actual/High)	94,184 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210830-019		30/08/2021	07:53	FN	Butanona Normal Saline	3MM Whatman Sílica gel	239 20		2 231	0	pH (Low/Actual/High)	91,202 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210830-027		30/08/2021	10:52	LG	Butanona Normal Saline	3MM Whatman Sílica gel	89,6 1,9		0,1 21,1	0	pH (Low/Actual/High)	91,628 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210830-022		30/08/2021	10:07	BB	Citrato de Sódio 0,1M	Sílica gel	11,2		0,3	0	pH (Low/Actual/High)	97,391 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210830-043		30/08/2021	15:38	LG	Citrato de Sódio 0,1M	Sílica gel	3,1		0,02	0	pH (Low/Actual/High)	99,359 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210830-044		30/08/2021	16:23	JS	Citrato de Sódio 0,1M	Sílica gel	13		0,3	0	pH (Low/Actual/High)	97,744 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210830-012	RPH	30/08/2021	03:55	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	876 74		2 973	0	pH (Low/Actual/High)	92,704 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210830-026	RPH	30/08/2021	10:49	LG	Acetona Normal Saline	3MM Whatman 3MM Whatman	114 3,5		0,5 120	0	pH (Low/Actual/High)	96,729 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210830-011		30/08/2021	03:53	PP	Butanona	3MM Whatman	498		10	0	pH (Low/Actual/High)	98,031 %	Pass 5,00 <= 7,00 <= 7,00
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210830-021		30/08/2021	07:48	BB	Butanona	3MM Whatman	256		1	0	pH (Low/Actual/High)	99,611 %	Pass 5,00 <= 7,00 <= 7,00
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210830-028		30/08/2021	10:54	LG	Butanona	3MM Whatman	339		2	0	pH (Low/Actual/High)	99,413 %	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
MAA-99mTc Lot # K-20210830-008		30/08/2021 03:46	PP	Butanona		3MM Whatman		526		2	0	99,621 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-009		30/08/2021 03:49	PP	Butanona		3MM Whatman		159		1	0	99,375 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-010		30/08/2021 03:50	PP	Butanona		3MM Whatman		180		6	0	96,774 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-029		30/08/2021 10:56	LG	Butanona		3MM Whatman		40		1	0	97,561 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-030		30/08/2021 10:58	LG	Butanona		3MM Whatman		48		1,5	0	96,97 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-031		30/08/2021 10:59	LG	Butanona		3MM Whatman		67		1	0	98,529 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-032		30/08/2021 11:02	LG	Butanona		3MM Whatman		21,5		0,3	0	98,624 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-035		30/08/2021 11:23	LG	Butanona		3MM Whatman		79,5		0,2	0	99,749 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-036		30/08/2021 11:24	LG	Butanona		3MM Whatman		178,5		4,5	0	97,541 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-037		30/08/2021 11:27	LG	Butanona		3MM Whatman		127,5		2,5	0	98,077 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-038		30/08/2021 11:30	LG	Butanona		3MM Whatman		126		0,3	0	99,762 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-039		30/08/2021 11:33	LG	Butanona		3MM Whatman		171		3	0	98,276 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210830-040		30/08/2021 11:48	LG	Butanona		3MM Whatman		114		2	0	98,276 %	Pass	
											pH (Low/Actual/High)	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
MDP-99mTc Lot # K-20210830-006		30/08/2021 03:30 PP	Acetona Normal Saline		3MM Whatman 3MM Whatman			1934 12		1 1008	0	pH (Low/Actual/High)	98,772 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210830-007		30/08/2021 03:33 PP	Acetona Normal Saline		3MM Whatman 3MM Whatman			2326 26		20 1212	0	pH (Low/Actual/High)	97,047 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210830-015		30/08/2021 07:08 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			388 2		4 390	0	pH (Low/Actual/High)	98,469 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210830-020		30/08/2021 07:30 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			429 12		2 1045	0	pH (Low/Actual/High)	98,401 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210830-025		30/08/2021 10:33 LG	Acetona Normal Saline		3MM Whatman 3MM Whatman			351 0		1 906	0	pH (Low/Actual/High)	99,716 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210830-033		30/08/2021 11:04 LG	Acetona Normal Saline		3MM Whatman 3MM Whatman			331 2		0 362	0	pH (Low/Actual/High)	99,451 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20210830-001		30/08/2021 02:14 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2065 35		64 2380	0	pH (Low/Actual/High)	95,545 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210830-002		30/08/2021 02:15 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1311 11		30 2768	0	pH (Low/Actual/High)	97,367 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210830-003		30/08/2021 02:44 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2138 10		40 1947	0	pH (Low/Actual/High)	97,652 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210830-004		30/08/2021 02:50 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2305 49		14 3222	0	pH (Low/Actual/High)	97,898 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210830-005		30/08/2021 02:51 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1925 4		35 2638	0	pH (Low/Actual/High)	98,063 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210830-013		30/08/2021 04:11 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1447 17		31 1283	0	pH (Low/Actual/High)	96,595 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210830-016		30/08/2021 07:11 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			210 1		6 244	0	pH (Low/Actual/High)	96,814 %	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-20210830-017		30/08/2021 07:30 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			954 13		13 1152	0	pH (Low/Actual/High)	97,54 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210830-023		30/08/2021 10:09 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			395 19		4 1390	0	pH (Low/Actual/High)	97,649 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210830-024		30/08/2021 10:31 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			916 13		20 923	0	pH (Low/Actual/High)	96,474 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210830-034		30/08/2021 11:07 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			436 16		2 1079	0	pH (Low/Actual/High)	98,082 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210830-014		30/08/2021 06:52 FN	Acetato de amônio 1M:Metanol		Sílica gel			0,7		79,5	0	pH (Low/Actual/High)	99,127 %	Pass 4,00 <= 6,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210830-041		30/08/2021 12:36 LG	Acetato de amônio 1M:Metanol		Sílica gel			0,09		5,98	0	pH (Low/Actual/High)	98,517 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210830-042		30/08/2021 13:12 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,2		15,21	0	pH (Low/Actual/High)	98,702 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210830-001		30/08/2021 01:57 PP	Butanona		3MM Whatman			17		4997	0	pH (Low/Actual/High)	99,661 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210830-002		30/08/2021 02:00 PP	Butanona		3MM Whatman			133		4594	0	pH (Low/Actual/High)	97,186 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210830-003		30/08/2021 02:46 PP	Butanona		3MM Whatman			10		2639	0	pH (Low/Actual/High)	99,622 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210830-004		30/08/2021 02:46 PP	Butanona		3MM Whatman			15		1211	0	pH (Low/Actual/High)	98,777 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210830-005		30/08/2021 03:43 PP	Butanona		3MM Whatman			8		1378	0	pH (Low/Actual/High)	99,423 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210830-007		30/08/2021 06:59 FN	Butanona		3MM Whatman			2		247	0	pH (Low/Actual/High)	99,197 %	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-20210830-008		30/08/2021 07:09	FN	Butanona		3MM Whatman		6		2827	0		99,788 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210830-009		30/08/2021 07:26	FN	Butanona		3MM Whatman		1		310	0		99,678 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210830-010		30/08/2021 10:06	JS	Butanona		3MM Whatman		1		206	0		99,517 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210830-012		30/08/2021 10:28	JS	Butanona		3MM Whatman		6		1056	0		99,435 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210830-013		30/08/2021 10:50	LG	Butanona		3MM Whatman		7		1494	0		99,534 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210830-014		30/08/2021 11:05	LG	Butanona		3MM Whatman		4		278	0		98,582 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210830-015		30/08/2021 12:08	LG	Butanona		3MM Whatman		3		260	0		98,859 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210830-016		30/08/2021 12:12	LG	Butanona		3MM Whatman		2		285	0		99,303 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210830-017		30/08/2021 12:15	LG	Butanona		3MM Whatman		2		222	0		99,107 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210830-018		30/08/2021 12:18	LG	Butanona		3MM Whatman		8		373	0		97,90 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido e Incolor		