



# 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 06/07/2021 To 06/07/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210706-024		06/07/2021	07:30	GF	Butanona Normal Saline	3MM Whatman Sílica gel	76 2,4		1,3 80	0	pH (Low/Actual/High)	95,406 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210706-025		06/07/2021	07:35	GF	Butanona Normal Saline	3MM Whatman Sílica gel	87 5,2		2,1 64	0	pH (Low/Actual/High)	90,129 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210706-026		06/07/2021	07:35	GF	Butanona Normal Saline	3MM Whatman Sílica gel	55 0,4		0,6 69,5	0	pH (Low/Actual/High)	98,349 %	Pass
Límpido/Incolor													
DOTATATE-68Ga Lot # K-20210706-020		06/07/2021	06:41	MP	Citrato de Sódio 0,1M Metanol/Acetato de Amonio 1	Sílica gel Sílica gel	65,18 7		4,5 75	0	pH (Low/Actual/High)	85,005 %	Fail
Límpido e Incolor													
DOTATATE-68Ga Lot # K-20210706-051		06/07/2021	12:40	MP	Citrato de Sódio 0,1M Metanol/Acetato de Amonio 1	Sílica gel Sílica gel	43 15		11 38	0	pH (Low/Actual/High)	51,328 %	Fail
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210706-027		06/07/2021	07:38	GF	Citrato de Sódio 0,1M	Sílica gel	11,58		0,11	0	pH (Low/Actual/High)	99,059 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210706-052		06/07/2021	13:18										%
DTPA-99mTc Lot # K-20210706-008	RPH	06/07/2021	03:26	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	651 33		5 829	0	pH (Low/Actual/High)	95,409 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210706-031	RPH	06/07/2021	08:04	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	448 10		2 274	0	pH (Low/Actual/High)	96,034 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210706-037	RPH	06/07/2021	10:13	JS	Acetona Normal Saline	3MM Whatman 3MM Whatman	2370 2		1 2150	0	pH (Low/Actual/High)	99,865 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210706-048	RPH	06/07/2021	10:56	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	381 18		9 546	0	pH (Low/Actual/High)	94,501 %	Pass
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-20210706-009	06/07/2021	03:28	PP	Butanona		3MM	Whatman		224		6	0	97,391 %	Pass	
								Límpido/Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
FITATO-99mTc Lot # K-20210706-030	06/07/2021	08:02	FN	Butanona		3MM	Whatman		384		1	0	99,74 %	Pass	
								Límpido/Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
MAA-99mTc Lot # K-20210706-011	06/07/2021	03:49	PP	Butanona		3MM	Whatman		341		12	0	96,601 %	Pass	
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210706-012	06/07/2021	03:53	PP	Butanona		3MM	Whatman		263		7	0	97,407 %	Pass	
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210706-013	06/07/2021	03:55	PP	Butanona		3MM	Whatman		232		2	0	99,145 %	Pass	
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210706-014	06/07/2021	03:57	PP	Butanona		3MM	Whatman		223		1	0	99,554 %	Pass	
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210706-015	06/07/2021	03:58	PP	Butanona		3MM	Whatman		223		5	0	97,807 %	Pass	
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210706-016	06/07/2021	04:09	PP	Butanona		3MM	Whatman		146		4	0	97,333 %	Pass	
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210706-017	06/07/2021	04:12	PP	Butanona		3MM	Whatman		144		4	0	97,297 %	Pass	
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210706-018	06/07/2021	04:15	PP	Butanona		3MM	Whatman		155		6	0	96,273 %	Pass	
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210706-032	06/07/2021	08:07	FN	Butanona		3MM	Whatman		53		2	0	96,364 %	Pass	
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210706-038	06/07/2021	10:18	JS	Butanona		3MM	Whatman		187		1	0	99,468 %	Pass	
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210706-039	06/07/2021	10:21	JS	Butanona		3MM	Whatman		57		2	0	96,61 %	Pass	
								Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 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
MAA-99mTc Lot # K-20210706-040		06/07/2021 10:24 JS	Butanona		3MM	Whatman		61		1	0	98,387 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210706-041		06/07/2021 10:27 JS	Butanona		3MM	Whatman		83		2	0	97,647 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210706-042		06/07/2021 10:31 JS	Butanona		3MM	Whatman		355		7	0	98,066 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210706-049		06/07/2021 10:59 JS	Butanona		3MM	Whatman		87		3	0	96,667 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210706-050		06/07/2021 11:02 WG	Butanona		3MM	Whatman		741		14	0	98,146 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MDP-99mTc Lot # K-20210706-006		06/07/2021 03:07 PP	Acetona		3MM	Whatman		1056		5	0	99,439 %	Pass	
			Normal Saline		3MM	Whatman		1		1113	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210706-007		06/07/2021 03:10 PP	Acetona		3MM	Whatman		1151		6	0	99,261 %	Pass	
			Normal Saline		3MM	Whatman		3		1356	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210706-022		06/07/2021 06:45 GF	Acetona		3MM	Whatman		441		1	0	98,447 %	Pass	
			Normal Saline		3MM	Whatman		8		595	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210706-023		06/07/2021 07:29 GF	Acetona		3MM	Whatman		838		3	0	99,255 %	Pass	
			Normal Saline		3MM	Whatman		2		513	pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210706-033		06/07/2021 08:27 FN	Acetona		3MM	Whatman		777		2	0	98,968 %	Pass	
			Normal Saline		3MM	Whatman		4		512	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210706-001		06/07/2021 02:04 PP	Normal Saline		Sílica gel			1404		6	0	99,10 %	Pass	
			Metanol		3MM	Whatman		9		1886	pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210706-002		06/07/2021 02:30 PP	Normal Saline		Sílica gel			2108		35	0	97,336 %	Pass	
			Metanol		3MM	Whatman		17		1633	pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210706-003		06/07/2021 02:31 PP	Normal Saline		Sílica gel			2905		21	0	98,713 %	Pass	
			Metanol		3MM	Whatman		13		2272	pH (Low/Actual/High)	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-20210706-004	06/07/2021	03:00	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2439 43		30 2224	0	pH (Low/Actual/High)	96,888 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210706-005	06/07/2021	03:04	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2383 14		32 2926	0	pH (Low/Actual/High)	98,199 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210706-019	06/07/2021	06:40	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			1105 23		20 991	0	pH (Low/Actual/High)	95,954 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210706-021	06/07/2021	06:44	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			1159 25		36 885	0	pH (Low/Actual/High)	94,24 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210706-029	06/07/2021	07:51	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			980 4		21 1367	0	pH (Low/Actual/High)	97,61 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210706-035	06/07/2021	10:05	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			990 13		12 1013	0	pH (Low/Actual/High)	97,535 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210706-036	06/07/2021	10:06	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			933 12		32 1032	0	pH (Low/Actual/High)	95,535 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210706-043	06/07/2021	10:39	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			3111 83		12 1908	0	pH (Low/Actual/High)	95,447 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210706-010	06/07/2021	03:31	PP	Butanona Normal Saline	3MM Whatman 3MM Whatman			836 1		4 516	0	pH (Low/Actual/High)	99,33 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210706-028	06/07/2021	07:44	FN	Butanona Normal Saline	3MM Whatman 3MM Whatman			207 2		2 239	0	pH (Low/Actual/High)	98,213 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210706-034	06/07/2021	09:49	BB	Acetato de amônio	Sílica gel			0,4		31,2	0	pH (Low/Actual/High)	98,734 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210706-001	06/07/2021	02:01	PP	Butanona	3MM Whatman			1		1327	0	pH (Low/Actual/High)	99,925 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210706-002	06/07/2021	02:24	PP	Butanona	3MM Whatman			1		548	0	pH (Low/Actual/High)	99,818 %	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-20210706-003		06/07/2021 02:58	PP	Butanona		3MM Whatman		60		1631	0	96,452 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210706-004		06/07/2021 03:02	PP	Butanona		3MM Whatman		22		704	0	96,97 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210706-005		06/07/2021 03:24	PP	Butanona		3MM Whatman		4		230	0	98,291 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210706-006		06/07/2021 06:37	GF	Butanona		3MM Whatman		3		381	0	99,219 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210706-008		06/07/2021 06:41	GF	Butanona		3MM Whatman		2		718	0	99,722 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210706-009		06/07/2021 07:23	GF	Butanona		3MM Whatman		6		326	0	98,193 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210706-011		06/07/2021 07:48	GF	Butanona		3MM Whatman		52		1374	0	96,353 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210706-012		06/07/2021 07:59	GF	Butanona		3MM Whatman		3		672	0	99,556 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210706-014		06/07/2021 09:57	JS	Butanona		3MM Whatman		9		2590	0	99,654 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210706-015		06/07/2021 10:02	JS	Butanona		3MM Whatman		1		138	0	99,281 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210706-016		06/07/2021 10:11	JS	Butanona		3MM Whatman		12		1274	0	99,067 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210706-017		06/07/2021 10:40	JS	Butanona		3MM Whatman		31		1837	0	98,34 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
TRODAT-99mTc Lot # K-20210706-044		06/07/2021 10:47	WG	Normal Saline		Sílica gel		78		1,7	0	95,669 %	Pass	
				Butanona		3MM Whatman		2		89		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-20210706-045		06/07/2021 10:48	WG	Normal Saline Butanona	Silica gel 3MM Whatman			54,6 2,7		2 61	0 pH (Low/Actual/High)	92,228 %		Pass
								Límpido/Incolor				6,50 <= 7,00 <= 8,50		
TRODAT-99mTc Lot # K-20210706-046		06/07/2021 10:49	WG	Normal Saline Butanona	Silica gel 3MM Whatman			122,8 2,4		3 96,5	0 pH (Low/Actual/High)	95,189 %		Pass
								Límpido/Incolor				6,50 <= 7,00 <= 8,50		
TRODAT-99mTc Lot # K-20210706-047		06/07/2021 10:51	WG	Normal Saline Butanona	Silica gel 3MM Whatman			52,3 4		1,3 83,9	0 pH (Low/Actual/High)	93,024 %		Pass
								Límpido/Incolor				6,50 <= 7,00 <= 8,50		