



# 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 17/08/2021 To 17/08/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210817-014		17/08/2021	04:09	PP	Butanona Normal Saline	3MM Whatman Sílica gel	277 15		2 206	0	pH (Low/Actual/High)	92,496 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210817-025		17/08/2021	07:36	FN	Butanona Normal Saline	3MM Whatman Sílica gel	185,8 25		1,2 2190	0	pH (Low/Actual/High)	98,23 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210817-026		17/08/2021	07:36	FN	Butanona Normal Saline	3MM Whatman Sílica gel	193,3 12		7,2 344	0	pH (Low/Actual/High)	93,038 %	Pass
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210817-021		17/08/2021	06:52	FN	Citrato de Sódio 0,1M	Sílica gel	33,6		0,3	0	pH (Low/Actual/High)	99,115 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210817-029		17/08/2021	07:45	FN	Citrato de Sódio 0,1M	Sílica gel	29,1		0,1	0	pH (Low/Actual/High)	99,658 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210817-043		17/08/2021	12:40	JS	Citrato de Sódio 0,1M	Sílica gel	18,4		0,3	0	pH (Low/Actual/High)	98,396 %	Pass
Límpido e Incolor													
DTPA-99mTc Lot # K-20210817-007	RPH	17/08/2021	03:29	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	505 12		6 472	0	pH (Low/Actual/High)	96,346 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210817-022	RPH	17/08/2021	07:14	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	653 12		11 598	0	pH (Low/Actual/High)	96,376 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210817-032	RPH	17/08/2021	09:31	LG	Acetona Normal Saline	3MM Whatman 3MM Whatman	370 6		3 244	0	pH (Low/Actual/High)	96,796 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20210817-006		17/08/2021	03:18	PP	Butanona	3MM Whatman	313		1	0	pH (Low/Actual/High)	99,682 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20210817-033		17/08/2021	09:33	LG	Butanona	3MM Whatman	165		0	0	pH (Low/Actual/High)	100,00 %	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
MAA-99mTc Lot # K-20210817-008		17/08/2021 03:45	PP	Butanona		3MM Whatman		298		1	0	99,666 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-009		17/08/2021 03:47	PP	Butanona		3MM Whatman		226		4	0	98,261 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-010		17/08/2021 03:48	PP	Butanona		3MM Whatman		211		1	0	99,528 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-011		17/08/2021 03:50	PP	Butanona		3MM Whatman		293		2	0	99,322 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-012		17/08/2021 03:51	PP	Butanona		3MM Whatman		270		2	0	99,265 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-013		17/08/2021 03:53	PP	Butanona		3MM Whatman		120		1	0	99,174 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-016		17/08/2021 04:18	PP	Butanona		3MM Whatman		160		4	0	97,561 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-017		17/08/2021 04:20	PP	Butanona		3MM Whatman		100		1	0	99,01 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-018		17/08/2021 04:21	PP	Butanona		3MM Whatman		357		1	0	99,721 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-024		17/08/2021 07:19	FN	Butanona		3MM Whatman		172,1		0,4	0	99,768 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-041		17/08/2021 10:43	LG	Butanona		3MM Whatman		89,9		2,2	0	97,611 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-042		17/08/2021 10:45	LG	Butanona		3MM Whatman		108		3	0	97,297 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210817-044		17/08/2021 14:35	WG	Butanona		3MM Whatman		158,4		0,5	0	99,685 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 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
MAA-99mTc Lot # K-20210817-045		17/08/2021 14:35	WG	Butanona		3MM Whatman		116,5		1,3	0	98,896 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210817-046		17/08/2021 14:37	WG	Butanona		3MM Whatman		102,8		2,1	0	97,998 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210817-047		17/08/2021 14:38	WG	Butanona		3MM Whatman		136,7		2	0	98,558 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210817-048		17/08/2021 14:39	WG	Butanona		3MM Whatman		132,9		0,5	0	99,625 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210817-049		17/08/2021 14:41	WG	Butanona		3MM Whatman		142,4		4,3	0	97,069 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20210817-004		17/08/2021 03:00	PP	Acetona		3MM Whatman		851		1	0	90,597 %	Pass	
				Normal Saline		3MM Whatman		26		254		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210817-019		17/08/2021 04:25	PP	Acetona		3MM Whatman		1581		3	0	97,883 %	Pass	
				Normal Saline		3MM Whatman		32		1628		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210817-028		17/08/2021 07:45	FN	Acetona		3MM Whatman		1047		5	0	98,433 %	Pass	
				Normal Saline		3MM Whatman		16		1450		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210817-030		17/08/2021 07:59	FN	Acetona		3MM Whatman		1762		2	0	99,621 %	Pass	
				Normal Saline		3MM Whatman		3		1128		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210817-001		17/08/2021 02:26	PP	Normal Saline		Sílica gel		1691		44	0	95,814 %	Pass	
				Metanol		3MM Whatman		50		2980		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210817-002		17/08/2021 02:33	PP	Normal Saline		Sílica gel		1539		17	0	98,171 %	Pass	
				Metanol		3MM Whatman		25		3370		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210817-003		17/08/2021 02:56	PP	Normal Saline		Sílica gel		2643		40	0	97,423 %	Pass	
				Metanol		3MM Whatman		39		3551		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210817-005		17/08/2021 03:15	PP	Normal Saline		Sílica gel		2289		75	0	95,856 %	Pass	
				Metanol		3MM Whatman		22		2242		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-20210817-015	17/08/2021	04:10	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1637 43		26 3093	0	pH (Low/Actual/High)	97,065 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210817-020	17/08/2021	06:39	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			226 20		3 1989	0	pH (Low/Actual/High)	97,694 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210817-027	17/08/2021	07:39	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			1930 8		30 1091	0	pH (Low/Actual/High)	97,741 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210817-031	17/08/2021	08:47	LG	Normal Saline Metanol	Sílica gel 3MM Whatman			1052 2		14 597	0	pH (Low/Actual/High)	98,353 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210817-034	17/08/2021	09:40	LG	Normal Saline Metanol	Sílica gel 3MM Whatman			434 2		5 390	0	pH (Low/Actual/High)	98,351 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210817-036	17/08/2021	10:10	LG	Normal Saline Metanol	Sílica gel 3MM Whatman			330 2		3 456	0	pH (Low/Actual/High)	98,662 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210817-023	17/08/2021	07:17	FN	Butanona Normal Saline	3MM Whatman 3MM Whatman			650 13		1 736	0	pH (Low/Actual/High)	98,111 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210817-035	17/08/2021	09:58	BB	Acetato de amônio 1M:Metanol	Sílica gel			0,3		9,8	0	pH (Low/Actual/High)	97,03 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210817-050	17/08/2021	15:33												%
Tecnécio-99m Lot # E-20210817-001	17/08/2021	01:51	PP	Butanona	3MM Whatman			3		3306	0	pH (Low/Actual/High)	99,909 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210817-002	17/08/2021	02:28	PP	Butanona	3MM Whatman			6		4267	0	pH (Low/Actual/High)	99,86 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210817-003	17/08/2021	02:54	PP	Butanona	3MM Whatman			7		995	0	pH (Low/Actual/High)	99,301 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210817-004	17/08/2021	03:12	PP	Butanona	3MM Whatman			23		1184	0	pH (Low/Actual/High)	98,094 %	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-20210817-005		17/08/2021 03:41	PP	Butanona		3MM Whatman		30		1963	0		98,495 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210817-006		17/08/2021 04:05	PP	Butanona		3MM Whatman		4		3927	0		99,898 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210817-007		17/08/2021 06:36	FN	Butanona		3MM Whatman		5		425	0		98,837 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210817-009		17/08/2021 07:11	FN	Butanona		3MM Whatman		3		293	0		98,986 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210817-010		17/08/2021 07:38	FN	Butanona		3MM Whatman		4		1024	0		99,611 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210817-012		17/08/2021 07:56	FN	Butanona		3MM Whatman		6		1850	0		99,677 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210817-013		17/08/2021 08:43	LG	Butanona		3MM Whatman		0		2,26	0		100,00 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210817-014		17/08/2021 09:25	LG	Butanona		3MM Whatman		4		666	0		99,403 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210817-016		17/08/2021 10:05	LG	Butanona		3MM Whatman		1		255	0		99,609 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210817-017		17/08/2021 10:12	LG	Butanona		3MM Whatman		1		597	0		99,833 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210817-019		17/08/2021 14:25	WG	Butanona		3MM Whatman		6		2503	0		99,761 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
TRODAT-99mTc Lot # K-20210817-037		17/08/2021 10:26	LG	Normal Saline		Sílica gel		100		1	0		99,01 %	Pass
				Butanona		3MM Whatman		0		83,5		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210817-038		17/08/2021 10:27	LG	Normal Saline		Sílica gel		91,7		1,3	0		98,142 %	Pass
				Butanona		3MM Whatman		0,4		86,6		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		17/08/2021 10:28	LG	Normal Saline	Silica gel			76,5		1,5	0		94,231 %	Pass
Lot # K-20210817-039				Butanona	3MM Whatman			2,8		70	pH (Low/Actual/High)		6,50 <= 7,00 <= 8,50	
											Límpido/Incolor			
TRODAT-99mTc		17/08/2021 10:29	LG	Normal Saline	Silica gel			69,5		2	0		96,523 %	Pass
Lot # K-20210817-040				Butanona	3MM Whatman			0,5		73	pH (Low/Actual/High)		6,50 <= 7,00 <= 8,50	
											Límpido/Incolor			