



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 07/06/2021 To 07/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210607-025		07/06/2021	07:42	GF	Butanona	3MM Whatman	111		1,2	0		94,289 %	Pass
					Normal Saline	Sílica gel	5,5		113	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
Límpido/Incolor													
DMSA-99mTc Lot # K-20210607-026		07/06/2021	07:45	GF	Butanona	3MM Whatman	110,1		1,4	0		95,759 %	Pass
					Normal Saline	Sílica gel	2,8		91	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
Límpido/Incolor													
DMSA-99mTc Lot # K-20210607-033		07/06/2021	10:25	WG	Butanona	3MM Whatman	161,9		2,3	0		97,243 %	Pass
					Normal Saline	Sílica gel	1,4		101,8	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
Límpido/Incolor													
DMSA-99mTc Lot # K-20210607-036		07/06/2021	10:43	WG	Butanona	3MM Whatman	131,9		0,2	0		93,45 %	Pass
					Normal Saline	Sílica gel	12,4		181,4	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
Límpido/Incolor													
DOTATATE-68Ga Lot # K-20210607-041		07/06/2021	14:40	WG	Citrato de Sódio 0,1M	Sílica gel	87,3		8,5	0		78,701 %	Fail
					Metanol/Acetato de Amonio 1	Sílica gel	14,8		104,3	pH (Low/Actual/High)	4,00 <= 4,50	<= 8,00	
Límpido e Incolor													
DOTATATE-68Ga Lot # K-20210607-042		07/06/2021	14:44	WG	Citrato de Sódio 0,1M	Sílica gel	32,4		2,2	0		65,632 %	Fail
					Metanol/Acetato de Amonio 1	Sílica gel	12,1		31,1	pH (Low/Actual/High)	4,00 <= 4,50	<= 8,00	
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210607-031		07/06/2021	09:48	JS	Citrato de Sódio 0,1M	Sílica gel	24,5		0,3	0		98,79 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210607-037		07/06/2021	10:51	JS	Citrato de Sódio 0,1M	Sílica gel	32,5		0,3	0		99,085 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
Límpido e Incolor													
DTPA-99mTc Lot # K-20210607-012	RPH	07/06/2021	03:56	PP	Acetona	3MM Whatman	1658		17	0		93,387 %	Pass
					Normal Saline	3MM Whatman	37		624	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
Límpido/Incolor													
DTPA-99mTc Lot # K-20210607-030	RPH	07/06/2021	09:46	WG	Acetona	3MM Whatman	644		5	0		97,623 %	Pass
					Normal Saline	3MM Whatman	8		490	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
Límpido/Incolor													
FITATO-99mTc Lot # K-20210607-011		07/06/2021	03:30	PP	Butanona	3MM Whatman	646		5	0		99,232 %	Pass
										pH (Low/Actual/High)	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-20210607-032		07/06/2021 10:09	WG	Butanona		3MM Whatman		146,8		2,6	0		98,26 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
												Límpido/Incolor		
MAA-99mTc Lot # K-20210607-013		07/06/2021 03:58	PP	Butanona		3MM Whatman		151		3	0		98,052 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210607-014		07/06/2021 04:00	PP	Butanona		3MM Whatman		204		2	0		99,029 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210607-015		07/06/2021 04:03	PP	Butanona		3MM Whatman		248		1	0		99,598 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210607-028		07/06/2021 07:52	GF	Butanona		3MM Whatman		84,5		1,1	0		98,715 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210607-034		07/06/2021 10:37	WG	Butanona		3MM Whatman		159,6		0,1	0		99,937 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210607-035		07/06/2021 10:38	WG	Butanona		3MM Whatman		166,6		1,5	0		99,108 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210607-038		07/06/2021 11:13	WG	Butanona		3MM Whatman		178,9		4,6	0		97,493 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210607-039		07/06/2021 11:14	WG	Butanona		3MM Whatman		111,2		1,1	0		99,02 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20210607-007		07/06/2021 03:22	PP	Acetona		3MM Whatman		2111		4	0		98,561 %	Pass
				Normal Saline		3MM Whatman		12		948		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210607-008		07/06/2021 03:23	PP	Acetona		3MM Whatman		1452		6	0		98,073 %	Pass
				Normal Saline		3MM Whatman		14		910		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210607-009		07/06/2021 03:24	PP	Acetona		3MM Whatman		2222		1	0		99,906 %	Pass
				Normal Saline		3MM Whatman		1		2047		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210607-010		07/06/2021 03:26	PP	Acetona		3MM Whatman		753		1	0		98,093 %	Pass
				Normal Saline		3MM Whatman		30		1661		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-20210607-021		07/06/2021 06:54 GF	Acetona Normal Saline		3MM Whatman 3MM Whatman			832 6		2 762	0 pH (Low/Actual/High)	98,979 % 4,00 <= 5,00 <= 7,80	Pass	
Límpido/Incolor														
MDP-99mTc Lot # K-20210607-022		07/06/2021 06:57 GF	Acetona Normal Saline		3MM Whatman 3MM Whatman			587 6		1 615	0 pH (Low/Actual/High)	98,864 % 4,00 <= 6,00 <= 7,80	Pass	
Límpido/Incolor														
MDP-99mTc Lot # K-20210607-024		07/06/2021 07:16 GF	Acetona Normal Saline		3MM Whatman 3MM Whatman			362 35		1 770	0 pH (Low/Actual/High)	95,377 % 4,00 <= 6,00 <= 7,80	Pass	
Límpido/Incolor														
MDP-99mTc Lot # K-20210607-027		07/06/2021 07:49 GF	Acetona Normal Saline		3MM Whatman 3MM Whatman			432 0		0 721	0 pH (Low/Actual/High)	100,00 % 4,00 <= 6,00 <= 7,80	Pass	
Límpido/Incolor														
MDP-99mTc Lot # K-20210607-029		07/06/2021 09:43 WG	Acetona Normal Saline		3MM Whatman 3MM Whatman			578 4		6 389	0 pH (Low/Actual/High)	97,955 % 4,00 <= 6,00 <= 7,80	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210607-001		07/06/2021 02:12 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1650 47		30 2967	0 pH (Low/Actual/High)	96,655 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210607-002		07/06/2021 02:13 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1474 1		24 1869	0 pH (Low/Actual/High)	98,344 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210607-003		07/06/2021 02:19 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1808 67		39 3616	0 pH (Low/Actual/High)	96,069 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210607-004		07/06/2021 02:20 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1065 97		12 2499	0 pH (Low/Actual/High)	95,149 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210607-005		07/06/2021 03:03 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1455 7		22 2590	0 pH (Low/Actual/High)	98,241 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210607-006		07/06/2021 03:04 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1505 102		30 3427	0 pH (Low/Actual/High)	95,155 % 5,00 <= 6,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210607-017		07/06/2021 06:40 GF	Normal Saline Metanol		Sílica gel 3MM Whatman			920 1		19 1128	0 pH (Low/Actual/High)	97,888 % 5,00 <= 5,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20210607-019		07/06/2021 06:43 GF	Normal Saline Metanol		Sílica gel 3MM Whatman			1118 14		34 1540	0 pH (Low/Actual/High)	96,148 % 5,00 <= 6,00 <= 6,00	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
MIBI-99mTc Lot # K-20210607-020	07/06/2021	06:47	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			887 23		16 1870	0	pH (Low/Actual/High)	97,013 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
PIRO-99mTc Lot # K-20210607-023	07/06/2021	07:10	GF	Butanona Normal Saline	3MM Whatman 3MM Whatman			238 1		1 234	0	pH (Low/Actual/High)	99,156 %	Pass 5,00 <= 6,00 <= 7,00
														Límpido/Incolor
PSMA-68Ga Lot # K-20210607-018	07/06/2021	06:40	GF	Acetato de amônio 1M:Metanol	Sílica gel			0,5		31	0	pH (Low/Actual/High)	98,413 %	Pass 4,00 <= 6,00 <= 8,00
														Límpido e Incolor
PSMA-68Ga Lot # K-20210607-040	07/06/2021	12:52	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,2		32,6	0	pH (Low/Actual/High)	99,39 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-001	07/06/2021	02:00	PP	Butanona	3MM Whatman			2		533	0	pH (Low/Actual/High)	99,626 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-002	07/06/2021	02:14	PP	Butanona	3MM Whatman			40		3442	0	pH (Low/Actual/High)	98,851 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-003	07/06/2021	02:58	PP	Butanona	3MM Whatman			37		717	0	pH (Low/Actual/High)	95,093 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-004	07/06/2021	03:17	PP	Butanona	3MM Whatman			14		305	0	pH (Low/Actual/High)	95,611 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-005	07/06/2021	03:54	PP	Butanona	3MM Whatman			19		1263	0	pH (Low/Actual/High)	98,518 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-006	07/06/2021	06:31	GF	Butanona	3MM Whatman			2		289	0	pH (Low/Actual/High)	99,313 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-009	07/06/2021	06:44	GF	Butanona	3MM Whatman			0		309	0	pH (Low/Actual/High)	100,00 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-010	07/06/2021	07:01	GF	Butanona	3MM Whatman			0		978	0	pH (Low/Actual/High)	100,00 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-011	07/06/2021	07:46	GF	Butanona	3MM Whatman			4		1397	0	pH (Low/Actual/High)	99,714 %	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-20210607-012		07/06/2021 08:11	GF	Butanona		3MM Whatman		1		229	0			99,565 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-013		07/06/2021 09:38	BB	Butanona		3MM Whatman		52		4122	0			98,754 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-015		07/06/2021 10:19	WG	Butanona		3MM Whatman		2		919	0			99,783 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-017		07/06/2021 11:10	WG	Butanona		3MM Whatman		24		1272	0			98,148 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-019		07/06/2021 14:21	WG	Butanona		3MM Whatman		9		618	0			98,565 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-020		07/06/2021 14:29	WG	Butanona		3MM Whatman		1		1031	0			99,903 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-021		07/06/2021 14:32	WG	Butanona		3MM Whatman		10		976	0			98,986 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210607-022		07/06/2021 14:34	WG	Butanona		3MM Whatman		47		1308	0			96,531 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor