



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 14/06/2021 To 14/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210614-027		14/06/2021	07:31	WG	Butanona Normal Saline	3MM Whatman Sílica gel	114,6 6,1		3 166,7	0	pH (Low/Actual/High)	93,919 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210614-028		14/06/2021	08:01	WG	Butanona Normal Saline	3MM Whatman Sílica gel	134,9 4		1,7 144	0	pH (Low/Actual/High)	96,053 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210614-038		14/06/2021	10:41	WG	Butanona Normal Saline	3MM Whatman Sílica gel	241 7,9		4 154,4	0	pH (Low/Actual/High)	93,50 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210614-039		14/06/2021	10:43	WG	Butanona Normal Saline	3MM Whatman Sílica gel	222 5,9		6 145,9	0	pH (Low/Actual/High)	93,482 %	Pass
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210614-032		14/06/2021	09:53	BB	Citrato de Sódio 0,1M	Sílica gel	29,3		0,3	0	pH (Low/Actual/High)	98,986 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210614-041		14/06/2021	10:55	JS	Citrato de Sódio 0,1M	Sílica gel	32,6		0,4	0	pH (Low/Actual/High)	98,788 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210614-043		14/06/2021	15:55	JS	Citrato de Sódio 0,1M	Sílica gel	13,52		0,3	0	pH (Low/Actual/High)	97,829 %	Pass
Límpido e Incolor													
DTPA-99mTc Lot # K-20210614-010	RPH	14/06/2021	03:07	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	899 10		1 525	0	pH (Low/Actual/High)	98,02 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210614-040	RPH	14/06/2021	10:43	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	330 1,1		1 117,7	0	pH (Low/Actual/High)	98,772 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20210614-011		14/06/2021	03:09	PP	Butanona	3MM Whatman	3352		5	0	pH (Low/Actual/High)	99,851 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20210614-025		14/06/2021	07:21	WG	Butanona	3MM Whatman	663		3	0	pH (Low/Actual/High)	99,55 %	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-20210614-012		14/06/2021 03:56	PP	Butanona		3MM Whatman		2542		28	0	98,911 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210614-013		14/06/2021 03:59	BB	Butanona		3MM Whatman		235		1	0	99,576 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210614-014		14/06/2021 04:03	PP	Butanona		3MM Whatman		266		6	0	97,794 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210614-016		14/06/2021 04:06	PP	Butanona		3MM Whatman		2589		11	0	99,577 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210614-015		14/06/2021 04:06	PP	Butanona		3MM Whatman		2296		9	0	99,61 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210614-029		14/06/2021 08:03	WG	Butanona		3MM Whatman		65,3		1,8	0	97,317 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210614-033		14/06/2021 10:11	WG	Butanona		3MM Whatman		226		10	0	95,763 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210614-034		14/06/2021 10:14	WG	Butanona		3MM Whatman		91,6		1,1	0	98,813 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210614-035		14/06/2021 10:15	WG	Butanona		3MM Whatman		318		3	0	99,065 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210614-036		14/06/2021 10:21	WG	Butanona		3MM Whatman		244		5	0	97,992 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210614-037		14/06/2021 10:25	WG	Butanona		3MM Whatman		212		8	0	96,364 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MDP-99mTc Lot # K-20210614-007		14/06/2021 03:03	PP	Acetona		3MM Whatman		4015		50	0	98,123 %	Pass	
				Normal Saline		3MM Whatman		26		3993		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210614-008		14/06/2021 03:04	PP	Acetona		3MM Whatman		2096		25	0	95,785 %	Pass	
				Normal Saline		3MM Whatman		32		1022		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-20210614-009		14/06/2021 03:05	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman			4351 19		12 3938	0	pH (Low/Actual/High)	99,245 %	Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20210614-018		14/06/2021 04:14	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman			3920 47		16 3715	0	pH (Low/Actual/High)	98,344 %	Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20210614-019		14/06/2021 04:17	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman			4355 51		5 3702	0	pH (Low/Actual/High)	98,526 %	Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20210614-024		14/06/2021 06:56	GF	Acetona Normal Saline	3MM Whatman 3MM Whatman			261 0		2 268	0	pH (Low/Actual/High)	99,24 %	Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20210614-026		14/06/2021 07:28	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			1521 4		24 728	0	pH (Low/Actual/High)	97,90 %	Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20210614-030		14/06/2021 08:05	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			784 2		20 729	0	pH (Low/Actual/High)	97,239 %	Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20210614-031		14/06/2021 09:40	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			1358 25		19 1184	0	pH (Low/Actual/High)	96,552 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210614-001		14/06/2021 02:12	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1593 2		24 1382	0	pH (Low/Actual/High)	98,371 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210614-002		14/06/2021 02:14	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1183 26		42 2269	0	pH (Low/Actual/High)	95,439 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210614-003		14/06/2021 02:21	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2121 31		44 3651	0	pH (Low/Actual/High)	97,126 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210614-004		14/06/2021 02:22	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1692 30		23 2142	0	pH (Low/Actual/High)	97,278 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210614-005		14/06/2021 02:56	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2891 117		29 3162	0	pH (Low/Actual/High)	95,439 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210614-006		14/06/2021 02:57	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2458 26		32 2114	0	pH (Low/Actual/High)	97,50 %	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-20210614-020	14/06/2021	06:27	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			242 4		1 347	0	pH (Low/Actual/High)	98,449 %	Pass 5,00 <= 5,00 <= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210614-021	14/06/2021	06:31	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			262 1		2 291	0	pH (Low/Actual/High)	98,90 %	Pass 5,00 <= 5,00 <= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210614-023	14/06/2021	06:54	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			805 7		7 1389	0	pH (Low/Actual/High)	98,636 %	Pass 5,00 <= 5,00 <= 6,00
												Límpido/Incolor		
PIRO-99mTc Lot # K-20210614-017	14/06/2021	04:11	PP	Butanona Normal Saline	3MM Whatman 3MM Whatman			3226 11		10 2680	0	pH (Low/Actual/High)	99,282 %	Pass 5,00 <= 6,00 <= 7,00
												Límpido/Incolor		
PSMA-68Ga Lot # K-20210614-022	14/06/2021	06:43	GF	Acetato de amônio	Sílica gel			0,1		39,8	0	pH (Low/Actual/High)	99,749 %	Pass 4,00 <= 6,00 <= 8,00
												Límpido e Incolor		
PSMA-68Ga Lot # K-20210614-042	14/06/2021	12:47	JS	Acetato de amônio	Sílica gel			0,3		32,6	0	pH (Low/Actual/High)	99,088 %	Pass 4,00 <= 5,00 <= 8,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210614-001	14/06/2021	02:08	PP	Butanona	3MM Whatman			22		3756	0	pH (Low/Actual/High)	99,418 %	Pass 5,00 <= 6,00 <= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210614-002	14/06/2021	02:16	PP	Butanona	3MM Whatman			12		2175	0	pH (Low/Actual/High)	99,451 %	Pass 5,00 <= 6,00 <= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210614-003	14/06/2021	02:52	PP	Butanona	3MM Whatman			1		341	0	pH (Low/Actual/High)	99,708 %	Pass 5,00 <= 6,00 <= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210614-004	14/06/2021	02:59	PP	Butanona	3MM Whatman			23		3650	0	pH (Low/Actual/High)	99,374 %	Pass 5,00 <= 6,00 <= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210614-005	14/06/2021	04:09	PP	Butanona	3MM Whatman			2		710	0	pH (Low/Actual/High)	99,719 %	Pass 5,00 <= 6,00 <= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210614-006	14/06/2021	06:26	GF	Butanona	3MM Whatman			1		264	0	pH (Low/Actual/High)	99,623 %	Pass 5,00 <= 5,00 <= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210614-008	14/06/2021	06:50	GF	Butanona	3MM Whatman			2		410	0	pH (Low/Actual/High)	99,515 %	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
Tecnício-99m Lot # E-20210614-009		14/06/2021 07:23	GF	Butanona		3MM Whatman		6		1535	0	99,611 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210614-010		14/06/2021 07:47	WG	Butanona		3MM Whatman		12		874	0	98,646 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210614-011		14/06/2021 07:56	WG	Butanona		3MM Whatman		15		822	0	98,208 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210614-012		14/06/2021 09:37	WG	Butanona		3MM Whatman		12		1425	0	99,165 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210614-013		14/06/2021 09:43	WG	Butanona		3MM Whatman		2		873	0	99,771 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210614-014		14/06/2021 09:44	WG	Butanona		3MM Whatman		15		894	0	98,35 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210614-015		14/06/2021 09:48	WG	Butanona		3MM Whatman		4		934	0	99,574 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210614-016		14/06/2021 09:51	WG	Butanona		3MM Whatman		9		695	0	98,722 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210614-017		14/06/2021 09:51	WG	Butanona		3MM Whatman		1		1611	0	99,938 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210614-019		14/06/2021 09:58	WG	Butanona		3MM Whatman		6		738	0	99,194 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210614-022		14/06/2021 14:22	SB	Butanona		3MM Whatman		8		1015	0	99,218 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210614-023		14/06/2021 14:22	SB	Butanona		3MM Whatman		0,8		402	0	99,801 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	