



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 23/07/2021 To 23/07/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210723-021		23/07/2021	07:32	WG	Butanona Normal Saline	3MM Whatman Sílica gel	172,4 4		2 92,8	0	pH (Low/Actual/High)	94,721 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210723-022		23/07/2021	07:33	WG	Butanona Normal Saline	3MM Whatman Sílica gel	316 7		4 244	0	pH (Low/Actual/High)	95,961 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210723-023		23/07/2021	07:34	WG	Butanona Normal Saline	3MM Whatman Sílica gel	304 3		2 271	0	pH (Low/Actual/High)	98,252 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210723-024		23/07/2021	07:36	WG	Butanona Normal Saline	3MM Whatman Sílica gel	300 0,9		1 248	0	pH (Low/Actual/High)	99,306 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210723-026		23/07/2021	08:01	WG	Butanona Normal Saline	3MM Whatman Sílica gel	195 0,8		5 110,2	0	pH (Low/Actual/High)	96,779 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210723-027		23/07/2021	08:02	WG	Butanona Normal Saline	3MM Whatman Sílica gel	199 2		5 220	0	pH (Low/Actual/High)	96,648 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210723-033		23/07/2021	10:51	JS	Butanona Normal Saline	3MM Whatman Sílica gel	78 2		0,9 98	0	pH (Low/Actual/High)	96,859 %	Pass
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210723-036		23/07/2021	13:06	JS	Citrato de Sódio 0,1M	Sílica gel	36,6		0,2	0	pH (Low/Actual/High)	99,457 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210723-037		23/07/2021	14:04	JS	Citrato de Sódio 0,1M	Sílica gel	36,5		0,2	0	pH (Low/Actual/High)	99,455 %	Pass
Límpido e Incolor													
DTPA-99mTc Lot # K-20210723-008	RPH	23/07/2021	03:36	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	214 4		2 115,5	0	pH (Low/Actual/High)	95,727 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210723-016	RPH	23/07/2021	07:07	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	223 5		1 237	0	pH (Low/Actual/High)	97,487 %	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
DTPA-99mTc Lot # K-20210723-030	RPH	23/07/2021	10:04	JS	Acetona Normal Saline	3MM	Whatman		226 6		3 707	0	pH (Low/Actual/High)	97,848 %	Pass
														3,80 <= 6,00	<= 7,50
															Límpido/Incolor
FITATO-99mTc Lot # K-20210723-006		23/07/2021	03:26	FN	Butanona	3MM	Whatman		353		1	0	pH (Low/Actual/High)	99,718 %	Pass
														5,00 <= 6,00	<= 7,00
															Límpido/Incolor
FITATO-99mTc Lot # K-20210723-028		23/07/2021	08:11	WG	Butanona	3MM	Whatman		314		10	0	pH (Low/Actual/High)	96,914 %	Pass
														5,00 <= 6,00	<= 7,00
															Límpido/Incolor
MAA-99mTc Lot # K-20210723-009		23/07/2021	03:49	FN	Butanona	3MM	Whatman		153,6		2	0	pH (Low/Actual/High)	98,715 %	Pass
														3,00 <= 6,00	<= 6,00
															Turvo/Incolor
MAA-99mTc Lot # K-20210723-010		23/07/2021	03:50	FN	Butanona	3MM	Whatman		228		2	0	pH (Low/Actual/High)	99,13 %	Pass
														3,00 <= 6,00	<= 6,00
															Turvo/Incolor
MAA-99mTc Lot # K-20210723-011		23/07/2021	03:52	FN	Butanona	3MM	Whatman		217		1	0	pH (Low/Actual/High)	99,541 %	Pass
														3,00 <= 6,00	<= 6,00
															Turvo/Incolor
MAA-99mTc Lot # K-20210723-018		23/07/2021	07:21	FN	Butanona	3MM	Whatman		225		2	0	pH (Low/Actual/High)	99,119 %	Pass
														3,00 <= 5,00	<= 6,00
															Turvo/Incolor
MAA-99mTc Lot # K-20210723-019		23/07/2021	07:22	FN	Butanona	3MM	Whatman		198,2		2	0	pH (Low/Actual/High)	99,001 %	Pass
														3,00 <= 6,00	<= 6,00
															Turvo/Incolor
MDP-99mTc Lot # K-20210723-005		23/07/2021	03:23	FN	Acetona Normal Saline	3MM	Whatman		1239 12		1 1298	0	pH (Low/Actual/High)	99,003 %	Pass
														4,00 <= 5,00	<= 7,80
															Límpido/Incolor
MDP-99mTc Lot # K-20210723-020		23/07/2021	07:24	WG	Acetona Normal Saline	3MM	Whatman		928 9		1 949	0	pH (Low/Actual/High)	98,953 %	Pass
														4,00 <= 6,00	<= 7,80
															Límpido/Incolor
MDP-99mTc Lot # K-20210723-032		23/07/2021	10:07	JS	Acetona Normal Saline	3MM	Whatman		222 4		1 641	0	pH (Low/Actual/High)	98,931 %	Pass
														4,00 <= 5,00	<= 7,80
															Límpido/Incolor
MIBI-99mTc Lot # K-20210723-001		23/07/2021	02:05	FN	Normal Saline Metanol	Sílica gel			1611 12		20 1486	0	pH (Low/Actual/High)	97,973 %	Pass
														5,00 <= 6,00	<= 6,00
															Límpido/Incolor
MIBI-99mTc Lot # K-20210723-002		23/07/2021	02:08	FN	Normal Saline Metanol	Sílica gel			211 2		4 213	0	pH (Low/Actual/High)	97,209 %	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-20210723-003		23/07/2021 02:10 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1307 2		20 243	0	pH (Low/Actual/High)	97,677 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210723-004		23/07/2021 03:08 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1954 12		20 1248	0	pH (Low/Actual/High)	98,034 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210723-007		23/07/2021 03:31 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			754 12		6 629	0	pH (Low/Actual/High)	97,338 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210723-012		23/07/2021 04:07 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1868 2		20 218	0	pH (Low/Actual/High)	98,032 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210723-013		23/07/2021 04:10 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1089 12		20 1439	0	pH (Low/Actual/High)	97,37 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210723-015		23/07/2021 06:59 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			879 1		6 1389	0	pH (Low/Actual/High)	99,25 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210723-017		23/07/2021 07:08 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			861 12		20 792	0	pH (Low/Actual/High)	96,237 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210723-025		23/07/2021 07:50 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			1049 25		8 1850	0	pH (Low/Actual/High)	97,91 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210723-029		23/07/2021 10:04 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1552 35		20 1494	0	pH (Low/Actual/High)	96,439 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210723-034		23/07/2021 11:05 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			191 1		1,6 235	0	pH (Low/Actual/High)	98,746 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210723-035		23/07/2021 11:17 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			958 2		13 1448	0	pH (Low/Actual/High)	98,523 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210723-014		23/07/2021 06:50 FN	Acetato de amônio 1M:Metanol		Sílica gel			2,3		82,6	0	pH (Low/Actual/High)	97,291 %	Pass 4,00 <= 6,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210723-031		23/07/2021 10:09 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,2		23,9	0	pH (Low/Actual/High)	99,17 %	Pass 4,00 <= 5,00 <= 8,00
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-20210723-001		23/07/2021 02:00	FN	Butanona		3MM Whatman		2		1265	0	99,842 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-002		23/07/2021 03:06	FN	Butanona		3MM Whatman		1		221	0	99,55 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-003		23/07/2021 03:21	FN	Butanona		3MM Whatman		2		145	0	98,639 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-005		23/07/2021 03:28	FN	Butanona		3MM Whatman		1		164	0	99,394 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-004		23/07/2021 03:28	FN	Butanona		3MM Whatman		2		1325	0	99,849 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-006		23/07/2021 03:34	FN	Butanona		3MM Whatman		1		233	0	99,573 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-007		23/07/2021 03:47	FN	Butanona		3MM Whatman		1		1226	0	99,919 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-008		23/07/2021 04:05	FN	Butanona		3MM Whatman		1		568	0	99,824 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-010		23/07/2021 06:55	FN	Butanona		3MM Whatman		2		1403	0	99,858 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-011		23/07/2021 07:02	FN	Butanona		3MM Whatman		1		256	0	99,611 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-012		23/07/2021 07:04	FN	Butanona		3MM Whatman		2		255	0	99,222 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-013		23/07/2021 07:17	FN	Butanona		3MM Whatman		2		235	0	99,156 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210723-014		23/07/2021 07:28	WG	Butanona		3MM Whatman		1,1		106,8	0	98,981 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 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
Tecnécio-99m Lot # E-20210723-015		23/07/2021 07:47	WG	Butanona		3MM Whatman		2		122,6	0			98,395 % Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210723-016		23/07/2021 10:00	JS	Butanona		3MM Whatman		0		539	0			100,00 % Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210723-018		23/07/2021 10:49	JS	Butanona		3MM Whatman		1		621	0			99,839 % Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210723-019		23/07/2021 11:02	JS	Butanona		3MM Whatman		1		403	0			99,752 % Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210723-020		23/07/2021 11:15	MP	Butanona		3MM Whatman		1		530	0			99,812 % Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor