



# 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 04/02/2022 To 04/02/2022

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20220204-013		04/02/2022	04:02	PM	Butanona Normal Saline	3MM Whatman Sílica gel	167,9 3,5		0,8 115,7	0	pH (Low/Actual/High)	96,59 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220204-024		04/02/2022	07:23	GS	Butanona Normal Saline	3MM Whatman Sílica gel	172,4 5		0,6 218	0	pH (Low/Actual/High)	97,411 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220204-026		04/02/2022	07:30	GS	Butanona Normal Saline	3MM Whatman Sílica gel	173,4 3,1		0,3 164,1	0	pH (Low/Actual/High)	97,973 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220204-029		04/02/2022	08:04	GS	Butanona Normal Saline	3MM Whatman Sílica gel	157,9 4,4		1,1 129,9	0	pH (Low/Actual/High)	96,032 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220204-030		04/02/2022	08:05	GS	Butanona Normal Saline	3MM Whatman Sílica gel	146,7 5		0,2 104,7	0	pH (Low/Actual/High)	95,306 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220204-031		04/02/2022	08:05	GS	Butanona Normal Saline	3MM Whatman Sílica gel	112,2 10		0,9 223	0	pH (Low/Actual/High)	94,912 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220204-038		04/02/2022	09:44	LG	Butanona Normal Saline	3MM Whatman Sílica gel	112,2 3,1		0,2 83,3	0	pH (Low/Actual/High)	96,234 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20220204-042		04/02/2022	10:28	LG	Butanona Normal Saline	3MM Whatman Sílica gel	118 6		1 93	0	pH (Low/Actual/High)	93,099 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20220204-045		04/02/2022	12:50	JS	Citrato de Sódio 0,1M	Sílica gel	25,3		0,5	0	pH (Low/Actual/High)	98,062 %	Pass 4,00 <= 6,00 <= 8,00
Límpido e Incolor													
DTPA-99mTc Lot # K-20220204-007	RPH	04/02/2022	03:29	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	561 2		3 708	0	pH (Low/Actual/High)	99,186 %	Pass 3,80 <= 6,00 <= 7,50
Límpido/Incolor													
DTPA-99mTc Lot # K-20220204-008	RPH	04/02/2022	03:31	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	921 3		8 445	0	pH (Low/Actual/High)	98,469 %	Pass 3,80 <= 6,00 <= 7,50
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
DTPA-99mTc Lot # K-20220204-016	RPH	04/02/2022	04:21	PM	Acetona Normal Saline	3MM	Whatman		356 2		6 292	0	pH (Low/Actual/High)	97,662 %	Pass
															3,80 <= 6,00 <= 7,50
															Límpido/Incolor
DTPA-99mTc Lot # K-20220204-035	RPH	04/02/2022	09:30	LG	Acetona Normal Saline	3MM	Whatman		279 10		2 238	0	pH (Low/Actual/High)	95,256 %	Pass
															3,80 <= 5,00 <= 7,50
															Límpido/Incolor
FITATO-99mTc Lot # K-20220204-015		04/02/2022	03:33	PM	Butanona	3MM	Whatman		489		5	0	pH (Low/Actual/High)	98,988 %	Pass
															5,00 <= 7,00 <= 7,00
															Límpido/Incolor
FITATO-99mTc Lot # K-20220204-032		04/02/2022	08:17	GS	Butanona	3MM	Whatman		255		3	0	pH (Low/Actual/High)	98,837 %	Pass
															5,00 <= 6,00 <= 7,00
															Límpido/Incolor
MAA-99mTc Lot # K-20220204-017		04/02/2022	04:23	PM	Butanona	3MM	Whatman		350		5	0	pH (Low/Actual/High)	98,592 %	Pass
															3,00 <= 6,00 <= 6,00
															Turvo/Incolor
MAA-99mTc Lot # K-20220204-036		04/02/2022	09:41	LG	Butanona	3MM	Whatman		103,5		4	0	pH (Low/Actual/High)	96,279 %	Pass
															3,00 <= 5,00 <= 6,00
															Turvo/Incolor
MAA-99mTc Lot # K-20220204-037		04/02/2022	09:42	LG	Butanona	3MM	Whatman		79,2		4	0	pH (Low/Actual/High)	95,192 %	Pass
															3,00 <= 5,00 <= 6,00
															Turvo/Incolor
MAA-99mTc Lot # K-20220204-043		04/02/2022	10:31	LG	Butanona	3MM	Whatman		74,5		3	0	pH (Low/Actual/High)	96,129 %	Pass
															3,00 <= 5,00 <= 6,00
															Turvo/Incolor
MAA-99mTc Lot # K-20220204-044		04/02/2022	10:35	LG	Butanona	3MM	Whatman		143		7	0	pH (Low/Actual/High)	95,333 %	Pass
															3,00 <= 5,00 <= 6,00
															Turvo/Incolor
MAA-99mTc Lot # K-20220204-046		04/02/2022	14:34	WG	Butanona	3MM	Whatman		136,1		0,9	0	pH (Low/Actual/High)	99,343 %	Pass
															3,00 <= 6,00 <= 6,00
															Turvo/Incolor
MDP-99mTc Lot # K-20220204-006		04/02/2022	03:28	PM	Acetona Normal Saline	3MM	Whatman		1132 11		3 867	0	pH (Low/Actual/High)	98,483 %	Pass
															4,00 <= 6,00 <= 7,80
															Límpido/Incolor
MDP-99mTc Lot # K-20220204-014		04/02/2022	04:18	PM	Acetona Normal Saline	3MM	Whatman		948 7		3 1067	0	pH (Low/Actual/High)	99,033 %	Pass
															4,00 <= 6,00 <= 7,80
															Límpido/Incolor
MDP-99mTc Lot # K-20220204-019		04/02/2022	06:52	GS	Acetona Normal Saline	3MM	Whatman		397 11		1 466	0	pH (Low/Actual/High)	97,443 %	Pass
															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-20220204-022		04/02/2022 07:14	GS	Acetona Normal Saline	3MM Whatman 3MM Whatman			826 21		36 787	0	pH (Low/Actual/High)	93,225 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20220204-025		04/02/2022 07:27	GS	Acetona Normal Saline	3MM Whatman 3MM Whatman			969 12		16 855	0	pH (Low/Actual/High)	96,992 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20220204-027		04/02/2022 07:55	GS	Acetona Normal Saline	3MM Whatman 3MM Whatman			377 9		3 389	0	pH (Low/Actual/High)	96,949 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20220204-028		04/02/2022 07:58	GS	Acetona Normal Saline	3MM Whatman 3MM Whatman			357 2		1 366	0	pH (Low/Actual/High)	99,177 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20220204-034		04/02/2022 08:55	LG	Acetona Normal Saline	3MM Whatman 3MM Whatman			1013 23		2 1155	0	pH (Low/Actual/High)	97,85 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20220204-041		04/02/2022 10:10	LG	Acetona Normal Saline	3MM Whatman 3MM Whatman			1063 4		2 1090	0	pH (Low/Actual/High)	99,447 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20220204-001		04/02/2022 01:58	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			1318 5		8 1963	0	pH (Low/Actual/High)	99,143 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220204-002		04/02/2022 01:59	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			1460 1		10 2034	0	pH (Low/Actual/High)	99,271 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220204-003		04/02/2022 02:03	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1571 15		27 1490	0	pH (Low/Actual/High)	97,314 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220204-004		04/02/2022 02:04	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1671 40		9 1785	0	pH (Low/Actual/High)	97,273 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220204-005		04/02/2022 02:49	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1136 9		18 1858	0	pH (Low/Actual/High)	97,958 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220204-010		04/02/2022 03:53	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			690 20		6 878	0	pH (Low/Actual/High)	96,911 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220204-011		04/02/2022 03:59	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			674 4		18 987	0	pH (Low/Actual/High)	96,995 %	Pass 5,00 <= 5,00 <= 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-20220204-012		04/02/2022 04:01 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			613 14		2 830	0	pH (Low/Actual/High)	98,016 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220204-020		04/02/2022 06:56 GS	Normal Saline Metanol		Sílica gel 3MM Whatman			2,06 6		0,05 1876	0	pH (Low/Actual/High)	97,312 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220204-021		04/02/2022 07:08 GS	Normal Saline Metanol		Sílica gel 3MM Whatman			2 13		0,03 1971	0	pH (Low/Actual/High)	97,867 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220204-023		04/02/2022 07:22 GS	Normal Saline Metanol		Sílica gel 3MM Whatman			1194 16		15 1338	0	pH (Low/Actual/High)	97,578 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220204-033		04/02/2022 08:54 LG	Normal Saline Metanol		Sílica gel 3MM Whatman			1317 3		22 1940	0	pH (Low/Actual/High)	98,203 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20220204-018		04/02/2022 06:43 GS	Acetato de amônio 1M:Metanol		Sílica gel			0,6		54,5	0	pH (Low/Actual/High)	98,911 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20220204-040		04/02/2022 09:52 LG	Acetato de amônio 1M:Metanol		Sílica gel			1		22,3	0	pH (Low/Actual/High)	95,708 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20220204-001		04/02/2022 01:44 MB	Butanona		3MM Whatman			16		1114	0	pH (Low/Actual/High)	98,584 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20220204-002		04/02/2022 01:52 PM	Butanona		3MM Whatman			6		719	0	pH (Low/Actual/High)	99,172 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20220204-004		04/02/2022 03:25 PM	Butanona		3MM Whatman			25		563	0	pH (Low/Actual/High)	95,748 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20220204-003		04/02/2022 03:25 PM	Butanona		3MM Whatman			1		231	0	pH (Low/Actual/High)	99,569 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20220204-005		04/02/2022 03:40 PM	Butanona		3MM Whatman			31		924	0	pH (Low/Actual/High)	96,754 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20220204-006		04/02/2022 03:53 PM	Butanona		3MM Whatman			7		228	0	pH (Low/Actual/High)	97,021 %	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-20220204-007		04/02/2022 03:56 PM	Butanona		3MM	Whatman		3		202	0		98,537 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220204-008		04/02/2022 03:59 PM	Butanona		3MM	Whatman		8		170	0		95,506 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220204-010		04/02/2022 04:16 PM	Butanona		3MM	Whatman		7		232	0		97,071 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220204-011		04/02/2022 04:20 PM	Butanona		3MM	Whatman		8		1096	0		99,275 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20220204-013		04/02/2022 06:41 GS	Butanona		3MM	Whatman		5		350	0		98,592 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
Tecnécio-99m Lot # E-20220204-014		04/02/2022 06:49 BB	Butanona		3MM	Whatman		3		221	0		98,661 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
Tecnécio-99m Lot # E-20220204-015		04/02/2022 06:59 GS	Butanona		3MM	Whatman		7		399	0		98,276 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
Tecnécio-99m Lot # E-20220204-016		04/02/2022 07:19 GS	Butanona		3MM	Whatman		6		392	0		98,492 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
Tecnécio-99m Lot # E-20220204-018		04/02/2022 07:52 GS	Butanona		3MM	Whatman		0,3		172,2	0		99,826 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
Tecnécio-99m Lot # E-20220204-017		04/02/2022 07:52 GS	Butanona		3MM	Whatman		0,2		93,8	0		99,787 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
Tecnécio-99m Lot # E-20220204-019		04/02/2022 08:01 GS	Butanona		3MM	Whatman		3		468	0		99,363 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
Tecnécio-99m Lot # E-20220204-020		04/02/2022 08:13 GS	Butanona		3MM	Whatman		20		418	0		95,434 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
Tecnécio-99m Lot # E-20220204-021		04/02/2022 08:52 LG	Butanona		3MM	Whatman		0,01		2,85	0		99,65 %	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-20220204-022		04/02/2022 09:37	LG	Butanona		3MM Whatman		0,05		2,06	0		97,63 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20220204-025		04/02/2022 14:27	WG	Butanona		3MM Whatman		9		386	0		97,722 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido e Incolor		