



# 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 04/03/2022 To 04/03/2022

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20220304-010		04/03/2022	04:04	KAF	Butanona Normal Saline	3MM Whatman Sílica gel	876 6,4		1 205,1	0	pH (Low/Actual/High)	96,86 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220304-024		04/03/2022	07:26	PM	Butanona Normal Saline	3MM Whatman Sílica gel	328 12		4 241	0	pH (Low/Actual/High)	94,052 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220304-026		04/03/2022	07:45	PM	Butanona Normal Saline	3MM Whatman Sílica gel	1289 9,7		14 173,6	0	pH (Low/Actual/High)	93,634 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220304-027		04/03/2022	08:06	PM	Butanona Normal Saline	3MM Whatman Sílica gel	212 4		2 158	0	pH (Low/Actual/High)	96,596 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220304-028		04/03/2022	08:08	PM	Butanona Normal Saline	3MM Whatman Sílica gel	238 11		2 205	0	pH (Low/Actual/High)	94,074 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220304-036		04/03/2022	10:19	MB	Butanona Normal Saline	3MM Whatman Sílica gel	116,2 8,6		0,9 185,8	0	pH (Low/Actual/High)	94,808 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20220304-037		04/03/2022	10:23	MB	Butanona Normal Saline	3MM Whatman Sílica gel	151,4 3,8		1,7 72,1	0	pH (Low/Actual/High)	93,883 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20220304-039		04/03/2022	12:50	JS	Citrato de Sódio 0,1M	Sílica gel	16,7		0,4	0	pH (Low/Actual/High)	97,661 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20220304-015	RPH	04/03/2022	04:23	KAF	Acetona Normal Saline	3MM Whatman 3MM Whatman	458 11		2 485	0	pH (Low/Actual/High)	97,347 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20220304-016	RPH	04/03/2022	04:24	KAF	Acetona Normal Saline	3MM Whatman 3MM Whatman	380 4		3 391	0	pH (Low/Actual/High)	98,204 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20220304-034	RPH	04/03/2022	09:23	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	859 10		4 755	0	pH (Low/Actual/High)	98,229 %	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
FITATO-99mTc Lot # K-20220304-008		04/03/2022 03:58	KAF	Butanona		3MM Whatman		1675		9	0	99,466 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
												Límpido/Incolor		
FITATO-99mTc Lot # K-20220304-022		04/03/2022 07:16	PM	Butanona		3MM Whatman		953		3	0	99,686 %	Pass	
											pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00	
												Límpido/Incolor		
MAA-99mTc Lot # K-20220304-013		04/03/2022 04:19	KAF	Butanona		3MM Whatman		113		2	0	98,261 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20220304-014		04/03/2022 04:21	KAF	Butanona		3MM Whatman		126		2	0	98,438 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
												Turvo/Incolor		
MAA-99mTc Lot # K-20220304-038		04/03/2022 11:55	MB	Butanona		3MM Whatman		102,8		1,9	0	98,185 %	Pass	
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
												Turvo/Incolor		
MDP-99mTc Lot # K-20220304-011		04/03/2022 04:07	KAF	Acetona		3MM Whatman		834		3	0	99,529 %	Pass	
				Normal Saline		3MM Whatman		1		884	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20220304-012		04/03/2022 04:08	KAF	Acetona		3MM Whatman		1148		7	0	98,24 %	Pass	
				Normal Saline		3MM Whatman		12		1028	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20220304-021		04/03/2022 06:50	PM	Acetona		3MM Whatman		938		3	0	99,199 %	Pass	
				Normal Saline		3MM Whatman		4		826	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20220304-025		04/03/2022 07:41	PM	Acetona		3MM Whatman		2605		5	0	99,51 %	Pass	
				Normal Saline		3MM Whatman		5		1673	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20220304-029		04/03/2022 08:12	PM	Acetona		3MM Whatman		1425		4	0	99,09 %	Pass	
				Normal Saline		3MM Whatman		11		1736	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
												Límpido/Incolor		
MDP-99mTc Lot # K-20220304-032		04/03/2022 09:13	PM	Acetona		3MM Whatman		1935		3	0	99,356 %	Pass	
				Normal Saline		3MM Whatman		7		1425	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
												Límpido/Incolor		
MIBI-99mTc Lot # K-20220304-001		04/03/2022 02:03	KAF	Normal Saline		Sílica gel		942		15	0	98,147 %	Pass	
				Metanol		3MM Whatman		4		1399	pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
												Límpido/Incolor		
MIBI-99mTc Lot # K-20220304-002		04/03/2022 02:03	KAF	Normal Saline		Sílica gel		735		15	0	97,573 %	Pass	
				Metanol		3MM Whatman		8		1867	pH (Low/Actual/High)	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-20220304-003		04/03/2022 02:04	KAF	Normal Saline Metanol	Sílica gel 3MM Whatman			832 10		11 1496	0	pH (Low/Actual/High)	98,031 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220304-004		04/03/2022 02:10	KAF	Normal Saline Metanol	Sílica gel 3MM Whatman			1417 8		23 1971	0	pH (Low/Actual/High)	97,999 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220304-005		04/03/2022 02:12	KAF	Normal Saline Metanol	Sílica gel 3MM Whatman			2112 8		31 1976	0	pH (Low/Actual/High)	98,15 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220304-006		04/03/2022 02:12	KAF	Normal Saline Metanol	Sílica gel 3MM Whatman			1407 14		14 1182	0	pH (Low/Actual/High)	97,844 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220304-007		04/03/2022 03:55	KAF	Normal Saline Metanol	Sílica gel 3MM Whatman			1505 8		22 1521	0	pH (Low/Actual/High)	98,036 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220304-017		04/03/2022 04:26	KAF	Normal Saline Metanol	Sílica gel 3MM Whatman			1699 15		2 2140	0	pH (Low/Actual/High)	99,186 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220304-018		04/03/2022 05:05	KAF	Normal Saline Metanol	Sílica gel 3MM Whatman			1044 6		17 2835	0	pH (Low/Actual/High)	98,187 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220304-019		04/03/2022 06:47	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1071 10		10 2641	0	pH (Low/Actual/High)	98,698 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220304-030		04/03/2022 08:25	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1944 28		27 2495	0	pH (Low/Actual/High)	97,52 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220304-031		04/03/2022 09:11	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			2650 10		45 2612	0	pH (Low/Actual/High)	97,949 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20220304-033		04/03/2022 09:17	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			2008 42		40 2693	0	pH (Low/Actual/High)	96,511 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20220304-009		04/03/2022 04:01	KAF	Butanona Normal Saline	3MM Whatman 3MM Whatman			555 3		1 416	0	pH (Low/Actual/High)	99,104 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20220304-023		04/03/2022 07:24	PM	Butanona Normal Saline	3MM Whatman 3MM Whatman			658 2		3 744	0	pH (Low/Actual/High)	99,278 %	Pass 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
PSMA-68Ga Lot # K-20220304-020		04/03/2022 06:51 PM	Acetato de amônio 1M:Metanol	Sílica gel				1,4	41,6		0	96,744 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 6,00	<= 8,00	
PSMA-68Ga Lot # K-20220304-035		04/03/2022 09:53 PM	Acetato de amônio 1M:Metanol	Sílica gel				1,5	59		0	97,521 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 6,00	<= 8,00	
Tecnécio-99m Lot # E-20220304-001		04/03/2022 01:40 KAF	Butanona		3MM Whatman			46	9165		0	99,501 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220304-002		04/03/2022 01:54 KAF	Butanona		3MM Whatman			21	5524		0	99,621 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220304-003		04/03/2022 03:50 KAF	Butanona		3MM Whatman			24	2128		0	98,885 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220304-004		04/03/2022 04:02 KAF	Butanona		3MM Whatman			7	3697		0	99,811 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220304-005		04/03/2022 04:15 KAF	Butanona		3MM Whatman			92	2828		0	96,849 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220304-006		04/03/2022 05:02 KAF	Butanona		3MM Whatman			7	2557		0	99,727 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220304-007		04/03/2022 06:40 PM	Butanona		3MM Whatman			14	3437		0	99,594 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220304-008		04/03/2022 06:42 PM	Butanona		3MM Whatman			8	1102		0	99,279 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220304-010		04/03/2022 07:36 PM	Butanona		3MM Whatman			20	2100		0	99,057 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220304-011		04/03/2022 07:37 PM	Butanona		3MM Whatman			49	2466		0	98,052 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20220304-012		04/03/2022 08:22 PM	Butanona		3MM Whatman			24	8444		0	99,717 %	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		04/03/2022 09:07 PM	Butanona		3MM	Whatman		34		5686	0		99,406 %	Pass
Lot # E-20220304-013											pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
								Límpido e Incolor						