



## 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 14/05/2021 To 14/05/2021

Product:	Manuf:	Calibration D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210514-027		14/05/2021 07:44	GF	Butanona	3MM Whatman	67		1,4	0		92,64 %	Pass
				Normal Saline	Silica gel	5,6		99,8	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor												
DMSA-99mTc Lot # K-20210514-028		14/05/2021 07:45	JS	Butanona	3MM Whatman	103,5		2,1	0		92,094 %	Pass
				Normal Saline	Silica gel	7		111,3	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor												
DMSA-99mTc Lot # K-20210514-029		14/05/2021 07:47	JS	Butanona	3MM Whatman	123,8		1,2	0		92,381 %	Pass
				Normal Saline	Silica gel	5,9		82,7	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor												
DMSA-99mTc Lot # K-20210514-031		14/05/2021 08:08	JS	Butanona	3MM Whatman	193,4		5,6	0		91,413 %	Pass
				Normal Saline	Silica gel	6,8		111	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor												
DMSA-99mTc Lot # K-20210514-036		14/05/2021 10:27	WG	Butanona	3MM Whatman	268		11	0		94,554 %	Pass
				Normal Saline	Silica gel	4		262	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor												
DOTATOC-68Ga Lot # K-20210514-037		14/05/2021 12:34	JS	Citrato de Sódio 0,1M	Silica gel	40,2		0,4	0		99,015 %	Pass
									pH (Low/Actual/High)	4,00 <= 6,00 <= 8,00		
Límpido e Incolor												
DTPA-99mTc Lot # K-20210514-010	RPH	14/05/2021 03:25	PP	Acetona	3MM Whatman	1779		9	0		99,42 %	Pass
				Normal Saline	3MM Whatman	1		1296	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor												
DTPA-99mTc Lot # K-20210514-012	RPH	14/05/2021 03:40	PP	Acetona	3MM Whatman	211		2	0		94,79 %	Pass
				Normal Saline	3MM Whatman	53		1188	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor												
DTPA-99mTc Lot # K-20210514-017	RPH	14/05/2021 04:06	PP	Acetona	3MM Whatman	1232		31	0		93,053 %	Pass
				Normal Saline	3MM Whatman	46		978	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor												
DTPA-99mTc Lot # K-20210514-025	RPH	14/05/2021 07:09	GF	Acetona	3MM Whatman	409		4	0		95,906 %	Pass
				Normal Saline	3MM Whatman	8		248	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor												
DTPA-99mTc Lot # K-20210514-034	RPH	14/05/2021 09:23	JS	Acetona	3MM Whatman	905		10	0		97,48 %	Pass
				Normal Saline	3MM Whatman	12		829	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor												

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210514-008		14/05/2021 03:20 PP	Butanona		3MM	Whatman		787		1	0	99,873 %	Pass	
							Límpido/Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
FITATO-99mTc Lot # K-20210514-026		14/05/2021 07:12 GF	Butanona		3MM	Whatman		267		1	0	99,627 %	Pass	
							Límpido/Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
MAA-99mTc Lot # K-20210514-013		14/05/2021 03:59 PP	Butanona		3MM	Whatman		400		5	0	98,765 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210514-014		14/05/2021 04:00 PP	Butanona		3MM	Whatman		435		1	0	99,771 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210514-015		14/05/2021 04:02 PP	Butanona		3MM	Whatman		561		11	0	98,077 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210514-016		14/05/2021 04:04 PP	Butanona		3MM	Whatman		575		1	0	99,826 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210514-018		14/05/2021 04:15 PP	Butanona		3MM	Whatman		1256		5	0	99,603 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210514-019		14/05/2021 04:17 PP	Butanona		3MM	Whatman		245		2	0	99,19 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210514-020		14/05/2021 04:19 PP	Butanona		3MM	Whatman		157		1	0	99,367 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MDP-99mTc Lot # K-20210514-007		14/05/2021 03:18 PP	Acetona		3MM	Whatman		210		2	0	97,444 %	Pass	
			Normal Saline		3MM	Whatman		24		1464	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210514-009		14/05/2021 03:22 PP	Acetona		3MM	Whatman		2046		4	0	99,333 %	Pass	
			Normal Saline		3MM	Whatman		1		211	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210514-011		14/05/2021 03:35 PP	Acetona		3MM	Whatman		1357		11	0	97,248 %	Pass	
			Normal Saline		3MM	Whatman		26		1309	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210514-024		14/05/2021 06:55 GF	Acetona		3MM	Whatman		646		3	0	99,284 %	Pass	
			Normal Saline		3MM	Whatman		2		785	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
							Límpido/Incolor							

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210514-030		14/05/2021 07:53 GF	Acetona Normal Saline		3MM Whatman 3MM Whatman			555 15		1 605	0	pH (Low/Actual/High)	97,401 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210514-032		14/05/2021 08:13 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			1155 12		9 992	0	pH (Low/Actual/High)	98,032 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20210514-001		14/05/2021 02:12 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3049 31		7 3056	0	pH (Low/Actual/High)	98,767 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210514-002		14/05/2021 02:16 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			378 10		9 3039	0	pH (Low/Actual/High)	97,346 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210514-003		14/05/2021 02:17 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			313 3		5 411	0	pH (Low/Actual/High)	97,703 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210514-004		14/05/2021 02:23 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			314 4		8 409	0	pH (Low/Actual/High)	96,547 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210514-005		14/05/2021 02:55 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			418 27		8 4021	0	pH (Low/Actual/High)	97,455 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210514-006		14/05/2021 02:56 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			4016 23		5 4061	0	pH (Low/Actual/High)	99,312 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210514-022		14/05/2021 06:38 GF	Normal Saline Metanol		Sílica gel 3MM Whatman			947 8		13 1092	0	pH (Low/Actual/High)	97,919 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210514-023		14/05/2021 06:39 GF	Normal Saline Metanol		Sílica gel 3MM Whatman			893 7		29 807	0	pH (Low/Actual/High)	95,995 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210514-033		14/05/2021 09:14 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			1505 5		20 1938	0	pH (Low/Actual/High)	98,431 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210514-021		14/05/2021 06:38 GF	Acetato de amônio 1M:Metanol		Sílica gel			0,4		37,5	0	pH (Low/Actual/High)	98,945 %	Pass 4,00 <= 6,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210514-035		14/05/2021 09:31 BB	Acetato de amônio 1M:Metanol		Sílica gel			0,2		47,4	0	pH (Low/Actual/High)	99,58 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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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-20210514-001		14/05/2021 02:08 PP	Butanona		3MM Whatman			1		165	0	99,398 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-002		14/05/2021 02:19 PP	Butanona		3MM Whatman			1		191	0	99,479 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-003		14/05/2021 03:12 PP	Butanona		3MM Whatman			1		264	0	99,623 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-004		14/05/2021 03:21 PP	Butanona		3MM Whatman			10		4010	0	99,751 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-005		14/05/2021 03:35 PP	Butanona		3MM Whatman			9		403	0	97,816 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-006		14/05/2021 03:56 PP	Butanona		3MM Whatman			6		324	0	98,182 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-007		14/05/2021 06:33 GF	Butanona		3MM Whatman			18		763	0	97,695 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-009		14/05/2021 06:51 GF	Butanona		3MM Whatman			20		1832	0	98,92 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-010		14/05/2021 07:38 GF	Butanona		3MM Whatman			1		290	0	99,656 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-011		14/05/2021 07:43 GF	Butanona		3MM Whatman			5		625	0	99,206 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-012		14/05/2021 08:05 JS	Butanona		3MM Whatman			1		2230	0	99,955 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-013		14/05/2021 09:04 WG	Butanona		3MM Whatman			60		9813	0	99,392 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210514-015		14/05/2021 11:50 JS	Butanona		3MM Whatman			2		3445	0	99,942 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
											Límpido e Incolor			

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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