



# 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 22/05/2021 To 22/05/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DOTATOC-68Ga Lot # K-20210522-015		22/05/2021	05:26	WG	Citrato de Sódio 0,1M	Sílica gel	62,3		1,4	0		97,802 %	Pass
										pH (Low/Actual/High)		4,00 <= 5,00 <= 8,00	
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210522-010	RPH	22/05/2021	03:43	WG	Acetona	3MM Whatman	819		12	0		96,142 %	Pass
					Normal Saline	3MM Whatman	14		566			3,80 <= 6,00 <= 7,50	
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210522-013		22/05/2021	03:48	WG	Butanona	3MM Whatman	580		1	0		99,828 %	Pass
										pH (Low/Actual/High)		5,00 <= 6,00 <= 7,00	
						Límpido/Incolor							
MAA-99mTc Lot # K-20210522-011		22/05/2021	03:43	WG	Butanona	3MM Whatman	195,3		9,7	0		95,268 %	Pass
										pH (Low/Actual/High)		3,00 <= 6,00 <= 6,00	
						Turvo/Incolor							
MAA-99mTc Lot # K-20210522-009		22/05/2021	03:43	WG	Butanona	3MM Whatman	190		7	0		96,447 %	Pass
										pH (Low/Actual/High)		3,00 <= 6,00 <= 6,00	
						Turvo/Incolor							
MAA-99mTc Lot # K-20210522-012		22/05/2021	03:45	WG	Butanona	3MM Whatman	52,8		2	0		96,35 %	Pass
										pH (Low/Actual/High)		3,00 <= 6,00 <= 6,00	
						Turvo/Incolor							
MDP-99mTc Lot # K-20210522-005		22/05/2021	02:15	WG	Acetona	3MM Whatman	341		3	0		98,953 %	Pass
					Normal Saline	3MM Whatman	1		572			4,00 <= 6,00 <= 7,80	
						Límpido/Incolor							
MDP-99mTc Lot # K-20210522-006		22/05/2021	03:08	WG	Acetona	3MM Whatman	721		6	0		97,396 %	Pass
					Normal Saline	3MM Whatman	13		718			4,00 <= 6,00 <= 7,80	
						Límpido/Incolor							
MDP-99mTc Lot # K-20210522-008		22/05/2021	03:41	WG	Acetona	3MM Whatman	783		24	0		95,147 %	Pass
					Normal Saline	3MM Whatman	19		992			4,00 <= 6,00 <= 7,80	
						Límpido/Incolor							
MDP-99mTc Lot # K-20210522-014		22/05/2021	03:52	WG	Acetona	3MM Whatman	1168		2	0		99,377 %	Pass
					Normal Saline	3MM Whatman	6		1320			4,00 <= 7,00 <= 7,80	
						Límpido/Incolor							
MIBI-99mTc Lot # K-20210522-001		22/05/2021	02:15	WG	Normal Saline	Sílica gel	2255		12	0		98,785 %	Pass
					Metanol	3MM Whatman	23		3332			5,00 <= 6,00 <= 6,00	
						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
MIBI-99mTc Lot # K-20210522-002		22/05/2021 02:21	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1718 12		4 1256	0	pH (Low/Actual/High)	98,821 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210522-003		22/05/2021 02:28	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1645 8		35 2411	0	pH (Low/Actual/High)	97,586 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210522-004		22/05/2021 02:28	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1842 23		5 2343	0	pH (Low/Actual/High)	98,757 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210522-007		22/05/2021 03:40	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1933 7		4 1936	0	pH (Low/Actual/High)	99,433 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido/Incolor
Tecnécio-99m Lot # E-20210522-001		22/05/2021 02:12	WG	Butanona	3MM Whatman			10		1478	0	pH (Low/Actual/High)	99,328 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210522-002		22/05/2021 02:23	WG	Butanona	3MM Whatman			56		2780	0	pH (Low/Actual/High)	98,025 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210522-003		22/05/2021 03:36	WG	Butanona	3MM Whatman			17		901	0	pH (Low/Actual/High)	98,148 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210522-004		22/05/2021 03:39	WG	Butanona	3MM Whatman			89		6570	0	pH (Low/Actual/High)	98,663 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210522-005		22/05/2021 04:15	WG	Butanona	3MM Whatman			9		456	0	pH (Low/Actual/High)	98,065 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210522-008		22/05/2021 04:17	WG	Butanona	3MM Whatman			8		1378	0	pH (Low/Actual/High)	99,423 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210522-006		22/05/2021 04:17	WG	Butanona	3MM Whatman			14		893	0	pH (Low/Actual/High)	98,456 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210522-007		22/05/2021 04:18	WG	Butanona	3MM Whatman			11		1263	0	pH (Low/Actual/High)	99,137 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210522-009		22/05/2021 04:24	WG	Butanona	3MM Whatman			6		897	0	pH (Low/Actual/High)	99,336 %	Pass 5,00 <= 6,00 <= 6,00
														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-20210522-010		22/05/2021 04:24	WG	Butanona		3MM Whatman		89		1998	0	95,736 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210522-011		22/05/2021 04:31	WG	Butanona		3MM Whatman		54		1546	0	96,625 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210522-012		22/05/2021 04:32	WG	Butanona		3MM Whatman		5		1143	0	99,564 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			
Tecnécio-99m Lot # E-20210522-013		22/05/2021 04:38	WG	Butanona		3MM Whatman		34		1883	0	98,226 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
											Límpido e Incolor			

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

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