



# 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 03/06/2021 To 03/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210603-011		03/06/2021	04:03	WG	Butanona Normal Saline	3MM Whatman Sílica gel	93,6 0,5		2 66,3	0		97,159 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210603-016		03/06/2021	07:34	WG	Butanona Normal Saline	3MM Whatman Sílica gel	147,6 4,1		1,8 103,8	0		94,995 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210603-018		03/06/2021	08:02	WG	Butanona Normal Saline	3MM Whatman Sílica gel	124,3 0,5		4,1 83,1	0		96,209 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210603-024		03/06/2021	10:09	WG	Butanona Normal Saline	3MM Whatman Sílica gel	122,9 2,9		3 95,7	0		94,676 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DOTATOC-68Ga Lot # K-20210603-012		03/06/2021	06:50	WG	Citrato de Sódio 0,1M	Sílica gel	17,2		0,2	0		98,851 %	Pass
						Límpido e Incolor				pH (Low/Actual/High)		4,00 <= 6,00	<= 8,00
DOTATOC-68Ga Lot # K-20210603-025		03/06/2021	12:50	BB	Citrato de Sódio 0,1M	Sílica gel	33		0,3	0		99,099 %	Pass
						Límpido e Incolor				pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
DOTATOC-68Ga Lot # K-20210603-026		03/06/2021	13:44	BB	Citrato de Sódio 0,1M	Sílica gel	46,8		0,4	0		99,153 %	Pass
						Límpido e Incolor				pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
DOTATOC-68Ga Lot # K-20210603-027		03/06/2021	14:35	BB	Citrato de Sódio 0,1M	Sílica gel	19,4		0,5	0		97,487 %	Pass
						Límpido e Incolor				pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
DTPA-99mTc Lot # K-20210603-015	RPH	03/06/2021	07:16	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	532 12		5 305	0		95,283 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
DTPA-99mTc Lot # K-20210603-022	RPH	03/06/2021	10:00	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	621 3		2 688	0		99,245 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
FITATO-99mTc Lot # K-20210603-004		03/06/2021	03:08	WG	Butanona	3MM Whatman	266		2	0		99,254 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		5,00 <= 6,00	<= 7,00

Product:	Manuf:	Calibration D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
MAA-99mTc Lot # K-20210603-008		03/06/2021 03:53	WG	Butanona		3MM Whatman		99,8		0,8	0	99,205 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210603-009		03/06/2021 03:55	WG	Butanona		3MM Whatman		102,3		1,2	0	98,841 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210603-023		03/06/2021 10:05	WG	Butanona		3MM Whatman		159,8		1,5	0	99,07 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MDP-99mTc Lot # K-20210603-003		03/06/2021 03:05	WG	Acetona		3MM Whatman		367		2	0	97,105 %	Pass	
				Normal Saline		3MM Whatman		6		249		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210603-005		03/06/2021 03:19	WG	Acetona		3MM Whatman		1456		14	0	98,253 %	Pass	
				Normal Saline		3MM Whatman		9		1124		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210603-007		03/06/2021 03:48	WG	Acetona		3MM Whatman		1267		21	0	98,057 %	Pass	
				Normal Saline		3MM Whatman		3		956		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210603-010		03/06/2021 04:02	WG	Acetona		3MM Whatman		1117		3	0	98,89 %	Pass	
				Normal Saline		3MM Whatman		7		824		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210603-014		03/06/2021 07:08	WG	Acetona		3MM Whatman		961		2	0	99,059 %	Pass	
				Normal Saline		3MM Whatman		6		812		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20210603-017		03/06/2021 07:37	WG	Acetona		3MM Whatman		480		1	0	99,073 %	Pass	
				Normal Saline		3MM Whatman		3		414		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MIBI-99mTc Lot # K-20210603-001		03/06/2021 02:50	WG	Normal Saline		Sílica gel		958		29	0	96,11 %	Pass	
				Metanol		3MM Whatman		12		1249		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210603-002		03/06/2021 02:56	WG	Normal Saline		Sílica gel		1034		22	0	97,598 %	Pass	
				Metanol		3MM Whatman		7		2190		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210603-006		03/06/2021 03:44	WG	Normal Saline		Sílica gel		1195		7	0	99,275 %	Pass	
				Metanol		3MM Whatman		2,2		1543		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20210603-013		03/06/2021 07:04	WG	Normal Saline		Sílica gel		1698		2	0	99,403 %	Pass	
				Metanol		3MM Whatman		9		1867		pH (Low/Actual/High)	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-20210603-021	03/06/2021	10:00	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1169 6		7 1721	0		99,057 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido/Incolor
PSMA-68Ga Lot # K-20210603-019	03/06/2021	09:32	WG	Acetato de amônio 1M:Metanol	Sílica gel			0,2		18,24	0		98,915 %	Pass
												pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210603-001	03/06/2021	02:46	WG	Butanona	3MM Whatman			1		400	0		99,751 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210603-002	03/06/2021	02:46	WG	Butanona	3MM Whatman			10		1074	0		99,077 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210603-003	03/06/2021	03:03	WG	Butanona	3MM Whatman			9		678	0		98,69 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210603-004	03/06/2021	03:17	WG	Butanona	3MM Whatman			1,5		224,8	0		99,337 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210603-005	03/06/2021	03:42	WG	Butanona	3MM Whatman			2		149,3	0		98,678 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210603-006	03/06/2021	03:45	WG	Butanona	3MM Whatman			2,7		288,6	0		99,073 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210603-008	03/06/2021	07:01	WG	Butanona	3MM Whatman			13		1249	0		98,97 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210603-009	03/06/2021	07:04	WG	Butanona	3MM Whatman			8		339	0		97,695 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210603-010	03/06/2021	07:13	WG	Butanona	3MM Whatman			12		1042	0		98,861 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210603-012	03/06/2021	09:54	WG	Butanona	3MM Whatman			1		1498	0		99,933 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210603-013	03/06/2021	09:57	WG	Butanona	3MM Whatman			6		2397	0		99,75 %	Pass
												pH (Low/Actual/High)	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
TRODAT-99mTc		03/06/2021 09:57	WG	Normal Saline	Silica gel			103,1		2,6	0		91,762 %	Pass
Lot # K-20210603-020				Butanona	3MM Whatman			10,4		169,6	pH (Low/Actual/High)		6,50 <= 7,00 <= 8,50	
								Límpido/Incolor						