



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 29/12/2021 To 29/12/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211229-011		29/12/2021	04:12	MB	Butanona Normal Saline	3MM Whatman Sílica gel	150 1,5		2,1 126,2	0	pH (Low/Actual/High)	97,445 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211229-020		29/12/2021	07:33	PM	Butanona Normal Saline	3MM Whatman Sílica gel	171,3 10		1,1 157	0	pH (Low/Actual/High)	93,374 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211229-021		29/12/2021	07:35	PM	Butanona Normal Saline	3MM Whatman Sílica gel	216,1 2,2		7,4 185,3	0	pH (Low/Actual/High)	95,516 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211229-033		29/12/2021	10:05	VS	Butanona Normal Saline	3MM Whatman Sílica gel	237 1,3		2 269,4	0	pH (Low/Actual/High)	98,683 %	Pass
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20211229-028		29/12/2021	09:41	VS	Citrato de Sódio 0,1M	Sílica gel	719		5	0	pH (Low/Actual/High)	99,309 %	Pass
Límpido e Incolor													
DTPA-99mTc Lot # K-20211229-006	RPH	29/12/2021	03:38	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	481 26		4 473	0	pH (Low/Actual/High)	93,965 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20211229-023	RPH	29/12/2021	07:43	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	429 13		2 371	0	pH (Low/Actual/High)	96,151 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20211229-026	RPH	29/12/2021	09:26	VS	Acetona Normal Saline	3MM Whatman 3MM Whatman	311 8		4 331	0	pH (Low/Actual/High)	96,37 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20211229-005		29/12/2021	03:37	MB	Butanona	3MM Whatman	314		3	0	pH (Low/Actual/High)	99,054 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20211229-022		29/12/2021	07:39	PM	Butanona	3MM Whatman	902		3	0	pH (Low/Actual/High)	99,669 %	Pass
Límpido/Incolor													
MAA-99mTc Lot # K-20211229-008		29/12/2021	04:00	MB	Butanona	3MM Whatman	301		1	0	pH (Low/Actual/High)	99,669 %	Pass
Turvo/Incolor													

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-20211229-013		29/12/2021 04:18	MB	Butanona		3MM Whatman		272		2	0	99,27 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211229-024		29/12/2021 07:44	PM	Butanona		3MM Whatman		289		12	0	96,013 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211229-029		29/12/2021 10:02	VS	Butanona		3MM Whatman		169		4	0	97,688 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211229-030		29/12/2021 10:03	VS	Butanona		3MM Whatman		335		4	0	98,82 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211229-031		29/12/2021 10:04	VS	Butanona		3MM Whatman		318		7	0	97,846 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211229-032		29/12/2021 10:05	VS	Butanona		3MM Whatman		494		8	0	98,406 %	Pass	
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MDP-99mTc Lot # K-20211229-007		29/12/2021 03:46	MB	Acetona		3MM Whatman		860		3	0	98,737 %	Pass	
				Normal Saline		3MM Whatman		8		866		pH (Low/Actual/High)	4,00 <= 4,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211229-009		29/12/2021 04:10	MB	Acetona		3MM Whatman		634		3	0	95,061 %	Pass	
				Normal Saline		3MM Whatman		21		449		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211229-018		29/12/2021 07:04	PM	Acetona		3MM Whatman		1043		9	0	98,815 %	Pass	
				Normal Saline		3MM Whatman		3		908		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211229-019		29/12/2021 07:08	PM	Acetona		3MM Whatman		1132		8	0	97,001 %	Pass	
				Normal Saline		3MM Whatman		26		1106		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211229-025		29/12/2021 09:06	VS	Acetona		3MM Whatman		1360		5	0	99,441 %	Pass	
				Normal Saline		3MM Whatman		3		1557		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211229-034		29/12/2021 10:25	MB	Acetona		3MM Whatman		765		3	0	99,483 %	Pass	
				Normal Saline		3MM Whatman		1		791		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MIBI-99mTc Lot # K-20211229-001		29/12/2021 02:34	MB	Normal Saline		Sílica gel		848		25	0	95,151 %	Pass	
				Metanol		3MM Whatman		38		1876		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-20211229-002		29/12/2021 02:38	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			976 29		14 2116	0	pH (Low/Actual/High)	97,234 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211229-003		29/12/2021 03:32	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			418 3		7 705	0	pH (Low/Actual/High)	97,929 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211229-004		29/12/2021 03:33	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			504 4		6 668	0	pH (Low/Actual/High)	98,228 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211229-012		29/12/2021 04:11	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			584 3		7 936	0	pH (Low/Actual/High)	98,496 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211229-010		29/12/2021 04:11	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1185 8		25 1649	0	pH (Low/Actual/High)	97,451 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211229-015		29/12/2021 06:49	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1402 12		12 1440	0	pH (Low/Actual/High)	98,325 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211229-016		29/12/2021 06:50	PM	Normal Saline Metanol	Sílica gel 3MM Whatman			1045 1		21 807	0	pH (Low/Actual/High)	97,906 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211229-027		29/12/2021 09:37	VS	Normal Saline Metanol	Sílica gel 3MM Whatman			2762 2		11 305	0	pH (Low/Actual/High)	98,952 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211229-035		29/12/2021 10:28	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			404 2		2 495	0	pH (Low/Actual/High)	99,105 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20211229-017		29/12/2021 06:49	MB	Acetato de amônio 1M:Metanol	Sílica gel			0,3		30,1	0	pH (Low/Actual/High)	99,013 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20211229-036		29/12/2021 12:42	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,4		32,6	0	pH (Low/Actual/High)	98,788 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211229-001		29/12/2021 02:31	MB	Butanona	3MM Whatman			3		554	0	pH (Low/Actual/High)	99,461 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211229-002		29/12/2021 02:36	MB	Butanona	3MM Whatman			4		174	0	pH (Low/Actual/High)	97,753 %	Pass 5,00 <= 5,00 <= 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-20211229-003		29/12/2021 02:40	MB	Butanona		3MM Whatman		3		692	0		99,568 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-004		29/12/2021 03:28	MB	Butanona		3MM Whatman		3		196	0		98,492 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-005		29/12/2021 03:28	MB	Butanona		3MM Whatman		22		844	0		97,46 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-006		29/12/2021 03:47	MB	Butanona		3MM Whatman		14		559	0		97,557 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-008		29/12/2021 04:05	MB	Butanona		3MM Whatman		3		2819	0		99,894 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-007		29/12/2021 04:05	MB	Butanona		3MM Whatman		18		1912	0		99,067 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-009		29/12/2021 04:07	MB	Butanona		3MM Whatman		1		129	0		99,231 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-010		29/12/2021 05:00	PM	Butanona		3MM Whatman		3		1831	0		99,836 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-011		29/12/2021 06:38	PM	Butanona		3MM Whatman		4		1082	0		99,632 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-012		29/12/2021 06:38	PM	Butanona		3MM Whatman		5		574	0		99,136 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-014		29/12/2021 07:00	PM	Butanona		3MM Whatman		15		1920	0		99,225 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-015		29/12/2021 07:05	PM	Butanona		3MM Whatman		14		689	0		98,009 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
Tecnécio-99m Lot # E-20211229-016		29/12/2021 07:29	PM	Butanona		3MM Whatman		8		1429	0		99,443 %	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-20211229-017		29/12/2021 08:48 PM	Butanona		3MM	Whatman		4		1158	0		99,656 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211229-018		29/12/2021 09:02 PM	Butanona		3MM	Whatman		1		2693	0		99,963 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211229-019		29/12/2021 09:19 VS	Butanona		3MM	Whatman		2		145	0		98,639 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211229-020		29/12/2021 09:34 VS	Butanona		3MM	Whatman		4		753	0		99,472 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211229-022		29/12/2021 10:21 VS	Butanona		3MM	Whatman		10		335	0		97,101 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211229-023		29/12/2021 10:25 VS	Butanona		3MM	Whatman		7		272	0		97,491 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211229-024		29/12/2021 10:33 JS	Butanona		3MM	Whatman		14		2057	0		99,324 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20211229-026		29/12/2021 13:24												%
Tecnécio-99m Lot # E-20211229-027		29/12/2021 13:25												%