



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 10/06/2021 To 10/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210610-010		10/06/2021	04:03	PP	Butanona	3MM Whatman	188		1	0		94,526 %	Pass
					Normal Saline	Silica gel	9		173	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DMSA-99mTc Lot # K-20210610-025		10/06/2021	08:01	WG	Butanona	3MM Whatman	147,7		0,8	0		92,942 %	Pass
					Normal Saline	Silica gel	6,8		97,5	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DMSA-99mTc Lot # K-20210610-026		10/06/2021	08:02	WG	Butanona	3MM Whatman	167,9		2,3	0		94,016 %	Pass
					Normal Saline	Silica gel	6,5		133,8	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DMSA-99mTc Lot # K-20210610-038		10/06/2021	10:41	WG	Butanona	3MM Whatman	169,3		5	0		92,955 %	Pass
					Normal Saline	Silica gel	5,4		123,9	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DOTATATE-68Ga Lot # K-20210610-044		10/06/2021	15:28	JS	Citrato de Sódio 0,1M	Silica gel	40,5		2,4	0		67,379 %	Fail
					Metanol/Acetato de Amonio 1	Silica gel	20		54	pH (Low/Actual/High)	4,00 <= 4,50 <= 8,00		
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210610-016		10/06/2021	06:52	BB	Citrato de Sódio 0,1M	Silica gel	21,6		0,6	0		97,297 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210610-043		10/06/2021	12:58	JS	Citrato de Sódio 0,1M	Silica gel	32,9		0,3	0		99,096 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210610-045		10/06/2021	16:32	JS	Citrato de Sódio 0,1M	Silica gel	46,3		0,4	0		99,143 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
Límpido e Incolor													
DTPA-99mTc Lot # K-20210610-005	RPH	10/06/2021	03:12	PP	Acetona	3MM Whatman	1232		9	0		96,769 %	Pass
					Normal Saline	3MM Whatman	22		856	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor													
DTPA-99mTc Lot # K-20210610-008	RPH	10/06/2021	03:35	PP	Acetona	3MM Whatman	1117		1	0		99,398 %	Pass
					Normal Saline	3MM Whatman	5		970	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor													
DTPA-99mTc Lot # K-20210610-021	RPH	10/06/2021	07:18	FN	Acetona	3MM Whatman	751		32	0		91,292 %	Pass
					Normal Saline	3MM Whatman	25		516	pH (Low/Actual/High)	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
DTPA-99mTc Lot # K-20210610-023	RPH	10/06/2021 08:02	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman			290 10		1 312	0 pH (Low/Actual/High)	96,551 % 3,80 <= 6,00 <= 7,50		Pass
Límpido/Incolor														
DTPA-99mTc Lot # K-20210610-037	RPH	10/06/2021 10:40	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			349 5		4 261	0 pH (Low/Actual/High)	96,987 % 3,80 <= 6,00 <= 7,50		Pass
Límpido/Incolor														
FITATO-99mTc Lot # K-20210610-006		10/06/2021 03:15	PP	Butanona	3MM Whatman			508		12	0 pH (Low/Actual/High)	97,692 % 5,00 <= 6,00 <= 7,00		Pass
Límpido/Incolor														
FITATO-99mTc Lot # K-20210610-022		10/06/2021 07:21	FN	Butanona	3MM Whatman			223		3	0 pH (Low/Actual/High)	98,673 % 5,00 <= 6,00 <= 7,00		Pass
Límpido/Incolor														
MAA-99mTc Lot # K-20210610-011		10/06/2021 04:05	PP	Butanona	3MM Whatman			220		1	0 pH (Low/Actual/High)	99,548 % 3,00 <= 6,00 <= 6,00		Pass
Turvo/Incolor														
MAA-99mTc Lot # K-20210610-012		10/06/2021 04:07	PP	Butanona	3MM Whatman			220		2	0 pH (Low/Actual/High)	99,099 % 3,00 <= 6,00 <= 6,00		Pass
Turvo/Incolor														
MAA-99mTc Lot # K-20210610-013		10/06/2021 04:09	PP	Butanona	3MM Whatman			273		4	0 pH (Low/Actual/High)	98,556 % 3,00 <= 6,00 <= 6,00		Pass
Turvo/Incolor														
MAA-99mTc Lot # K-20210610-041		10/06/2021 11:24	JS	Butanona	3MM Whatman			26,8		0,5	0 pH (Low/Actual/High)	98,168 % 3,00 <= 6,00 <= 6,00		Pass
Turvo/Incolor														
MDP-99mTc Lot # K-20210610-004		10/06/2021 03:09	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman			1548 22		3 1191	0 pH (Low/Actual/High)	97,993 % 4,00 <= 6,00 <= 7,80		Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20210610-007		10/06/2021 03:27	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman			2051 20		9 1473	0 pH (Low/Actual/High)	98,224 % 4,00 <= 6,00 <= 7,80		Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20210610-009		10/06/2021 03:38	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman			1292 40		1 855	0 pH (Low/Actual/High)	95,453 % 4,00 <= 6,00 <= 7,80		Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20210610-014		10/06/2021 04:21	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman			1268 1		1 860	0 pH (Low/Actual/High)	99,805 % 4,00 <= 6,00 <= 7,80		Pass
Límpido/Incolor														
MDP-99mTc Lot # K-20210610-020		10/06/2021 07:12	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman			714 6		1 648	0 pH (Low/Actual/High)	98,943 % 4,00 <= 6,00 <= 7,80		Pass
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
MDP-99mTc Lot # K-20210610-036		10/06/2021 10:27	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			987 24		4 1390	0 pH (Low/Actual/High)	97,899 % 4,00 <= 6,00 <= 7,80		Pass
														Límpido/Incolor
MIBI-99mTc Lot # K-20210610-002		10/06/2021 02:41	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1568 11		36 1777	0 pH (Low/Actual/High)	97,14 % 5,00 <= 6,00 <= 6,00		Pass
														Límpido/Incolor
MIBI-99mTc Lot # K-20210610-001		10/06/2021 02:42	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2058 14		11 2021	0 pH (Low/Actual/High)	98,78 % 5,00 <= 6,00 <= 6,00		Pass
														Límpido/Incolor
MIBI-99mTc Lot # K-20210610-003		10/06/2021 02:53	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1609 30		33 3065	0 pH (Low/Actual/High)	97,021 % 5,00 <= 6,00 <= 6,00		Pass
														Límpido/Incolor
MIBI-99mTc Lot # K-20210610-015		10/06/2021 04:27	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2201 70		47 2629	0 pH (Low/Actual/High)	95,316 % 5,00 <= 6,00 <= 6,00		Pass
														Límpido/Incolor
MIBI-99mTc Lot # K-20210610-017		10/06/2021 06:57	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			1134 14		20 1516	0 pH (Low/Actual/High)	97,352 % 5,00 <= 6,00 <= 6,00		Pass
														Límpido/Incolor
MIBI-99mTc Lot # K-20210610-018		10/06/2021 07:03	FN	Normal Saline Metanol	Sílica gel 3MM Whatman			632 6		10 549	0 pH (Low/Actual/High)	97,361 % 5,00 <= 6,00 <= 6,00		Pass
														Límpido/Incolor
MIBI-99mTc Lot # K-20210610-024		10/06/2021 07:56	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			673 8		3 747	0 pH (Low/Actual/High)	98,497 % 5,00 <= 6,00 <= 6,00		Pass
														Límpido/Incolor
MIBI-99mTc Lot # K-20210610-028		10/06/2021 10:02	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			548 9		28 816	0 pH (Low/Actual/High)	94,048 % 5,00 <= 6,00 <= 6,00		Pass
														Límpido/Incolor
MIBI-99mTc Lot # K-20210610-035		10/06/2021 10:20	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			931 3		3 1093	0 pH (Low/Actual/High)	99,405 % 5,00 <= 6,00 <= 6,00		Pass
														Límpido/Incolor
MIBI-99mTc Lot # K-20210610-042		10/06/2021 10:51	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			592 1		8 591	0 pH (Low/Actual/High)	98,498 % 5,00 <= 6,00 <= 6,00		Pass
														Límpido/Incolor
MIBI-99mTc Lot # K-20210610-040		10/06/2021 11:01	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			25,6 0,2		1 23,6	0 pH (Low/Actual/High)	95,40 % 5,00 <= 5,00 <= 6,00		Pass
														Límpido/Incolor
PIRO-99mTc Lot # K-20210610-019		10/06/2021 07:08	FN	Butanona Normal Saline	3MM Whatman 3MM Whatman			479 2		1 408	0 pH (Low/Actual/High)	99,304 % 5,00 <= 6,00 <= 7,00		Pass
														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-20210610-027		10/06/2021 09:48	BB	Acetato de amônio 1M:Metanol	Sílica gel			0,1		31,5	0		99,684 %	Pass
												pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-001		10/06/2021 02:37	PP	Butanona		3MM Whatman		10		850	0		98,837 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-002		10/06/2021 02:39	PP	Butanona		3MM Whatman		58		1536	0		96,361 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-003		10/06/2021 02:47	PP	Butanona		3MM Whatman		2		620	0		99,678 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-004		10/06/2021 02:52	PP	Butanona		3MM Whatman		6		289	0		97,966 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-005		10/06/2021 02:56	PP	Butanona		3MM Whatman		2		240	0		99,174 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-006		10/06/2021 03:07	PP	Butanona		3MM Whatman		4		993	0		99,599 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-007		10/06/2021 03:25	PP	Butanona		3MM Whatman		3		4061	0		99,926 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-008		10/06/2021 03:36	PP	Butanona		3MM Whatman		8		1048	0		99,242 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-009		10/06/2021 04:24	PP	Butanona		3MM Whatman		15		352	0		95,913 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-011		10/06/2021 06:56	FN	Butanona		3MM Whatman		2		1524	0		99,869 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-012		10/06/2021 07:01	FN	Butanona		3MM Whatman		3		1755	0		99,829 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210610-013		10/06/2021 07:02	FN	Butanona		3MM Whatman		2		144,7	0		98,637 %	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
Tecnécio-99m Lot # E-20210610-014		10/06/2021 07:15	FN	Butanona		3MM Whatman		2		919	0	99,783 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20210610-015		10/06/2021 07:47	FN	Butanona		3MM Whatman		3		281	0	98,944 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20210610-016		10/06/2021 07:53	FN	Butanona		3MM Whatman		2		229	0	99,134 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20210610-018		10/06/2021 09:58	BB	Butanona		3MM Whatman		2		1458	0	99,863 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20210610-019		10/06/2021 09:58	WG	Butanona		3MM Whatman		5		293	0	98,322 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20210610-020		10/06/2021 10:14	WG	Butanona		3MM Whatman		29		1281	0	97,786 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20210610-021		10/06/2021 10:25	WG	Butanona		3MM Whatman		16		805	0	98,051 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20210610-022		10/06/2021 10:30	WG	Butanona		3MM Whatman		11		559	0	98,07 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20210610-023		10/06/2021 10:39	WG	Butanona		3MM Whatman		7		818	0	99,152 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
Tecnécio-99m Lot # E-20210610-024		10/06/2021 10:58	WG	Butanona		3MM Whatman		33		1306	0	97,535 %	Pass	
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
TRODAT-99mTc Lot # K-20210610-029		10/06/2021 10:06	WG	Normal Saline		Sílica gel		118,9		8,6	0	92,298 %	Pass	
				Butanona		3MM Whatman		2		207		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20210610-030		10/06/2021 10:07	WG	Normal Saline		Sílica gel		136,6		4,9	0	93,103 %	Pass	
				Butanona		3MM Whatman		6,8		191,2		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20210610-031		10/06/2021 10:08	WG	Normal Saline		Sílica gel		122,5		9,7	0	92,013 %	Pass	
				Butanona		3MM Whatman		1,1		168,3		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
							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
TRODAT-99mTc Lot # K-20210610-032		10/06/2021 10:10	WG	Normal Saline Butanona	Sílica gel 3MM Whatman			73,8 2,6	1,8 88,6	0		pH (Low/Actual/High)	94,768 %	Pass
														6,50 <= 7,00 <= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210610-033		10/06/2021 10:12	WG	Normal Saline Butanona	Sílica gel 3MM Whatman			82,2 6,3	1 100,2	0		pH (Low/Actual/High)	92,883 %	Pass
														6,50 <= 7,00 <= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210610-034		10/06/2021 10:16	WG	Normal Saline Butanona	Sílica gel 3MM Whatman			72,3 2	5 130,5	0		pH (Low/Actual/High)	92,022 %	Pass
														6,50 <= 7,00 <= 8,50
														Límpido/Incolor