



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 21/12/2021 To 21/12/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211221-014		21/12/2021	04:00	MB	Butanona	3MM Whatman	213		1	0		97,517 %	Pass
					Normal Saline	Silica gel	5		243	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	Límpido/Incolor
DMSA-99mTc Lot # K-20211221-015		21/12/2021	04:02	MB	Butanona	3MM Whatman	253		2	0		97,259 %	Pass
					Normal Saline	Silica gel	3		150,3	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	Límpido/Incolor
DMSA-99mTc Lot # K-20211221-024		21/12/2021	07:44	MB	Butanona	3MM Whatman	158,9		5,7	0		94,434 %	Pass
					Normal Saline	Silica gel	2,7		125,7	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	Límpido/Incolor
DMSA-99mTc Lot # K-20211221-025		21/12/2021	07:46	MB	Butanona	3MM Whatman	175,8		0,7	0		94,623 %	Pass
					Normal Saline	Silica gel	7,8		148,8	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	Límpido/Incolor
DMSA-99mTc Lot # K-20211221-048		21/12/2021	11:07	MB	Butanona	3MM Whatman	39,4		0,7	0,6		98,223 %	Pass
					Normal Saline	Silica gel	1,1		33	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	Límpido/Incolor
DOTATOC-68Ga Lot # K-20211221-034		21/12/2021	09:40	MB	Citrato de Sódio 0,1M	Silica gel	43,3		2	0		95,585 %	Pass
DOTATOC-68Ga Lot # K-20211221-050		21/12/2021	12:37	MB	Citrato de Sódio 0,1M	Silica gel	78,5		2,1	0		97,395 %	Pass
DOTATOC-68Ga Lot # K-20211221-051		21/12/2021	13:29	JS	Citrato de Sódio 0,1M	Silica gel	33,6		0,3	0		99,115 %	Pass
DTPA-99mTc Lot # K-20211221-012	RPH	21/12/2021	03:55	MB	Acetona	3MM Whatman	915		6	0		98,556 %	Pass
					Normal Saline	3MM Whatman	8		1001	pH (Low/Actual/High)	3,80 <= 5,00	<= 7,50	Límpido/Incolor
DTPA-99mTc Lot # K-20211221-013	RPH	21/12/2021	03:58	MB	Acetona	3MM Whatman	606		4	0		98,144 %	Pass
					Normal Saline	3MM Whatman	7		576	pH (Low/Actual/High)	3,80 <= 5,00	<= 7,50	Límpido/Incolor
DTPA-99mTc Lot # K-20211221-022	RPH	21/12/2021	07:34	MB	Acetona	3MM Whatman	605,9		0,6	0		95,808 %	Pass
					Normal Saline	3MM Whatman	23,9		560	pH (Low/Actual/High)	3,80 <= 5,00	<= 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-20211221-023	RPH	21/12/2021 07:37	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			686 27,6	1,3 620,3	0		95,551 %	Pass	3,80 <= 5,00 <= 7,50
Límpido/Incolor														
DTPA-99mTc Lot # K-20211221-033	RPH	21/12/2021 09:35	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			111,2 1	0,7 113,5	0,6		99,557 %	Pass	3,80 <= 5,00 <= 7,50
Límpido/Incolor														
FITATO-99mTc Lot # K-20211221-009		21/12/2021 03:47	MB	Butanona	3MM Whatman			359	3	0		99,171 %	Pass	5,00 <= 7,00 <= 7,00
Límpido/Incolor														
FITATO-99mTc Lot # K-20211221-030		21/12/2021 08:48	MB	Butanona	3MM Whatman			386	2	0		99,485 %	Pass	5,00 <= 6,00 <= 7,00
Límpido/Incolor														
MAA-99mTc Lot # K-20211221-016		21/12/2021 04:18	MB	Butanona	3MM Whatman			428	2	0		99,535 %	Pass	3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211221-027		21/12/2021 07:51	MB	Butanona	3MM Whatman			128	2,6	0		98,009 %	Pass	3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211221-028		21/12/2021 07:53	MB	Butanona	3MM Whatman			129,5	1	0		99,234 %	Pass	3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211221-035		21/12/2021 09:51	MB	Butanona	3MM Whatman			64,4	0,2	0,6		100,00 %	Pass	3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211221-036		21/12/2021 09:54	MB	Butanona	3MM Whatman			67,4	1	0,6		99,405 %	Pass	3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211221-045		21/12/2021 10:16	MB	Butanona	3MM Whatman			67,2	0,6	0,6		100,00 %	Pass	3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MDP-99mTc Lot # K-20211221-010		21/12/2021 03:51	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			1151 22	5 1370	0		97,987 %	Pass	4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211221-020		21/12/2021 07:03	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			862 2	7,7 1125	0		98,937 %	Pass	4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211221-026		21/12/2021 07:48	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			1388 13	6 1310	0		98,587 %	Pass	4,00 <= 6,00 <= 7,80
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-20211221-031		21/12/2021 08:51	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			806 4		4 769	0 pH (Low/Actual/High)	98,989 % 4,00 <= 5,00 <= 7,80	Pass	
Límpido/Incolor														
MDP-99mTc Lot # K-20211221-041		21/12/2021 10:05	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			293 5		1 416	0,6 pH (Low/Actual/High)	98,815 % 4,00 <= 5,00 <= 7,80	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-001		21/12/2021 01:59	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1351 11		39 1848	0 pH (Low/Actual/High)	96,603 % 5,00 <= 5,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-002		21/12/2021 02:01	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			979,6 23		12,9 1721	0 pH (Low/Actual/High)	97,381 % 5,00 <= 5,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-003		21/12/2021 02:05	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			780,8 11,3		10,1 855,5	0 pH (Low/Actual/High)	97,419 % 5,00 <= 5,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-004		21/12/2021 02:31	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			969,3 3		16,1 1655	0 pH (Low/Actual/High)	98,185 % 5,00 <= 5,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-005		21/12/2021 02:32	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1254 23		21 1998	0 pH (Low/Actual/High)	97,215 % 5,00 <= 5,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-006		21/12/2021 02:35	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1210 23		14 1938	0 pH (Low/Actual/High)	97,683 % 5,00 <= 5,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-007		21/12/2021 03:28	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1418 30		15 1891	0 pH (Low/Actual/High)	97,392 % 5,00 <= 5,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-008		21/12/2021 03:29	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1642 14		17 1598	0 pH (Low/Actual/High)	98,107 % 5,00 <= 5,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-017		21/12/2021 06:54	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1305 33		18 1904	0 pH (Low/Actual/High)	96,936 % 5,00 <= 5,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-018		21/12/2021 06:55	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1277 29		18 1705	0 pH (Low/Actual/High)	96,938 % 5,00 <= 5,00 <= 6,00	Pass	
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-019		21/12/2021 07:00	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1295 4		8 2628	0 pH (Low/Actual/High)	99,234 % 5,00 <= 5,00 <= 6,00	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
MIBI-99mTc Lot # K-20211221-029	21/12/2021	08:08	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1788 5		5 235	0 pH (Low/Actual/High)	97,638 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-032	21/12/2021	09:25	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			65,5 0,6		2 70,7	0,6 pH (Low/Actual/High)	97,888 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-047	21/12/2021	11:22	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			188 3		6 248	0,6 pH (Low/Actual/High)	96,238 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211221-049	21/12/2021	11:54	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			218 4		6 950	0,6 pH (Low/Actual/High)	97,219 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
Octreo-99mTc Lot # K-20211221-046	21/12/2021	10:54	MB	Butanona Citrato de Sódio 0,1M Metanol/ Acetato Amônio 1M	Sílica gel Sílica gel Sílica gel			45,5 36 0,3		1,5 3,6 47,1	0,6 pH (Low/Actual/High)	90,222 %	Pass	5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20211221-011	21/12/2021	03:54	MB	Butanona Normal Saline	3MM Whatman 3MM Whatman			416 5		5 498	0 pH (Low/Actual/High)	97,818 %	Pass	5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20211221-021	21/12/2021	07:12	MB	Butanona Normal Saline	3MM Whatman 3MM Whatman			456,6 4,7		2,1 464,3	0 pH (Low/Actual/High)	98,54 %	Pass	5,00 <= 5,00 <= 7,00
Límpido/Incolor														
Tecnécio-99m Lot # E-20211221-001	21/12/2021	01:29	MB	Butanona	3MM Whatman			6		5549	0 pH (Low/Actual/High)	99,892 %	Pass	5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211221-002	21/12/2021	01:55	MB	Butanona	3MM Whatman			31		4586	0 pH (Low/Actual/High)	99,329 %	Pass	5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211221-003	21/12/2021	02:23	MB	Butanona	3MM Whatman			28		4150	0 pH (Low/Actual/High)	99,33 %	Pass	5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211221-004	21/12/2021	02:26	MB	Butanona	3MM Whatman			7,6		847,3	0 pH (Low/Actual/High)	99,111 %	Pass	5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211221-005	21/12/2021	03:23	MB	Butanona	3MM Whatman			8		1200	0 pH (Low/Actual/High)	99,338 %	Pass	5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211221-006	21/12/2021	03:49	MB	Butanona	3MM Whatman			1		2331	0 pH (Low/Actual/High)	99,957 %	Pass	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-20211221-007		21/12/2021 06:47	MB	Butanona		3MM Whatman		5		4885	0		99,898 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211221-008		21/12/2021 06:58	MB	Butanona		3MM Whatman		3		644,5	0		99,537 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211221-009		21/12/2021 07:30	MB	Butanona		3MM Whatman		12		1219	0		99,025 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211221-010		21/12/2021 07:40	MB	Butanona		3MM Whatman		19		2025	0		99,07 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211221-011		21/12/2021 08:05	MB	Butanona		3MM Whatman		12,2		913,3	0		98,682 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211221-012		21/12/2021 09:20	MB	Butanona		3MM Whatman		3		1770	0		99,831 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211221-014		21/12/2021 09:46	MB	Butanona		3MM Whatman		1		207	0,6		99,807 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211221-015		21/12/2021 10:53	MB	Butanona		3MM Whatman		5		729	0,6		99,40 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
Tecnécio-99m Lot # E-20211221-016		21/12/2021 11:53	MB	Butanona		3MM Whatman		2		778	0,6		99,82 %	Pass
							Límpido e Incolor					pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
TRODAT-99mTc Lot # K-20211221-037		21/12/2021 10:02	MB	Normal Saline		Sílica gel		38,6		2,3	0,6		95,477 %	Pass
				Butanona		3MM Whatman		0,7		42			pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211221-038		21/12/2021 10:03	MB	Normal Saline		Sílica gel		42,3		0,5	0,6		96,909 %	Pass
				Butanona		3MM Whatman		2		44,5			pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211221-039		21/12/2021 10:03	MB	Normal Saline		Sílica gel		38,1		1,9	0,6		91,742 %	Pass
				Butanona		3MM Whatman		3		47,1			pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50
							Límpido/Incolor							
TRODAT-99mTc Lot # K-20211221-040		21/12/2021 10:04	MB	Normal Saline		Sílica gel		42,8		0,3	0,6		99,366 %	Pass
				Butanona		3MM Whatman		0,9		47,6			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-20211221-042		21/12/2021 10:14 MB	Normal Saline Butanona		Sílica gel 3MM Whatman			27,2 2,1		1,6 43,4	0,6 pH (Low/Actual/High)	92,991 %		Pass 6,50 <= 7,00 <= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20211221-043		21/12/2021 10:14 MB	Normal Saline Butanona		Sílica gel 3MM Whatman			44,2 0,4		1,4 35,6	0,6 pH (Low/Actual/High)	98,198 %		Pass 6,50 <= 7,00 <= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20211221-044		21/12/2021 10:15 MB	Normal Saline Butanona		Sílica gel 3MM Whatman			24,8 0,5		2 43,5	0,6 pH (Low/Actual/High)	94,531 %		Pass 6,50 <= 7,00 <= 8,50
														Límpido/Incolor