



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 17/12/2021 To 17/12/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc		17/12/2021	04:03	BB	Butanona	3MM Whatman	275		2	0		98,043 %	Pass
Lot # K-20211217-015					Normal Saline	Silica gel	2,3		184	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		17/12/2021	07:49	MB	Butanona	3MM Whatman	224		3	0		94,827 %	Pass
Lot # K-20211217-024					Normal Saline	Silica gel	3		74,9	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		17/12/2021	07:51	MB	Butanona	3MM Whatman	159,2		1	0		98,826 %	Pass
Lot # K-20211217-025					Normal Saline	Silica gel	0,8		144,8	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		17/12/2021	07:53	MB	Butanona	3MM Whatman	270		1	0		94,717 %	Pass
Lot # K-20211217-026					Normal Saline	Silica gel	6		116,1	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		17/12/2021	08:03	MB	Butanona	3MM Whatman	149,7		0,4	0		95,37 %	Pass
Lot # K-20211217-030					Normal Saline	Silica gel	4,9		107,4	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		17/12/2021	10:34	YD	Butanona	3MM Whatman	98		1,9	0		90,809 %	Pass
Lot # K-20211217-040					Normal Saline	Silica gel	6,4		81,4	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		17/12/2021	10:41	YD	Butanona	3MM Whatman	151,9		0,4	0		98,575 %	Pass
Lot # K-20211217-041					Normal Saline	Silica gel	1,3		110,5	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DOTATOC-68Ga		17/12/2021	12:47	YD	Citrato de Sódio 0,1M	Silica gel	23,4		0,7	0		97,095 %	Pass
Lot # K-20211217-043										pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
						Límpido e Incolor							
DTPA-99mTc	RPH	17/12/2021	03:45	BB	Acetona	3MM Whatman	488		3	0		94,766 %	Pass
Lot # K-20211217-011					Normal Saline	3MM Whatman	19		392	pH (Low/Actual/High)		3,80 <= 5,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	17/12/2021	03:47	BB	Acetona	3MM Whatman	617		4	0		97,249 %	Pass
Lot # K-20211217-012					Normal Saline	3MM Whatman	13		604	pH (Low/Actual/High)		3,80 <= 5,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	17/12/2021	03:48	BB	Acetona	3MM Whatman	767		3	0		98,153 %	Pass
Lot # K-20211217-013					Normal Saline	3MM Whatman	8		541	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-20211217-023	RPH	17/12/2021 07:34	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			517,2 2,8	7,1 564,4	0		98,152 %	Pass	3,80 <= 5,00 <= 7,50
Límpido/Incolor														
DTPA-99mTc Lot # K-20211217-034	RPH	17/12/2021 09:25	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			379 6	1 276	0		97,609 %	Pass	3,80 <= 5,00 <= 7,50
Límpido/Incolor														
FITATO-99mTc Lot # K-20211217-007		17/12/2021 03:06	BB	Butanona	3MM Whatman			365	2	0		99,455 %	Pass	5,00 <= 7,00 <= 7,00
Límpido/Incolor														
FITATO-99mTc Lot # K-20211217-027		17/12/2021 07:56	MB	Butanona	3MM Whatman			314,7	1,9	0		99,40 %	Pass	5,00 <= 5,00 <= 7,00
Límpido/Incolor														
MAA-99mTc Lot # K-20211217-016		17/12/2021 04:15	BB	Butanona	3MM Whatman			381	3	0		99,219 %	Pass	3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211217-028		17/12/2021 07:59	MB	Butanona	3MM Whatman			94,3	2,6	0		97,317 %	Pass	3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211217-029		17/12/2021 08:01	MB	Butanona	3MM Whatman			107,4	0,8	0		99,261 %	Pass	3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211217-035		17/12/2021 09:26	MB	Butanona	3MM Whatman			179,9	0,1	0		99,944 %	Pass	3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MAA-99mTc Lot # K-20211217-042		17/12/2021 11:03	YD	Butanona	3MM Whatman			114	0,9	0		99,217 %	Pass	3,00 <= 5,00 <= 6,00
Turvo/Incolor														
MDP-99mTc Lot # K-20211217-006		17/12/2021 02:59	BB	Acetona Normal Saline	3MM Whatman 3MM Whatman			1076 13	3 1101	0		98,555 %	Pass	4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211217-008		17/12/2021 03:12	BB	Acetona Normal Saline	3MM Whatman 3MM Whatman			1057 12	7 801	0		97,866 %	Pass	4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211217-009		17/12/2021 03:14	BB	Acetona Normal Saline	3MM Whatman 3MM Whatman			565 7	1 889	0		99,042 %	Pass	4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211217-021		17/12/2021 07:19	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			673,3 15,5	1 615,7	0		97,396 %	Pass	4,00 <= 5,00 <= 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-20211217-022		17/12/2021 07:26	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			905,9 2		1 1030	0	pH (Low/Actual/High)	99,696 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211217-031		17/12/2021 08:10	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			551 6		0 770	0	pH (Low/Actual/High)	99,227 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211217-036		17/12/2021 09:30	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			1147 11		3 925	0	pH (Low/Actual/High)	98,564 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211217-038		17/12/2021 10:06	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman			406 2		2 402	0	pH (Low/Actual/High)	99,015 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20211217-001		17/12/2021 01:56	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1071 6		18 1458	0	pH (Low/Actual/High)	97,937 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211217-002		17/12/2021 01:59	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1160 9		7 1607	0	pH (Low/Actual/High)	98,843 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211217-003		17/12/2021 02:04	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1259 23		19 1578	0	pH (Low/Actual/High)	97,077 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211217-004		17/12/2021 02:05	BB	Normal Saline Metanol	Sílica gel 3MM Whatman			1151 12		10 1466	0	pH (Low/Actual/High)	98,327 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211217-005		17/12/2021 02:05	BB	Normal Saline Metanol	Sílica gel 3MM Whatman			1158 3		10 1455	0	pH (Low/Actual/High)	98,938 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211217-010		17/12/2021 03:33	BB	Normal Saline Metanol	Sílica gel 3MM Whatman			1108 1		10 1882	0	pH (Low/Actual/High)	99,052 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211217-017		17/12/2021 06:31	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			970,5 17		17,9 1230	0	pH (Low/Actual/High)	96,826 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211217-018		17/12/2021 06:34	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			730,3 25		8,8 1089	0	pH (Low/Actual/High)	96,565 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211217-020		17/12/2021 07:12	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1048 7		9 1387	0	pH (Low/Actual/High)	98,646 %	Pass 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-20211217-032	17/12/2021	08:30	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			642 6		10 759	0	pH (Low/Actual/High)	97,682 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211217-033	17/12/2021	08:36	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			959 4		3 205	0	pH (Low/Actual/High)	97,774 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211217-039	17/12/2021	10:08	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1206 3		2 1435	0	pH (Low/Actual/High)	99,626 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido/Incolor
PIRO-99mTc Lot # K-20211217-014	17/12/2021	03:50	BB	Butanona Normal Saline	3MM Whatman 3MM Whatman			349 11		0 371	0	pH (Low/Actual/High)	97,12 %	Pass 5,00 <= 6,00 <= 7,00
														Límpido/Incolor
PSMA-68Ga Lot # K-20211217-019	17/12/2021	06:54	MB	Acetato de amônio 1M:Metanol	Sílica gel			0,7		22,5	0	pH (Low/Actual/High)	96,983 %	Pass 4,00 <= 6,00 <= 8,00
														Límpido e Incolor
PSMA-68Ga Lot # K-20211217-037	17/12/2021	09:55	MB	Acetato de amônio 1M:Metanol	Sílica gel			2		318	0	pH (Low/Actual/High)	99,375 %	Pass 4,00 <= 5,00 <= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-001	17/12/2021	01:37	MB	Butanona	3MM Whatman			1		2102	0	pH (Low/Actual/High)	99,952 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-002	17/12/2021	01:57	MB	Butanona	3MM Whatman			49		2189	0	pH (Low/Actual/High)	97,811 %	Pass 5,00 <= 5,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-003	17/12/2021	01:59	BB	Butanona	3MM Whatman			1		1220	0	pH (Low/Actual/High)	99,918 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-004	17/12/2021	02:08	BB	Butanona	3MM Whatman			3		1009	0	pH (Low/Actual/High)	99,704 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-005	17/12/2021	03:07	BB	Butanona	3MM Whatman			6		1085	0	pH (Low/Actual/High)	99,45 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-006	17/12/2021	03:31	BB	Butanona	3MM Whatman			5		2213	0	pH (Low/Actual/High)	99,775 %	Pass 5,00 <= 6,00 <= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-007	17/12/2021	03:42	BB	Butanona	3MM Whatman			10		1985	0	pH (Low/Actual/High)	99,499 %	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-20211217-008		17/12/2021 06:29	MB	Butanona		3MM Whatman		6		2597	0		99,769 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-010		17/12/2021 07:10	MB	Butanona		3MM Whatman		2		566	0		99,648 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-011		17/12/2021 07:16	MB	Butanona		3MM Whatman		1,7		258,3	0		99,346 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-012		17/12/2021 07:24	MB	Butanona		3MM Whatman		0,7		118,5	0		99,413 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-013		17/12/2021 07:46	MB	Butanona		3MM Whatman		19		1132	0		98,349 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-014		17/12/2021 08:26	MB	Butanona		3MM Whatman		4		1267	0		99,685 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-015		17/12/2021 08:35	MB	Butanona		3MM Whatman		1		207	0		99,519 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-016		17/12/2021 09:21	MB	Butanona		3MM Whatman		2		840	0		99,762 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-018		17/12/2021 09:56	MB	Butanona		3MM Whatman		2		299	0		99,336 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211217-019		17/12/2021 10:29	MB	Butanona		3MM Whatman		4		1542	0		99,741 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor