



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 05/11/2021 To 05/11/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211105-016		05/11/2021	07:14	WG	Butanona Normal Saline	3MM Whatman Sílica gel	257 5,6		3 127,9	0	pH (Low/Actual/High)	94,651 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211105-017		05/11/2021	07:16	WG	Butanona Normal Saline	3MM Whatman Sílica gel	122,8 3,5		0,7 57,2	0	pH (Low/Actual/High)	93,667 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211105-020		05/11/2021	07:52	WG	Butanona Normal Saline	3MM Whatman Sílica gel	127,9 1,6		0,3 77,7	0	pH (Low/Actual/High)	97,748 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211105-022		05/11/2021	08:01	WG	Butanona Normal Saline	3MM Whatman Sílica gel	111,8 3,7		0,6 91,8	0	pH (Low/Actual/High)	95,592 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20211105-028		05/11/2021	10:44	JS	Butanona Normal Saline	3MM Whatman Sílica gel	67,8 1,7		1,2 77	0	pH (Low/Actual/High)	96,101 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20211105-037		05/11/2021	12:52	JS	Citrato de Sódio 0,1M	Sílica gel	31,9		0,3	0	pH (Low/Actual/High)	99,068 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20211105-038		05/11/2021	15:46	JS	Citrato de Sódio 0,1M	Sílica gel	23,6		0,4	0	pH (Low/Actual/High)	98,333 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20211105-003	RPH	05/11/2021	03:26	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	243 3		4 394	0	pH (Low/Actual/High)	97,625 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211105-006	RPH	05/11/2021	03:42	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	334 3		3 457	0	pH (Low/Actual/High)	98,458 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211105-018	RPH	05/11/2021	07:27	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	315 1		7 302	0	pH (Low/Actual/High)	97,496 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20211105-032	RPH	05/11/2021	11:42	JS	Acetona Normal Saline	3MM Whatman 3MM Whatman	201 9		9 240	0	pH (Low/Actual/High)	92,10 %	Pass 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
FITATO-99mTc Lot # K-20211105-009		05/11/2021 04:42	MB	Butanona		3MM Whatman		163		4	0		97,605 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
														Límpido/Incolor
FITATO-99mTc Lot # K-20211105-031		05/11/2021 11:39	WG	Butanona		3MM Whatman		451		3	0		99,339 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
														Límpido/Incolor
MAA-99mTc Lot # K-20211105-008		05/11/2021 04:39	MB	Butanona		3MM Whatman		358		6	0		98,352 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211105-034		05/11/2021 12:11	WG	Butanona		3MM Whatman		299		4	0		98,68 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20211105-035		05/11/2021 12:15	WG	Butanona		3MM Whatman		185,6		4,2	0		97,787 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MDP-99mTc Lot # K-20211105-004		05/11/2021 03:36	MB	Acetona		3MM Whatman		746		2	0		97,401 %	Pass
				Normal Saline		3MM Whatman		19		796		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211105-010		05/11/2021 04:45	MB	Acetona		3MM Whatman		184,1		1,8	0		96,41 %	Pass
				Normal Saline		3MM Whatman		5		185,7		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211105-019		05/11/2021 07:27	WG	Acetona		3MM Whatman		608		7	0		98,263 %	Pass
				Normal Saline		3MM Whatman		3		498		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211105-023		05/11/2021 08:03	WG	Acetona		3MM Whatman		117,7		3,3	0		96,597 %	Pass
				Normal Saline		3MM Whatman		1,3		191,1		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211105-027		05/11/2021 10:24	JS	Acetona		3MM Whatman		986		6	0		98,874 %	Pass
				Normal Saline		3MM Whatman		5		954		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
														Límpido/Incolor
MDP-99mTc Lot # K-20211105-033		05/11/2021 12:06	WG	Acetona		3MM Whatman		493		3	0		99,044 %	Pass
				Normal Saline		3MM Whatman		2		568		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
														Límpido/Incolor
MIBI-99mTc Lot # K-20211105-001		05/11/2021 03:06	MB	Normal Saline		Sílica gel		271		19	0		92,47 %	Pass
				Metanol		3MM Whatman		4		405		pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido/Incolor
MIBI-99mTc Lot # K-20211105-002		05/11/2021 03:13	MB	Normal Saline		Sílica gel		226		4	0		97,751 %	Pass
				Metanol		3MM Whatman		2		390		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-20211105-005		05/11/2021 03:41	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			687 4		10 419	0	pH (Low/Actual/High)	97,62 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211105-007		05/11/2021 04:38	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			695 9		22 1123	0	pH (Low/Actual/High)	96,137 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211105-011		05/11/2021 04:50	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			217 11		4 203	0	pH (Low/Actual/High)	93,05 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211105-012		05/11/2021 04:57	MB	Normal Saline Metanol	Sílica gel 3MM Whatman			1003 36		14 1054	0	pH (Low/Actual/High)	95,321 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211105-014		05/11/2021 07:09	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			744 15		14 1393	0	pH (Low/Actual/High)	97,088 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211105-015		05/11/2021 07:10	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1257 5		18 959	0	pH (Low/Actual/High)	98,07 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211105-021		05/11/2021 07:59	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1075 11		6 1322	0	pH (Low/Actual/High)	98,62 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211105-025		05/11/2021 10:07	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			729 20		1 1187	0	pH (Low/Actual/High)	98,206 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211105-026		05/11/2021 10:16	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			589 2		6 354	0	pH (Low/Actual/High)	98,43 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211105-029		05/11/2021 11:05	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			277 2		4 638	0	pH (Low/Actual/High)	98,264 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211105-030		05/11/2021 11:27	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			528 1		10 430	0	pH (Low/Actual/High)	97,909 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211105-036		05/11/2021 12:40	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			832 1		3 646	0	pH (Low/Actual/High)	99,486 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20211105-013		05/11/2021 06:46	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,4		89,4	0	pH (Low/Actual/High)	99,555 %	Pass 4,00 <= 5,00 <= 8,00
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
PSMA-68Ga Lot # K-20211105-024		05/11/2021 09:56	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,3		12,4	0		97,638 %	Pass
												pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-001		05/11/2021 02:53	MB	Butanona		3MM Whatman		21		490	0		95,89 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-002		05/11/2021 02:53	MB	Butanona		3MM Whatman		7		471	0		98,536 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-003		05/11/2021 03:11	MB	Butanona		3MM Whatman		2		498	0		99,60 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-004		05/11/2021 03:24	MB	Butanona		3MM Whatman		2		175	0		98,87 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-005		05/11/2021 03:33	MB	Butanona		3MM Whatman		4		264	0		98,507 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-006		05/11/2021 03:40	MB	Butanona		3MM Whatman		5		917	0		99,458 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-007		05/11/2021 04:35	MB	Butanona		3MM Whatman		5		367	0		98,656 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-008		05/11/2021 04:35	MB	Butanona		3MM Whatman		6		197	0		97,044 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-009		05/11/2021 04:36	MB	Butanona		3MM Whatman		4		383	0		98,966 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-010		05/11/2021 04:36	MB	Butanona		3MM Whatman		0,1		61	0		99,836 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-013		05/11/2021 07:06	WG	Butanona		3MM Whatman		2		388	0		99,487 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-014		05/11/2021 07:06	WG	Butanona		3MM Whatman		10		551	0		98,217 %	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-20211105-012		05/11/2021 07:06	WG	Butanona		3MM Whatman		6		460	0		98,712 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-015		05/11/2021 07:18	WG	Butanona		3MM Whatman		11		516	0		97,913 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-016		05/11/2021 07:24	WG	Butanona		3MM Whatman		0,8		135,9	0		99,415 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-018		05/11/2021 07:58	WG	Butanona		3MM Whatman		0,8		94,3	0		99,159 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-017		05/11/2021 07:58	WG	Butanona		3MM Whatman		3		291	0		98,98 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-020		05/11/2021 10:05	WG	Butanona		3MM Whatman		12		383	0		96,962 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-021		05/11/2021 10:13	JS	Butanona		3MM Whatman		2		1546	0		99,871 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-022		05/11/2021 10:21	JS	Butanona		3MM Whatman		2		1978	0		99,899 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-023		05/11/2021 11:02	JS	Butanona		3MM Whatman		3		219	0		98,649 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-024		05/11/2021 11:24	JS	Butanona		3MM Whatman		0,9		139	0		99,357 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-025		05/11/2021 11:32	JS	Butanona		3MM Whatman		1		119	0		99,167 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-026		05/11/2021 11:56	WG	Butanona		3MM Whatman		1		728	0		99,863 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211105-027		05/11/2021 12:37	WG	Butanona		3MM Whatman		5		743	0		99,332 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor