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 12/01/2021 To 12/01/2021

Product:	Manuf:	Calibration D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc		12/01/2021 07:38	JS	Butanona	3MM Whatman	1025		3	0		99,458 %	Pass
Lot # K-20210112-026				Normal Saline	Sílica gel	2		798	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
					Límpido/Incolor							
DMSA-99mTc		12/01/2021 07:39	JS	Butanona	3MM Whatman	130		1	0		98,293 %	Pass
Lot # K-20210112-027				Normal Saline	Sílica gel	1		105	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
					Límpido/Incolor							
DMSA-99mTc		12/01/2021 10:12	MP	Butanona	3MM Whatman	906		3	0		94,083 %	Pass
Lot # K-20210112-037				Normal Saline	Sílica gel	10		169	pH (Low/Actual/High)		2,00 <= 2,00	<= 3,00
					Límpido/Incolor							
DOTATOC-68Ga		12/01/2021 06:53	BB	Citrato de Sódio 0,5M	Sílica gel	9,82		0,1	0		98,992 %	Pass
Lot # K-20210112-018									pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
					Límpido e Incolor							
DTPA-99mTc	RPH	12/01/2021 03:35	BB	Acetona	3MM Whatman	1155		1	0		98,912 %	Pass
Lot # K-20210112-007				Normal Saline	3MM Whatman	6		593	pH (Low/Actual/High)		3,80 <= 5,00	<= 7,50
					Límpido/Incolor							
DTPA-99mTc	RPH	12/01/2021 03:36	BB	Acetona	3MM Whatman	673		6	0		97,543 %	Pass
Lot # K-20210112-008				Normal Saline	3MM Whatman	14		876	pH (Low/Actual/High)		3,80 <= 5,00	<= 7,50
					Límpido/Incolor							
DTPA-99mTc	RPH	12/01/2021 07:19	JS	Acetona	3MM Whatman	202		3	0		96,802 %	Pass
Lot # K-20210112-023				Normal Saline	3MM Whatman	3		170	pH (Low/Actual/High)		3,80 <= 7,00	<= 7,50
					Límpido/Incolor							
DTPA-99mTc	RPH	12/01/2021 10:27	MP	Acetona	3MM Whatman	183		2	0		96,422 %	Pass
Lot # K-20210112-043				Normal Saline	3MM Whatman	20		781	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
					Límpido/Incolor							
DTPA-99mTc	RPH	12/01/2021 10:52	MP	Acetona	3MM Whatman	710		4	0		98,44 %	Pass
Lot # K-20210112-046				Normal Saline	3MM Whatman	10		990	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
					Límpido/Incolor							
FITATO-99mTc		12/01/2021 03:20	BB	Butanona	3MM Whatman	570		2	0		99,65 %	Pass
Lot # K-20210112-006									pH (Low/Actual/High)		5,00 <= 7,00	<= 7,00
					Límpido/Incolor							
FITATO-99mTc		12/01/2021 08:42	MP	Butanona	3MM Whatman	572		0	0		100,00 %	Pass
Lot # K-20210112-031									pH (Low/Actual/High)		5,00 <= 6,00	<= 7,00
					Límpido/Incolor							

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

Printed: 12/01/2021 17:23:00

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		12/01/2021 04:01	BB	Butanona		3MM	Whatman		125,4	0,7		0		99,445 %	Pass
Lot # K-20210112-011												pH (Low/Actual/High)		3,00 <= 5,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 04:03	BB	Butanona		3MM	Whatman		248	1		0		99,598 %	Pass
Lot # K-20210112-012												pH (Low/Actual/High)		3,00 <= 5,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 04:05	BB	Butanona		3MM	Whatman		165	2,7		0		98,39 %	Pass
Lot # K-20210112-013												pH (Low/Actual/High)		3,00 <= 5,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 04:07	BB	Butanona		3MM	Whatman		223	7		0		96,957 %	Pass
Lot # K-20210112-014												pH (Low/Actual/High)		3,00 <= 5,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 04:09	BB	Butanona		3MM	Whatman		109,9	2		0		98,213 %	Pass
Lot # K-20210112-015												pH (Low/Actual/High)		3,00 <= 5,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 10:15	MP	Butanona		3MM	Whatman		172	2		0		98,851 %	Pass
Lot # K-20210112-038												pH (Low/Actual/High)		3,00 <= 3,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 10:18	MP	Butanona		3MM	Whatman		158	2		0		98,75 %	Pass
Lot # K-20210112-039												pH (Low/Actual/High)		3,00 <= 3,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 10:20	MP	Butanona		3MM	Whatman		353	3		0		99,157 %	Pass
Lot # K-20210112-040												pH (Low/Actual/High)		3,00 <= 3,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 10:22	MP	Butanona		3MM	Whatman		187	3		0		98,421 %	Pass
Lot # K-20210112-041												pH (Low/Actual/High)		3,00 <= 3,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 10:24	MP	Butanona		3MM	Whatman		387	3		0		99,231 %	Pass
Lot # K-20210112-042												pH (Low/Actual/High)		3,00 <= 3,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 10:49	MP	Butanona		3MM	Whatman		188	3		0		98,429 %	Pass
Lot # K-20210112-044												pH (Low/Actual/High)		3,00 <= 3,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 10:50	MP	Butanona		3MM	Whatman		221	4		0		98,222 %	Pass
Lot # K-20210112-045												pH (Low/Actual/High)		3,00 <= 3,00	<= 6,00
								Turvo/Incolor							
MAA-99mTc		12/01/2021 11:21	MP	Butanona		3MM	Whatman		235	1		0		99,576 %	Pass
Lot # K-20210112-047												pH (Low/Actual/High)		3,00 <= 6,00	<= 6,00
								Turvo/Incolor							

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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		12/01/2021	03:57 BB	Acetona		3MM	Whatman		1256	3		0		99,607 %	Pass
Lot # K-20210112-009				Normal Saline		3MM	Whatman		1	646		pH (Low/Actual/High)		4,00 <= 5,00 <= 7,80	
								Límpido/Incolor							
MDP-99mTc		12/01/2021	03:58 BB	Acetona		3MM	Whatman		735	10		0		96,361 %	Pass
Lot # K-20210112-010				Normal Saline		3MM	Whatman		11	468		pH (Low/Actual/High)		4,00 <= 5,00 <= 7,80	
								Límpido/Incolor							
MDP-99mTc		12/01/2021	04:13 BB	Acetona		3MM	Whatman		815	3		0		98,169 %	Pass
Lot # K-20210112-016				Normal Saline		3MM	Whatman		11	740		pH (Low/Actual/High)		4,00 <= 6,00 <= 7,80	
								Límpido/Incolor							
MDP-99mTc		12/01/2021	07:12 JS	Acetona		3MM	Whatman		626	1		0		98,969 %	Pass
Lot # K-20210112-021				Normal Saline		3MM	Whatman		5	569		pH (Low/Actual/High)		4,00 <= 5,00 <= 7,80	
								Límpido/Incolor							
MDP-99mTc		12/01/2021	07:16 JS	Acetona		3MM	Whatman		485	1		0		97,548 %	Pass
Lot # K-20210112-022				Normal Saline		3MM	Whatman		23	1001		pH (Low/Actual/High)		4,00 <= 5,00 <= 7,80	
								Límpido/Incolor							
MDP-99mTc		12/01/2021	07:23 JS	Acetona		3MM	Whatman		249	3		0		97,238 %	Pass
Lot # K-20210112-024				Normal Saline		3MM	Whatman		8	501		pH (Low/Actual/High)		4,00 <= 5,00 <= 7,80	
								Límpido/Incolor							
MDP-99mTc		12/01/2021	07:24 JS	Acetona		3MM	Whatman		1231	1		0		99,466 %	Pass
Lot # K-20210112-025				Normal Saline		3MM	Whatman		1	220		pH (Low/Actual/High)		4,00 <= 5,00 <= 7,80	
								Límpido/Incolor							
MIBI-99mTc		12/01/2021	02:10 JS	Normal Saline		Sílica gel			1974	10		0		96,242 %	Pass
Lot # K-20210112-001				Metanol		3MM	Whatman		55	1635		pH (Low/Actual/High)		5,00 <= 5,00 <= 6,00	
								Límpido/Incolor							
MIBI-99mTc		12/01/2021	02:31 JS	Normal Saline		Sílica gel			866	12		0		98,43 %	Pass
Lot # K-20210112-002				Metanol		3MM	Whatman		3	1471		pH (Low/Actual/High)		5,00 <= 5,00 <= 6,00	
								Límpido/Incolor							
MIBI-99mTc		12/01/2021	02:32 JS	Normal Saline		Sílica gel			1335	4		0		97,259 %	Pass
Lot # K-20210112-003				Metanol		3MM	Whatman		21	839		pH (Low/Actual/High)		5,00 <= 5,00 <= 6,00	
								Límpido/Incolor							
MIBI-99mTc		12/01/2021	02:39 BB	Normal Saline		Sílica gel			1598	25		0		96,25 %	Pass
Lot # K-20210112-004				Metanol		3MM	Whatman		43	1903		pH (Low/Actual/High)		5,00 <= 5,00 <= 6,00	
								Límpido/Incolor							
MIBI-99mTc		12/01/2021	02:40 JS	Normal Saline		Sílica gel			1207	14		0		98,134 %	Pass
Lot # K-20210112-005				Metanol		3MM	Whatman		13	1793		pH (Low/Actual/High)		5,00 <= 5,00 <= 6,00	
								Límpido/Incolor							
MIBI-99mTc		12/01/2021	06:41 JS	Normal Saline		Sílica gel			1098	23		0		97,149 %	Pass
Lot # K-20210112-017				Metanol		3MM	Whatman		9	1117		pH (Low/Actual/High)		5,00 <= 5,00 <= 6,00	
								Límpido/Incolor							

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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		12/01/2021	07:49 JS	Normal Saline		Sílica gel			1732	34		0		97,871 %	Pass
Lot # K-20210112-028				Metanol		3MM Whatman			4	1961		pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
								Límpido/Incolor							
MIBI-99mTc		12/01/2021	08:07 JS	Normal Saline		Sílica gel			261	11		0		94,313 %	Pass
Lot # K-20210112-029				Metanol		3MM Whatman			17	1018		pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
								Límpido/Incolor							
MIBI-99mTc		12/01/2021	08:10 JS	Normal Saline		Sílica gel			249	5		0		96,197 %	Pass
Lot # K-20210112-030				Metanol		3MM Whatman			4	214		pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
								Límpido/Incolor							
MIBI-99mTc		12/01/2021	09:51 MP	Normal Saline		Sílica gel			1636	20		0		98,083 %	Pass
Lot # K-20210112-033				Metanol		3MM Whatman			6	840		pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
								Límpido/Incolor							
PIRO-99mTc		12/01/2021	07:05 JS	Butanona		3MM Whatman			286	1		0		98,422 %	Pass
Lot # K-20210112-019				Normal Saline		3MM Whatman			3	241		pH (Low/Actual/High)		5,00 <= 5,00	<= 7,00
								Límpido/Incolor							
PIRO-99mTc		12/01/2021	07:07 JS	Butanona		3MM Whatman			498	2		0		94,405 %	Pass
Lot # K-20210112-020				Normal Saline		3MM Whatman			24	438		pH (Low/Actual/High)		5,00 <= 5,00	<= 7,00
								Límpido/Incolor							
PSMA-177Lu		12/01/2021	08:00 MP	Citrato de Sódio 0,5M		Sílica gel			498	1		0		99,80 %	Pass
Lot # Lu-21-0006-01												pH (Low/Actual/High)		4,00 <= 4,50	<= 5,00
								Limpido							
QC Notes: HPLC 97,92%															
PSMA-177Lu		12/01/2021	08:00 MP	Citrato de Sódio 0,5M		Sílica gel			663	2		0		99,699 %	Pass
Lot # Lu-21-0006-01												pH (Low/Actual/High)		4,00 <= 4,50	<= 5,00
								Limpido							
QC Notes: HPLC 99,72%															
PSMA-68Ga		12/01/2021	09:38 BB	Acetato de amônio 1M:Metanol		Sílica gel			0,2	21,9		0		99,095 %	Pass
Lot # K-20210112-032												pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
								Límpido e Incolor							
Tecnécio-99m		12/01/2021	01:56 BB	Butanona		3MM Whatman			15	2230		0		99,332 %	Pass
Lot # E-20210112-001												pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
								Límpido e Incolor							
Tecnécio-99m		12/01/2021	02:16 JS	Butanona		3MM Whatman			1	206		0		99,517 %	Pass
Lot # E-20210112-002												pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
								Límpido e Incolor							
Tecnécio-99m		12/01/2021	02:36 JS	Butanona		3MM Whatman			5	367		0		98,656 %	Pass
Lot # E-20210112-004												pH (Low/Actual/High)		5,00 <= 5,00	<= 6,00
								Límpido e Incolor							

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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		12/01/2021 02:36	JS	Butanona		3MM	Whatman		2	1096		0		99,818 %	Pass
Lot # E-20210112-003												pH (Low/Actual/High)		5,00 <= 5,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 03:54	BB	Butanona		3MM	Whatman		8	4211		0		99,81 %	Pass
Lot # E-20210112-005												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 06:41	JS	Butanona		3MM	Whatman		9	582		0		98,477 %	Pass
Lot # E-20210112-006												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 07:14	JS	Butanona		3MM	Whatman		2	327		0		99,392 %	Pass
Lot # E-20210112-008												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 07:47	JS	Butanona		3MM	Whatman		4	793		0		99,498 %	Pass
Lot # E-20210112-009												pH (Low/Actual/High)		5,00 <= 5,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 08:04	JS	Butanona		3MM	Whatman		1	367		0		99,728 %	Pass
Lot # E-20210112-010												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 09:49	MP	Butanona		3MM	Whatman		3	306		0		99,029 %	Pass
Lot # E-20210112-012												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 09:54	MP	Butanona		3MM	Whatman		1	156		0		99,363 %	Pass
Lot # E-20210112-013												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 13:19	SB	Butanona		3MM	Whatman		1	326		0		99,694 %	Pass
Lot # E-20210112-014												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 13:36	WG	Butanona		3MM	Whatman		3	735		0		99,593 %	Pass
Lot # E-20210112-016												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 13:36	WG	Butanona		3MM	Whatman		6	859		0		99,306 %	Pass
Lot # E-20210112-015												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 13:38	WG	Butanona		3MM	Whatman		3	672		0		99,556 %	Pass
Lot # E-20210112-017												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00	
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 13:41	WG	Butanona		3MM	Whatman		3	606		0		99,507 %	Pass
Lot # E-20210112-018												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00	
								Límpido e Incolor							

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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		12/01/2021 13:44	WG	Butanona		3MM	Whatman		7	507		0		98,638 %	Pass
Lot # E-20210112-019												pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 13:46	WG	Butanona		3MM	Whatman		2	533		0		99,626 %	Pass
Lot # E-20210112-020												pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 13:49	WG	Butanona		3MM	Whatman		2	602		0		99,669 %	Pass
Lot # E-20210112-021												pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 13:55	WG	Butanona		3MM	Whatman		3	881		0		99,661 %	Pass
Lot # E-20210112-022												pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
								Límpido e Incolor							
Tecnécio-99m		12/01/2021 13:56	WG	Butanona		3MM	Whatman		0,1	131,5		0		99,924 %	Pass
Lot # E-20210112-023												pH (Low/Actual/High)		5,00 <= 6,00	<= 6,00
								Límpido e Incolor							
TRODAT-99mTc		12/01/2021 10:06	MP	Normal Saline		Sílica gel			135	4		0		94,345 %	Pass
Lot # K-20210112-034				Butanona		3MM	Whatman		4	140		pH (Low/Actual/High)		6,50 <= 7,00	<= 8,50
								Límpido/Incolor							
TRODAT-99mTc		12/01/2021 10:07	MP	Normal Saline		Sílica gel			154	3		0		95,386 %	Pass
Lot # K-20210112-035				Butanona		3MM	Whatman		5	180		pH (Low/Actual/High)		6,50 <= 7,00	<= 8,50
								Límpido/Incolor							
TRODAT-99mTc		12/01/2021 10:08	MP	Normal Saline		Sílica gel			300	10		0		95,065 %	Pass
Lot # K-20210112-036				Butanona		3MM	Whatman		2	115		pH (Low/Actual/High)		6,50 <= 7,00	<= 8,50
								Límpido/Incolor							

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.