



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 10/08/2021 To 10/08/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210810-014		10/08/2021	04:08	FN	Butanona Normal Saline	3MM Whatman Sílica gel	190,8 11,2		6 151,9	0	pH (Low/Actual/High)	90,084 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210810-025		10/08/2021	07:34	FN	Butanona Normal Saline	3MM Whatman Sílica gel	180,9 10,2		3,2 159,5	0	pH (Low/Actual/High)	92,251 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210810-026		10/08/2021	07:36	FN	Butanona Normal Saline	3MM Whatman Sílica gel	139,1 5,1		1,4 83,5	0	pH (Low/Actual/High)	93,247 %	Pass
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210810-020		10/08/2021	07:01	FN	Citrato de Sódio 0,1M	Sílica gel	25,3		0,5	0	pH (Low/Actual/High)	98,062 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210810-048		10/08/2021	12:54	JS	Citrato de Sódio 0,1M	Sílica gel	24,93		0,1	0	pH (Low/Actual/High)	99,60 %	Pass
Límpido e Incolor													
DTPA-99mTc Lot # K-20210810-013	RPH	10/08/2021	04:06	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	664 12		15 564	0	pH (Low/Actual/High)	95,708 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210810-024	RPH	10/08/2021	07:30	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	442 12		5 546	0	pH (Low/Actual/High)	96,731 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210810-034	RPH	10/08/2021	09:19	BB	Acetona Normal Saline	3MM Whatman 3MM Whatman	306 8		6 155	0	pH (Low/Actual/High)	93,169 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20210810-006		10/08/2021	03:26	FN	Butanona	3MM Whatman	369		1	0	pH (Low/Actual/High)	99,73 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20210810-027		10/08/2021	07:38	FN	Butanona	3MM Whatman	350		3	0	pH (Low/Actual/High)	99,15 %	Pass
Límpido/Incolor													
MAA-99mTc Lot # K-20210810-007		10/08/2021	03:42	FN	Butanona	3MM Whatman	98,7		2,2	0	pH (Low/Actual/High)	97,82 %	Pass
Turvo/Incolor													

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 Lot # K-20210810-008		10/08/2021 03:44	FN	Butanona		3MM Whatman		175,3		2,7	0		98,483 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-009		10/08/2021 03:46	FN	Butanona		3MM Whatman		132,3		2,3	0		98,291 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-010		10/08/2021 03:48	FN	Butanona		3MM Whatman		113,6		1,6	0		98,611 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-011		10/08/2021 03:50	FN	Butanona		3MM Whatman		144,4		1,7	0		98,836 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-012		10/08/2021 03:53	FN	Butanona		3MM Whatman		109,5		2,1	0		98,118 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-015		10/08/2021 04:11	FN	Butanona		3MM Whatman		47,9		2,1	0		95,80 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-016		10/08/2021 04:13	BB	Butanona		3MM Whatman		34,3		0,8	0		97,721 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-028		10/08/2021 07:57	FN	Butanona		3MM Whatman		124,5		1,5	0		98,81 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-029		10/08/2021 07:59	FN	Butanona		3MM Whatman		227		1	0		99,561 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-036		10/08/2021 09:41	WG	Butanona		3MM Whatman		245		1	0		99,593 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-037		10/08/2021 09:45	WG	Butanona		3MM Whatman		240		1	0		99,585 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-038		10/08/2021 09:49	WG	Butanona		3MM Whatman		197,5		1,8	0		99,097 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210810-045		10/08/2021 10:52	WG	Butanona		3MM Whatman		110,7		1,4	0		98,751 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
														Turvo/Incolor

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 Lot # K-20210810-046		10/08/2021 10:54	WG	Butanona		3MM Whatman		286		2	0		99,306 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210810-047		10/08/2021 10:56	WG	Butanona		3MM Whatman		231		2	0		99,142 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210810-049		10/08/2021 15:09	WG	Butanona		3MM Whatman		56,9		0,7	0		98,785 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20210810-005		10/08/2021 03:23	FN	Acetona		3MM Whatman		1454		3	0		99,41 %	Pass
				Normal Saline		3MM Whatman		4		1037		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210810-022		10/08/2021 07:26	FN	Acetona		3MM Whatman		210		1	0		98,447 %	Pass
				Normal Saline		3MM Whatman		3		275		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210810-033		10/08/2021 08:50	JS	Acetona		3MM Whatman		375		2	0		99,118 %	Pass
				Normal Saline		3MM Whatman		3		850		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210810-001		10/08/2021 02:25	FN	Normal Saline		Sílica gel		1099		20	0		97,263 %	Pass
				Metanol		3MM Whatman		12		1252		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210810-002		10/08/2021 02:31	FN	Normal Saline		Sílica gel		452		12	0		96,11 %	Pass
				Metanol		3MM Whatman		7		530		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210810-003		10/08/2021 02:32	FN	Normal Saline		Sílica gel		1971		20	0		98,364 %	Pass
				Metanol		3MM Whatman		12		1887		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210810-004		10/08/2021 03:18	FN	Normal Saline		Sílica gel		697		12	0		97,063 %	Pass
				Metanol		3MM Whatman		6		476		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210810-017		10/08/2021 05:48	BB	Normal Saline		Sílica gel		1777		38	0		97,12 %	Pass
				Metanol		3MM Whatman		15		1892		pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210810-018		10/08/2021 06:04	FN	Normal Saline		Sílica gel		1257		20	0		97,55 %	Pass
				Metanol		3MM Whatman		10		1121		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210810-019		10/08/2021 06:05	FN	Normal Saline		Sílica gel		1700		30	0		97,365 %	Pass
				Metanol		3MM Whatman		12		1320		pH (Low/Actual/High)	5,00 <= 6,00	<= 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-20210810-030		10/08/2021 08:45 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			258 5		6 1323	0	pH (Low/Actual/High)	97,351 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210810-032		10/08/2021 08:53 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			950 1		3 1749	0	pH (Low/Actual/High)	99,628 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210810-035		10/08/2021 09:25 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			715 9		11 828	0	pH (Low/Actual/High)	97,41 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210810-021		10/08/2021 07:24 FN	Butanona Normal Saline		3MM Whatman 3MM Whatman			397 1		1 328	0	pH (Low/Actual/High)	99,445 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210810-023		10/08/2021 07:28 FN	Butanona Normal Saline		3MM Whatman 3MM Whatman			241 3		2 487	0	pH (Low/Actual/High)	98,565 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210810-039		10/08/2021 09:58 WG	Acetato de amônio 1M:Metanol		Sílica gel			0,8		19,5	0	pH (Low/Actual/High)	96,059 %	Pass 4,00 <= 7,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210810-040		10/08/2021 10:30 WG	Acetato de amônio 1M:Metanol		Sílica gel			0,2		27,9	0	pH (Low/Actual/High)	99,288 %	Pass 4,00 <= 7,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210810-050		10/08/2021 15:43 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,4		13,7	0	pH (Low/Actual/High)	97,163 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210810-001		10/08/2021 02:23 FN	Butanona		3MM Whatman			2		276	0	pH (Low/Actual/High)	99,281 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210810-002		10/08/2021 02:27 FN	Butanona		3MM Whatman			2		541	0	pH (Low/Actual/High)	99,632 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210810-003		10/08/2021 03:15 FN	Butanona		3MM Whatman			1		1276	0	pH (Low/Actual/High)	99,922 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210810-004		10/08/2021 03:37 FN	Butanona		3MM Whatman			2,3		102,9	0	pH (Low/Actual/High)	97,814 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210810-005		10/08/2021 06:00 BB	Butanona		3MM Whatman			4		649	0	pH (Low/Actual/High)	99,387 %	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-20210810-007		10/08/2021 07:21	FN	Butanona		3MM Whatman		2		794	0	99,749 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210810-008		10/08/2021 08:43	JS	Butanona		3MM Whatman		4		482	0	99,177 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210810-009		10/08/2021 08:51	BB	Butanona		3MM Whatman		2		512	0	99,611 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210810-010		10/08/2021 09:20	BB	Butanona		3MM Whatman		8		1728	0	99,539 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210810-012		10/08/2021 10:17	WG	Butanona		3MM Whatman		3		1684	0	99,822 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210810-015		10/08/2021 14:59	WG	Butanona		3MM Whatman		5		395	0	98,75 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
TRODAT-99mTc Lot # K-20210810-041		10/08/2021 10:44	WG	Normal Saline		Sílica gel		89,7		1,5	0	96,18 %	Pass	
				Butanona		3MM Whatman		3		134,9	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210810-042		10/08/2021 10:45	WG	Normal Saline		Sílica gel		138,7		2,7	0	97,577 %	Pass	
				Butanona		3MM Whatman		1		193,9	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210810-043		10/08/2021 10:46	WG	Normal Saline		Sílica gel		171,2		2,4	0	97,345 %	Pass	
				Butanona		3MM Whatman		1,8		139,6	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210810-044		10/08/2021 10:47	WG	Normal Saline		Sílica gel		126,4		1,7	0	97,825 %	Pass	
				Butanona		3MM Whatman		1,5		175,5	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
														Límpido/Incolor